COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Agreement State Program

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Instructions: See the appropriate **NUREG-1556 Consolidated Guidance** for detailed instructions for completing application. Send **two** copies of the completed application with attachments to: Bureau of Radiation Protection, P.O. Box 8469, Harrisburg, Pa 17105-8469.

If this is an application for a NEW license, it must include remittance for the appropriate annual fee. NEW license applications cannot be accepted without payment of the annual fee. Applicants for a NEW license or RENEWAL must also submit the Department's General Information Form (GIF).

NOTE: The possession and use of byproduct, source and special nuclear materials is NOT covered by this application. Licenses for the use of byproduct, source, and special nuclear material in Pennsylvania are under the jurisdiction of the U.S. Nuclear Regulatory Commission.

1. This an application for *(check appropriate block)*: ☐ A. New License ☐ B. Amendment to License Number _____ ☐ C. Renewal of License Number _____	2. Name and Mailing Address of Applicant (include Zip Code):
3. Address(es) where Licensed Material will be used, possessed or stored:	4. Contact Person for this Application: Telephone Number:

Submit Items 5 through 11 on 8-1/5" X 11" paper. The type and scope of information to be provided is described in the appropriate NUREG 1556 series.

5. Radioactive Material A. Element and mass number; B. chemical and/or physical form; and C. maximum amount that will be possessed at any one time.	6. Purpose(s) for which licensed material will be used	
7. Individual(s) responsible for Radiation Safety Program, their training experience and e-mail address(es).	8. Training for individuals working in or frequenting restricted areas	
9. Facilities and Equipment	10. Radiation Safety Program	
11. Waste Management	12. License Fees (25 Pa. Code, Ch. 218, App. A) (New Licenses Only) Fee Category:	Amount Enclosed $

13. Certification (must be completed by applicant). The applicant understands that all statements and representations made in this application are binding upon the applicant.

The applicant and any official executing this certification on behalf of the applicant, named in Item 2, certify that this application is prepared in conformity with Article V, Radiological Health, of the Department of Environmental Protection and that all information contained herein is true and correct.

Warning: The Statements Contained or Referenced Herein Are Made Subject to the Provisions of 18 Pa. Consolidated Statutes, Section 4904 (Relating to Penalties for Unsworn False Statements to Governmental Authorities).

Type or Printed Name	Signature
Title	Date

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Fee Category	Amount Received	Check Number	Comments
Approved By			

STAFF TECHNICAL REPORT SERIES:

CONDUCTING RADIOLOGICAL PERFORMANCE ASSESSMENTS FOR LLRW DISPOSAL IN PENNSYLVANIA

Commonwealth of Pennsylvania
Department of Environmental Protection
Bureau of Radiation Protection
Harrisburg, PA

http://www.dep.state.pa.us/
(choose information by subject/choose Radiation Protection)

June 1998

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GLOSSARY

Container—The first enclosure that encompasses the radioactive waste.

Containment—The function of isolating radioactive waste from the biosphere by emplacement of the waste within a container, waste module, or disposal unit.

Custodial agency—An agency of the government designated by the Governor to act on behalf of the government owner of the disposal site. The agency is responsible for the long-term monitoring and care of the disposal site. The term does not include the department.

Disposal facility—The buildings, equipment, and other engineered features, including disposal units and temporary holding facilities, within the disposal site that are used for the disposal of low-level radioactive waste.

Disposal site—The property, including improvements thereon, that is used for disposal of low-level radioactive waste. The term consists of the disposal units and the buffer zone.

Disposal unit—A discrete portion of the disposal site into which waste is placed for disposal.

Hazardous life—The time required for radioactive materials to decay to safe levels of radioactivity, as defined by the time period for the concentration of radioactive materials within a given container or package to decay to maximum permissible concentrations as defined by federal law or by standards to be set by the host state, whichever is more restrictive.

Hazardous life standard—The hazardous life of the waste is the amount of time that it takes for the disposed low-level radioactive waste to decay to levels so that it can be demonstrated that unrestricted use of the site would result in a dose to a member of the public using the site that is no greater than the dose from natural background radioactivity, in the soil, prior to the site being used for disposal (236.508 relating to determination of hazardous life of the waste).

Inadvertent intruder—A person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

Long-term care period—The period of time that includes both the active and passive institutional control periods.

i) Active institutional control period—The period of time following site closure and the post-closure observation and maintenance period during which active access control, surveillance, monitoring, and custodial care are maintained. This period will last for a minimum of 100 years.

ii) Passive institutional control period—The period of time after the active institutional control period during which monitoring and passive access control of the facility is maintained. This period will be at least as long as the hazardous life of the radioactive waste.

Monitoring—Observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

Stability—Structural stability.

Surveillance—Monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license, permit, and regulatory requirements.

Waste module—A discrete assembly of waste containers within a disposal unit.

1. INTRODUCTION

The regulations in Title 25 of the Pennsylvania Code, Chapter 236, "Low-Level Radioactive Waste Management and Disposal" (25 PA 236), identify the need for performance assessment in developing and licensing a low-level radioactive waste (LLRW) disposal facility. Although the regulations address general aspects of performance assessment, they do not discuss the associated technical complexities and issues.

This report focuses on LLRW facility performance assessment as it applies to protection of the public (25 PA 236.13 and 236.15) and inadvertent intruders (25 PA 236.14). Specifically, it addresses radiation exposures that the public could receive from accidental or otherwise unintended releases of radioactive contaminants during and following disposal facility operations, and it addresses radiation exposures that an inadvertent intruder could receive after the facility's institutional control period ends.

Section 2 of this report presents a summary of the Pennsylvania regulations applicable to assessing the performance of LLRW disposal facilities. Section 3 discusses in detail the elements and steps of the performance assessment process.

2. REGULATORY REVIEW

2.1 CAPSULIZED REVIEW

Subchapters B and D of 25 PA 236 establish the technical requirements for the LLRW disposal site and facility. These criteria require that:

(a) The disposal site be capable of being modeled and analyzed (236.142).

(b) The disposal facility complement and augment the site's ability to meet the performance objectives (236.301).

(c) The facility independently comply with the performance objective relating to protection of the public through the active institutional control period (236.314).

Numerous regulatory requirements can be satisfied only through the use of the performance assessment process. The performance assessment process may be used to justify selection of the disposal site, to demonstrate that the disposal system will meet or contribute to meeting all the performance objectives, and to determine whether constraints must be placed on waste to be received at the disposal facility in order to meet the hazardous life standard (236.508).

2.1.1 Justifying Site Suitability

The use of the performance assessment process should be a consideration in justifying the selection of the disposal site (236.204(2)(vi)). Even without detailed and final information about the waste to be disposed of and the disposal facility to be constructed, the performance assessment process provides indications of the relative merits of individual sites. If the assumed characteristics of waste to be disposed of and the selected disposal facility are used in assessing the relative performance of the three potentially suitable sites, the performance assessment process will produce estimates of relative performance for each site being considered.

2.1.2 Guiding Site Characterization

A license applicant can ensure that limited resources are committed most effectively during site characterization through the use of the performance assessment process. The applicant also can ensure that the site information required as input to performance assessments presented in the license application is obtained in adequate detail during site characterization. More detailed guidance on this potential application of the performance assessment process is presented in a future staff technical report, *Characterization of Sites for Low-Level Radioactive Waste Disposal in Pennsylvania* (PADEP, 1997c).

2.1.3 Demonstrating That Performance Objectives Are Met

The applicant must demonstrate that the proposed disposal system (i.e., site, waste, and facility) will satisfy all four performance objectives contained in 25 PA 236.13 through 236.16. Two of the four performance objectives (236.13 and 236.14) can be shown to be satisfied through the use of the performance assessment process.

- Concentrations of radioactive material that may be released to the general environment in groundwater, surface water, air, soil, plants, or animals may not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public. Releases of radioactivity in effluents to the general environment shall be as low as reasonably achievable and within the most restrictive Federal and Commonwealth regulations and standards that are applicable (25 PA 236.13).

- Design, operation, and closure of the disposal facility shall ensure protection of an individual from inadvertently intruding into the disposal site and occupying the site or contacting the waste after active institutional controls over the disposal site have been removed (25 PA 236.14).

A portion of the third performance objective (i.e., 25 PA 236.15) can be shown to be satisfied through the use of the performance assessment process.

- Operations at the disposal facility shall be conducted in compliance with the standards for radiation protection in Chapter 219 (relating to standards for protection against radiation), except for releases of radioactivity in effluents from the disposal facility, which shall be

governed by § 236.13 (relating to protection of the general population and environment from releases of radioactivity). Effort shall be made to maintain radiation exposures as low as is reasonably achievable (25 PA 236.15).

This performance objective addresses exposures that members of the public could receive during disposal facility operations (e.g., accidents, spills, and direct radiation). While the license applicant must address potential exposures to disposal facility workers to completely demonstrate compliance with this performance objective, worker safety is not addressed in this staff technical report.

The fourth performance objective (25 PA 236.16) requires that the disposal site be stable in the long-term without relying on ongoing active maintenance. As with the other performance objectives, this requirement must be shown to be satisfied. However, performance assessments are not required to demonstrate compliance with 25 PA 236.16.

In addition to the general statements of the performance objectives, the regulations require that specific pathway analyses be conducted and included in the license application (25 PA 236.209).

2.1.4 Determining the Need for Constraints on Waste To Be Disposed of

The hazardous life standard must be satisfied before the license for an LLRW facility may be terminated (25 PA 236.247(c)). The regulatory decision to terminate the license will not be made for many years. However, the department (by policy) has determined that the hazardous life of disposed waste must not exceed the expected performance of the disposal facility. This potentially imposes constraints on the facility's waste acceptance criteria. The applicant must demonstrate that the hazardous life of waste it will accept for disposal will not exceed the expected performance of the disposal facility. This can be accomplished only through the use of the performance assessment process.

2.1.5 Preparing the Impact Analysis Report

The applicant must include in its license application an Impact Analysis Report that addresses radiological and nonradiological impacts, impacts on groundwater and surface water quality, and long-term public health and environmental impacts (25 PA 236.204(2)). Many of these topics can be addressed only through the use of the performance assessment process.

2.2 TECHNICAL REQUIREMENTS AND ANALYSES

Radiological performance assessments are conducted to demonstrate that an LLRW disposal facility will meet all applicable performance objectives. The performance of the disposal facility must be assessed and reported in connection with several licensing decisions. The 25 PA 236 requirements that directly apply to the performance assessment process are described in this subsection.

To meet the site suitability requirements, the applicant "...shall clearly demonstrate that the preferred site meets the Phase I and Phase II siting requirements and contributes to compliance with the performance objectives of Subchapter A..." (25 PA 236.141(b)). Satisfaction of the site suitability requirements requires that the site be capable of being characterized, modeled, analyzed, and monitored. Specifically, "...characterization shall be adequate to define characteristics and conditions, both onsite and offsite, through monitoring, analysis, modeling and demonstration, to substantiate that the site can satisfy site suitability requirements and meet the performance objectives" (25 PA 236.142). The required "modeling" refers directly to the performance assessment process.

Subchapter D of 25 PA 236 establishes the design requirements for the LLRW disposal facility. The design criteria "...require the applicant to demonstrate that the disposal technology can complement and augment the site's ability to meet the performance objectives of Subchapter A..." (25 PA 236.301(b)). Section 236.314(c) states that the disposal facility must independently comply with the performance objectives that concern protecting the public through the active institutional control period. Furthermore, the "...facility design shall, to the extent practicable, limit radiation exposures to the inadvertent intruder to an annual whole body dose equivalent of 25 millirems" (25 PA 236.320(c)). The performance assessment process must be used to demonstrate compliance with these performance objectives and criteria (25 PA 236.330).

Having addressed the site suitability and facility design requirements, the applicant must obtain a license to construct and operate the LLRW disposal facility. The applicant must prepare and submit a license application for department review.

The applicant also must include in the license application the technical analyses necessary to demonstrate that the performance objectives of Subchapter A will be met. Specific technical analyses that are pertinent to protecting the public and inadvertent intruders include the following:

- Pathway analyses demonstrating protection of the general population from releases of radioactivity. Pathways must include air, soil, groundwater, surface water, plant and animal uptake, and exhumation by burrowing animals. These analyses must clearly identify and differentiate between the roles that natural site characteristics and design features perform in isolating and segregating the wastes (25 PA 236.209(1)). These analyses must also provide assurance that exposures to humans from the release of radioactivity will not exceed the limits stated in 25 PA 236.13.

- Analyses of the protection of individuals from inadvertent intrusion. These analyses must ensure that waste classification and waste segregation requirements will be met and that barriers to inadvertent intrusion will be provided (25 PA 236.209(2)).

- Analyses of the protection provided to individuals during operations. These analyses must assess expected exposures resulting from routine operations and likely accidents during waste handling, storage, and disposal. Exposures to members of the general public must satisfy the standards of 25 PA 236.13, while those to workers at the facility must satisfy the requirements of 25 PA 219 (25 PA 236.209(3)).

These requirements can be satisfied only through modeling and simulation activities that are integral to the performance assessment process.

The license application must include the Impact Analysis Report, which addresses the impact of licensing the disposal facility. This report must include several evaluations and discussions of human health and environmental impacts. Evaluations that must be provided by applying the performance assessment process include the following:

- A detailed assessment of the radiological impacts on public health and the environment (25 PA 236.204(2)(i)).

- A discussion of long-term public health and environmental impacts, including those from closure, decommissioning, decontamination, and reclamation of the site and facilities associated with the licensed activities and management of radioactive materials that will remain on-site after closure, decommissioning, decontamination, and reclamation (25 PA 236.204(2)(iii)).

- A justification for the choice of the proposed site over other preferred, potentially suitable sites (25 PA 236.204(2)(vi)).

The department will not issue a license unless the applicant demonstrates the following:

- The operation will not endanger public health, safety, and welfare, or the environment (25 PA 236.225(1)).

- The proposed disposal site; disposal facility design; disposal facility operations, including equipment, facilities, and procedures; disposal site closure; and post-closure institutional control are adequate to protect public health and safety by providing assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in 25 PA 236.13 (relating to protection of the general population and environment from releases of radioactivity) (25 PA 36.225(4)).

- The applicant's proposed disposal site; disposal facility design; disposal facility operations, including equipment, facilities and procedures; disposal site closure; and post-closure institutional control are adequate to protect public health and safety by providing assurance that individual inadvertent intruders are protected in accordance with the performance objective in 25 PA 236.14 (relating to protection of individuals from inadvertent intrusion) (25 PA 236.225(5)).

These demonstrations can be accomplished only through use of the performance assessment process, which is described in Section 3.

3. PERFORMANCE ASSESSMENT PROCESS

The performance assessment process is used to project the performance of an LLRW disposal system under current and possible future conditions. Performance assessment plays an important role in all phases of the life of the disposal facility, including siting, design, construction, operation, and closure. This section describes the steps required to conduct a performance assessment and discusses specific issues that affect the conduct of various activities in the performance assessment process.

The performance assessment process consists of a sequence of technical activities that are coordinated to produce estimates of the potential impact of the disposal system on human health and the environment (see Figure 3-1). The major steps of a performance assessment are as follows:

- Characterize the disposal system (i.e., the waste, natural site, and disposal facility).
- Identify potential radiation exposures (i.e., potential receptors, exposure scenarios, and exposure pathways).
- Develop conceptual exposure models (i.e., contaminant release mechanisms, transport pathways, and uptake modes).
- Develop calculational tools (i.e., mathematical models and computer codes).
- Estimate and evaluate potential radiation exposures (using baseline results, sensitivity analyses, uncertainty analyses, and review of results).
- Revise inputs, models, and assumptions as appropriate.

The performance assessment process is iterative. The quantity and quality of data and information that it requires generally increase as the development of the disposal facility progresses. The growing availability of information will generally require that the performance assessment process be repeated with revised inputs and/or conceptual models. Subsections 3.1 through 3.7 of this document discuss these steps.

Appendix A lists reports from several state and federal agencies on various aspects of the performance assessment process. Several of these reports have been issued by agencies that have

Figure 0-1 Sequence of Activities Involved in the Performance Assessment Process

no regulatory standing in the Commonwealth or address types of radioactive waste other than LLRW. These resources are included because they help provide a broad perspective on the current level of expertise on the performance assessment process. Reading and reviewing the documents listed in Appendix A will provide more detailed information on the purpose and nature of performance assessment.

Commonwealth regulations require the applicant to develop and implement a quality assurance/quality control (QA/QC) program (25 PA 236.207) that will, in part, control the collection and management of data and information used in siting. Data that may influence the performance assessment results should be acquired and managed according to provisions of the QA/QC program. The applicant should ensure that any revised data or results are properly incorporated into the database for use in future assessments.

3.1 CHARACTERIZE THE DISPOSAL SYSTEM

A disposal system consists of three physical components: the waste inventory, natural site, and disposal facility (see Figure 3-2). Each of these components must be thoroughly understood for the performance assessment to accurately represent the performance of the disposal system. The following subsections discuss the steps required to characterize these elements. Additional guidance on the types of data needed to characterize the disposal system is provided in PADEP, 1997d and PADEP, 1997e.

3.1.1 Characterize the Waste

An accurate assessment of the potential impacts of the disposal facility on human health and the environment requires a thorough understanding of the nature of the waste to be disposed of. Radionuclide inventories and leaching characteristics should be developed for each combination of waste stream, waste class, and waste form that will be disposed of at the facility. Other important waste stream parameters also should be provided, including disposal volumes and physical, chemical, waste container, and waste stability characteristics. The potential for gas generation in the waste, including radon, carbon dioxide, methane, and hydrogen gases, also should be addressed.

Figure 0-2 Disposal System Components of an LLRW Disposal Facility

In addition to the aforementioned characteristics, information on the radiation levels at the surfaces of the waste containers is required. This information is used to characterize potential exposures to members of the public adjacent to the disposal facility, direct exposures to disposal facility workers, and exposures that occur during waste transport and handling.

Actual waste characteristics information will be available only after disposal facility operations begin. Prior to that time, information should be collected from expected LLRW generators to develop the best possible estimates of the types and quantities of waste requiring disposal. These estimates should be updated as appropriate to maintain an accurate understanding of the waste to be disposed of at the facility. All projected waste characteristics must be provided in the license application. Radionuclide concentrations, waste volumes, and radiation levels should be presented for each combination of waste form, waste stream, and waste class.

3.1.2 Characterize the Natural Site

The site characteristics that must be considered in the performance assessment are geology, groundwater hydrology, surface water hydrology, meteorology, soil features, biotic features, and demography. See PADEP, 1997c for additional guidance on characterizing the natural site. The following specific site characterization data are required for the performance assessment:

- Geology—Topography, stratigraphy, structure, and soil characteristics.
- Groundwater—Hydraulic conductivity, hydraulic potential, porosity, flow directions, water-bearing capacity, moisture content, ion exchange characteristics, pH, depth to local groundwater, and groundwater chemistry.
- Surface water hydrology—Runoff rates, runoff drainage patterns, the potential for flooding, indications of surface water discharge, and other surface water characteristics (e.g., dimensions, flow rates, temperatures, mixing characteristics, and water chemistry).
- Site meteorology—Wind speed, direction, and frequency; atmospheric stability classes; air temperature; precipitation; evapotranspiration; and atmospheric water content.
- Biota—Potential for plant uptake of radionuclides, evapotranspiration effects, and the potential for animal intrusion into the facility.

- Demography—Population distribution by distance and direction from the site, projected growth patterns, potable water sources, food production patterns, and food consumption patterns.

Based on the results of the site characterization, design basis conditions and their effects on the facility's projected performance should be identified. These conditions may include the probable maximum precipitation event, probable maximum flood, design wind speed, critical temperatures, and seasonally high water tables.

3.1.3 Characterize the Disposal Facility

Characterization of the disposal facility should address all principal design features or features that contribute to the facility's ability to satisfy performance objectives and technical requirements (PADEP, 1997d and PADEP, 1997e). The principal design features to address are the engineered cover system, disposal units, waste modules, intruder barriers, percolating water drainage systems, contaminant retarding components, surface water drainage systems, disposal unit monitoring systems, environmental monitoring systems, and the buffer zone. Guidance on designing engineered structures to provide enhanced containment is provided in PADEP, 1998.

The descriptions of principal design features should include the following elements:

- Textual descriptions.
- Layout drawings (to scale).
- Plan views (to scale).
- Cross-sectional views (to scale).
- Design details and justifications.
- Material specifications.

The license applicant also should describe the relationship of the disposal facility to the natural site, including existing water wells, the potential for natural resource exploitation, topography, the potential for surface water runon, and the potential for flooding of the site.

A general understanding of key operating activities and practices should be demonstrated. Descriptions of these activities should include the movement of waste containers from arrival at the receiving area until

the disposal unit is closed, with no intention of further contact with the waste. Of particular importance are the waste handling or processing operations that have the greatest potential for accidental releases.

The general condition of the disposal facility following its closure must be defined to allow an accurate assessment of performance. Issues such as facility decontamination and decommissioning, engineered cover system integrity, surface drainage, erosion protection, intruder protection, subsidence, settlement, and geotechnical stability should be addressed when defining these conditions. Information on the conditions of the facility following decommissioning will become more detailed as decommissioning approaches.

3.2 SYSTEM PERFORMANCE ASSUMPTIONS

Though not explicitly shown in Figure 3-1, an important step must be taken after the disposal system is characterized but before the balance of performance assessment activities commence. This step has far-reaching effects on all subsequent activities because it determines the range of conditions under which the disposal system's performance will be assessed.

As part of the uncertainty analyses (described in Subsection 3.6.2), the applicant should assess disposal system performance under three major sets of system performance assumptions that affect the results of radiation exposure scenarios. These sets of assumptions correspond to three possible conditions in which the disposal system may exist:

- Expected performance.
- Design basis performance.
- Degraded performance.

The characteristics of these three sets of system performance assumptions are described generally in the following paragraphs.

Under expected performance, the applicant should take account of all design features provided and their expected performance capacity. Typically, engineered components are designed to a particular standard or set of criteria. To provide assurance that a design component is likely to perform as required, the component is provided with capacity beyond that required to achieve the design standard

or satisfy design criteria. This excess capacity is referred to as the design margin. The applicant may account for the beneficial effects of this excess design capacity in projecting the expected performance of the disposal system. Also, the applicant may take credit for the extended duration of the passive institutional control period and the beneficial effects that monitoring and associated maintenance activities would have on the performance of the disposal facility.

Under design basis performance, the applicant should impose the unique requirements of Pennsylvania regulations as they relate to design goals and service life (25 PA 236.314(d) and 236.322(b)). Under these conditions, the applicant may take credit for the extended duration of the passive institutional control period and the beneficial effects that monitoring and associated maintenance activities would have on the performance of the disposal facility.

Under degraded performance, the applicant should apply the philosophy that the U.S. Nuclear Regulatory Commission (NRC) outlines in 10 Code of Federal Regulations (CFR) 61. That is, the applicant should not take credit for the beneficial effects of any maintenance activities that might be planned for the first 100 years after facility closure. Although the principal design features will have been designed with substantially longer service lives, conservative assumptions, consistent with those expected by NRC, should be made to discount the beneficial effects of the extended service lives.

Initially many aspects of a performance assessment (e.g., waste site and facility) must be evaluated individually. However, all aspects must be combined eventually in a comprehensive, integrated analysis to demonstrate that the entire disposal system will perform as required. Once the behavior and performance of individual components are determined, their influence on other components must be considered. The constraints on assumed conditions imposed by interfaces between various components must be considered in the comprehensive, integrated analyses of system performance, and the comprehensive, integrated performance of the system must be assessed under each set of system performance assumptions.

3.3 IDENTIFY POTENTIAL RADIATION EXPOSURES

The potential for human exposures to radiation depends on the extent and nature of human activity in areas containing or potentially contaminated with radioactivity. The assessment of these exposures requires identifying the potential receptors and defining the applicable exposure scenarios. These aspects of the performance assessment are discussed in the following subsections.

3.3.1 Identify Potential Receptors

The performance objectives for an LLRW disposal facility require that members of the public be protected from the effects of potential releases of radioactivity from the facility and that potential inadvertent intruders be protected from the waste. The performance assessment for the facility must provide reasonable assurance that these objectives will be met.

The applicant should identify and characterize those persons who may be exposed to the waste itself or to radioactivity released from the waste. Persons whose potential for exposure should be evaluated include:

- Persons residing at or near the boundary of the disposal facility during and following disposal operations.
- Persons who inadvertently intrude into the disposal site (whether or not into the waste itself) following an assumed loss of active institutional control (nominally, 100 years after facility closure).

The department has determined that only those persons considered by other regulatory agencies (such as NRC and U.S. Environmental Protection Agency), and for whom assumptions are internally consistent, need be considered in the performance assessment process. Furthermore, the department does not require that intentional intruders be protected following the site's assumed loss of institutional control.

Internal consistency refers to conditions inherent in defining the potentially exposed individual. If a particular scenario assumes a condition or characteristic in defining one aspect of the scenario, it should not violate that condition or characteristic in defining another aspect. For example, Commonwealth

regulatory siting requirements disallow construction of the facility within a coastal floodplain (25 PA 236.126(a)(2)). Therefore, it would not be internally consistent to postulate conditions at the disposal site that are typical of a coastal floodplain.

In identifying potentially exposed individuals, the applicant should consider the effects of the three sets of system performance assumptions described in Subsection 3.2.

3.3.2 Define Radiation Exposure Scenarios

Having identified the potential receptors as described in Subsection 3.3.1, the applicant should characterize situations in which persons may be exposed to the waste or to releases from the disposal facility. These situations, or exposure scenarios, should be broad enough in scope to reasonably demonstrate that no individual will receive radiation exposures greater than those received by the individuals chosen for evaluation. Exposure scenarios should address the potential for both acute and chronic exposures. The exposure scenarios that should be considered in a performance assessment include the following:

- Normal Operations—Adjacent Resident.
- Accidental Operating Conditions—Adjacent Resident.
- Post-Closure—Adjacent Resident.
- Passive Institutional Control Intruder—Drilling.
- Passive Institutional Control Intruder—Construction.
- Passive Institutional Control Intruder—Discovery.
- Passive Institutional Control Intruder—Agriculture.

The likely radiation exposures to members of the public residing near the disposal facility should be estimated for normal operations (Normal Operations—Adjacent Resident). Normal operational releases such as those from contaminated surfaces, although they may be extremely small, should be estimated and shown to satisfy the performance objective stated in 25 PA 236.13. Radiation exposures from normal operations may also occur from the external gamma radiation levels of the waste containers and modules being handled at the facility. Exposure of members of the public residing adjacent to or near the disposal facility to external gamma radiation that originates from waste containers should be estimated.

Radioactive releases during accidental operating conditions, whether of natural or artificial origin (Accidental Operating Conditions—Adjacent Resident), also should be estimated. The applicant should identify a set of accidents that involve a variety of waste containers and waste types (i.e., waste streams, waste forms, and waste classes). Bounding conditions within the set of accidents should be identified and worst cases evaluated to determine limiting potential radiation exposures to those residing near the facility. Accidental operational conditions may also exist in which members of the public may receive abnormal external radiation exposures because of the accident conditions. These exposures also should be evaluated.

The Post-Closure—Adjacent Resident scenario considers the impact from waste disposal on the nearest potential resident. Contaminated water from the disposal units is assumed to flow vertically to the regional aquifer, then horizontally to a well. The well is assumed to supply the resident with water for direct consumption, irrigation or watering of crops, and watering cattle raised as a source of food. The resident receives doses from external radiation, ingesting contaminated water and foodstuffs, and inhaling airborne radionuclides transported from the disposal site or suspended from soil surfaces following irrigation or watering.

A unique aspect of Pennsylvania regulations is the explicit requirement that the license applicant demonstrate that potential radiation exposures to inadvertent intruders will not exceed 25 millirems per year (25 PA 236.320(c)). To satisfy this requirement, each of the intrusion scenarios described in the paragraphs that follow (and others that are reasonable, considering the characteristics of the disposal facility and natural site) must be characterized sufficiently to allow radiation exposures to be calculated.

In the Passive Institutional Control Intruder—Drilling scenario, the intruder is assumed to come onto the site after the end of active institutional control to develop a water well. In the well drilling process, the driller encounters the waste and unknowingly brings a small amount of it to the surface, where it is spread over a limited area. However, members of the drilling crew eventually recognize the unusual character of the material being brought to the surface, terminate drilling activities, and move away from the waste. Before withdrawing, the crew members are exposed briefly to direct external gamma radiation, and may inhale or ingest suspended radionuclides.

The Passive Institutional Control Intruder—Construction scenario involves an intruder who comes onto the site after the end of active institutional control and constructs a home at a location adjacent to that where Passive Institutional Control Intruder—Drilling activities occurred. The individual is assumed to excavate a basement for the house and, depending upon the relative depths of the basement excavation and disposed waste, may encounter the disposal unit during excavation. If the disposal unit is structurally intact, the intruder recognizes an unusual condition, ceases excavation activities, and withdraws after only brief exposure to external gamma radiation, shielded by the disposal unit roof. If, however, the disposal unit is not structurally intact, the intruder continues excavation to the desired depth for the home's basement. If the intruder contacts the waste, he or she may inhale and ingest suspended radionuclides and be exposed to external gamma radiation from the excavated material and waste.

The Passive Institutional Control Intruder—Discovery scenario is similar to the Passive Institutional Control Intruder—Construction scenario. In this scenario, however, the intruder recognizes that he or she is digging into very unusual material as soon as the waste is encountered. The individual abandons construction efforts and, consequently, is exposed for a much shorter period. Exposures to the intruder would most likely be limited to inhalation of suspended radionuclides and external radiation from the waste.

In the Passive Institutional Control Intruder—Agriculture scenario, the intruder is assumed to take residency in the home constructed under the Passive Institutional Control Intruder—Construction scenario. The individual grows crops in contaminated material brought to the surface during basement excavation and well drilling activities, and irrigates or waters the crops with contaminated well water. Animals consume contaminated pasture grass and water from the well. Water drawn from the well serves as a source of drinking water for the intruder. The individual is assumed to inhale suspended radionuclides, consume contaminated foodstuffs and water, and receive external radiation from excavated and buried waste.

The preceding scenario descriptions should not be rigidly applied. Rather, they should be modified as necessary to account for the specific characteristics of the disposal site and facility. For example, drilling techniques used in a locale for well development may typically involve sufficient amounts of water that

suspension of radionuclides in the air is not reasonable. To account for this fact, the characteristics of the Passive Institutional Control Intruder—Drilling scenario should be appropriately revised.

For all intrusion scenarios, the applicant should consider the effects that variations in waste characteristics could have on the projected radiation exposures to inadvertent intruders. Overall waste concentrations must satisfy waste characteristics requirements of 25 PA 236, Subchapter F. However, because the radionuclide concentrations are not likely to be constant across all wastes, these variations should be addressed. Intrusion into waste of atypical but acceptably high concentrations should be evaluated. To the extent that such variations affect the projected radiation exposures to members of the public, their effects on these projections should also be considered.

In describing exposure scenarios, the applicant should consider the effects and constraints associated with the three sets of system performance assumptions described in Subsection 3.2.

3.4 DEVELOP CONCEPTUAL EXPOSURE MODELS

Conceptual models should be developed for each of the exposure scenarios defined in the previous step (see Subsection 3.3 and Figure 3-1). The development of conceptual models defines the release mechanisms, transport pathways, and modes of uptake that combine to produce the postulated exposures. The following subsections discuss typical release mechanisms, transport pathways, and uptake modes, as well as the information required to evaluate them.

3.4.1 Identify Radionuclide Release Mechanisms

The applicant should identify and describe the phenomena and processes that control or influence the release of radionuclides from the disposal facility, including:

- Water infiltration.
- Disposal unit and waste module degradation.
- Leaching.
- Gas generation.

Estimating water infiltration requires knowledge of site meteorological conditions, facility surface water control and drainage features, engineered cover system design, waste characteristics, disposal unit structural features, and groundwater system characteristics. Water infiltration can be estimated only with some knowledge or indication of the condition of the engineered cover system. The condition of the cover system depends directly upon the condition and function of the disposal unit, upon which it is constructed and upon which it depends for stability and integrity. Conversely, the disposal unit depends upon the cover system for protection from conditions that induce degradation processes. These effects should be considered in projecting infiltration through the cover system.

Disposal unit and waste module degradation is influenced by several factors. These include concrete characteristics, the environment in which the structures are placed, the physical loads to which the structures are subjected, and the characteristics of the waste (NRC, 1991c). Additional guidance on projecting disposal unit and waste module degradation is provided in PADEP, 1998.

In the performance assessment, the applicant should take no credit for any beneficial effects of the container in which the waste arrives at the disposal facility (i.e., the shipping container). However, the applicant may take credit for the beneficial effects of the engineered cover, disposal unit, and waste module (to the extent that such effects are justified by qualified data, technical analyses, or reference to work by others) in conducting radiological performance assessments. In contrast, the applicant may only consider the beneficial effects of the disposal unit in demonstrating leak resistance as required by 25 PA 236.314(b)(1).

Leaching of radioactive contaminants from the waste into water is especially important where the potential exists for contaminant migration through the groundwater pathway (NRC, 1991c). Leaching of radioactive contaminants depends on the physical waste form, chemical characteristics of each radionuclide, and availability of water in the disposal unit. Mechanisms for radioactive releases from the waste include distribution coefficient (K_d) leaching, diffusion, and leaching resulting from corrosion. The applicant should carefully consider the applicability of these mechanisms to ensure that release projections are conservative yet realistic.

Gas generation may occur if the waste contains tritium, carbon, or radium. Carbon and tritium may be generated from biological or chemical decomposition. Radon is a product of radioactive decay within the uranium and thorium decay chains. The applicant should assess releases of radioactive gases from the disposal unit directly to the atmosphere.

3.4.2 Identify Radionuclide Transport Pathways

For each radiation exposure scenario considered, the applicant should identify and describe pathways by which radionuclides released from the disposal unit may be transported away from the disposal unit (PADEP, 1997d and PADEP, 1997e). These include:

- Groundwater.
- Surface water.
- Atmospheric diffusion and dispersion.
- Gaseous releases through the cover system.
- Intrusion into the waste.
- Food chain transport.

The groundwater pathway may be especially important in assessing the performance of a disposal system in areas characterized by high precipitation and shallow regional aquifers. In such areas, radionuclides released from the waste may migrate vertically through the unsaturated zone and horizontally in saturated media to a nearby well or point of discharge. Factors that should be considered in assessing the transport of contaminants from the disposal unit via the groundwater pathway include water infiltration, geologic characteristics, hydrologic characteristics, and sorption phenomena.

The surface water pathway includes the transport of radionuclides to both moving and standing water bodies. Factors requiring consideration include flow rates, mixing characteristics, water chemistry, and water body dimensions. The applicant also should consider contaminant deposition to sediments.

Gases generated by chemical decomposition of the waste (tritium or carbon) or radioactive decay (radon) can diffuse through disposal structures and the engineered cover system and be released. The factors that influence the diffusion of such gases include the diffusion coefficient of the gas in the

construction materials and soils and the design of the structures and cover systems. Variations in barometric pressure also may affect the rate at which gases are transported from the disposal unit.

Atmospheric diffusion and dispersion involve the transport of radionuclides released from the disposal unit into the atmosphere. The releases may be gaseous or particulate in form. The applicant should consider wind speed distribution, wind direction distribution, stability conditions, resuspension, deposition, and washout in assessing the behavior of contaminants in the atmosphere.

Intrusion into the waste may result in the accumulation of waste constituents at the surface of the disposal facility. Intrusion may occur from human activities or biointrusion. Primary modes of human intrusion include excavation into the disposal unit and drilling. Biointrusion may occur from plant root penetration into the waste or animal burrowing. These models of intrusion are of lesser significance because the waste will be contained inside engineered structures into which biointrusion is less likely. The extent of root penetration is influenced by moisture conditions at the site, soil characteristics, the presence of engineered structures, and the plant species that are indigenous to the area, including those plants that establish themselves over the stabilized facility, or those that may grow as a result of plant succession. The extent of animal burrowing depends on the species indigenous to the area and their typical behaviors.

The food chain pathway is a potentially important means of radionuclide transport. Plants may become contaminated by extending their roots into the waste, growing in contaminated soil, or consuming contaminated water. Animals may become contaminated through direct contact with waste or by consuming contaminated water or plants. Information needed to assess the effects of the plant and animal food chains includes:

- Plant species.
- Animal species.
- Cover systems characteristics.
- Water and food consumption rates.
- Plant uptake factors (e.g., from soil to plant tissue).

Transport of radioactive contaminants from the waste form through surrounding materials (such as grout, concrete, and sand backfill) and environmental media must be closely coordinated and integrated with

the modeling of water infiltration, structural stability, and releases from waste forms. The applicant should ensure that assumptions made in evaluating each aspect of release and transport from the disposal unit are internally consistent. Further, the applicant should consider and evaluate the system performance conditions, as described in Subsection 3.2.

3.4.3 Identify Radionuclide Uptake Modes

The applicant should identify and describe all phenomena that influence human exposure to external radiation or human uptake of radionuclides, including:

- Water ingestion.
- Food ingestion.
- Inhalation.
- External radiation.
- Dermal absorption.

Ingestion of contaminated water and food results in internal doses. The magnitude of the dose received by an individual who consumes contaminated water or food depends on several factors, including the radionuclides present in the water or food and their concentrations in each, the water or food consumption rate, and the fraction of the person's diet that consists of contaminated foodstuffs.

Internal doses may also result from the inhalation of radioactivity. The dose received from inhalation is a function of the radionuclide concentration in the air, inhalation rate, particle size distribution, distribution of radionuclides by particle size, and length of time a person breathes contaminated air.

An individual may receive external radiation from waste being handled at the disposal facility or from radionuclides that have migrated from the site. The magnitude of the exposure through this mode is determined by:

- Radionuclide concentrations in the waste or contaminated media.
- The configuration of the waste or contaminated media.
- Characteristics of shielding provided by operational activities, contaminated media, and material between the source and the exposed individual.

- The distance between the source and the exposed individual.
- The length of time the individual is exposed to the radiation.

Absorption of radiological contaminants through the skin is not expected to be significant unless tritium is present. Nevertheless, the applicant should assess the extent to which this uptake mode may influence the performance of the disposal facility.

3.5 IDENTIFY AND/OR DEVELOP CALCULATIONAL TOOLS

Once a conceptual exposure model is developed, the applicant should determine appropriate mathematical representations of each model component (see Figure 3-1). This process involves identifying models available for each phenomenon, evaluating model characteristics and capabilities, comparing model characteristics and capabilities to the most important aspects of the phenomena, and selecting the preferred model. Typical categories include:

- Site characterization.
- Waste characterization.
- Facility design.
- Structural degradation.
- Infiltration and water management.
- Radionuclide release from the waste.
- Radionuclide transport.
- Food chain.
- Radionuclide uptake.
- Dose.
- Risk.

In general, there are several mathematical representations or models for each release mechanism, transport pathway, and uptake mode. Some models of a given phenomenon are simpler than others, and each has its own data requirements. The applicant should evaluate the ability of each model to represent the actual phenomenon, considering the limitations and strengths of each. Normally, one model will offer advantages for a particular aspect of the performance assessment. Occasionally, multiple models may be used to represent a single aspect of the analysis to provide perspective in the performance assessment process.

Most models of release mechanisms, transport pathways, and uptake modes have been implemented as computer codes and are widely available. Computer codes may be dedicated to evaluating a single phenomenon or may analyze the performance of the entire disposal system under certain conditions. Codes with a narrow scope tend to be more complex, while those that address the entire disposal system typically are more superficial. Highly specialized codes usually have very detailed data requirements, while system-level codes require less detailed data requirements.

As the amount of site-specific data increases, existing codes may require modification to adequately represent the phenomena at the disposal facility. When such modifications are necessary or preferable, the applicant should ensure that the resulting code is properly implemented and documented. The performance of the code should be benchmarked and validated to the extent practical. The applicant also should provide and describe all code modifications for department review and evaluation.

As a general rule, the model selected should be no more sophisticated than is necessary to adequately represent the actual phenomenon. Furthermore, the sophistication of the model(s) used in the performance assessment should be consistent with the level of detail of data available for input.

In developing calculational tools, the applicant should ensure that all phenomena and processes possible under the three sets of system performance assumptions described in Subsection 3.2 are addressed.

3.6 ESTIMATE AND EVALUATE POTENTIAL RADIATION EXPOSURES

Once the first four major steps of the performance assessment have been completed, the applicant can begin to evaluate the performance of the LLRW disposal system (see Figure 3-1). The assessment will project the extent to which the disposal system satisfies the performance objectives, identify key input parameters used in the analysis, and examine the effects of uncertainty on the projected results. Following the assessment, the applicant should review the results for reasonability and for consistency with data collected during characterization efforts. These aspects of the performance assessment are discussed in the following subsections.

3.6.1 Calculate Radiological Performance

Performance assessment simulations project the extent of compliance with the performance objectives under the three major sets of system performance assumptions described in Subsection 3.2. Under each set of system performance assumptions (i.e., expected, design basis, and degraded), the applicant must justify or assume many conditions of the environmental or disposal features. The applicant should ensure that these justifications and assumptions and the associated simulations are conservative (i.e., that the projected radiation exposures will not be understated), but also realistic. Extreme levels of conservatism may not be useful.

The groundwater pathway typically is of great interest in the LLRW disposal facility licensing process and has a substantial potential to produce the most restrictive radiation exposures to members of the public. Therefore, the applicant should ensure that releases to and transport through the groundwater pathway are thoroughly and comprehensively evaluated. The hydraulic performance of the engineered cover system, disposal unit, waste modules, and waste form has critical effects on the performance of the groundwater pathway. Thus, the applicant should address the performance of each of these components under the three major sets of system performance assumptions. That is, the applicant should project radiation exposures under expected conditions, design basis conditions, and degraded conditions.

The applicant should ensure that water balance calculations are performed, justified, and reported under the three sets of assumptions that affect the evaluation of all radiation exposure scenarios (again, see Subsection 3.2). The effects between the cover system, disposal unit, and waste module must be addressed in detail in evaluating water infiltration into the waste module and releases of radioactive material from the disposal unit. The applicant should address in detail the effects of structural and hydraulic degradation. Phenomena and effects such as concrete degradation, cover settlement, cover differential settlement, desiccation cracking of clay, freeze-thaw damage to low-permeability (clay) layers, intrusion by plants and animals, plant succession, and the increase of effective layer permeability over time should be taken into consideration.

Performance assessments (i.e., radiation exposure simulations) should provide assurance that projected peak exposure rates will not exceed the limits of 25 PA 236.13 for at least 1,000 years following cessation of disposal operations. Thus, for the purpose of determining compliance with the quantitative limits of Pennsylvania regulatory requirements (i.e., 25 PA 236.13) to protect members of the general public, the applicant must project radiation exposure rates and explain in detail the performance assessment results for at least 1,000 years following cessation of disposal operations. Performance assessment results within this time horizon also form the basis for judging acceptability of efforts to design and construct the disposal facility to meet the zero-release goal of Pennsylvania regulations (25 PA 236.301(b)).

Quantitative radiation exposure projections for times following 1,000 years after cessation of disposal operations, although characterized by larger uncertainties, also provide useful information that should be considered in the design process and in making licensing decisions. Therefore, the department will view these results from a broader perspective than implied by the quantitative dose limits of the performance objectives of 25 PA 236. The department will consider radiation exposure projections for times later than 1,000 years after cessation of disposal operations to gain needed perspective and understanding about the relative contributions the site and the facility design make toward meeting performance objectives. Thus, for the purpose of conveying a broader perspective on the long-term performance of the disposal facility, the applicant must present and explain projections of radiation exposures for 10,000 years following cessation of disposal operations. In addition, the applicant must carry out quantitative analyses until changes in projected radiation exposure rates with time have stabilized.

In assessing the performance of the disposal facility, the applicant should not take credit for the integrity of containers in which waste is received at the disposal facility (i.e., shipping containers). The period over which the integrity of these containers can be assured is sufficiently short that the containers can have no appreciable effect on disposal system performance in the time frames over which performance must be projected and reported. In contrast, the applicant should demonstrate that the disposal unit will retain its integrity (with regard to its structural and hydraulic properties) for a time sufficient to provide reasonable assurance that leak resistance will be provided for at least 100 years, as required by 25 PA 236.314(b)(1).

The applicant should ensure that radiation exposures are estimated using standard methodologies, assumptions, and conversion factors, as appropriate. For example, the dose conversion factors published in Federal Guidance Reports 11 and 12 (EPA, 1988 and EPA, 1993) should be used. Assumptions about the mass and consumption rates of persons assumed to potentially be exposed to radioactive contaminants should be consistent with guidance provided in EPA, 1991, or should be justified using site-specific conditions, information, and data.

The assessment of radiation exposures should be conducted in sufficient detail that the relative contributions of the disposal facility and the natural site can be distinguished, as required by Pennsylvania regulations (25 PA 236.209(1)). To comply with this requirement, the applicant may need to model the disposal system iteratively. In each iteration, the applicant might account for only those physical components whose contribution is being evaluated in that iteration.

In calculating projected exposures, the applicant should ensure that the effects of all conditions defined or inferred by the three sets of system performance assumptions are assessed (see Subsection 3.2).

3.6.2 Perform Sensitivity and Uncertainty Analyses

A significant element of the performance assessment is the analysis of its sensitivities and uncertainties (NRC, 1990 and DOE, 1990). Sensitivity analyses are conducted to identify important elements and parameters of the system, and involve estimates of changes in performance measures produced by changes in the variables of the system. Uncertainty analyses are conducted to identify uncertainties associated with the important elements and parameters of the system, and understand the impacts these uncertainties have on the conclusions drawn from the calculated performance measures. The disposal system can be judged to comply with the performance objectives only after all relevant uncertainties in analyses have been considered.

Sensitivity analyses typically involve changing each model parameter while leaving all other parameters at their nominal values, and then quantifying the relative effect of this change on the model projection. Through this process, the parameters having the greatest influence on the model projections are identified.

The sensitivity analysis may be conducted before or after the uncertainty analysis is conducted. When conducted prior to the uncertainty analysis, the sensitivity analysis may help limit the scope of the uncertainty analysis by determining which model input parameters significantly affect the projected facility performance. In this sequence of events, the uncertainty analysis considers only the most sensitive parameters in the model. In other situations, a sensitivity analysis will use simulation results from an uncertainty analysis as input to statistical software to determine parameter sensitivities.

Sensitivity analysis allows the applicant and the department to focus on the model parameters of greatest consequence to the projected results. The results of the analysis may justify the use of simpler models, or they may provide insights into how the disposal system functions.

The need for uncertainty analysis arises from the fact that environmental and dose assessment models are inherently uncertain. Uncertainty in model projections arise from a number of sources. NRC has categorized these uncertainties as follows (NRC, 1994):

- Uncertainty in conceptual and mathematical models (model uncertainty).
- Uncertainty about the future state of the site (scenario uncertainty).
- Uncertainty in the input data used in the models (parameter uncertainty).

Model uncertainty pertains to the uncertainty associated with formulating the conceptual models of the disposal system and implementing those models as analytical or numerical solutions in computer codes. Uncertainties in the conceptual models may arise from limitations in the site data, ambiguities in interpreting site features, or inadequacies in the knowledge of relevant site processes. Sources of mathematical model uncertainties include the use of inappropriate mathematical approximations of environmental phenomena and errors introduced during coding. The analysis of model uncertainty generally involves collecting data to test or validate specific submodels or developing alternative models for possible future site conditions.

Analysis of scenario uncertainty considers errors introduced in model projections resulting from incorrect assumptions about the future state of the disposal site. The assumed future state of the site used in defining and justifying the exposure scenarios may not correspond to all possible future site conditions. The effects of scenario uncertainty typically are evaluated by selecting a comprehensive set

of exposure scenarios that accounts for disturbances to the disposal system that result from unanticipated processes and events.

In addressing scenario uncertainty, the applicant must project facility performance under the three major sets of system performance assumptions defined in Subsection 3.2 of this document. As a minimum, the applicant must evaluate the disposal system performance under the various constraints of the expected, design basis, and degraded conditions. Such evaluations will necessitate that the applicant project or assume (and justify) performance of principal design features under philosophical conditions consistent with and comparable to those of the three major sets of system performance assumptions.

Parameter uncertainty deals with the input parameters used in the mathematical models. Sources of parameter uncertainty include uncertainty associated with laboratory and field measurements, uncertainty in determining parameter values for use in a model, and uncertainty associated with the intrinsic variability of natural systems. Parameter uncertainties could be evaluated using one of several methods (NRC, 1994), including:

- Analytical methods and stochastic approaches.
- Monte Carlo methods, which include random and Latin Hypercube sampling approaches.
- Response surface methodology, which requires development of a simple approximation of a complex model.

3.6.3 Review Calculated Results for Reasonability and Consistency with Assumed Conditions/Preliminary Data

The applicant should review the results of all performance assessment calculations to ensure that they are reasonable and internally consistent. The results should be compared with assumed conditions to ensure that no logical contradiction exists. If calculated results infer a condition that is different from an assumed condition, the applicant should pursue the issue to determine whether the assumed condition should be revised, or whether aspects of the modeling process should be questioned.

The process of judging the reasonability of calculated results requires knowledge of the sensitivities and uncertainties. The results of the sensitivity and uncertainty analyses, and the perspective they provide, can help in evaluating whether calculated results are reasonable or require revision.

3.7 REVISE INPUTS, MODELS, AND ASSUMPTIONS

Upon reviewing the results of the performance assessment, the applicant should determine the need for revisions to the modeling process (see Figure 3-1). The extent of revisions may be as superficial as revising selected input parameter values. However, the review of the results may also reveal that the entire performance assessment process should be revised.

The applicant should consider the potential effects that any data revisions may have on performance assessment results. If the revisions are expected to have important effects, the assessment should be revised for consistency with the data revisions. The applicant also should subject the revised performance assessment to similar scrutiny to ensure that it is reasonable and internally consistent.

Revisions in the performance assessment process may be made within a particular stage of the facility life, or as the facility evolves from one stage to the next. If the revisions are made within a single facility stage, they may be made to virtually any step in the performance assessment process (see Figure 3-1). If the facility is progressing from one stage to the next, all steps in the process should be reviewed and previous decisions evaluated according to the most recent and complete information available.

REFERENCES

PADEP (Pennsylvania Department of Environmental Protection). 1997a. *Staff Technical Report: Overview of the Staff Technical Report Series.* (in preparation).

PADEP (Pennsylvania Department of Environmental Protection). 1998. *Staff Technical Report: Use of Engineered Structures to Provide Enhanced Containment.* June 1998.

PADEP (Pennsylvania Department of Environmental Protection). 1997c. *Staff Technical Report: Characterization of Sites for Low-Level Radioactive Waste Disposal in Pennsylvania.* (in preparation).

PADEP (Pennsylvania Department of Environmental Protection). 1997d. *Format and Content of the Low-Level Radioactive Waste Disposal Facility License Application.* (in preparation).

PADEP (Pennsylvania Department of Environmental Protection). 1997e. *Guidance for Review of the Low-Level Radioactive Waste Disposal Facility License Application.* (in preparation).

DOE (U.S. Department of Energy). 1990. "Guidelines for Sensitivity and Uncertainty Analyses of Performance Assessment Computer Codes." Prepared by EG&G Idaho, Inc., DOE/LLW-100, September 1990.

EPA (U.S. Environmental Protection Agency). 1988. "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion." Prepared by Oak Ridge National Laboratory, Federal Guidance Report No. 11.

EPA (U.S. Environmental Protection Agency). 1991. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual, Supplemental Guidance — Standard Default Exposure Factors.* OSWER Directive 9285.6-03.

EPA (U.S. Environmental Protection Agency). 1993. *External Exposure to Radionuclides in Air, Water, and Soil.* Prepared by Oak Ridge National Laboratory, Federal Guidance Report No. 12.

NRC (U.S. Nuclear Regulatory Commission). 1990. "A Performance Assessment Methodology for Low-Level Waste Facilities." Prepared by Science Applications International Corporation. NUREG/CR-5532. July 1990.

NRC (U.S. Nuclear Regulatory Commission). 1991. "Selection of Models to Calculate the LLRW Source Term." Prepared by Brookhaven National Laboratory. Upton, NY, NUREG/CR-5773. October 1991.

NRC (U.S. Nuclear Regulatory Commission). 1994. *Branch Technical Position on Performance Assessment for Low-Level Radioactive Waste Disposal Facilities.* Draft Report. January 1994.

APPENDIX A

TECHNICAL RESOURCES ON PERFORMANCE ASSESSMENT

APPENDIX A TECHNICAL RESOURCES ON PERFORMANCE ASSESSMENT

The following publications provide guidance for conducting radiological performance assessments. Several of these reports have been issued by agencies that have no regulatory standing in the Commonwealth or address types of radioactive waste other than low-level radioactive waste (LLRW). These resources are included because they help provide a broad perspective on the current level of expertise on the performance assessment process. Reading and reviewing these documents will provide more detailed information on the purpose and nature of performance assessment.

U.S. Nuclear Regulatory Commission

> Kozak, M.W. et al., 1990. "Background Information for the Development of a Low-Level Waste Performance Assessment Methodology, Computer Code Implementation and Assessment." Prepared by Sandia National Laboratories for the U.S. Nuclear Regulatory Commission, NUREG/CR-5453.

This document provides the implementation and assessment of computer codes for an LLRW performance assessment methodology. It presents a comparison between simple and complicated codes for groundwater transport, source term, surface water transport, air transport, food chain, and dosimetry analyses. Details of recommended analytical methods are given, along with sensitivity analyses that demonstrate important aspects of the solutions.

> Davis, P.A. et al. 1990. *Uncertainties Associated with Performance Assessment of High-Level Radioactive Waste Repositories, A Summary Report.* Prepared by Sandia National Laboratories for the U.S. Nuclear Regulatory Commission, NUREG/CR-5211.

This publication summarizes work in the topical area of uncertainty associated with performance assessments of high-level radioactive waste repositories. Three major categories of uncertainty covered in this report are uncertainty in the future state of the disposal system; uncertainty in models needed to simulate the behavior of disposal systems; and uncertainty in data, parameters, and coefficients needed for the analysis of systems.

Kozak, M.W. et al. 1990. *A Performance Assessment Methodology for Low-Level Waste Facilities.* Prepared by Sandia National Laboratories for the U.S. Nuclear Regulatory Commission, NUREG/CR-5532.

This report provides a summary of background reports on the development of the methodology for LLRW facility performance assessment, as well as an overview of the models and codes selected for the methodology. It includes a discussion of models and associated assumptions appropriate for each phase of the methodology.

Sullivan, T.M. 1991. "Selection of Models to Calculate the LLW Source Term." Prepared by Brookhaven National Laboratory for the U.S. Nuclear Regulatory Commission, NUREG/CR-5773.

This document provides a brief overview of disposal practices and reviews existing source-term models as background for selecting appropriate models for estimating the source term. It presents the rationale for selecting and mathematical details of the models, and provides guidance on combining the inventory data with appropriate mechanisms describing release from the disposal facility.

Sullivan, T.M. and C.J. Suen. 1991. *Low-Level Waste Source Term Model Development and Testing.* Prepared by Brookhaven National Laboratory for the U.S Nuclear Regulatory Commission, NUREG/CR-5681.

This publication develops a system model capable of predicting radionuclide release rates from a shallow land burial facility. It discusses models that predict water flow and radionuclide transport in detail, and presents results obtained from applying the models to shallow land burial trenches over a range of expected conditions.

Walton, J.C. et al. 1990. "Models for Estimation of Service Life of Concrete Barriers in Low-Level Radioactive Waste Disposal." Prepared by the Idaho National Engineering Laboratory, EG&G Idaho, Inc., for the U.S. Nuclear Regulatory Commission, NUREG/CR-5542.

This report reviews mathematical models for estimating the degradation rate of concrete in typical LLRW disposal facility service environments. The bases for models taken from the literature are explained. Example calculations are included to illustrate the application of the models and to indicate the types of predictions that can be expected from the models.

U.S. Nuclear Regulatory Commission. 1994. "Draft Branch Technical Position on Performance Assessment for Low-Level Waste Disposal Facilities." Low-Level Waste Management Branch, January 1994.

NRC developed this technical position paper to provide license applicants, licensees, states, and compacts with an acceptable strategy and methodology for performing the technical analysis required to demonstrate compliance with 10 CFR 61.

Pommersheim, J.M. and J.R. Clifton. 1991. "Models of Transport Processes in Concrete." Prepared by the National Institute of Standards and Technology for the U.S. Nuclear Regulatory Commission, NUREG/CR-4269.

This report discusses and presents models suitable for modeling the long-term performance of concrete structures. Conceptual and mathematical models for modeling the ingress of aggressive ions into the structures and the leaching of constituents from the concrete are presented. The application of these models to long-term performance assessments is discussed.

MacKenzie, D.R. et al. 1986. "Preliminary Assessment of the Performance of Concrete as a Structural Material for Alternative Low-Level Radioactive Waste Disposal Technologies." Prepared by Brookhaven National Laboratory for the U.S. Nuclear Regulatory Commission, NUREG/CR-4714.

This study develops information required to evaluate the long-term performance of concrete as a structural material for LLRW disposal. Information in the literature is reviewed and analyzed, and criteria for evaluating the performance of concrete are identified. The properties of coatings and their possible use in protecting the concrete are discussed. Accelerated and long-term testing of concrete is discussed, with emphasis on its application to modeling long-term performance.

Walton, J.C. and R.R. Seitz. 1991. "Performance of Intact and Partially Degraded Concrete Barriers in Limiting Fluid Flow." Prepared by EG&G Idaho, Inc. for the U.S. Nuclear Regulatory Commission, NUREG/CR-5614.

This document examines the factors that control fluid flow through intact and degraded concrete disposal facilities. Simplified models are presented for estimating the buildup of fluid above a vault; fluid flow through and around intact vaults; through flaws in coatings/liners applied to a vault; and through

cracks in a concrete vault; and the influence of different backfill materials around the outside of the vault. Example calculations are provided to illustrate the parameters and processes that influence fluid flow.

U.S. Nuclear Regulatory Commission. 1991. *Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility, Safety Analysis Report.* NUREG-1199, Rev. 2, January 1991.

This document explains what information must be provided in a Safety Analysis Report for an LLRW disposal facility. The section on safety (performance) assessment discusses the release of radioactivity from the facility, intruder protection, and long-term stability of the disposal site.

U.S. Nuclear Regulatory Commission. 1991. "Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility." NUREG-12009, Rev. 2, January 1991.

This report provides guidance to NRC staff reviewers who perform safety reviews of applications to construct and operate LLRW disposal facilities. It describes the types of performance assessment analyses it expects to be performed, reported, and justified. Important aspects of the performance assessment considered in the report include characteristics of the waste, infiltration, potential releases under normal and accident conditions, transfer of releases to human access locations, intruder protection, and long-term stability.

U.S. Department of Energy

Case, M.J. and M.D. Otis. 1988. "Guidelines for Radiological Performance Assessment of DOE Low-Level Radioactive Waste Disposal Sites," U.S. Department of Energy, DOE/LLW-62T.

This document provides guidance for conducting radiological performance assessments of U.S. Department of Energy LLRW disposal facilities. Discussions on performance assessment criteria, screening techniques used to focus resources on critical components, selection and/or development of suitable models, and techniques for comparing assessment results with performance objectives are included.

Maheras, S.J. and M.R. Kotecki. 1990. *Guidelines for Sensitivity and Uncertainty Analyses of Performance Assessment Computer Codes*. U.S. Department of Energy, DOE\LLW-100.

This report discusses the steps taken in performing sensitivity and uncertainty analyses of a LLRW disposal facility performance assessment. Techniques for conducting the uncertainty analysis, including analytical Monte Carlo, response surface, and differential methods, are discussed. Sensitivity analysis techniques discussed include coefficient and correlation methods.

Kennedy, W.E. Jr. and R.A. Peloquin. 1988. *Intruder Scenarios for Site-Specific Low-Level Radioactive Waste Classification.* U.S. Department of Energy, DOE\LLW-71T.

This report describes the types of intruder scenarios that should be considered when assessing potential intruder doses. It provides the results of generic calculations performed using unit concentrations of various radionuclides as a comparison of the magnitude of importance of the various intruder exposure scenarios, and shows the relationship between the generic doses and waste classification limits for defense wastes.

State Agencies

New York State Department of Environmental Conservation. 1988. *Supplement to the July 1987 Draft Environmental Impact Statement for Promulgation of 6NYCRR Part 382: Regulations for Low-Level Radioactive Waste Disposal Facilities, Modeling and Dose Assessment of Alternative Low-Level Radioactive Waste Disposal Methods in New York State.* Division of Hazardous Substances Regulation, Bureau of Radiation.

This report discusses modeling and dose assessment techniques of alternative LLRW disposal methods in accordance with the New York State regulations for LLRW disposal facilities (6NYCRR Part 382).

ATTENTION

Title 25 of the Pennsylvania Code is available electronically at:

www.pacode.com

25 ENVIRONMENTAL PROTECTION

Article V: Radiological Health

Pennsylvania has incorporated by reference the Federal radiation protection regulations found in 10 CFR Parts 19-150.

The federal regulations can be accessed at

http://www.nrc.gov/reading-rm/doc-collections/cfr/

Guidance to complete an Application is contained in the

NUREG 1556 Series

This guidance can be accessed at

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html

for the entire series.

Requirements for Low-Level Radioactive

Waste Minimization Plans

Pennsylvania Department of
Environmental Protection
Bureau of Radiation Protection

July 1998

Low-Level Radioactive Waste Minimization Program Plans (Final July 1998)

This document serves two purposes: 1) establish guidelines and criteria that department personnel can convert to regulatory requirements in a future rulemaking (i.e., generator permitting regulations as specified at Section 310 of Act 1988-12); and 2) provide low-level radioactive waste generators with advance notice of the department's intended approach for regulating waste minimization programs. The rulemaking process will be completed immediately prior to the start-up of regional disposal facility operations.

These preliminary activities will serve to provide all interested parties the opportunity to participate in establishing the framework of the future rulemaking package and to provide generators time to develop waste minimization program plans in advance of anticipated regulations, without worry of unreasonable schedules or regulatory oversight during plan development. It also provides a time period to determine if the criteria will serve the intended function (i.e., minimizing the toxicity and volume of low-level radioactive waste that must be disposed) prior to implementing regulations.

It is important to note that the document is directed at all generators that produce waste that must be disposed at the regional facility because the Low-Level Radioactive Waste Disposal Act (Act 1988-12) does not include a provision exempting small quantity generators from preparing waste minimization plans. However, the document does include provisions to minimize the administrative burden of preparing waste minimization plans or reports.

This document also may be used outside of the anticipated rulemaking process. Generators are encouraged to use this document as a guideline for designing and implementing voluntary waste minimization programs.

This final document is a revision of documents presented to the department's Low-Level Waste Advisory Committee (LLWAC) on December 12, 1997, March 12, 1998 and June 11, 1998. The document is organized according to the following sections: 1.0 Statutory Authority; 2.0 General Provisions; 3.0 Waste Minimization Plan Requirements; and 4.0 Oversight and Enforcement.

1.0 Statutory Authority

1. Waste minimization plan requirements will be included as part of the generator permitting regulations. The rulemaking package will be promulgated under the authority of the following statutes:

   Sections 310 and 302 of the Low-Level Radioactive Waste Disposal Act.

   Section 302 of the Radiation Protection Act.

   Section 1920-A of The Administrative Code of 1929.

   1.2 The following words and terms have the following meanings unless the context clearly indicates otherwise:

   Broker - Any intermediate person who collects, consolidates, handles, treats, processes, stores, packages, ships or otherwise has responsibility for or possesses low-level radioactive waste.

   Commission - The Appalachian States Low-Level Radioactive Waste Commission.

   Department - The Pennsylvania Department of Environmental Protection of the Commonwealth.

   Generator - A person whose activity results in the production of low-level radioactive waste requiring disposal.

Person - Any individual, corporation, partnership, association, public or private institution, cooperative enterprise, municipal authority, public utility, trust, estate, group, Federal Government or agency, other than the United States Nuclear Regulatory Commission or any successor thereto, state institution and agency, or any other legal entity whatsoever which is recognized by law as the subject of rights and duties. In any provision of the Low-Level Radioactive Waste Disposal Act (Act 1988-12) prescribing a fine, imprisonment or penalty, or any combination of the foregoing, the term "person" shall include officers and directors of any corporation or other legal entity having officers and directors.

Recycle - The reuse of radioactive materials. It includes on-site, "in-process" recycling and both on-site and off-site beneficial reuse under controlled (i.e., licensed or permitted) conditions.

Regional facility - A facility which has been approved by the commission and licensed under Act 1988-12 for the disposal of low-level radioactive waste.

Toxicity - The physical and chemical form and radiological properties of a radionuclide, that makes it available to interact, directly or indirectly, with the human body.

Toxicity reduction - Waste avoidance, recycling or the treatment of waste to lessen its availability to interact, directly or indirectly, with the human body.

Waste - Low-level radioactive waste.

Waste stream - A type or category of low-level radioactive waste such as: dry active waste, ion exchange resins, etc. Waste stream types or categories shall be consistent with the waste stream code designations contained in the department's quarterly reporting system (see attachment A for specific waste stream codes) or designations specified on the regional facility manifest forms (to be developed).

2.0 General Provisions

2.1 It is the policy of the department to encourage all users of radioactive materials to implement programs that minimize the generation of LLRW. Radioactive materials users seeking to implement waste minimization programs and users with active waste minimization programs are encouraged to embrace or enhance programs that include the continuous cycle of planning, implementing, reviewing and improving the actions that a person takes to meet its environmental obligations. The Bureau of Radiation Protection proposes to work with radioactive material users as they design and implement their waste minimization programs.

This policy will be backed by two specific actions that will take effect when regional facility operations begin; 1) adoption of a regional facility disposal fee schedule that encourages reduction of the toxicity and volume of LLRW, and 2) requiring, as a condition of issuing a regional facility access permit, that a waste generator have a plan for reducing the toxicity and volume of LLRW requiring disposal.

2. Waste minimization plans shall cover a five-year time period and address activities that reflect current operating practices and project anticipated future operating practices. Waste minimization plans shall be prepared in a manner that affords generators maximum flexibility in accommodating practice changes that result in further toxicity or waste volume reductions without having to request permit amendments. In addition, generators may choose to discuss past conditions to document and illustrate voluntary waste minimization practices (i.e., up to the effective date of promulgation of the generator permitting regulations specified at Section 310 of Act 1988-12 at startup of regional facility operations). Finally, each generator shall assure that implementation actions included in individual waste minimization plans (i.e., a plan covering any

five-year period) will not adversely affect (i.e., increase the toxicity or volume of LLRW requiring disposal) future decontamination and decommissioning activities.

Plans shall address the minimization of both the toxicity and volume of wastes generated. In situations where toxicity and volume minimization are mutually exclusive, preference shall be given to toxicity minimization.

The most effective method for minimizing waste toxicity and volume is source reduction/waste avoidance. Consequently, source reduction/waste avoidance should take precedence over other waste minimization practices. The priority of methods to be considered when designing and implementing a waste minimization plan and program are presented in order of preference:

1. Source reduction/waste avoidance: includes any practice that reduces the amount of radioactive materials entering a waste stream. This practice is conducted prior to recycling, treatment or disposal. Examples of source reduction/waste avoidance include but are not limited to; procedure or process modifications, technology or equipment modifications, materials segregation and substitution, and product redesign.

2. Recycle: pertains to the recycle/reuse of radioactive materials. It includes on-site, "in-process" recycling and both on-site and off-site beneficial reuse under controlled (i.e., licensed or permitted) conditions.

3. Treatment: includes any physical alteration of a waste stream that results in either or both the reduction of toxicity and volume of waste requiring disposal. Examples of treatment include but are not limited to; chemical or mechanical methods to remove radioactive materials from an item, solidification or encapsulation to make the radioactive materials more resistant to leaching and transport, separation, compaction, and incineration.

All waste minimization methods shall minimize the generation of secondary waste streams (including the generation of mixed wastes) and be conducted in compliance with all regulatory requirements.

3.0 Waste Minimization Plan Requirements

1. Waste Minimization Plan

A person whose activity results in the production of LLRW requiring disposal and seeks to dispose of the waste at the regional facility, is required to obtain a regional facility access permit. Preparation and a commitment to implement a waste minimization plan are a condition for receiving a permit for access. The plan shall satisfy the requirements described in section 3.1.1.

A person that certifies it is a one-time generator can satisfy waste minimization plan requirements by preparing and submitting a waste minimization report with its permit application. The report shall satisfy the requirements described in section 3.1.2.

1. Content of a Waste Minimization Plan

A person seeking a regional facility access permit is required to prepare and implement a waste minimization plan consistent with and in proportion to the amount and toxicity of radioactive materials used by the generator (see one-time generator exception, section 3.1.2). The same types of information are requested from all persons. Waste minimization plans shall consist of:

1. A statement of management commitment and support.

2. A summary discussion of the activities that result in the generation of waste and a description of the methods (i.e., the procedures and operations used to minimize the toxicity and volume of LLRW including; source reduction, recycle, treatment, etc., as discussed under section 2.2 of this document) that will be implemented to minimize the amounts of waste generated. For example, a generator may describe waste minimization methods as, "filtering and dewatering of liquid wastes," and "radionuclide segregation for decay-in-storage".

3. Generator-specified waste minimization goals including numeric goals and/or process goals.

4. A description of the program that will be used to assess the effectiveness of the waste minimization plan.

2. Content of a Waste Minimization Report

It is recognized that some persons that seek a regional facility access permit will be one-time waste generators. It is the department's intent to minimize administrative burdens on such persons and to assure that the minimal amount of waste is generated. Waste minimization reports shall consist of:

1. A statement from the person that it is a one-time waste generator (e.g., a scrap metal recycler that unknowingly received a radioactive source, a school that discovered old radioactive items as a result of cleaning out science labs, etc.).

2. A description of the events and/or activities that caused the wastes to be generated and require disposal.

3. Descriptions of the processes that will be or were implemented to minimize the amounts of waste generated and requiring disposal.

2. Waste Minimization Plan and Waste Minimization Report Reviews

An initial waste minimization plan or report shall be included as part of the generator's application for a regional facility access permit. It will be reviewed during the permit application review process.

Administrative procedures such as: verification of receipt of a generator's permit application; revising the permit application; requirements for issuance of a permit; conditions of the permit; etc., will be prepared as part of the broader rulemaking package for permitting generators, brokers and carriers access to the regional LLRW disposal facility (i.e., regional facility access permit). The procedures will include a requirement that an approved waste minimization plan or report is a condition for issuance of the regional facility access permit.

1.

2. Waste Minimization Plan Review

The department will review waste minimization plans for completeness, and to ensure that the plans are prepared in accordance with the Act and regulations. Reviewers are advised to consider generators discussions of: historic and planned waste minimization efforts for its licensed activities; anticipated product, process or service changes that may affect waste generation activities; justifications involving ALARA considerations, and health and safety versus cost considerations; and compliance with other regulations and regulatory guides that affect waste minimization plan decisionmaking. Such information will assist the department in evaluating the generator's overall approach and commitment to implementing waste minimization activities.

Reviewers also are advised to compare a generator's waste minimization plan against waste minimization plans of similar generator types (e.g., government, utility, industrial, etc.) as a method for determining the reasonableness of the specific waste minimization goals proposed by a generator.

Generators' waste minimization plans will be reviewed for the following:

1. A signed statement of support from management, committing to implement its waste minimization plan. This statement should be reviewed for the inclusion of the following types of information: commitment to waste minimization and the establishment of specific minimization goals and a commitment to provide funding for the waste minimization program; provisions for employee training and involvement; and a commitment to conduct periodic assessments to assure plan compliance and identification of opportunities for continued improvement (i.e., further waste minimization). The statement shall be evaluated for signature by a duly designated officer of the organization.

2. A summary discussion of the activities that result in the generation of waste and a description of the processes that will be implemented to minimize the amounts of waste generated. This section should be reviewed for the inclusion of a summary of the activities that result in the generation of waste requiring disposal. Summaries should be organized by waste stream (e.g., as reported by the generator on its quarterly reports to the department or on the generator's waste manifest forms). Proprietary information need not be disclosed in waste minimization plans. However, generators shall allow department personnel access to additional detailed records during site visits and inspections.

   Reviewers are advised to compare the generator's summary discussions against selected quarterly reports and waste manifest forms to confirm all reported waste streams are addressed in the waste minimization plan.

3. Generator-specified waste minimization goals. This section should be reviewed for the inclusion of the following types of information; priorities, methods, schedules and specific goals for minimizing the waste streams identified and discussed in section 3.1.1.2. This information will be reviewed in conjunction with the evaluation conducted under section 3.2.1.2 to understand the schedule for implementation, the waste minimization processes to be implemented (e.g., source reduction, recycle, etc.), priorities for waste stream minimization, and to confirm the generator considered all waste streams.

4. Inclusion of a program to periodically assess conformance with, and effectiveness of, the waste minimization plan. This section should be reviewed for the following types of information: identification of position (s) responsible for conducting the assessments; duties, responsibilities and authority of the position (s) responsible for conducting the assessments; frequency of assessments as related to generator-specific radioactive material use practices; and provisions for continuous improvement.

2. Waste Minimization Report Review

The department will review waste minimization reports to confirm that the generator submitted a statement certifying that it is a one-time generator; the statement was signed by a duly designated officer of the organization; and to confirm that the generator will or has implemented methods to minimize the toxicity and volume of waste requiring disposal.

3. Waste Minimization Plan Approval

The inclusion of an acceptable waste minimization plan or waste minimization report will be a condition for issuing a regional facility access permit.

The department will commit to a specific duration of time for reviewing and acting (i.e., approval or disapproval) on waste minimization plans and reports. This commitment will be included as part of the broader rulemaking package for permitting generators, brokers, and carriers access to the regional LLRW disposal facility.

4. Waste Minimization Plan Changes

Generators are required to submit revised waste minimization plans:

1. In conjunction with a permit renewal (i.e., every five years) for continued access to the regional facility. At a minimum, the generator shall assess its radioactive material use activities relative to opportunities for improved waste minimization. The generator shall document the assessment. If its radioactive material use activities are unchanged, the generator shall indicate that waste minimization plan changes are not required. If the assessment indicates opportunity for improved waste minimization, a revised plan shall be submitted with the permit renewal application.

2. When periodic assessment of waste minimization activities indicate a trend significantly different than expected (e.g., goals are not being achieved or activities are not being implemented).

Revised waste minimization plans shall conform to the requirements of "Content of a Waste Minimization Plan" (3.1.1). Waste minimization plan revisions shall be highlighted and justified where necessary (e.g., a less aggressive waste minimization goal due to the potential for increased exposure to workers or the public).

4.0 Oversight and Enforcement

1. Oversight

The department will determine the adequacy of generators' waste minimization programs through conduct of oversight activities.

1) The department will monitor waste minimization progress through analysis of generators quarterly and annual waste generation reports and information contained on waste manifest forms received at the regional facility.

2) The department may conduct inspections at generator facilities. The purpose of the inspections is to confirm waste minimization plan implementation. This includes exploring options for working with the Appalachian Compact party states and the Appalachian States Low-Level Radioactive Waste Commission to implement an effective on-site inspection program.

2. Enforcement

Enforcement options will be included as a separate section in the broader rulemaking package for permitting generators, brokers and carriers access to the regional facility.

It is anticipated that negative inspection findings will be categorized as "Level III" violations which are defined as "an act or omission, contrary to applicable statutes, regulations, or department orders which include violations that are administrative or clerical in nature and do not result in radiation exposure, radioactive contamination of the environment, or pose a threat to public health and safety."

Initial actions of the department will be to work closely with a generator to assist it in complying with the Act and regulations. Upon exhausting other options, the department may, in situations where generators

continuously and/or purposefully neglect to implement their approved waste minimization plans, terminate the generator's regional facility access permit.

Attachment A

Waste Stream Codes for PA DEP LLRW Database

STREAMCODE	STREAMNAME
00	NONE
01	ANIMAL CARCASSES OR NON-INFECTIOUS BIOLOGICAL WASTE
02	DRY ACTIVE WASTE - COMPACTED BY COMPACTOR
03	DRY ACTIVE WASTE - NON-COMPACTED
04	DRY ACTIVE WASTE - SUPER COMPACTED BY COMPACTOR
05	FILTER MEDIA - DEWATERED
06	FILTER MEDIA - SOLIDIFIED
07	GASEOUS SOURCES
08	INCINERATOR ASH OR RESIDUALS
09	ION EXCHANGE RESINS - DEWATERED
10	ION EXCHANGE RESINS - SOLIDIFIED
11	IRRADIATED REACTOR OR POOL COMPONENTS
12	LIQUID AQUEOUS - ABSORBED
13	LIQUID AQUEOUS - SOLIDIFIED
14	LIQUID ORGANICS, INCLUDING CONTAMINATED OIL
15	LIQUID SCINTILLATION (FLUIDS OR VIALS)
17	RADIOACTIVE SEALED SOURCES, DEVICES, OR GAUGES
18	SOLIDIFIED EVAPORATOR BOTTOMS/CONCENTRATIONS/SUMP SLUDGE
19	VITRIFIED ASH OR RESINS
99	OTHER* CONTACT PA DEP BEFORE USING THIS CODE: 1-800-232-2786

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STAFF TECHNICAL REPORT SERIES:

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June 1998

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APPENDIX A—TECHNICAL RESOURCES FOR THE DESIGN AND CONSTRUCTION OF ENGINEERED STRUCTURES

List of Figures

GLOSSARY/definitions

Concrete structure—A general term for any number of elements that comprise the disposal unit, such as floors, walls, and ceilings.

Container—The first enclosure that encompasses the low-level radioactive waste. In demonstrating compliance with enhanced containment requirements a concrete overpack, or similar package, is considered to be a container.

Containment—The function of isolating radioactive waste from the biosphere by emplacement of the waste within a container, waste module, or disposal unit.

Disposal facility—The buildings, equipment, and other engineered features, including disposal units and temporary holding facilities, within the disposal site that are used for the disposal of low-level radioactive waste.

Disposal site—The property, including improvements thereon, that are used for disposal of low-level radioactive waste. The term consists of the disposal units and the buffer zone.

Disposal unit—A discrete portion of the disposal site into which waste is placed for disposal.

Engineered structure—A manmade state-of-the-art barrier designed to:

1. Provide additional measures for containment of radioactive waste from the environment.

1. Provide protection for an inadvertent intruder.

1. Provide stability of the disposal facility.

1. Prevent radioactive release.

In demonstrating compliance with enhanced containment requirements, the disposal unit must function as the engineered structure.

Enhanced containment—Additional isolation of the radioactive waste from the environment as provided by engineered structures.

Leak resistance—The material properties of the disposal facility design that retard or prevent migration of water.

Post-closure observation and maintenance period. The period of time following site closure during which the site operator is preparing the site for transfer to the custodial agency.

Waste—Low-level radioactive waste.

Waste module—A discrete assembly of waste containers within a disposal unit. A waste module is established when two interior walls are constructed within a disposal unit. The purpose of a waste module is to enable detection and identification of water or leached radioactive materials within a disposal unit.

1. INTRODUCTION

The Pennsylvania Department of Environmental Protection (the Department) is responsible for promulgating regulations that govern the siting, design, construction, operation, closure, and post-closure maintenance of a low-level radioactive waste (LLRW) disposal facility in the Commonwealth of Pennsylvania (the Commonwealth) (CPA 88). These regulations are contained in Title 25 of the Pennsylvania Code, Chapter 236, entitled "Low-Level Radioactive Waste Management and Disposal" (25 PA 236) (CPA 89).

Subchapter D of 25 PA 236 identifies the design criteria for the Pennsylvania LLRW disposal facility. General design criteria call for an above-grade disposal facility designed, constructed, and operated with a goal of zero release of radioactive material. Furthermore, the disposal facility must be designed to complement and augment the ability of the disposal (natural) site to meet the performance objectives contained in 25 PA 236.13 through 236.16. Among the specific design requirements of 25 PA 236 is one that calls for the use of engineered structures in the design and construction of the disposal facility. The function of these engineered structures is to provide enhanced containment, or additional isolation, of the LLRW from the environment.

In compliance with the general design guidance, the Pennsylvania LLRW disposal facility will consist of a series of above-grade concrete disposal units. Packaged waste will be placed in reinforced concrete overpacks which, in turn, will be placed in the disposal units.

The Department considers the concrete overpacks to be the first enclosure, or container, that contains the radioactive waste. Since Pennsylvania regulations do not allow reliance on the waste container as a means of meeting the requirements for enhanced containment, only the disposal units can be relied upon to provide enhanced containment of the waste therein.

Justifying the use of the concrete disposal units to provide enhanced containment is the subject of this staff technical report. This report discusses important issues in designing, constructing, monitoring, and closing the LLRW disposal facility. Key aspects of the long-term performance of engineered concrete structures are also addressed.

Section 2 of this report begins with a review of the regulatory requirements that apply to the use of engineered structures, in general, and the concrete disposal units, in particular, to provide enhanced containment of LLRW. Section 3 presents a number of issues related to the design and construction of concrete disposal units, monitoring of the structures, and the evaluation of the long-term performance of the disposal units. Section 4 provides regulatory guidance on the design, construction, monitoring, and long-term performance modeling of the concrete disposal units for LLRW disposal.

It is envisioned that the applicant will reference and utilize this staff technical report in the following manner:

- Utilize the regulatory requirements (summarized in Section 2) and the regulatory guidance (Section 4) as the focal point for demonstrating compliance with enhanced containment requirements and ensuring long-term performance of the disposal facility.

- Review the various degradation mechanisms that can affect concrete and disposal unit performance (i.e., Subsection 3.4), when evaluating the natural site conditions and available cement pastes and aggregates for the concrete.

- Consider and implement the necessary codes and standards, quality programs, and monitoring techniques (i.e., Subsections 3.1, 3.2, 3.3, and 3.5) required to mitigate potential degradation mechanisms and conditions and to ensure the long-term performance of the engineered structures and disposal units.

2. REVIEW OF COMMONWEALTH REGULATORY REQUIREMENTS

The Pennsylvania Code (25 PA 236) establishes the requirements for LLRW disposal in the Commonwealth (CPA 89). It is based on Title 10 of the Code of Federal Regulations, Part 61 (10 CFR 61), "Licensing Requirements for Land Disposal of Radioactive Waste" (NRC 82). While 25 PA 236 is compatible with 10 CFR 61, it contains additional requirements specific to the development of a LLRW disposal facility in Pennsylvania. 25 PA 236 forms the sole basis for regulating LLRW disposal in the Commonwealth.

25 PA 236 establishes the requirement that enhanced containment be provided through the use of engineered structures (25 PA 236.314(a)). Enhanced containment is defined as "Additional isolation of the radioactive waste from the environment..." (25 PA 236.2). An engineered structure, in turn, is defined as a manmade, state-of-the-art barrier that is "...intended to improve the disposal facility's ability to meet the performance objectives [of 25 PA 236.13 through 25 PA 236.16]" (25 PA 236.2). The structure is designed to provide:

- Additional measures for containing radioactive waste from the environment.
- Protection for inadvertent intruders.
- Stability to the disposal facility.
- Prevention of radioactive releases.

Special requirements are placed upon the engineered structures used to provide enhanced containment. At a minimum, these structures shall provide the following:

- Leak resistance for at least 100 years following the post-closure observation and maintenance period (25 PA 236.314(b)(1)).
- Structural stability to the disposal units (25 PA 236.314(b)(2)).

The design goal of the engineered structures must be such that stability of the Class A LLRW disposal unit is provided for 100 years. Stability of the Class B disposal units must be provided for 300 years, while provisions must be made to ensure structural stability of disposal units containing Class C LLRW and mixed waste for 500 years (25 PA 236.314(d)).

As stated earlier, enhanced containment requirements cannot be satisfied by the waste container itself (25 PA 236.314(a)). The waste container is defined as the first enclosure that contains the LLRW (25 PA 236.2), and is interpreted by the Department to be the concrete overpacks included in the conceptual design of the disposal facility. Based on this interpretation, the concrete overpacks cannot satisfy the requirements for enhanced containment. Thus, the concrete disposal units included in the facility design must be capable of meeting the requirements discussed above. Consequently, this report focuses on key design, construction, and performance issues as they relate to the disposal units.

RELYING ON THE DISPOSAL Unit TO PROVIDE ENHANCED CONTAINMENT

25 PA 236 requires that engineered structures be used to enhance the containment of LLRW in the disposal facility. However, it provides no information on how to design or build these structures, or on how to assess their performance to demonstrate that they satisfy the minimum performance requirements. The following discussion provides background information on these topics and supplies the perspective necessary to understand the regulatory guidance provided in Section 4. Subsection 3.1 addresses important aspects of the design of the concrete disposal units, while Subsection 3.2 presents issues related to disposal unit construction. Subsection 3.3 presents monitoring approaches that may be used to verify proper functioning of the disposal units. Subsection 3.4 considers the durability of concrete, the processes by which concrete degrades, and the types of long-term performance modeling that are generally used to demonstrate that the disposal units function properly. Subsection 3.5 presents the importance of formal quality assurance (QA) and quality control (QC) programs. Appendix A lists several technical resources that consider in greater detail many of these aspects of engineered structures.

DISPOSAL UNIT DESIGN

The ability of the concrete disposal units to provide satisfactory long-term performance will depend on the manner in which they are designed and constructed. This section discusses several aspects of the design process that are unique to using concrete as a building material in LLRW disposal applications. Unique aspects of the construction process are presented in Subsection 3.2.

The codes, standards, and guidance established for the design of reinforced concrete structures are discussed below. The codes and standards established by the American Concrete Institute (ACI) address most of the state-of-the-art technologies for the design and construction of reinforced concrete structures. These codes and standards are presented in Subsection 3.1.1, while pertinent codes and standards issued by other organizations and regulatory agencies are presented in Subsection 3.1.2. General design approaches applicable to the concrete disposal units are presented in Subsection 3.1.3.

American Concrete Institute Codes and Standards

ACI has developed several codes and standards for the design of reinforced concrete structures (ACI 90). While the majority of these codes and standards pertain to the design of reinforced concrete structures in general, others specifically address the use of reinforced concrete in the nuclear industry. The following paragraphs summarize the principal ACI codes and standards.

ACI 350R-89, "Environmental Engineering Concrete Structures," provides recommendations for structural design, materials, and construction of concrete tanks, reservoirs, and other structures commonly used in water containment and in industrial and domestic water and wastewater treatment works. In these applications, dense, impermeable concrete with high resistance to chemical attack is required. Given the emphasis this code places on the low permeability of the concrete and its resistance to chemical attack, it is directly applicable to the design of concrete engineered structures as they are used in LLRW disposal facilities.

ACI 350R-89 also provides recommendations to maximize the watertightness and durability of the concrete. Important mechanisms of environmental attack are noted, including freeze-thaw attack, sulfate attack, and corrosion processes. Emphasis is placed upon structural design that minimizes the possibility of cracking. The code also discusses the design of construction joints for watertightness. Important material properties of admixtures, water, and aggregates, as well as construction details for placing concrete, for placing formwork, and for curing, are discussed. Finally, the code identifies ways to protect the reinforced concrete against chemical attack.

The ACI Guide to Durable Concrete (ACI 201.2R-77(82)) discusses significant causes of concrete deterioration and gives recommendations on how such damage may be avoided. Topics of discussion include freeze-thaw cycling, chemical exposure, abrasion, corrosion of steel reinforcement and other materials embedded in concrete, and chemical reactions of aggregates. The repair of damaged concrete and the use of coatings to enhance concrete durability are also discussed.

ACI Code 224.1R-89, "Causes, Evaluation, and Repair of Cracks in Concrete Structures," discusses the principal causes of cracking in concrete and recommends procedures for crack control. The code discusses the mechanisms of cracking in concrete, ways to control cracking due to drying shrinkage, and crack control for flexural members. Long-term effects of cracking are also addressed, including the long-term effects of an adverse environment in producing and enlarging concrete cracks. The primary environmental effect considered in the code deals with freeze-thaw cycling. The potential effects of alkali-aggregate reactions and applying de-icing salts to the concrete also are briefly considered.

The ACI 349-90 Series, "Code Requirements for Nuclear Safety Related Concrete Structures and Commentary," provides the minimum requirements for the design and construction of nuclear-safety-related concrete structures and structural elements for nuclear power generating stations. These structures and elements include concrete structures that support, house, or protect nuclear safety systems or components, or which are component parts of nuclear safety systems.

ACI 349-90 also discusses standards for tests and materials, construction requirements, general requirements, and structural systems or elements. It addresses specific topics such as materials, concrete quality, mixing and placement of concrete, construction

joints, details of reinforcement, analysis and design, strength and serviceability requirements, and flexural and axial loading. ACI 349-90 is more conservative than ACI 318 in terms of structural design requirements and, as such, is an excellent resource for the design of the disposal units. This code, however, is less conservative than ACI codes 224.1R-89 and 350R-89 with respect to limiting stresses and controlling cracking in structural elements. Consequently, it is important to consult these latter codes.

The ACI 318 Series, "Building Code Requirements and Commentaries for Concrete Structures," addresses the proper design and construction of reinforced concrete structures. The code discusses standards for tests and materials, construction requirements, general requirements, and structural systems and elements. Specific topics include permits and drawings, inspections, specifications, materials, concrete quality, mixing and placing, construction joints, reinforcement details, strength and serviceability, flexural and axial loads, and shear and torsion.

Other Codes and Standards

The NRC provides specific guidelines for the design of below-ground vaults and earth-mounded concrete bunkers in "Recommendations to the NRC for Review Criteria for Alternative Methods for Low-Level Radioactive Waste Disposal" (De 87). The recommendations and technical guidance given in these reports are based on civil and structural engineering experience that can be used for similar, reinforced concrete disposal structures.

American National Standards Institute ANSI A58.1-1982 (ANSI 82) gives structural design requirements for various loads, including dead, live, soil, wind, snow, rain, and earthquake loads under normal conditions. If structural steel is involved, the design guidance issued by the American Institute of Steel Construction's Manual of Steel Construction (AISC 89) is applicable for use in the design and construction of steel members.

General Design Approach

In designing concrete structures for use in LLRW disposal units, conservative but reasonable assumptions and approaches are used. Strategically selecting a design philosophy and design methods that provide assurance of long structural life is an important aspect of the design approach. These aspects of the design approach are discussed below.

An effective design will provide reasonable assurance that the disposal units will fulfill their long-term performance goals. To provide this assurance, long-term performance modeling of the disposal units is generally undertaken during the design phase. The results of the modeling are used to refine the basic design of the units to address disposal facility and site characteristics that may compromise the units' performance. Design modifications and modeling analyses are performed in an iterative fashion until an efficient, cost-effective design is identified. While the following discussion focuses on design, additional information about long-term performance modeling is presented in Subsection 3.4.

Design Philosophy

A design philosophy that has been used to ensure long structural life considers design conditions at early and late stages of the structure's life. During the structure's early years, while reinforcing steel is in generally excellent condition, the tensile strength of the steel is taken into account in designing the structure. Late in the life of the structure, when the reinforcing steel may not be sound, the design is based on a plain concrete structure (core) capable of bearing all loads that may exist at that time. Using this approach, the structural safety factor (i.e., the ratio of the structural strength and the forces and moments resulting from applied loads) can decline with time due to degradation mechanisms without jeopardizing structural stability.

Figure 3-1 illustrates some of the results of the general design philosophy described above. In the figure, the safety factor substantially exceeds unity in the early portion of the structure's life (from time 0 to time T_1), as long as reinforcing steel is intact. The safety factor declines slowly from time 0 to time T_1, the time at which corrosion of the steel reinforcement begins. Corrosion proceeds until the steel reinforcement makes no contribution to structural stability at time T_2. The period during which the steel corrodes, from T_1 to T_2, is characterized by a rapid decline in the safety factor. From time T_2 on, only a core of plain concrete remains, which must be capable of bearing all loads that may exist for the remaining life of the facility. Concrete degradation continues until time T_3, at which point the safety factor approaches unity and the structure is assumed to fail structurally.

The onset of steel corrosion can be controlled by specifying concrete with characteristics that retard the diffusion of oxygen and chlorides and by providing adequate concrete cover over the reinforcement. By selecting the design life to coincide with the onset of steel corrosion, when the structural safety factor is still well in excess of unity, assurance is provided that the disposal units will perform as required throughout their design life. In all likelihood, this approach will ensure that the disposal units will actually perform as required long beyond their design life. Such additional assurance will contribute to public and regulatory confidence that the disposal facility will adequately protect public health and the environment.

Figure -1 Summary of Safety Factor vs. Time for a Reinforced Concrete Structure

Design Method

The NRC recommends the strength design method for the design of reinforced concrete structures (De 87). In this approach the required strength, U, is set equal to or greater than the greatest of the following load combinations:

$U_1 = 1.4D + 1.4F + 1.7L + 1.7H + 1.7E$		**(3-1)**
$U_2 = 1.4D + 1.4F + 1.7L + 1.7H + 1.7W$		**(3-2)**
$U_3 = D + F + L + E + H + T$		**(3-3)**
$U_4 = D + F + L + W + H + T$		**(3-4)**

where

D = dead loads or related moments and forces

F = loads due to lateral and vertical pressure of incidental liquids, if applicable

L = live loads

H = loads due to earth pressure, if applicable

E = loads generated by the design-basis earthquake

W = loads from design wind pressure

T = loads from temperature differences within the structure

Any load that reduces the effects of other loads is assigned a coefficient of 0.9 if it can be demonstrated that the load is always present or occurs simultaneously with other loads.

In general, the thermal loads on the concrete disposal units, specified in Equations (3-3) and (3-4), are not expected to be great enough to dominate the design process. Consequently, the loading conditions represented by the first two equations will most likely prove limiting. Nevertheless, all loading conditions are typically evaluated to ensure the validity of this expectation and to allow appropriate response if the expectation is not supported.

In designing disposal units, the cover system self weight is considered to be a live load (with a load factor of 1.7), rather than a dead load (with a load factor of 1.4), for two reasons. First, the density of the soil used in cover construction can vary seasonally with water content. Second, because the construction tolerances are greater for earthwork than for concrete work, the as-built cover thickness may be greater than the design cover thickness.

The concrete elements and the reinforcement provided in the structure are designed to control cracking by considering the following two extreme cases:

1. The tensile strength of reinforcement is conservatively ignored in evaluating structural response under unfactored service load conditions. The concrete element thicknesses necessary to prevent potential cracking are determined using this case as the basis.

1. The tensile strength of concrete is conservatively ignored in evaluating structural response under service conditions so that the reinforcement bears all tensile forces. Reinforcement for Class A disposal units is designed to limit cracking under "normal exposure" and for other waste classes under "severe exposure" as specified in ACI 224 and ACI 350. The permissible values stated in these codes are compatible with the objective of minimizing concrete permeability and ensuring long-term durability.

An alternate design method, defined in ACI 318, may be used to calculate stresses in the concrete and reinforcement under service load conditions. This method is suitable for estimating potential cracking in concrete members while the reinforcement is in good condition. However, because the reinforcing steel will eventually corrode, the structure can be modeled as a plain concrete structure, as described above. The permissible stresses in the plain concrete due to factored loads are provided in ACI 318.1-83 (revised 1987). It is important that the expected strength of plain concrete structures, without reliance on reinforcement, be sufficient to withstand the factored service loads over the desired service life of the structure.

Concrete is typically designed with a compressive strength and water-to-cement ratio adequate to maintain its strength and minimize its permeability. Concrete that will be exposed to ambient weather conditions for long periods is air-entrained to provide additional protection from freezing. All construction joints are keyed and treated according to ACI recommendations. Continuous waterstops of 316L stainless steel may be provided at all construction joints in exterior members of the structure.

The concrete disposal units are designed to be stable against overturning and sliding under lateral loading conditions. Accordingly, the structural design is compatible with foundation soil conditions to prevent any adverse effects. Specifically, the maximum bearing on soil, maximum deformation or settlement, and maximum differential settlement are specified to preclude structural damage and damage to water barrier components (e.g., structural members, coatings, membranes, and the cover system).

Site characteristics, including site geology, seismology, meteorology, climatology, and hydrology, will influence the performance of the disposal units. The potential effects of these factors are considered in the facility design. Specifically, the design ensures that the disposal units can perform adequately under routine and extraordinary environmental conditions. As stated earlier in this section, the structure is designed with safety margins or factors that ensure it will perform adequately through the end of its design life, even under potentially adverse conditions.

DISPOSAL UNIT CONSTRUCTION

Proper construction practices take into account the quality of the materials used in the disposal units and the methods used to construct the units. Subsection 3.2.1 presents important aspects of selecting and testing materials suitable for construction. Codes and standards for construction techniques are addressed in Subsection 3.2.2.

Concrete Mix Characteristics

Numerous technical publications are available on selecting and testing materials for use in the construction of reinforced concrete structures. These resources include codes, tests, standards, specifications, guides, standard practices, special publications, and recommended practices issued by the American Society for Testing and Materials (ASTM, e.g., ASTM 93), the ACI (ACI 90), and the Nuclear Regulatory Commission (De 87). Key aspects of material quality and testing found in these publications are discussed below; however, it is important that a more complete review of these codes and standards be made before using them in the design of the reinforced concrete structure.

Portland cement concrete used to build the reinforced concrete structure typically is air-entrained and composed of a type of Portland cement, water, coarse and fine aggregate, and admixtures that will enhance the quality and durability of the concrete. High-range, water-reducing admixtures (HRWRA) may be added to reduce the water-cement ratio to 0.4 or less while maintaining a workable slump. A suitable slump range for the concrete is 5 to 7.5 cm (2 to 3 in.) without HRWRA, and 15 to 23 cm (6 to 9 in.) with HRWRA. The unconfined compressive strength of the concrete is at least 28 mPa (4000 psi) at 28 days, and the concrete contains 6 to 7 percent air by volume. The physical and mechanical properties of the concrete are established by an approved and certified testing laboratory based on trial mixtures and using the appropriate test methods and standards.

The Portland cement is chosen taking into account the environmental, loading, and durability requirements. The type of cement selected meets the appropriate requirements of ASTM C 150, "Standard Specification for Portland Cement." The coarse and fine aggregates used in the concrete are hard, durable aggregates that meet the requirements of ASTM C 33, "Standard Specification for Concrete Aggregates," while the mixing water is free of oils, organic matter, and other deleterious materials. Potable water is generally acceptable for mixing water, provided that chlorine content is limited to levels that do not compromise the durability of the structure.

Finely divided mineral admixtures that are cementitious, pozzolanic, or both may be used for partial replacement of Portland cement. Admixtures considered for use in the concrete meet the applicable requirements for the admixtures, "Chemical Admixtures for Concrete" (ACI 212.3R-91). A demonstration of the admixture's ability to enhance the quality and durability of the concrete is submitted to the regulatory agency before the start of construction. All admixtures are submitted for acceptance and evaluated for effectiveness and feasibility as recommended in ACI 212.3R-91.

Admixtures serve at least one of the following functions:

1. Ensure the proper entrainment of air.

1. Allow regulation of the amount of water in the mix.

1. Control the time of set.

1. Act as a void filler (e.g., as with mineral admixtures).

All admixtures used in the mix are composed of quality materials to ensure that the concrete will perform as expected and to obtain the desired engineering, physical, and mechanical properties.

If fly ash is used as a blend material, its volume is generally limited to less than 25 percent of the volume of cement. Similarly, when silica fume is used as a blend material, its volume is usually restricted to less than 15 percent of the volume of cement. To achieve adequate compressive strength, the ratio of water to cement plus blend material is typically between 0.2 and 0.3. This necessitates the use of an HRWRA to increase the slump to a value that produces a workable mixture compatible with placement requirements. The amount of HRWRA necessary to achieve this workability depends upon the amount of silica fume used. The relative quantities of fly ash, silica fume, and HRWRA required in the mix are typically determined by testing trial batches.

Reinforcing steel typically meets the requirements of ASTM A 615, A 616, and A 617, as appropriate, and may be epoxy-coated in accordance with the requirements of ASTM A 775. Bar supports and wire ties may also be epoxy-coated. Structural steel typically meets the requirements of ASTM A 36 and may be coated with epoxy or other acceptable coating material for protection against oxidation, corrosion, sulfate and chloride attack, and other degradation mechanisms.

Construction Methods for Reinforced Concrete Structures

The ACI has issued codes and standards on several aspects of the construction of reinforced concrete structures, including formwork; concrete measuring, mixing, placement, transport, consolidation, and curing; and reinforcing steel detail and construction (ACI 90). The following paragraphs summarize the important aspects of these codes and standards.

Guidelines for the layout, design, and construction of formwork are contained in ACI 347. This code includes design criteria for vertical and horizontal forces and lateral pressures, capacities of formwork accessories, preparation of formwork design drawings, construction and use of forms, and materials for formwork. The forms are constructed and erected in a manner consistent with industry standards that will facilitate a logical, well-engineered construction sequence that will produce the finished structure as required. Forms, shoring, and bracing are inspected to verify (1) the adequacy of their number and type, (2) their correct location, and (3) their required dimensions, alignment, and surface finish. The re-use of forms and formwork is typically limited to applications that will duplicate or equal the required quality of workmanship and finished structure.

Forms are properly supported, braced, and tied to maintain position and shape. Completed concrete work typically has a smooth finish and uniform color, and is level, plumb, and true. Forms are substantial and sufficiently tight to prevent leakage of cement paste or mortar. The exposed surfaces of the forms produce smooth, dense, and true finishes free of fins, imperfections, and other defects. The forms are not removed until the concrete has acquired sufficient strength to safely support its own weight and any loads placed on it. It is important that the methods for removing formwork prevent marring, breakage, and other damage to concrete.

Steel reinforcement includes reinforcing bars, stirrups, spirals, and other reinforcement materials with necessary wire ties, bar supports, spacers, block supports, and other devices required to install and properly secure reinforcement. Fabrication and placement of the reinforcement typically conform to the appropriate sections of ACI 318 or ACI 349 and ACI SP 66(88). Reinforcement is installed or placed in a manner consistent with good workmanship and applicable standards. It is free of loose rust or scale, grease, dirt, and any other coating that could reduce or destroy the bond between the steel and the concrete. The reinforcement is anchored so it does not move during concrete placement and vibration operations. The quality, location, and alignment of the reinforcement are confirmed prior to concrete placement.

The concrete mixture is proportioned as described in Subsection 3.2.1 of this staff technical report and in accordance with the provisions of ACI 211.1, Chapter 5. Concrete is mixed until the materials are uniformly distributed and is discharged completely before the mixer is recharged. Production of concrete proceeds in accordance with the applicable requirements of ACI 301.

The casting operations for the floors, walls, partitions, and roofs of concrete structures include the production, hauling, placement, vibration, finishing, and curing of the concrete. Whether the concrete is produced on-site or at an off-site plant, the production, transportation, and placement of concrete typically conform to the recommendations and provisions of ACI 304. Ready-mixed concrete complies with ASTM C 94. If the concrete is pumped into the forms, the pumping operations and equipment conform to the provisions of ACI 304.2. If the concrete is placed in the forms by conveyor belt, the operations and equipment conform to the provisions of ACI 304.4.

Mixed concrete is placed in the forms as quickly as possible to prevent segregation or loss of ingredients. Concrete is placed in a continuous and uninterrupted operation to form a monolithic structure, the components of which are securely bonded together. Concrete operations during hot or cold weather typically conform to ACI 305 or ACI 306, respectively.

Proper consolidation or vibration of concrete is essential to the construction of a durable concrete structure. Concrete is consolidated by vibration sufficient to work the concrete around reinforcement, around embedded items, and into corners of forms, thereby eliminating air or stone pockets. Consolidation operations conform to the provisions of ACI 309.

Following placement and finishing of the concrete, curing operations begin as appropriate, generally as soon as the concrete has lost its surface sheen. Curing operations conform to the provisions of ACI 308. If defects exist in the concrete, they are repaired according to the provisions of ACI 309.2R-90 or reconstructed.

A QA/QC program conforming with that described in "Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility" (Pe 87) also is implemented. This program specifies the frequency of sampling or testing to verify the design specifications during mixing and placement of concrete. The results of tests used to verify material characteristics and structural properties are included in the design documents.

MONITORING OF CONCRETE DISPOSAL UNITS

As discussed earlier, the concrete disposal units will deteriorate over time from loads, stresses, and chemical attack. The degradation of these structures will compromise their ability to resist leakage and provide structural stability and, therefore, to provide enhanced containment. The monitoring program provides information required to verify the ability of the disposal units to fulfill their intended functions.

The concrete disposal units may contribute to leak resistance directly or indirectly. The low permeability of good-quality concrete directly resists leakage by limiting the movement of water through the structure and thus through the waste. The disposal units may also contribute indirectly to leak resistance through their support of the cover system, which directs water away from the disposal system. Given the dual role of the disposal units, the monitoring program is designed to provide information about both the hydraulic and structural performance of the disposal units.

The ACI provides guidance for developing state-of-the-art concrete testing programs using nondestructive means ("In-Situ Non-Destructive Testing of Concrete," ACI SP-82). The available methods take two approaches to concrete testing. Under the first approach, one or more properties of the concrete are measured and used to estimate the material's strength, durability, and elastic parameters. The measured properties may include the concrete's hardness, its rebound number, its resistance to penetration, and its ability to propagate ultrasonic pulses. The second type of nondestructive test includes methods that determine the location and size of defects in the steel reinforcement, the moisture content of the concrete, and the existence of voids, cracks, honeycombing, and areas of poor consolidation in the concrete.

Reinforced concrete structures can be monitored to verify design assumptions about loads, stresses and strains, deflection, and settlement, and to evaluate performance. Strain measurements can be conducted to assess the stresses that develop at various locations within a structure. Relatively long-term measurements of strain in concrete or reinforcement can be made using several types of gauges, including Carlson strain meters, vibrating wire strain gauges, and Carlson reinforced concrete meters. Short-term measurements can be made with various embedded gauges such as Ailtech embeddable strain gauges and strain-gauged steel reinforcement.

Deflection measurements of a disposal unit can be made to determine its load-deformation characteristics. Generally, this involves taking measurements from observations made through geodetic triangulation of external targets attached to the structure. Settlement of the structural foundation can be monitored to detect potentially unsafe conditions before structural distress occurs.

Construction joints in the disposal structures will expand and contract with changes in temperature. Joint expansion may allow water to seep into the vaults and radionuclides to be released into the environment. This movement can be monitored with strategically placed meters or gauges. Joints can be monitored electrically with Carlson joint meters.

Different monitoring approaches are used to detect changes in humidity within the disposal units early in their lifetimes and to measure the rate at which water may flow through the units much later. Methods available for monitoring humidity in the disposal units include:

1. Soil gas sampling—Soil gas samples can be collected from several representative locations within the vault, at a frequency ranging from quarterly to annually. Gas can be withdrawn through small-diameter stainless-steel tubing and passed over a condensing coil until an adequate condensate volume is obtained. The humidity or moisture content of the gas can be inferred using the total volume of gas withdrawn and gas temperature.

1. Epithermal neutron logging—Access tubes can be installed to accommodate neutron density gauge probes, which measure the moisture content of soils inside the disposal unit.

By taking such measurements periodically, the temporal behavior of moisture within the disposal units can be determined.

For saturated conditions, monitoring wells can be incorporated in the disposal units for the collection and analysis of liquids in the drains and sumps of the disposal units and in the foundation. Monitoring wells can be designed and installed to last many years with minimal maintenance requirements. Monitoring wells placed in drain sumps provide an opportunity for determining the amount and characteristics of effluent from individual disposal units. These wells also permit the removal of leachate through pumping or bailing, if such measures become necessary.

Coatings, sealants, membranes, and joint materials used to construct the disposal units will eventually be covered and not be available for monitoring and inspection. Therefore, emphasis is placed on the initial fabrication, construction, and installation of these design features. Quality control measures for material type, quantity, quality, specification, and installation can be implemented during the construction period to maximize the likelihood that these barriers will perform suitably over extended periods.

LONG-TERM PERFORMANCE MODELING OF THE DISPOSAL UNITS

The engineered disposal units will function properly for extended periods to meet the requirements for the provision of enhanced containment. As discussed in Section 2, leak resistance is provided for at least 100 years following the post-closure observation and maintenance period. The time over which structural stability of the disposal units is demonstrated is specific to the type of waste, and ranges from 100 to 500 years.

The ability of the monitoring program discussed in Subsection 3.3 to demonstrate that the disposal units will fulfill their intended roles is limited because it indicates only past and current performance. Long-term performance modeling of the engineered structures, through its ability to project future performance, complements facility monitoring efforts. Together, monitoring and performance modeling provide a comprehensive approach for understanding the performance of the disposal units.

The ability to model or project the long-term performance of the engineered disposal units requires an understanding of the processes by which the concrete structures may deteriorate and fail. Toward this end, a summary of the primary mechanisms of concrete degradation is provided in Subsection 3.4.1. Subsection 3.4.2 considers the effects that degradation has upon the ability of the disposal units to perform their intended functions. Subsection 3.4.3 uses this information as the basis for discussing the considerations involved in long-term performance modeling of the disposal units.

Mechanisms of Concrete Degradation

Mechanisms of concrete degradation may be categorized in terms of how they attack concrete structures. The following discussion is organized in terms of three such mechanisms. Section 3.4.1.1 discusses surface attack mechanisms, which start at the surface of a concrete structure (e.g., roof or floor) and progress inward over time. Bulk attack mechanisms, which modify the properties of the concrete throughout the structure uniformly, are discussed in Subsection 3.4.1.2. Subsection 3.4.1.3 discusses the deterioration of steel reinforcement due to corrosion. Reinforcement corrosion differs from surface and bulk attack mechanisms in that it does not directly alter the material properties of the concrete itself.

Surface Attack Mechanisms

Sulfate attack is generally considered the most significant surface attack mechanism for concrete used in waste disposal facilities (At 84). In areas characterized by cold winters, freeze-thaw cycling may also present a serious threat to concrete used in disposal facilities. Impacts from freeze-thaw cycling are greatest for above-ground disposal facilities, or for below-ground facilities during the construction phase for as long as the concrete structures are exposed to freezing temperatures. Acid and microbiological attack of concrete are generally less significant. Each of these surface attack mechanisms is discussed briefly below.

Sulfate Attack—Sulfate attack generally manifests itself as expansion of the concrete and, ultimately, cracking. As the concrete cracks, its permeability increases, allowing water to penetrate more easily and thus accelerate deterioration. Sulfate attack can also result in a progressive loss of strength and mass due to deterioration in the cohesiveness of hydration products in the cement. Degradation of concrete from sulfate attack may occur through two distinctly different mechanisms. The mechanism that will predominate in a given situation depends upon the concentration and source of sulfate (i.e., the associated cation) in the groundwater and the composition of the cement paste in the concrete.

In the first mechanism of sulfate attack, alumina-bearing hydrates in the concrete are converted to ettringite ($3CaO \cdot Al_2O_3 \cdot 3CaSO_4 \cdot 32H_2O$) upon contact with sulfate in the presence of calcium hydroxide. The ettringite causes the concrete to expand, although the mechanism of this expansion is not well understood (pressure exerted by growing ettringite crystals and pressure exerted by poorly crystalline ettringite swelling as it adsorbs water in the alkaline environment are two prominent hypotheses [Me 86]).

In the second mechanism, sulfate attack converts the calcium hydroxide and the calcium-silicate-hydrate (C-S-H) phase of Portland cement paste to gypsum. The formation of gypsum may reduce the stiffness and strength of the concrete, followed by expansion and cracking. Eventually, the material may be transformed into a noncohesive mass. The severity of the damage inflicted on the concrete depends upon the cation (i.e., Na^+ or Mg^{2+}) associated with the sulfate. Sodium sulfate attack results in the formation of sodium hydroxide, which maintains the high alkalinity of the concrete and promotes the stability of the C-S-H phase. On the other hand, a reaction product of magnesium sulfate attack is magnesium hydroxide, which is relatively insoluble and less alkaline. This byproduct adds to the deleterious effects of sulfate by undermining the stability of the C-S-H phase in the concrete.

Freeze-Thaw Damage—Damp concrete may deteriorate when subjected to cycles of freezing and thawing. When water freezes in the pore system of the concrete, expansive stresses develop which, if greater than the concrete tensile strength, can result in severe cracking. Theories on the cause of these expansive stresses range from the volume expansion of water upon freezing (Po 45, Po 55) to the development of osmotic pressures within the concrete (Po 56, He 62).

The susceptibility of concrete to freeze-thaw damage is, in part, a function of the material's moisture content. Generally, concrete must be at least 70 to 80 percent saturated for freeze-thaw damage to occur (Me 86). The pore structure of the concrete also influences its susceptibility to freeze-thaw attack. Numerous uniformly spaced pores help minimize the buildup of expansive stresses within the concrete, thereby helping to prevent severe cracking. Thus, freeze-thaw damage can be limited or precluded by entraining air into the concrete mixture.

Acid Attack—In general, acid attack of a good-quality concrete will not occur if the concrete pH is 5 or greater. Acids are among the most aggressive of chemicals that attack concrete. Mineral acids such as sulfuric and nitric acids are extremely destructive and can rapidly destroy concrete. Other acids (namely, organic acids; water-soluble, low-molecular-weight acids; and insoluble, high-molecular-weight acids) attack concrete more slowly.

Acids react with the calcium hydroxide in the hydrated cement paste, producing water-soluble calcium compounds that are readily leached from the concrete. The dissolution of the concrete matrix destroys the binding ability of the cement paste, undermining the concrete's strength and potentially increasing its permeability. Sulfuric acid attack on concrete may cause additional deterioration due to sulfate attack.

The rate at which concrete deteriorates when subjected to acid attack depends upon the properties of the concrete, acid concentrations, and the diffusivity of acids in the concrete. The resistance of concrete to acid attack depends primarily on the properties and amount of cement, while the aggregate has only secondary effects.

Microbiological Attack—Concrete degradation due to microbial activity is thought to occur when microorganisms present in the environment produce mineral or organic acids that dissolve or disintegrate the concrete matrix (Ro 93). While the mechanism of attack is the same as that described for acid attack, some evidence exists that the presence of microorganisms greatly magnifies the intensity of attack.

Microorganisms that may have adverse effects on concrete include sulfur oxidizers, nitrifiers, and many species of heterotrophs (Ro 93). Sulfur-oxidizing bacteria are most often associated with the microbial degradation of concrete. These bacteria produce sulfuric acid as a metabolic end product, which is one of the more aggressive acids in terms of concrete attack. Nitrifiers obtain energy required for cell synthesis by oxidizing inorganic nitrogen compounds to nitrite and nitrate. The formation of nitrite and nitrate is accompanied by the release of hydrogen ions, forming nitrous and nitric acids. Heterotrophs include a variety of fungi, as well as anaerobic and aerobic bacteria that obtain energy by assimilating organic carbon sources. Many species of heterotrophs generate organic acids as metabolic byproducts, including lactic, citric, gluconic, and malic acids (Ro 93).

Bulk Attack Mechanisms

Bulk attack differs from surface attack in that the reactive components are wholly contained within the concrete. Bulk attack mechanisms include alkali and calcium hydroxide leaching, and alkali-aggregate reactions. Radiation damage to the structural characteristics of concrete are not credible at the low radiation levels that will characterize the Pennsylvania LLRW disposal facility (Ch 90).

Alkali and Calcium Hydroxide Leaching—Alkali hydroxides (NaOH and KOH) and calcium hydroxide ($Ca(OH)_2$) are leached from the cement phases when concrete is exposed to water. The loss of the alkalis and calcium from the concrete lowers the pH of the concrete, which, in turn, may hasten the onset of steel reinforcement corrosion. The loss of calcium also reduces concrete strength and increases the permeability of the concrete. Reductions in the strength of the concrete may undermine the ability of the disposal units to withstand the loads placed upon them. The amount of water contacting the waste may also increase as the permeability of the concrete increases, thereby hastening radionuclide leaching.

Alkali and calcium hydroxides may be leached from concrete due to diffusive and advective processes. Prior to significant deterioration and cracking of the concrete, diffusive losses are generally more significant. Following the loss of structural integrity and the subsequent increase in the amount of water penetrating the concrete, advective leaching will generally dominate.

The rates at which alkali and calcium hydroxides are leached from concrete are influenced by the concentrations of these compounds in the pore solution of the concrete, the percolation rate through the material, the chemistry of the groundwater, and the thickness of the concrete member. In general, alkali hydroxides are leached more quickly than calcium hydroxide because of their higher pore solution concentrations. Little or no dissolution of calcium hydroxide will occur if the groundwater is saturated or super-saturated with calcium carbonate. Reactive chemicals in the groundwater, such as magnesium and carbonate, accelerate the loss of calcium hydroxide (At 85).

Alkali-Aggregate Reaction—Alkali-aggregate attack refers to a class of deleterious reactions between the cement-phase alkalis and minerals in the aggregates used in the concrete mix. These reactions result in the formation of expansive products within the concrete matrix which, depending upon their distribution, may result in localized cracking or uniform expansion of the concrete structure. Cracking may be cosmetic or may compromise the integrity of the concrete vaults. Increases in the permeability of the concrete due to cracking may also occur.

Essentially all aggregates react to some degree with alkalis in the cement paste. These reactions are generally benign, and may even be favorable because they strengthen the bond between the aggregate and the hydrated paste. Damaging expansive reactions are known to occur, however, with certain siliceous and dolomitic limestone aggregates.

The alkali-aggregate reaction appears to begin when hydroxide ions split silica-oxygen bonds of the aggregate's silicate network. The depolymerized species then dissolve to form a hydrous alkali silicate gel, which promotes the absorption of water and swelling of the gel. The swelling reduces the rigidity of the aggregate, thereby allowing deeper diffusion of hydroxide ions into the aggregate. As the alkali-aggregate reaction proceeds, the amount of water absorbed increases and a dilute suspension of colloidal particles is formed. This dilute suspension can move into the surrounding concrete matrix. If sufficient expansive products form, the resulting internal pressures can cause the concrete to crack.

The extent of damage due to alkali-aggregate reaction is a function of many factors. The dissolution of the depolymerized aggregate depends strongly upon concrete pH, increasing by more than 1,000 times as pH increases from 12.5 to greater than 13. The extent of expansion due to water absorption depends upon the availability of water in the concrete. Finally, the structure of the aggregate and the distribution of the reactive material in the aggregate play important roles in the alkali-aggregate reaction.

Corrosion of Steel Reinforcement

Damage to concrete resulting from the corrosion of steel reinforcement manifests itself in expansion, cracking, and spalling of the concrete structure. In addition, the reinforced-concrete member may suffer structural damage due to the loss of bond between steel and concrete and the loss of reinforced cross-sectional area. Damage may proceed to the extent that structural failure occurs.

Corrosion of reinforcing steel is primarily an electrochemical process. An anode, a cathode, an electrical conductor, and an aqueous medium must be present for the process to occur. The metal surface upon which corrosion takes place is a composite of anodes and cathodes electrically connected through the body of the metal itself. At the anode, iron is electrochemically oxidized to ferrous ions, which are subsequently changed to oxides of iron through several complex reactions. Electrochemical reduction occurs at the cathode, which removes electrons from the oxidation site, thereby permitting additional production of ferrous ions.

Reinforcing steel is protected through passivation. In highly alkaline environments thin, continuous films of Fe_2O_3 and Fe_3O_4 form on the steel surface during the cement hydration process. As long as it is passivated, steel reinforcement does not undergo corrosion. If the steel is depassivated corrosion may begin.

The two major mechanisms of depassivation are carbonation and chloride ion penetration. Depassivation of steel reinforcement due to carbonation occurs as a result of a direct lowering of the pH of the concrete. Carbonation occurs as carbon dioxide diffuses into the concrete. Depassivation may also occur as chloride ions internal to, and at the surface of, concrete structures diffuse to the steel reinforcement. If chloride levels at the steel reinforcement reach sufficiently high levels, depassivation of the protective layer will occur and corrosion may commence. The concentration of chloride ions at the steel reinforcement that is required to depassivate the steel appears to be a function of the pH of the concrete (Ha 67). As discussed earlier, the pH of concrete is largely governed by the concentrations of alkali and calcium hydroxides in the material, and declines as these species are leached from the concrete. Reductions in pH tend to accelerate depassivation of the steel reinforcement.

The time to onset of corrosion depends upon several factors, including the thickness of the concrete cover over the reinforcing steel, the initial chloride concentration in the concrete, the effective diffusivity of chloride and carbon dioxide in the material, and the pH of the concrete. The penetration of chloride ions to the steel reinforcement is usually responsible for depassivation of the steel. Depassivation due to carbonation is generally a second-order effect.

Once initiated, the corrosion of steel reinforcement propagates at a rate determined by several factors, including the supply of oxygen at the reinforcement and the electrical resistance of the concrete. If the flux of oxygen at the steel reinforcement is limited, the corrosion rate will be slowed. Similarly, if the electrical resistance of the concrete is great enough, electron flow between the cathode and anode may slow or cease, thereby reducing rates of corrosion. In general, however, the time required to corrode the steel reinforcement is short compared to the time to onset of corrosion.

The Impacts of Concrete Degradation on Disposal Unit Performance

Subjected to continued physical and chemical deterioration, the concrete disposal units will eventually reach a point where they can no longer perform their intended function of providing enhanced containment. The extent and nature of the concrete failure will determine the severity of the damage inflicted and its impact on structure function.

The loads placed upon the concrete disposal units will vary with the facility configuration and the disposal units' locations relative to natural grade. The roof is subject to uniform loading due to the weight of the cover materials, and the weight of the roof itself. The walls of the vaults are subject to uniform loads due to the weight of the roof and walls and hydrostatic pressures resulting from lateral pressures from the soil backfill and waste. The floor is subject to the uniform loads from the disposed-of waste and the floor itself. The floor must also bear loads from the walls, including wall weight and loads transmitted to the walls from the roof and cover materials.

Cracking of concrete structures will occur when stresses in the disposal units resulting from the loads placed upon them exceed the tensile strength of the reinforced concrete. The extent of the cracking (as characterized by crack depth, width, and spacing) will depend upon the applied loads and characteristics of the structure being considered. Cracking due to shear or compressive forces placed on a concrete member will penetrate the entire structure at the time of crack initiation. In contrast, flexural cracking will extend through only a portion of a structure's thickness unless the force exceeds the structure's ultimate strength.

Cracks formed as a result of steel reinforcement corrosion will propagate outward from the site of corrosion to the surface of the concrete structrure. Consequently, in a concrete structure with a layer of steel reinforcement near each face, corrosion cracking will not penetrate the entire structure; an intact central portion of the component will remain. In contrast, cracks extending outward from a centrally placed, single layer of reinforcement will effectively penetrate the entire structural member.

The concrete disposal units can directly limit the passage of water through waste and can provide structural support to the cover, allowing that component to effectively exclude water. These two functions are affected differently when cracks are initiated and propagate through the roof, walls, and floor of a disposal unit. The ability of a concrete disposal unit to provide structural stability will generally not be compromised when cracks initially propagate through the concrete structures. Loss of the disposal unit's ability to support the cover system may occur if extensive or complete failure of the unit occurs and the backfill within the structure undergoes significant subsidence. Under these conditions, the concrete roof of the disposal unit may collapse, resulting in subsidence of the overlying cover system.

The propagation of cracks through a concrete disposal vault may have more immediate impacts upon the ability of the structure to directly resist leakage. That is, increased amounts of water may percolate through the newly formed cracks as soon as the cracks propagate through the disposal unit, even though the disposal unit remains structurally stable. The amount of water actually entering the failed disposal unit will depend upon the prevailing hydrologic conditions at the disposal site. If the soils surrounding the concrete structure are saturated, water may indeed flow through the newly formed cracks. On the other hand, water will continue to slowly percolate through the concrete matrix, rather than the cracks, if the soils surrounding the disposal unit are unsaturated.

Modeling the Long-Term Performance of the Disposal Units

The ability of the disposal units to resist leakage and provide structural stability is a direct function of the condition of the concrete of which they are constructed. Consequently, performance modeling of the disposal units requires that the degradation of the concrete by chemical and physical environmental agents be projected. Projected rates of degradation are used in conjunction with structural and cracking analyses to determine the extent and pattern of structure cracking. This information is used, in turn, to estimate rates of water percolation through the waste and the consequent radionuclide release rates, and to determine whether the structural stability of the disposal units has been compromised. The synergistic and interacting effects of concrete degradation, structural capacity, and water and contaminant transport must be addressed because of the potential to significantly affect the results and conclusions of long-term performance modeling.

Accurate projections of concrete degradation rates account for all degradation processes that pose a significant threat to the performance of the disposal units. These processes may include, but are not limited to, the mechanisms discussed in Subsection 3.4.1. Many of the degradation processes discussed there may not apply under the environmental conditions found at the disposal site. In this case, justification is provided that establishes the negligible effect the degradation processes are expected to have on the long-term performance of the disposal units.

The models and data required to project rates of concrete degradation depend upon those degradation processes deemed important. Many of the concrete degradation mechanisms, in turn, depend upon the rate of transport of aggressive chemicals into, or of constituents of the concrete out of, the concrete structures of the disposal units. Consequently, it is reasonable to expect that the models will need to be capable of projecting rates of advective and diffusive transport of various chemical compounds in the concrete. Data generally required in concrete degradation modeling include complete specifications of the concrete mix used in construction, selected properties of the completed concrete structures (e.g., pH, structure thickness, compressive strength, density, and porosity), rates of water percolation through the concrete, diffusion coefficients for the concrete and soils adjacent to the disposal units, and the chemical characteristics of liquids or vapors contacting the concrete structures. To the extent possible, all data used in the analysis are specific to the disposal site and materials used in disposal unit construction.

The structural and cracking analyses use the projected cumulative extent of deterioration to evaluate the ability of the concrete disposal units to bear design loads and, therefore, resist cracking. Basic structural information about the units is used in conjunction with loading data to determine the extent to which the concrete structures must deteriorate to permit cracking to begin. Depending upon the design of the disposal units, the analysis may require assessment of flexural, shear, tensile, and compressive crack development.

Once initiated, the propagation of the cracks through the affected structures may be tracked to estimate the structural and hydraulic impacts on the disposal units. Cracking will generally start at different times in the roofs, walls, and floors of the units because of the different structural characteristics and different loading conditions on these components. The overall impact of cracking on the performance of the disposal units will depend on which of the structures fail and the extent of the failure.

The results of the long-term performance modeling will allow an applicant to demonstrate compliance with the requirements calling for structural stability of the disposal units and leak resistance. The projected state of the disposal units within the 100- to 500-year time frame will provide information necessary to demonstrate that the structural stability requirement is met for the appropriate periods for the different classes of LLRW. The extent, or lack of, cracking projected to occur within 100 years of facility closure may be used to demonstrate satisfaction of the leak-resistance requirement. For instance, it may be concluded that leak resistance is achieved if it can be demonstrated that no cracks will penetrate the concrete structures of the disposal units at the end of this period.

The results of the long-term modeling of disposal unit performance will also play an important role in the radiological performance assessment conducted in support of the disposal facility license. The time(s) at which the disposal units are projected to structurally fail will play a role in evaluating potential exposures to persons who inadvertently intrude into the disposed-of waste. The results of the concrete-cracking analyses will provide information needed to estimate the amount of water contacting the waste and, hence, radionuclide release rates.

The models and data used to estimate the long-term performance of the concrete disposal units typically are expected to introduce a significant amount of uncertainty into the performance projections. It is important that efforts be made to quantify these uncertainties through the application of sensitivity and uncertainty analyses. These analyses account for errors that may be introduced by the models used in projecting disposal unit performance and the variability in the input parameters used in said models. The results of the analyses are used to estimate the impact these uncertainties have on the ability of the disposal units to provide enhanced containment of the disposed-of LLRW. It is important that the design of the sensitivity and uncertainty analyses be such that it fulfills the needs of the radiological performance assessment as well.

Long-term performance modeling of the disposal units is an important activity throughout the entire lifetime of the disposal facility. It will be used to help justify the selection of a suitable disposal site, to guide site characterization activities, to optimize disposal unit design and construction, and to formally demonstrate compliance with the performance objectives specified in 25 PA 236.11 through 236.16. Performance modeling will also play a role in the interpretation of disposal unit monitoring results and refinement of the monitoring program.

The amount and quality of information available to conduct long-term modeling of the disposal units generally increase as the development of the disposal facility progresses. Consequently, the modeling tends to be iterative to ensure that performance projections reflect the best available information about the disposal site and the disposal units. A more detailed discussion about the iterative nature of the performance modeling is provided in the Staff Technical Report entitled "Conducting Radiological Performance Assessments for LLRW Disposal in Pennsylvania" (CPA 97).

QA/QC PROGRAM

It is important that all activities involving the design, construction, monitoring, and long-term performance modeling of the concrete disposal units be performed properly and be well documented. Consequently, capable quality assurance (QA) and quality control (QC) programs are essential (Pe 87). The QA program documents the activities that will be undertaken and demonstrates that these activities will satisfy applicable criteria, procedures, and standards. The QC program causes confirmatory activities to be undertaken to ensure that all work is performed correctly, without errors, and with appropriate accuracy, completeness, and consistency.

The features of the QA and QC programs depend upon the stage of the disposal facility life cycle. During design, the emphasis of these programs is on ensuring that all data defining the site at which the disposal units will be constructed are properly considered in the design process. Additionally, attention is focused on the design calculations and evaluation to ensure that they are performed without procedural, methodological, and calculational error. During the construction phase, the QA and QC programs are concerned with ensuring that the design plans and specifications are properly incorporated and implemented in the construction activities. The focus of the QA and QC programs during monitoring is on ensuring that samples are collected and processed properly, that surveys are performed as specified, and that accountability for samples can be demonstrated. The QA and QC programs applied to long-term performance modeling concentrate on ensuring that the methods used to estimate facility performance are valid and implemented correctly.

REGULATORY GUIDANCE ON THE DESIGN, CONSTRUCTION, AND ASSESSMENT OF CONCRETE DISPOSAL UNITS

This section provides regulatory guidance with respect to important issues relevant to using concrete disposal units to provide enhanced containment of disposed-of LLRW. This guidance informs applicants of the types of information the Department will consider in its license application review with respect to fulfilling the requirement for enhanced containment of the disposed-of waste.

The guidance is organized in terms of the subject areas discussed in Section 3. Subsection 4.1 provides guidance on the design of the concrete disposal units, while Subsection 4.2 addresses disposal unit construction. Guidance on monitoring the engineered disposal units and modeling disposal units and modeling their long-term performance is provided in Subsections 4.3 and 4.4, respectively. Finally, guidance on the development and implementation of QA and QC programs is provided in Subsection 4.5.

REGULATORY GUIDANCE ON DISPOSAL UNIT DESIGN

The design of the concrete disposal units should be conducted taking into consideration the issues discussed in Subsection 3.1. The structural design of the vaults should maximize the ability of the structures to resist leakage. Furthermore, it should provide long-term stability of the cover system, thereby maximizing that component's ability to divert water from the disposed-of waste. The design and construction of the disposal units should be safe, practical, and based on proven engineering technology.

The design criteria, models, assumptions, data, analytical methods, and justifications used to develop the structural design for the disposal units should be reliable and well documented. Descriptive information, including plans, sections, and associated specifications, should be provided. Design documentation should include the following information:

1. Codes, standards, and guidance for the design of steel-reinforced concrete disposal units under an appropriate range of loading and environmental conditions.

1. Engineering drawings containing plans, elevations, sections, details, and notes.

1. Design criteria with justification.

1. Design calculations and analyses.

1. Assumptions and associated justifications.

Documentation of analyses should include, but not necessarily be limited to, the following items:

1. Structural description, geometry, and boundary or support conditions.

1. Material properties of concrete, steel, and foundation media.

1. Structural loading conditions, including a description of the method used to calculate the design-basis earthquake and associated structural responses.

1. Design calculations of critical elements, including the method of design analysis, assumptions, and demonstration of structural stability at the end of the design life.

1. Structural analysis and internal forces calculations for applied loads.

1. Steel reinforcement design justification.

1. Stress and strength calculations.

1. Cracking analyses.

1. Deflection analyses.

1. Structure and foundation stability analyses, including reaction calculations, static and dynamic settlement, differential settlement, and long-term consolidation analyses.

1. Radiation shielding analyses.

1. Structural degradation analyses and service-life projection.

1. A description of computer programs used in the design and analyses, including methods of validation.

1. A summary of verification results and comparisons with design acceptance criteria.

REGULATORY GUIDANCE ON DISPOSAL UNIT CONSTRUCTION

The regulatory guidance on disposal unit construction addresses the techniques and materials used in disposal unit fabrication. Subsection 4.2.1 discusses requirements as they pertain to the selection and use of concrete and concrete materials. Subsection 4.2.2 addresses the methods used to construct the disposal units.

Guidance on Concrete and Concrete Materials

Concrete and other materials used in the construction of the disposal units should be qualified and selected as described in Subsection 3.2.1 of this report. Materials should be capable of safely supporting the design loads and resisting deterioration due to chemical and physical attack from the environment. The concrete itself should be of low-permeability to minimize the potential for water percolation.

The engineering properties of the construction materials should be specified and verified. Materials intended for use in the disposal units should be tested and demonstrated to meet quality and durability specifications. Testing should be conducted to provide reasonable assurance that the materials and structures will contribute to long-term stability and integrity. Methods and procedures used to conduct these tests should be identified and evaluated to determine their applicability and adequacy.

The ability of the concrete disposal units to meet their design criteria while subjected to environmental degradation should be demonstrated. Aspects of material quality and durability should be specified and verified, including the resistance or response of the materials to deterioration or damage by freeze/thaw cycling; humidity; aging; fatigue; sulfate, chloride, and acid attack; abrasion; thermal fluctuations; wetting and drying; radiation; biodegradation; electrolysis; shrinkage; and cracking.

Verification of the engineering properties of the construction materials should be achieved through material testing. These tests should be performed as part of the design evaluation and be furnished as a part of the design package. Documentation of these tests should include the test name, the code or specification defining the test protocol and requirements, and the personnel and laboratory conducting each test.

Concrete testing should include determination of slump, air content, unit weight, unconfined compressive strength, and other physical properties as required to assess stability, durability, and serviceability. All constituents of the mix should be tested according to applicable code requirements and specifications, and should conform to the applicable specifications and standards.

All reinforcement and structural steel should be sampled, tested, and certified for use prior to its application at the construction site. Tests should be conducted in accordance with applicable regulations. Compliance of the steel products with applicable standards and specifications should be verified. All other materials used in the construction of the disposal units should be sampled and tested in accordance with approved and specified methods. These materials include chemical admixtures, curing compounds, membranes, moisture barriers (coatings, sealants, and membranes), and water. All materials should conform with the appropriate specifications and standards.

Guidance on Construction Methods

Construction of the disposal units should focus on controlling all conditions that affect construction quality, with reasonable concern for cost-effectiveness. These conditions are described in Subsection 3.2.2 of this report. Important aspects of the construction process that need to be considered include the sequence of construction activities, construction methods, equipment usage, quality control, and testing requirements. Construction, operational, closure, and maintenance activities may be conducted to the extent permitted by the design of the facility provided that conflicts between such activities are avoided. For example, construction, operation, and closure of different disposal units may occur simultaneously, provided that these activities do not interfere with one another and do not compromise the performance capabilities of the closed units.

Vehicular traffic and other construction activities should not adversely affect completed disposal units or those being constructed or operated. Structures, systems, and components should be constructed using methods and equipment that provide reasonable assurance of a high level of workmanship and competence consistent with established construction industry standards.

Construction documentation should include methods and procedures used to:

1. Prepare structural foundations.

1. Form or place formwork.

1. Place reinforcement.

1. Place construction joints, control joints, and expansion joints.

1. Proportion, batch, and mix concrete.

1. Transport and consolidate concrete.

1. Place, finish, and cure concrete.

1. Remove forms.

1. Seal access openings and joints.

1. Place moisture barriers.

REGULATORY GUIDANCE ON DISPOSAL UNIT MONITORING

The performance of the disposal units should be monitored, tested, and evaluated as discussed in Subsection 3.3 of this report. Results of monitoring, testing, and evaluation should be used to verify the validity of design assumptions and to provide reasonable assurance that the engineered structures will perform their regulatory functions. Monitoring should occur during the construction, operational, closure, and institutional control periods to demonstrate acceptable performance.

Monitoring should provide data and information sufficient to allow the effectiveness and performance of the disposal units to be assessed considering all known or suspected degradation mechanisms and forces. Structural monitoring should measure stresses within the structural members of the disposal units, deflections within key structural members, and pore pressures in the concrete. Differential settlement of backfill, the disposal units, and the cover system also should be monitored.

The performance of the reinforced concrete should be assessed using prototype disposal units and concrete samples at the disposal site. These prototype units and samples should be exposed to the same conditions as the actual disposal units (excluding disposed-of LLRW), thereby permitting assessment of performance under the actual chemical and physical conditions that prevail at the site.

Prototype disposal units or concrete samples should be tested using destructive and nondestructive methods. These units and samples should be sacrificed to evaluate penetration depths of aggressive ions (e.g., chloride, sulfate, and magnesium ions) and to assess the extent of corrosive processes. Visual inspection should be used to assess surface deterioration of the concrete, while the effects of freeze-thaw cycling should be assessed by measuring the concrete's modulus of elasticity. Measurements of the compressive strength and the permeability of the concrete to chloride ions and air should also be undertaken as part of the evaluation.

Provisions should be made to monitor the water content in disposal units under unsaturated and saturated conditions. Under unsaturated conditions, soil gas samples and neutron density gauges should be used to determine the water-vapor content inside the structures. For saturated conditions, monitoring wells should be incorporated in the disposal units and in the foundation. Monitoring should occur during the facility's construction, operating, closure, and institutional control periods.

The monitoring wells should be designed and constructed to minimize problems associated with sampling and interpreting the sample data. The wells should, at a minimum, permit measurement of water levels, allow water samples to be collected, and water to be pumped. Placement and characterization of the wells should allow water from around the disposal units (e.g., groundwater, rainwater, etc.) to be distinguished from that percolating through the structures.

Acceptable performance limits for the concrete vaults should be defined to aid in interpreting the performance monitoring results. These performance limits should be specific to the provision of leak resistance and structural stability. However, these limits should also be defined to meet a common goal, which is to ensure that the facility satisfies the performance objectives of 25 PA Code 236 (CPA 89). Performance limits should be based on appropriate regulations, codes, standards, and accepted engineering practices. Performance limits for structural stability should address permissible loads, stresses, deformations, and strains on the structure, foundation, backfill, and cover system. Performance limits for the materials used in construction may include acceptable rates of deterioration, corrosion, and cracking.

Failure to meet established performance limits during or following operations does not necessarily indicate facility failure. Rather, failure to meet the established limits aids in identifying potentially unacceptable conditions and indicates a need for additional information gathering, decision-making, and response. Appropriate responses include monitoring with increased intensity and implementing a variety of remedial actions.

REGULATORY GUIDANCE ON LONG-TERM PERFORMANCE ASSESSMENT

Long-term performance modeling of the disposal units should be conducted consistent with the discussion provided in Subsection 3.3. Performance modeling should provide a means for projecting the effectiveness of the disposal units over their service life, which may extend beyond 500 years. Modeling should provide information in addition to that gained through performance monitoring, which indicates only past and current performance. This information should be used to project the effects of facility construction, operation, closure, and long-term maintenance on facility workers, members of the public, and the environment. Modeling results should also be used to demonstrate compliance with the enhanced containment requirement of 25 PA 236.314(a).

The ability of concrete disposal units to resist leakage and remain structurally stable depends upon a host of facility- and site-specific factors. Important facility-specific factors include those discussed with respect to performance monitoring, such as structural attributes of the engineered system, properties of the materials used to construct the disposal units, and site meteorology and hydrology.

Performance modeling of the disposal units should consider all of the facility- and site-specific aspects that define the effectiveness of the disposal facility. Specifically, performance modeling of the concrete disposal units should account for the following:

1. Changes in the characteristics and capacities of the disposal units with time due to degradation.

1. The ability of the disposal units to bear design loads with changes in construction materials properties.

1. The ability of the disposal units to resist water movement through them.

1. Patterns of groundwater flow around and through the vaults.

Performance modeling should address the dynamic individual, synergistic, and interacting effects of concrete degradation, structural capacity, and water and contaminant transport over the life of the disposal units. Performance modeling should consider the effects of important concrete degradation mechanisms, including but not limited to sulfate attack, freeze-thaw cycling, calcium hydroxide leaching, and corrosion of steel reinforcement. Other degradation mechanisms may require consideration depending upon site environmental conditions and the characteristics of the materials used in the concrete mix. The dependency of structural performance on concrete durability should also be addressed in performance modeling. The relationship between the condition of the disposal units and the rates of water percolation through the structures should be established as part of the long-term performance modeling.

REGULATORY GUIDANCE ON QA/QC

The role of the QA/QC programs in the design, construction, monitoring, and long-term performance modeling of the concrete disposal units is discussed in Subsection 3.5. QA and QC programs must be developed and implemented to ensure that these activities are performed

properly and thoroughly documented. The QA program will ensure that the documentation needed to demonstrate what was done and whether work activities satisfy applicable criteria, procedures, and standards is generated. The QC program will ensure that confirmatory activities are performed to ensure that all work is done correctly, without errors, and with appropriate accuracy, completeness, and consistency.

The QA and QC programs should ensure that all site data are considered in the design of the disposal units. Furthermore, they should ensure that the design calculations and evaluation are performed properly, without procedural, methodological, and calculational errors. During the construction phase, the QA and QC programs should demonstrate that the design plans and specifications are properly incorporated and implemented in the construction activities. In terms of monitoring, the QA and QC programs should ensure that samples are collected and processed properly, that surveys are performed as specified, and that sample accountability can be demonstrated. Finally, the QA and QC programs should ensure that all methods used in long-term performance modeling are valid and that the calculations are performed without error.

A.

APPENDIX A

TECHNICAL RESOURCES FOR THE DESIGN AND CONSTRUCTION OF ENGINEERED STRUCTURES

The following publications provide additional guidance on various aspects of engineered structures and their application in LLRW disposal facilities. The topics they address include:

- Design and construction of disposal facilities using engineered structures.
- Selection of suitable materials for construction.
- Long-term performance of engineered structures.
- Issues relating to the licensing of the completed disposal facility.

These publications represent state and federal agency expertise with respect to designing, constructing, and evaluating the performance of engineered structures. As such, these publications provide applicants with a valuable resource on using engineered structures to provide enhanced containment at a Pennsylvania LLRW disposal facility.

The technical resources include technical position papers, regulatory guides, engineering codes and standards, and other guidance documents. Several of the technical resources are issued by agencies that have no regulatory standing in the Commonwealth, or address types of radioactive waste other than LLRW. These resources have been included because they provide a broad perspective of the current level of expertise in the use of engineered structures in LLRW disposal facilities.

No effort has been made to ensure that all such references have been included in this listing. Rather, those included are representative of the guidance available from existing sources.

A.1 U.S. NUCLEAR REGULATORY COMMISSION

The U.S. Nuclear Regulatory Commission (NRC) has published a number of topical reports, technical position papers, and regulatory guides on the use of concrete engineered structures and waste overpacks. These are summarized below.

A.1.1 Topical Reports

Walton, J.C., et al., 1990, "Models for Estimation of Service Life of Concrete Barriers in Low-Level Radioactive Waste Disposal," prepared by the Idaho National Engineering Laboratory, EG&G Idaho, Inc., for the U.S. Nuclear Regulatory Commission, NUREG/CR-5542.

> This report reviews mathematical models for estimating the degradation rate of concrete in typical LLRW disposal facility service environments. It explains the bases for models taken from the literature and includes example calculations to illustrate the application of the models and indicate the types of predictions that can be expected.

Pommersheim, J.M., and J.R. Clifton, 1991, "Models of Transport Processes in Concrete," prepared by the National Institute of Standards and Technology for the U.S. Nuclear Regulatory Commission, NUREG/CR-4269.

> This report discusses and presents models suitable for modeling the long-term performance of concrete structures. Conceptual and mathematical models for modeling

the ingress of aggressive ions into the structures and the leaching of constituents from the concrete are presented. The report also discusses the application of these models to long-term performance assessments.

MacKenzie, D.R., et al., 1986, "Preliminary Assessment of the Performance of Concrete as a Structural Material for Alternative Low-Level Radioactive Waste Disposal Technologies," prepared by Brookhaven National Laboratory for the U.S. Nuclear Regulatory Commission, NUREG/CR-4714.

This study develops information required to evaluate the long-term performance of concrete as a structural material for LLRW disposal. It reviews and analyzes information in the literature and identifies criteria for evaluating the performance of concrete. The properties of coatings and their possible use in protecting concrete are also discussed. Finally, the study discusses accelerated and long-term testing of concrete, with special reference to its application to modeling long-term performance.

Walton, J.C., and R.R. Seitz, 1991, "Performance of Intact and Partially Degraded Concrete Barriers in Limiting Fluid Flow," prepared by EG&G Idaho, Inc., for the U.S. Nuclear Regulatory Commission, NUREG/CR-5614.

This document examines the factors controlling fluid flow through intact and degraded concrete disposal facilities. It presents simplified models for estimating the buildup of fluid above a vault; fluid flow through and around intact vaults, through flaws in coatings/liners applied to a vault, and through cracks in a concrete vault; and the influence of different backfill materials around the outside of a vault. Example calculations are also provided to illustrate the parameters and processes that influence fluid flow.

U.S. Nuclear Regulatory Commission, 1991, "Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility, Safety Analysis Report," NUREG-1199, Rev. 2, January 1991.

This document describes the information that a Safety Analysis Report must contain. The chapter on safety (performance) assessment discusses the release of radioactivity from the facility, intruder protection, and long-term stability of the disposal site.

U.S. Nuclear Regulatory Commission, 1991, "Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility," NUREG-1200, Rev. 2, January 1991.

This report provides guidance to NRC staff reviewers who perform safety reviews of applications to construct and operate LLRW disposal facilities. It describes the types of performance assessment analyses the NRC expects to be performed, reported, and justified. The report considers several important aspects of performance assessment, including characteristics of the waste, infiltration, potential releases under normal and accident conditions, transfer of releases to human access locations, intruder protection, and long-term stability.

Cerven, F., and M.D. Otis, 1987, "Safety Assessment of Alternative to Shallow-Land Burial of Low-Level Radioactive Waste," NUREG/CR-4701, prepared for the U.S. Nuclear Regulatory Commission by EG&G Idaho, Inc., September 1987.

This document evaluates the relative importance of engineered barriers used in enhancements and alternatives to traditional shallow land burial of LLRW. The analysis

presented in the document ranks the contribution of various components to the performance of each disposal system by examining the failure of all possible combinations of components.

Denson, R.H., et al., 1987, "Recommendations to the NRC for Review Criteria for Alternative Methods of Low-Level Radioactive Waste Disposal," NUREG/CR-501, prepared for the U.S. Nuclear Regulatory Commission by the U.S. Army Engineer Waterways Experiment Station, December 1987.

This report presents general and specific design criteria for disposing of LLRW in earth-mounded concrete bunkers. It presents eight major review criteria categories and gives specific design review criteria for each of the eight major review criteria categories.

Soo, P., and L.W. Milian, 1989, "Sulfate Attack Resistance and Gamma Irradiation Resistance of Some Portland Cement Based Mortars," NUREG/CR-5279, prepared for the U.S. Nuclear Regulatory Commission by Brookhaven National Laboratory, March 1989.

This document reports the results of tests conducted to determine the effects of sulfate attack and gamma irradiation on cement mortar. Test measurements include the extent of change in the mortar and the time required for the change to occur.

Clifton, J.R., and L.I. Knab, 1989, "Service Life of Concrete," NUREG/CR-5466, prepared for the U.S. Nuclear Regulatory Commission by the National Institute of Standards and Technology, November 1989.

This report examines the basis for predicting the service life of concrete vaults used for LLRW disposal from accelerated testing and mathematical modeling of factors that affect the durability of concrete buried in the ground. It examines concrete degradation processes and recommends a research plan for developing methods for predicting the service life of concrete.

A.1.2 Technical Position Papers

U.S. Nuclear Regulatory Commission, 1994, "Draft Branch Technical Position on Performance Assessment for Low-Level Waste Disposal Facilities," Low-Level Waste Management Branch, January 1994.

This paper presents license applicants, licensees, states, compacts, and NRC staff with an acceptable strategy and methodology for performing the technical analysis required to show compliance with the performance objective in 10 CFR 61. The performance objective pertains to protecting the general public from radiological exposure.

A.1.3 Regulatory Guides

U.S. Nuclear Regulatory Commission, 1973, "Concrete Radiation Shields for Nuclear Power Plants," Regulatory Guide 1.69, December 1973.

This guide describes acceptable bases for implementing the radiological protection requirements of 10 CFR 20 and 10 CFR 50 with regard to designing and constructing concrete radiation shields in nuclear power plants.

U.S. Nuclear Regulatory Commission, 1976, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants," Regulatory Guide 1.94, April 1976.

This guide describes an acceptable method for complying with NRC regulations regarding quality assurance requirements for installing, inspecting, and testing structural concrete and steel during the construction phase of nuclear power plants.

A.2 STATE AGENCIES

New York State Department of Environmental Conservation, 1988, "Supplement to the July 1987 Draft Environmental Impact Statement for Promulgation of 6 NYCRR Part 382: Regulations for Low-Level Radioactive Waste Disposal Facilities, Modeling, and Dose Assessment of Alternative Low-Level Radioactive Waste Disposal Methods in New York State," Division of Hazardous Substances Regulation, Bureau of Radiation.

This report documents the environmental pathway and dose analyses presented in the 1987 New York Department of Environmental Conservation report entitled "Draft Environmental Impact Statement for Promulgation of 6 NYCRR Part 382: Regulations for Low-Level Radioactive Waste Disposal Facilities (Certification of Proposed Sites and Disposal Methods)." It also reports changes made in the parameters and calculations of the analyses.

A.3 AMERICAN SOCIETY FOR TESTING AND MATERIALS

The following publications provide guidance and requirements for selecting and testing concrete materials. They provide information needed for controlling the quality and durability of concrete and concrete materials used to build reinforced concrete structures.

- **ASTM A36-81a**, Standard Specification for Structural Steel.
- **ASTM A185-79**, Standard Specification for Welded Steel Wire Fabric for Concrete Reinforcement.
- **ASTM A496-78**, Standard Specification for Deformed Steel Wire for Concrete Reinforcement.
- **ASTM A497-79**, Standard Specification for Welded Deformed Steel Wire Fabric for Concrete Reinforcement.
- **ASTM A615-82**, Standard Specification for Deformed and Plain Billet-Steel Bars for Concrete Reinforcement.
- **ASTM A616-82a**, Standard Specification for Rail-Steel Deformed and Plain Bars for Concrete Reinforcement.
- **ASTM A617-82a**, Standard Specification for Axle-Steel Deformed and Plain Bars for Concrete Reinforcement.
- **ASTM A775-81**, Standard Specification for Epoxy-Coated Reinforcing Steel Bars.
- **ASTM C33-84**, Standard Specification for Concrete Aggregates.
- **ASTM C39-83b**, Standard Test Method for Compressive Strength of Cylindrical Concrete Specimens.
- **ASTM C88-83**, Standard Method of Test for Soundness of Aggregates by the Use of Sodium Sulfate or Magnesium Sulfate.

- **ASTM C94-83**, Standard Specification for Ready-Mixed Concrete.
- **ASTM C127-84**, Standard Test for Specific Gravity and Absorption of Coarse Aggregate.
- **ASTM C128-84**, Standard Test for Specific Gravity and Absorption of Fine Aggregates.
- **ASTM C136-83**, Standard Test for Sieve or Screen Analysis of Fine and Coarse Aggregate.
- **ASTM C138-81**, Standard Test Method for Unit Weight, Yield, and Air Content (Gravimetric) of Concrete.
- **ASTM C150-84**, Standard Specification for Portland Cement.
- **ASTM C173-78**, Standard Test Method for Air Content of Freshly Mixed Concrete by the Volumetric Method.
- **ASTM C227-81**, Standard Test for Potential Alkali Reactivity of Cement-Aggregate Combination (Mortar-Bar Method).
- **ASTM C231-82**, Standard Test Method for Air Content of Freshly Mixed Concrete by the Pressure Method.
- **ASTM C233-78**, Standard Method of Testing Air-Entraining Admixtures for Concrete.
- **ASTM C260-77**, Standard Specification for Air-Entraining Admixtures for Concrete.
- **ASTM C289-81**, Standard Method of Test for Potential Reactivity of Aggregates (Chemical Method).
- **ASTM C309-81**, Standard Specification for Liquid Membrane-Forming Compounds for Curing Concrete.
- **ASTM C494-82**, Standard Specification for Chemical Admixtures for Concrete.
- **ASTM C496-71**, (Reaffirmed 1979) Standard Method of Test for Splitting Tensile Strength of Cylindrical Concrete Specimens.
- **ASTM C512-82**, (Reaffirmed 1983) Standard Test Method for Creep of Concrete in Compression.
- **ASTM C618-84**, Standard Specification for Fly Ash and Raw or Calcined Natural Pozzolan for Use as a Mineral Admixture in Portland Cement Concrete.
- **ASTM C666-84**, Standard Test Method for Resistance of Concrete to Rapid Freezing and Thawing.
- **ASTM D994-71**, (1982) Standard Specification for Preformed Expansion Joint Filler for Concrete (Bituminous Type).
- **ASTM D1751-73**, (1978) Standard Specification for Preformed Expansion Joint Fillers for Concrete Paving and Structural Construction (Nonextruding and Resilient Bituminous Types).
- **ASTM D3744-79**, Standard Test Method for Aggregate Durability Index.

A.4 U.S. ARMY ENGINEER WATERWAYS EXPERIMENT STATION

The publications listed in this subsection pertain to selecting and testing concrete materials.

- **CRD-C 20**, Test Method for Resistance of Concrete to Rapid Freezing and Thawing.
- **CRD-C 48**, Method of Test for Water Permeability of Concrete.
- **CRD-C 52**, Test Method for Abrasion Resistance of Concrete or Mortar Surfaces by the Rotating-Cutter Method.
- **CRD-C 54**, Test Method for Creep of Concrete in Compression.
- **CRD-C 71**, Test Method of Ultimate Strain Capacity of Concrete.
- **CRD-C 400**, Requirements for Water for Use in Mixing or Curing Concrete.

A.5 AMERICAN CONCRETE INSTITUTE

The following publications provide guidance and requirements for selecting and testing concrete materials and constructing reinforced concrete structures. They include information on a number of construction aspects, including formwork, mixing and placement of concrete, curing of concrete, and steel reinforcement design and construction.

- **ACI 117-90/117R-90**, Standard Tolerances for Concrete Construction and Materials.
- **ACI 201.2-77 (82)**, Guide to Durable Concrete.
- **ACI 209R-82 (86)**, Prediction of Creep, Shrinkage, and Temperature Effects in Concrete Structures.
- **ACI 211.1-91**, Standard Practice for Selecting Proportions for Normal, Heavyweight, and Mass Concrete.
- **ACI 212.3R-91**, Chemical Admixtures for Concrete.
- **ACI 216R-89**, Guide for Determining the Fire Endurance of Concrete Elements.
- **ACI 221R-89**, Guide for Use of Normal Weight Aggregate in Concrete.
- **ACI 224R-89**, Control of Cracking in Concrete Structures.
- **ACI 301-89**, Specifications for Structural Concrete for Buildings.
- **ACI 304R-89**, Guide for Measuring, Mixing, Transporting, and Placing Concrete.
- **ACI 304.2R-91 Revised 1982**, Placing Concrete by Pumping Methods.
- **ACI 305R-91**, Hot Weather Concreting.
- **ACI 306R-88**, Cold Weather Concreting.
- **ACI 306.1-90**, Standard Specification for Cold Weather Concreting.

- **ACI 308-81 (86)**, Standard Practice for Curing Concrete.
- **ACI 309R-87**, Guide for Consolidation of Concrete.
- **ACI 318.1-89/318.1R-89**, Building Code Requirements for Structural Plain Concrete and Commentary.
- **ACI 347R-88**, Guide to Formwork for Concrete.
- **ACI 349-90/349R-90**, Code Requirements for Nuclear Safety Related Concrete Structures and Commentary.
- **ACI 350R-89**, Environmental Engineering Concrete Structures.
- **ACI 439.4R-89**, Steel Reinforcement-Physical Properties and U.S. Availability.
- **ACI 503R-89**, Use of Epoxy Compounds with Concrete.
- **ACI 504R-90**, Guide to Joint Sealants for Concrete Structures.
- **ACI 515.1R-79**, (85) A Guide to the Use of Waterproofing, Dampproofing, Protective, and Decorative Barrier Systems for Concrete.
- **ACI SP-66 (88)**, ACI Detailing Manual Includes 315-80 (Revised 1986), 315R-80 (Revised 1988), and Supporting Reference Data.
- **ACI SP-79**, Fly Ash, Silica Fume, Slag, and Other Mineral By-Products in Concrete (1984).
- **ACI SP-91**, Fly Ash, Silica Fume, Slag, and Natural Pozzolan in Concrete (1986).

appendix a

technical resources for the design and construction of engineered STRUCTURES

0. REFERENCES

ACI 90 American Concrete Institute, 1990, "ACI Manual of Concrete Practice-1990", Vols. 1 through 5.

AISC 89 American Institute of Steel Construction, 1989, Manual of Steel Construction, Ninth Edition.

ANSI 82 American National Standards Institute, 1982, "Minimum Design Loads for Buildings and Other Structures," ANSI A58.1-1982, March 10, 1982.

ASTM 93 American Society for Testing and Materials, 1993, Annual Book of ASTM Standards, Philadelphia, PA, Volumes 1.04 and 4.02.

At 84 Atkinson, A., and J.A. Hearne, 1984, "An Assessment of the Long-Term Durability of Concrete in Radioactive Waste Repositories," AERE Harwell, AERE-R11465.

At 85 Atkinson, A., 1985, "The Time-Dependence of pH Within a Repository for Radioactive Waste Disposal," Harwell Laboratory, AERE-R11777, April 1985.

Ch 90 Chang, Wallace and Nausherwan Hasan, "Concrete Longevity Overview," Ebasco Services, Inc., through EG&G Idaho, Inc., for U.S. Department of Energy, DOE/LLW-105, September 1990.

CPA 88 Commonwealth of Pennsylvania, 1988, "Low-Level Radioactive Waste Disposal Act," Act 1988-12.

CPA 89 Commonwealth of Pennsylvania, 1989, "Low-Level Radioactive Waste Management and Disposal," Pennsylvania Code, Title 25, Chapter 236, October 28, 1989.

CPA 97 Commonwealth of Pennsylvania, 1997, "Conducting Radiological Performance Assessments for LLRW Disposal in Pennsylvania," draft report, May 1997.

De 87 Denson, R.H., et al., 1987, "Recommendations to the NRC for Review Criteria for Alternative Methods of Low-Level Radioactive Waste Disposal," U.S. Nuclear Regulatory Commission, NUREG/CR-5041, December 1987.

Ha 67 Hausmann, D.A., 1967, "Steel Corrosion in Concrete," *Materials Protection*, November 19-23, 1967.

He 62 Helmuth, R.A., 1962, "Capillary Size Restrictions on Ice Formation in Hardened Portland Cement Pastes," Fourth International Symposium on Chemistry of Cement, Vol. 2:855-869 (published as Monograph 43, National Bureau of Standards).

Me 86 Mehta, P.K., 1986, "Concrete-Structure, Properties, and Materials," Prentice-Hall, New Jersey.

NRC 82 U.S. Nuclear Regulatory Commission, "Licensing Requirements for Land Disposal of Radioactive Waste," Code of Federal Regulations, Title 10, Part 61, Federal Register, Vol. 47, pp. 57463 et seq., December 27, 1982.

Pe 87 Pittiglio, C.L., 1987, "Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility," U.S. Nuclear Regulatory Commission, NUREG-1293, November 1987.

Po 45 Powers, T.C., 1945, "A Working Hypothesis for Further Studies of Frost Resistance of Concrete," ACI Journal Proceedings, Vol. 41(4):245-272.

Po 55 Powers, T.C., 1955, "Basic Considerations Relating to Freezing and Thawing Tests," Proceedings ASTM, Vol. 55:1132-1155.

Po 56 Powers, T.C., 1956, "Resistance of Concrete to Frost at Early Ages," Proceedings of RILEM Symposium on Winter Concreting (Copenhagen, 1956), Research Bulletin No. 71, Portland Cement Association.

Ro 93 Rogers, R.D., et al., 1993, "Microbial-Influenced Cement Degradation — Literature Review," prepared for the U.S. Nuclear Regulatory Commission, NUREG/CR-5987, March 1993.

Fact Sheet

Commonwealth of Pennsylvania • Department of Environmental Protection

RADIOACTIVE WASTE

INTRODUCTION

Radioactive waste is a by-product of nuclear power generation, nuclear weapons production, medical research, diagnosis and therapy; manufacture and usage of radioactive materials, and various kinds of scientific research. Radioactive materials contain unstable atoms or radionuclides which emit radiation.

Since the discovery of radiation in 1896, it has been studied thoroughly. Procedures and devices have been developed to control radiation to provide immense benefits to society. Since radiation is emitted by radioactive materials, the latter are utilized widely in such diverse fields as medicine, manufacturing, construction, power generation, space exploration, archeology and in various industrial and scientific research including genetics, biotechnology and agriculture.

Although life on earth is constantly exposed to radiation from cosmic and terrestrial sources, this fact sheet is about radioactive waste and not radiation. DEP has published other fact sheets that explain radiation and relevant issues.

CATEGORIES OF RADIOACTIVE WASTE

Radioactive waste is categorized based on the following factors: i) properties of the radionuclides and other materials present in the waste; ii) amount of radioactivity in the waste; iii) volume of waste; and iv) program or activity that generated the waste.

Based on the above listed factors, radioactive waste can be divided into the following major categories:

1. Spent Nuclear Fuel (SNF),
2. High-Level Radioactive Waste (HLRW),
3. Low-Level Radioactive Waste (LLRW),
4. Greater-Than-Class-C Low-Level Waste (GTCC),
5. Transuranic Radioactive Waste (TRU),
6. Mining and Mill Tailings Waste or 11e(2) by-product material, and
7. Mixed Waste.

SPENT NUCLEAR FUEL

Spent nuclear fuel is a by-product of nuclear power generation and defense production reactors used for producing fissile material for nuclear weapons. Fissile material is radioactive material that is capable of undergoing or sustaining nuclear fission. Fissile materials include some radionuclides of plutonium and uranium. Fission process is explained in paragraph 3 of this section (Spent Nuclear Fuel). SNF is defined as nuclear fuel that has been withdrawn from a nuclear reactor following irradiation, the component elements of which have not been separated by reprocessing.

Nuclear Energy has been used for generating electricity commercially in the United States for over 40 years. Nuclear power plants built across the nation generate about 20 percent of its electricity. They use slightly enriched uranium as fuel. Uranium is fabricated into ceramic pellets that are inserted into long zirconium tubes to make fuel rods. Fuel rods are bundled together into fuel assemblies and placed in the nuclear reactor in an arrangement designed for optimum operations.

Since uranium-235 is fissile, it is used in low concentration or enrichment as the basic ingredient of nuclear fuel. Fissile radionuclides split into smaller fragments when neutrons hit their nuclei in a process called fission. In a nuclear power plant, uranium fuel undergoes fission by means of a controlled neutron chain reaction to produce heat. Heat is used to produce steam which runs the steam turbine and generator to produce electricity. The fission process also produces fission products, which are smaller radionuclides that are highly radioactive, such as, cesium-137 and strontium-90. Some of the neutrons produced during fission sustain the chain reaction, while the rest are absorbed by uranium fuel to produce transuranic radionuclides of plutonium, americium, and others which are also very radioactive. The fission and transuranic products accumulate within the fuel rods and gradually reduce their efficiency. After about two years of operation, approximately one third of the nuclear fuel is removed and replaced with new fuel to optimize its efficiency. The removed fuel or SNF is intensely radioactive because of the accumulation of fission and transuranic products and their progeny. It also produces heat. It is therefore, stored under several feet of water in spent fuel pools built on the nuclear plant sites.

Newly removed SNF has to be stored in pools to cool down. Originally, the SNF pools at the nuclear plants were designed and built with the assumption that SNF would be stored under water for about six months at reactor sites and then shipped away to a reprocessing facility. Reprocessing of SNF involves chemical processing to separate unused uranium and plutonium from the fission products that accumulate in the fuel rods. Separated uranium can be refabricated into fuel for reuse. Reprocessing of some commercial SNF occurred in early 1970s, but later ceased because of regulatory and nuclear proliferation concerns. In contrast, SNF from defense production reactors is reprocessed and the separated uranium and plutonium used in nuclear weapons. Any

SNF that is not reprocessed is stored in pools or dry storage casks.

Disposal of SNF will require isolation, confinement and monitoring for long periods in a geologic repository. Since there is no repository for the disposal of SNF, and reprocessing is not a viable option for the SNF generated by commercial nuclear power plants, they have been expanding their existing storage capacities, including expansion of their fuel pools and the addition of dry storage. Several nuclear power plants have been forced to store their SNF in dry storage casks on site because their fuel pools have filled to capacity. In future, other nuclear plants may also have to add on-site dry cask storage. Beyond that, their only option will be to transport their SNF after it has been stored and cooled in the fuel pools for a few years to a geologic repository.

HIGH-LEVEL RADIOACTIVE WASTE

High-level radioactive waste consists of highly radioactive waste material that results from the reprocessing of SNF. It includes liquid waste produced directly in reprocessing, and any solid waste derived from that liquid which contains transuranic and fission products in concentrations requiring permanent isolation. It also includes any other nuclear waste which is combined with HLRW from fuel reprocessing, immobilized plutonium waste forms, or other highly radioactive material that the Nuclear Regulatory Commission (NRC) consistent with existing law, may determine to require permanent isolation. Most of the HLRW in the United States has been produced because of the nuclear weapons program, and is currently stored and managed by the Department of Energy (DOE). DOE is responsible for managing facilities where research is carried out in areas of nuclear energy and development of nuclear weapons. DOE facilities are located in several states across the country. All nuclear weapons in the US are produced and assembled at DOE facilities.

The radioactivity in HLRW comes from fission products and transuranic elements. Although radiation levels and health risks attributed to fission products, (cesium-137, strontium-90 and their progeny), decrease significantly in a few hundred years, risks due to long-lived radionuclides of uranium, americium, plutonium and their progeny contained in HLRW will not change over thousands of years. Therefore, disposal of HLRW will also require permanent isolation and confinement in a geologic repository. Congress has passed legislation that requires the DOE to develop a geologic repository for the disposal of the nation's SNF and HLRW. Disposal means the placement of SNF and HLRW in a repository with no foreseeable intent of recovery. A geologic repository is a system for permanently isolating and confining SNF and HLRW in a deep subsurface location to ensure minimum risk to the health and safety of the public and the environment.

Amount of SNF and HLRW

Since there is no repository for the disposal of SNF and HLRW, these wastes have accumulated at 72 commercial nuclear power plant sites across the nation, and five DOE sites where HLRW is also stored. DOE estimates that by the year 2011, the total SNF inventory at the commercial nuclear plants will be 63,000 metric tons of heavy metal (MTHM). DOE has about 7,000 MTHM of HLRW, DOE SNF and other similar materials stored at its facilities that will also require disposal. DOE plans to build the first repository with a capacity of 70,000 MTHM to accept 63,000 MTHM of commercial SNF and 7,000 MTHM of its own waste. Without fuel reprocessing, a second repository may be required for the disposal of additional quantities of commercial SNF and similar DOE waste.

LOW-LEVEL RADIOACTIVE WASTE

Low-level radioactive waste is the most common type of radioactive waste and is produced by nuclear power reactors, hospitals, universities, military and various industrial and research entities. It is also produced in large quantities at DOE facilities. It can also be generated from facility deactivation and decommissioning, environmental restoration, and the treatment and handling of transuranic (TRU) and mixed low-level waste (MLLW).

LLRW is defined as radioactive waste that is not HLRW, SNF, uranium mine and mill tailings [11e(2) by-product material], waste containing higher quantities of transuranic elements or radioactive wastes generated in the production of nuclear weapons. It, however, includes naturally occurring or accelerator-produced radioactive material or any other waste classified as LLRW by the federal acts. LLRW is trash or other materials that have been contaminated with radioactivity, such as contaminated protective clothing, paper, metal and glass items, ion exchange resins, filter media, solidified waste, incinerator ash, and some reactor components, radiation gauges and sealed sources. LLRW contains a broad spectrum of radionuclides, ranging from low activity and short half-lived ones to long-lived ones which are also found in HLRW and TRU waste in higher concentrations.

The NRC has specified a waste classification system for LLRW based on its potential hazards. It has also specified disposal and waste form requirements for each class of LLRW. These are described in Title 10 of the Code of Federal Regulations in Part 61 (10 CFR 61). Waste classification is determined by the presence of short- and/or long-lived radionuclides in concentrations specified in 10 CFR 61.55. LLRW is generally classified as Class A, Class B or Class C waste. Class A waste contains lower concentrations of radionuclides than Class B and Class C wastes, and it is usually segregated from other waste classes at the disposal site. About 95 percent of LLRW is Class A. Class B waste contains higher concentration of radionuclides than Class A waste and therefore must meet more rigorous waste form requirements to ensure stability after disposal. Class C waste contains higher concentrations of radionuclides than Class A or Class B waste and must meet not only more rigorous waste form requirements to ensure stability, but also requires additional measures at the disposal facility to protect against inadvertent intrusion. Less than one percent of LLRW falls under the Class C category.

Due to lower concentration of radionuclides, LLRW exhibits far lower direct radiation and inhalation/ingestion hazards, and therefore has been disposed by the shallow land burial method. The more recent designs of LLRW disposal facilities incorporate a series of engineered barriers, or layers of protection to isolate and contain the

LLRW, coupled with comprehensive monitoring systems to protect the health and safety of the public.

GREATER-THAN-CLASS-C LOW-LEVEL WASTE

Greater-than-Class-C low-level waste (GTCC) is a special category of LLRW. When the LLRW contains radionuclides listed in 10 CFR 61.55 but in concentrations higher than Class C limits, then it is called GTCC waste. GTCC waste determination is usually made on waste package basis. It generally consists of low volume but very high radioactivity waste.

GTCC waste is generally not considered suitable for near surface disposal because of its high specific activity. In fact, it does not have any upper concentration limits for its radionuclides. Under the federal Low-Level Waste Acts, its disposal falls under the responsibility of the DOE and is beyond the purview of the states. DOE can use a number of methods to dispose of these wastes, including deep borehole disposal, intermediate depth burial, and disposal in a geologic repository. However, there are no facilities at present that accept GTCC waste. Therefore it is being stored at facilities where it is generated.

GTCC waste is generated by DOE facilities, nuclear power reactors, university reactors, sealed-source manufacturers and users, irradiation laboratories, nonmedical academic institutions, and by businesses involved in fuel fabrication and industrial research and development. The power reactors produce GTCC as activated metal components, thimble plugs and assemblies, control rod blades, fuel pool vacuum filters and crud tank filters. The decommissioning of nuclear power reactors will generate more GTCC waste in the future. Sealed sources are small metallic capsules used in measurement and calibration devices which are used in various research, manufacturing, construction, and mining operations. DOE estimates that by the year 2035, the projected volume of GTCC waste will be 2010 cubic meters. DOE may decide to dispose of GTCC waste in the geologic repository along with SNF and LLRW.

TRANSURANIC RADIOACTIVE WASTE

Transuranic radioactive waste contains alpha emitting transuranic radionuclides (atomic numbers above 92) with half-lives of greater than 20 years, and whose combined activity level is at least 3,700 Becquerels per gram (Bq/gm) (100 nanocuries/gm) at the time of its initial characterization. The most significant radionuclides present in TRU waste are americium-241 and plutonium - 239. Other important radionuclides that may be found in TRU waste are fission products, reactor activation products and their progeny.

Most TRU waste is produced during processing required for nuclear weapons production, especially in fabrication of plutonium weapons components, recycling plutonium from production scrap, residues, retired weapons, and chemical separation of plutonium. TRU waste is also produced during fuel fabrication and decontamination of remotely handled hot cell items. Most of the TRU waste has been produced and stored at DOE facilities. TRU waste may include filters, glass, resins, salts, sludges, leaded rubber gloves, sand, slag, crucibles, ceramics, scrub alloys and miscellaneous compounds. Some TRU waste containing organic solutions, solvents, toxic metals, PCBs, acids and caustics is considered mixed TRU waste.

TRU waste can be categorized according to its external surface radiation dose rates as remote handled or contact handled. Waste with dose rates exceeding 2 millisieverts per hour (200 mrem/hr), requires special handling and is called remote-handled TRU waste. TRU waste below that dose rate is called contact-handled.

Before 1970, TRU waste was considered part of the LLRW category and disposed of in shallow land trenches. In 1970, the practice of burying TRU waste in shallow land trenches was discontinued. Since that time, it has been placed in retrievable storage typically in drums and boxes either on above or below grade soil-covered storage pads, or in buildings or tanks. In 1984, DOE revised the definition for TRU waste, raising the minimum concentration of TRU radionuclides from 10 to 100 nanocuries per gram. In March 1999, DOE opened the disposal facility for TRU waste called the Waste Isolation Pilot Plant (WIPP) in New Mexico.

MINING AND MILL TAILINGS WASTE

This category of waste constitutes the largest volume of radioactive waste produced due to the nuclear weapons program. This waste is produced during the mining, milling and concentration of uranium and thorium from ores processed primarily for their source material content. It is also called 11e(2) byproduct material because it is defined under Section 11e(2) of the Atomic Energy Act, as amended by Title II of the Uranium Mill Tailings Radiation Control Act (UMTRA) of 1978.

The vast majority of 11e(2) byproduct material consists of homogeneous sand or clay-like particles, produced during large-volume ore processing to extract uranium as a uranium oxide (U_3O_8) from natural ore as well as from support activities such as laboratory analyses and research. It is a large volume, low specific activity kind of waste which could have fallen under the LLRW category, had it not been a by-product of nuclear weapons program. But it also contains comparatively higher concentrations of long-lived alpha-emitting radionuclides of uranium, thorium -230, radium -226 and their progeny which render it unsuitable for shallow land burial. The radioactivity levels of this waste may vary from near background levels to above 1,000 picocuries per gram in some cases. It may also contain low concentrations of some toxic heavy metals such as lead, vanadium, chromium, and molybdenum. Background radiation means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee authorized to use radioactive materials. Background radiation does not include radiation from source, byproduct or special nuclear materials regulated by the NRC.

The uranium initially produced at the mines and mills was used as fuel for plutonium and tritium production reactors, reactors used for research, and electric power generation; nuclear weapon components, and naval programs. DOE

manages approximately 32 million cubic meters of 11e(2) byproduct material, of which about 65 percent may be attributed to nuclear weapons production, 27 percent from naval nuclear propulsion program, and eight percent from nonweapons activities. In addition to mill tailings, 11e(2) byproduct materials were produced from processing of imported high-grade pitchblende ores that produced smaller volume of residues, but which were much higher in radioactivity.

Sites that produced 11e(2) byproduct material are being remediated or cleaned up under UMTRA of 1978. When mill tailing sites are remediated, the dry tailings are collected and stabilized in large above-grade disposal cells which are capped to prevent their dispersion. Most sites managing 11e(2) material were originally owned and operated by companies that processed their own or government-owned ores. These sites are found in Utah, Colorado, New Mexico, Texas, Ohio, Missouri, New York, New Jersey and Pennsylvania. They fall under the following three types of sites: (1) sites subject to Title 1 of the UMTRA, (2) sites subject to Title II of UMTRA and Title X of the Energy Policy Act of 1992, and (3) sites that stored or processed ores or concentrates but do not fall under the above two categories.

Several of the sites being cleaned up come under the Formerly Used Sites Remedial Action Program (FUSRAP), which was operated by the DOE from its inception in 1974 until 1997, when Congress transferred the program to the Army Corps of Engineers (Corps). The radioactivity of FUSRAP waste typically varies from background levels to 8,000 picocuries per gram. According to the Corps, it may be disposed of at an LLRW disposal facility such as the Envirocare facility in Utah.

MIXED WASTE

Mixed waste has both radioactive and chemical hazardous constituents. It is regulated under two authorities: i) the Resource Conservation and Recovery Act (RCRA), as implemented by the Environmental Protection Agency (EPA) or authorized states for the hazardous waste component; and ii) the Atomic Energy Act of 1954, as amended, for the radiological component of mixed waste as implemented by either the DOE, NRC or its Agreement States. Pennsylvania is an authorized state to regulate hazardous waste. The radiological component for mixed waste may be source, special nuclear or byproduct material generated by non-DOE facilities. Although mixed waste was formally defined by statute in 1992, regulators recognized years earlier that it should be managed differently. DOE started managing its mixed low-level waste (MLLW) as a separate waste type in the 1980s.

Mixed waste is produced when radioactive materials are processed, chemically separated or treated. Therefore, mixed waste may be high-level, transuranic or low-level, depending on the concentration and characteristics of radionuclides present therein. High-level and trausuranic mixed wastes have been produced primarily because of the nuclear weapons program, and are managed by DOE at several of its facilities. The most common type of mixed waste is MLLW. MLLW is generated not only at DOE facilities but also by producers of petroleum, coal, iron, steel and other metals, chemicals, pharmaceuticals; academic, medical, and biological research and testing laboratories; and by facilities that use radionuclides and solvents or oils. The military uses armor-piercing shells and other ordnance which after firing may become MLLW. Hazardous constituents present in MLLW include toxic heavy metals, various organic and inorganic compounds, corrosive and other chemicals and solutions.

The storage, treatment and disposal of MLLW is subject to EPA, NRC, and state regulations. EPA is providing increased flexibility to facilities for managing MLLW and naturally occurring and/or accelerator-produced radioactive material (NARM) containing hazardous waste. The Agency is exempting mixed low-level waste from RCRA storage and treatment requirements as long as the waste is generated under a single NRC license, meets the conditions specified, and is stored and treated in a tank or container. In addition, MLLW and NARM, which meet applicable treatment standards, may be conditionally exempt from RCRA transportation and disposal requirements. This waste may be disposed of at low-level radioactive waste disposal facilities which are licensed by the NRC or Agreement States. The rule also provides additional flexibility for manifesting these wastes when they are destined for disposal at such facilities. Although mixed waste meeting the applicable conditions is exempt from certain RCRA requirements, it must still be managed as radioactive waste according to NRC regulations. Note that DOE disposal facilities are not eligible to accept the exempt waste since they are not subject to NRC regulation.

Additional Information

Additional information on radioactive waste may also be obtained by contacting the following organizations:

U.S. Nuclear Regulatory Commission
Office of Public Affairs
Washington, DC 20555
www.nrc.gov

U.S. Department of Energy
1000 Independence Ave., SW
Washington, DC 20585
www.energy.gov

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
www.epa.gov

Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington, DC 20006
www.nei.org

For more information, visit DEP's website at www.dep.state.pa.us, Keyword: "DEP Radiation."

Agreement State Application for Licensing the

Low-Level Radioactive Waste Disposal Facility

Commonwealth of Pennsylvania

Department of Environmental Protection

Bureau of Radiation Protection

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1. INTRODUCTION

The preparation, implementation, and completion of the low-level radioactive waste (LLRW) disposal facility licensing action is a complex and challenging task. It is imperative that appropriately trained personnel conduct a thorough, integrated review of the LLRW disposal facility license application, that the review process is controlled and documented, and that the results and conclusions of the review are clearly stated and defensible.

The purpose of this document is to describe the program that the department will follow when conducting the initial LLRW disposal facility license application review.

1.1 STATUTORY AUTHORITY

Responsibility for licensing and regulating the use and disposal of radioactive materials rests at the federal level with the U.S. Nuclear Regulatory Commission (NRC). However, under the terms of Section 274b of the Atomic Energy Act of 1954, as amended, a state that can demonstrate a regulatory program that is compatible with the federal regulatory program may receive NRC authorization to regulate the use and disposal of radioactive materials within that state.

Section 201 of the Pennsylvania Radiation Protection Act (P.L. 688, No. 147), authorizes the Governor, on behalf of the Commonwealth, to enter into agreements with federal agencies for the purpose of assuming authority to regulate the use and disposal of certain radioactive materials. In his December 1995 letter to NRC, Governor Ridge formally announced Pennsylvania's intent to assume Full Agreement State authorization from NRC, including the authority to regulate the disposal of LLRW.

Pennsylvania is serving as the first host state for a LLRW disposal facility for a four-state compact comprising Maryland, West Virginia, Delaware, and Pennsylvania under the Appalachian States Low-Level Radioactive Waste Compact Act (P.L. 539, No. 120). Section 301 of the Pennsylvania Low-Level Radioactive Waste Disposal Act of 1988 (35 P.S. 7130, the Act) designates the Department of Environmental Resources, now Environmental Protection (the department), as the agency responsible for promulgating and implementing a comprehensive program to regulate a LLRW disposal facility in the Commonwealth. Section 301 of the Act further stipulates that the regulatory program governing management and disposal of LLRW be consistent with the terms of the Agreement State Program authorized under Section 201 of the Radiation Protection Act.

Section 301 of the Low-Level Radioactive Waste Disposal Act also authorizes the department to license the regional low-level waste disposal facility operator in accordance with Section 308 of the Act and the regulations promulgated under the Act. The regulations for licensing a LLRW disposal facility are established in Title 25 of the Pennsylvania Code, Chapter 236, Low-Level Radioactive Waste Management and Disposal. NRC has found (February 4, 1993 letter) that the Chapter 236 regulations are compatible with applicable federal regulations.

1.2 CONTENTS

In addition to this Section, which identifies the statutory authority for regulating LLRW management and disposal activities within the Commonwealth, this document is composed of five sections.

Section 2 identifies the specific statutory requirements, regulations, and regulatory guidance documents that govern the application review process. Section 3 describes the structure of the LLRW licensing organization. The program and methods for controlling the license application review are summarized in Section 4.

The many steps of the license application review process are described in Section 5, beginning with receipt of the license application from the applicant. The final section (Section 6) describes preparation of the Safety Evaluation Report, license and license conditions or license denial, and a Comment and Response document.

2. STATUTORY AND REGULATORY FRAMEWORK

2.1 STATUTORY AND REGULATORY REQUIREMENTS FOR APPLICATION REVIEW

Requirements for licensing the LLRW disposal facility operator are identified in Section 308 of the Act. One of the requirements of Section 308 specifies that the department issue regulations relative to the procedure and requirements for licensing the regional facility operator.
The department has promulgated the required regulations in Title 25 of the Pennsylvania Code, Chapter 236, Low-Level Radioactive Waste Management and Disposal. The requirements for licensing the regional disposal facility operator and the license application review procedures and standards are described in Subchapter C of Chapter 236. Requirements for the content of the license application are specified in Sections 236.204 through 236.211. Review procedures and standards are presented in Sections 236.221 through 236.227 and amendments/changes to the license are contained in Sections 236.241 through 236.247.

2.2 LICENSING GUIDANCE

The department will issue three licensing documents that are directly related to the low-level radioactive waste disposal facility action. Specific information to be provided in the license application and the format for presenting the information required to fulfill the licensing requirements of Subchapter C of Chapter 236 and the Act will be presented in Format and Content of the Low-Level Radioactive Waste Disposal Facility License Application (analogous to NUREG 1199).
A companion document, Guidance for Review of the Low-Level Radioactive Waste Disposal Facility License Application (analogous to NUREG 1200), will facilitate the LLRW licensing organization's evaluation of the application. The document will be keyed to the chapters in the format and content document and it will address information such as acceptance criteria, applicable regulatory requirements and guidance, and regulatory findings. It is anticipated that the applicant will use both of these guidance documents in preparing the license application and that the department will use both documents in reviewing the application.
A third licensing document will be used by the department for managing the license application review. The document, Licensing Management Plan (analogous to NUREG 1274), establishes the requirements and controls necessary to ensure that the department's activities associated with the licensing process are adequately and effectively carried out. Implementation of this

document will enable the department to ensure that appropriately trained personnel will conduct a thorough, integrated review of the license application, that the review process is documented, and that the results and conclusions of the review are clearly stated and defensible.

The Department will not prepare and submit these three licensing documents as part of the formal request for the Agreement State status. The reason is that the Department has suspended its siting process and does not expect to receive a license application for the regional LLRW facility in the foreseeable future.

3. LLRW LICENSING ORGANIZATION AND RESOURCES

3.1 DEPARTMENT ORGANIZATION

The Act designates the Secretary of the department as the individual responsible for making the final licensing decision. The Secretary designated the Bureau of Radiation Protection as the lead for conducting the LLRW disposal facility license application review. Figure 3-1 shows the organizational structure of the department and the Bureau of Radiation Protection's position within the agency. The internal organizational structure of the Bureau of Radiation Protection is shown in Figure 3-2. A description of the LLRW licensing organization and a description of the resources available to augment the LLRW Licensing Organization are presented in the sections that follow.

3.2 LLRW LICENSING ORGANIZATION

The Director of the Bureau of Radiation Protection created the LLRW licensing organization shown in Figure 3-3 for the sole purpose of recommending a licensing decision for LLRW disposal activities.

The LLRW licensing organization is made up of personnel from the department. The key management positions of Director, Bureau of Radiation Protection; Chief, Nuclear Safety Division; and Chief, Low-Level Radioactive Waste Section, are staffed from within the Bureau of Radiation Protection. Outside resources of technical support contractors and other state agencies are available to augment the management and technical capabilities of the organization.

3.3 ROLES AND RESPONSIBILITIES

3.3.1 Director, Bureau of Radiation Protection

The Director, Bureau of Radiation Protection, is responsible for recommending the approval or disapproval of the license application to the Secretary. The Director, Bureau of Radiation Protection provides policy direction to the LLRW licensing organization and has the ultimate

Figure 0-1 DEP Organization Chart

Pennsylvania Department Of Environmental Protection

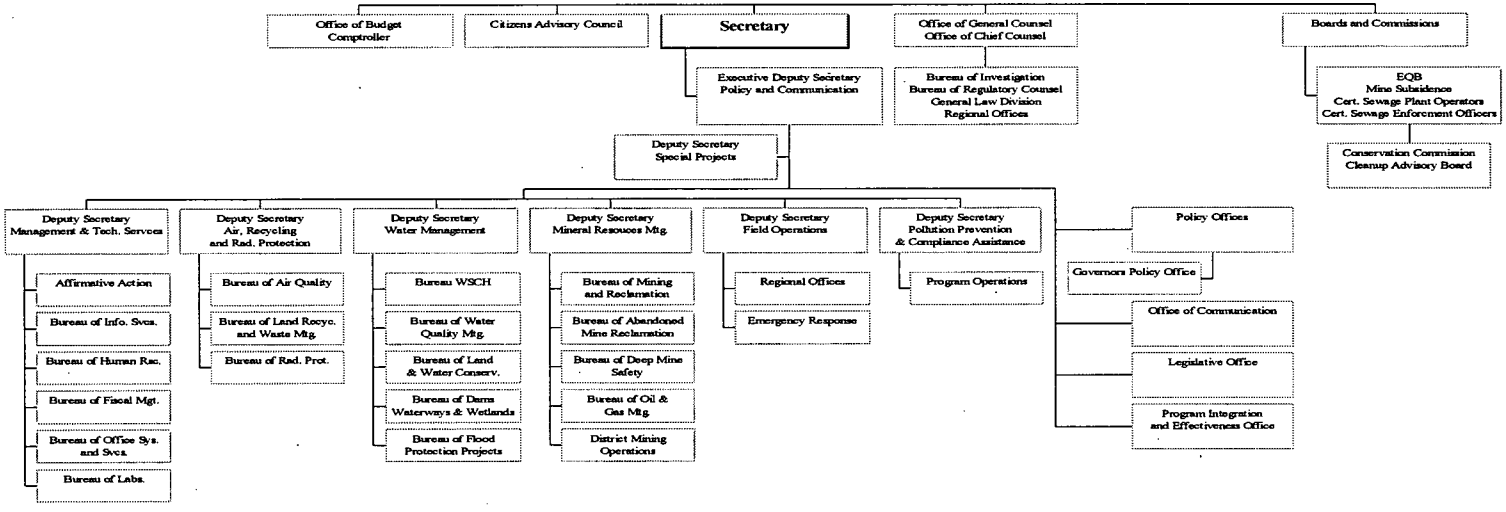


Figure 0-2 BRP Organization Chart

BUREAU OF RADIATION PROTECTION
Organizational Chart

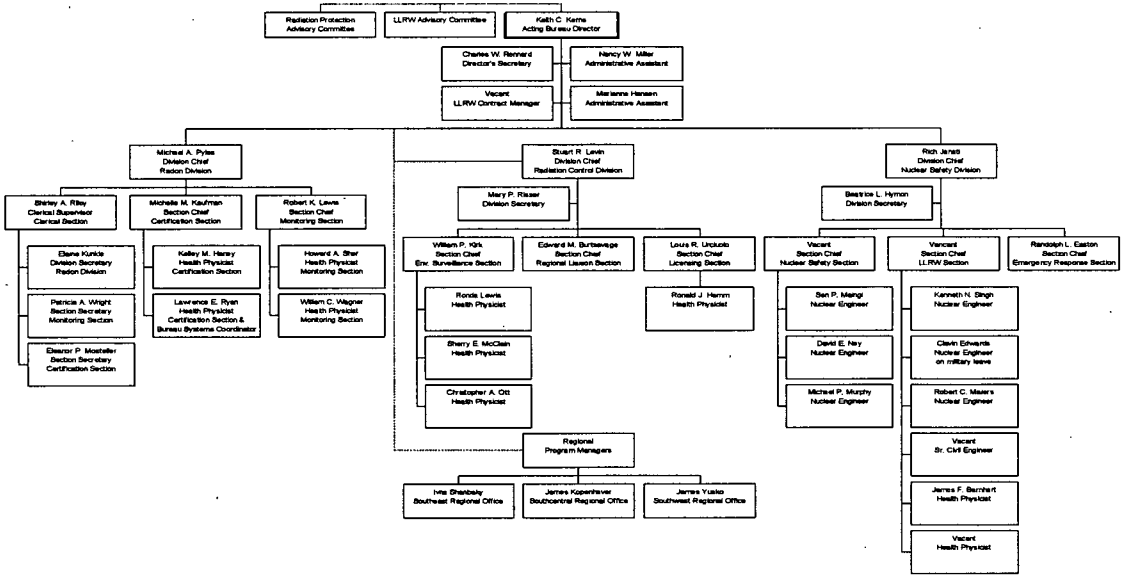
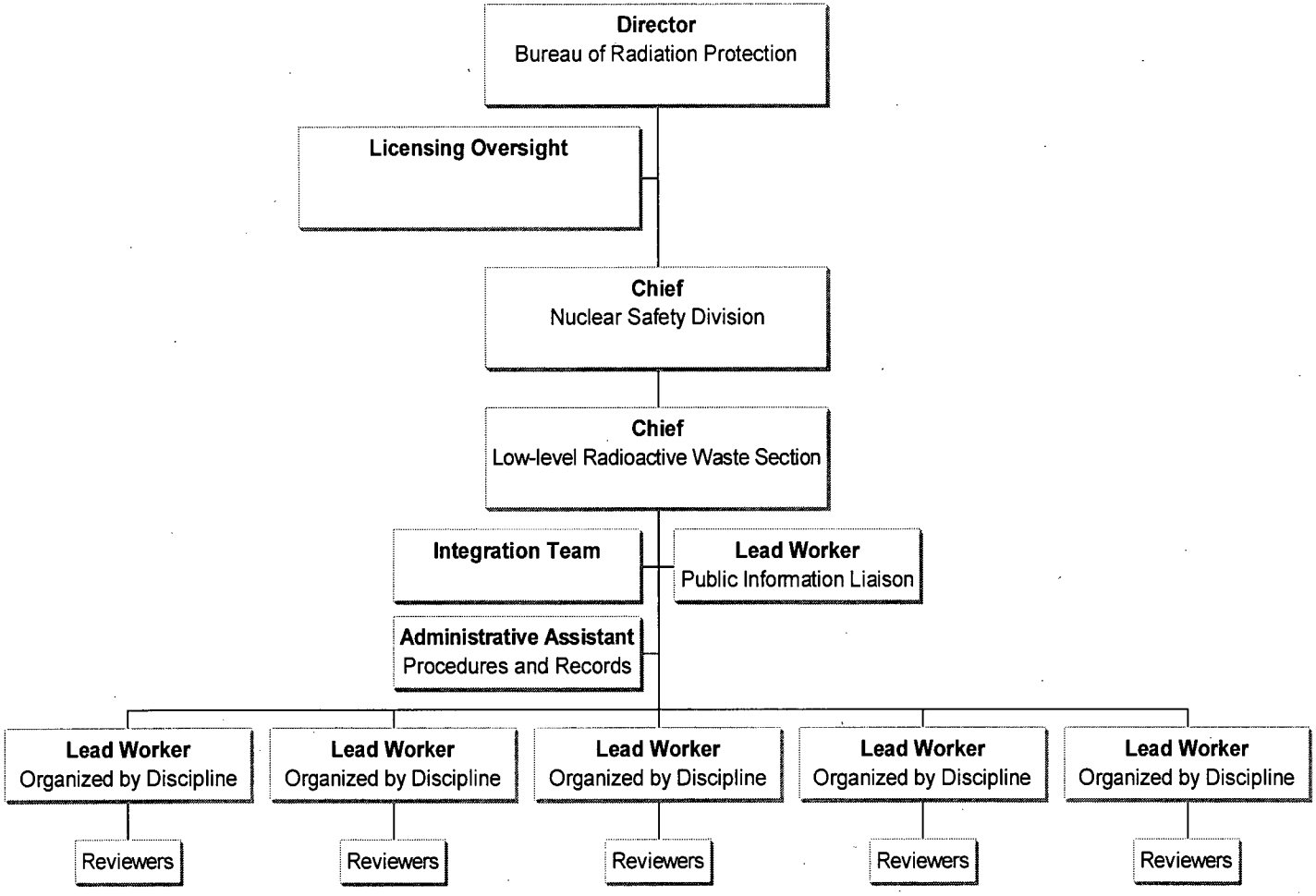


Figure 0-3 Low-Level Radioactive Waste Licensing Organization



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responsibility for making the licensing recommendation. The Director, Bureau of Radiation Protection is the primary contact between the department and the applicant on all matters regarding the license application. The Director, Bureau of Radiation Protection receives formal communication from the applicant including the license application itself.
The Director, Bureau of Radiation Protection is responsible for ensuring that the public is provided with the opportunity to review and comment on the license application and ensuring that all comments are considered prior to issuance of the licensing decision. The Director, Bureau of Radiation Protection is also responsible for ensuring that the Chief, Nuclear Safety Division, has sufficient resources for conducting a comprehensive and timely evaluation of the license application.

3.3.2 Licensing Oversight

The Licensing Oversight function is responsible for performing periodic assessments of the project to verify that all license application review activities are being conducted according to the requirements of the Licensing Management Plan and related procedures. The Licensing Oversight function is equivalent to the Division Chief level within the Bureau of Radiation Protection. Appointment to this position is made at the discretion of the Director, Bureau of Radiation Protection.

3.3.3 Chief, Nuclear Safety Division

The Chief, Nuclear Safety Division, has overall responsibility for ensuring that a comprehensive and technically adequate review is conducted on the license application in a timely manner. The Chief, Nuclear Safety Division, has the authority to plan, organize, staff, lead, and control project functions and activities. The Chief, Nuclear Safety Division, sets forth management requirements of the project with the assistance of the Chief, LLRW Section.
The Chief, Nuclear Safety Division, approves the selection of Integration Team members, Lead Workers, and Reviewers.

3.3.4 Chief, Low-Level Radioactive Waste Section

The Chief, LLRW Section, is responsible for managing the day-to-day activities of the project and the activities of the Integration Team. The Chief, LLRW Section, is responsible for ensuring that the license application review is fully integrated between disciplines, evaluating review

results, making conclusions regarding performance objectives and requirements for issuing the license, and preparing licensing documents.
The Chief, LLRW Section, recommends the selection of Integration Team members, Lead Workers, and Reviewers to the Chief, Nuclear Safety Division.
The Chief, LLRW Section, is also responsible for progress reporting, schedule, issue resolution, and other technical and management-related activities.

3.3.5 Integration Team

The Integration Team is made up of senior personnel representing several disciplines, legal counsel, and management with regulatory experience. The Integration Team is responsible for providing technical, legal, and management advice to the Chief, LLRW Section, ensuring proper integration during the review process, evaluating review results, and forming conclusions regarding performance objectives and requirements for issuing the license.
The Integration Team is also responsible for preparing the Safety Evaluation Report and other licensing documents.

3.3.6 Lead Workers

Lead Workers perform a technical and/or management role on the project depending on the qualifications and experience of the individual. Lead Workers are responsible for managing the day-to-day activities of assigned reviewers and conducting reviews of the license application within their area of expertise. The span of control for each Lead Worker corresponds to one or more sections of the license application as assigned by the Chief, LLRW Section (e.g., General Information, Description of Applicant, Quality Assurance/Quality Control, Site Characteristics, Waste Characteristics, Facility Design and Construction Plan, Facility Operations Plan, Health and Safety Plan, Facility Closure and Decommissioning Plan, Monitoring and Surveillance Plans, Performance Assessment, Impact Analysis Report, etc.).
Key responsibilities of Lead Workers include:

A. Conducting completeness reviews of assigned sections of the license application,

B. Managing and/or performing the detailed review of assigned sections of the license application and preparing interrogatories,

C. Reviewing draft interrogatories prepared by the reviewers and comment resolution,

D. Submitting draft interrogatories to the Integration Team for review,

E. Developing regulatory findings for assigned sections of the license application, and

F. Supporting the Integration Team in the development of the Safety Evaluation Report and other licensing documents.

3.3.7 Reviewers

Reviewers are responsible for reviewing assigned portions of the license application, providing comments and draft interrogatories to Lead Workers, and preparing input on assigned sections of the licensing documents.

3.3.8 Administrative Assistant, Procedures and Records

The Administrative Assistant, Procedures and Records, has overall responsibility for managing project-related documents and maintaining the procedures and records management system. Specific responsibilities include maintaining the Licensing Management Plan and related procedures, distributing and tracking controlled documents, tracking license application review documents, and collecting, filing, storing, and retrieving records.

3.3.9 Lead Worker, Public Information Liaison

The Lead Worker, Public Information Liaison, is responsible for accepting, sorting, and distributing input received from the public, the Low-Level Waste Advisory Committee, and host municipality or county; ensuring that responses are prepared for public comments; and responding to public inquiries regarding licensing activities. The Lead Worker, Public Information Liaison, is also responsible for preparing the Comment and Response document.

3.4 RESOURCES

Primary personnel resources for conducting the license application review resides within the Bureau of Radiation Protection. However, other sources of personnel resources may be accessed by the Director, Bureau of Radiation Protection for purposes of filling or augmenting LLRW licensing organization responsibilities. A description of additional personnel resources follows.

3.4.1 Legal Assistance

Legal services are provided through the Bureau of Regulatory Counsel. Counsel is available to provide advice on legal and policy matters impacting the Commonwealth's radiation protection program.

3.4.2 Other DEP Bureaus and Deputates

The Director, Bureau of Radiation Protection may, through coordination with executive management and according to department policies and procedures, obtain additional personnel support throughout the department. Department personnel are organized by Deputates and Bureaus (Figure 3-1). Department Deputates include: Air, Recycling, and Radiation Protection; Water Management; Management and Technical Services; Mineral Resources Management; Field Operations; and Pollution Prevention and Compliance Assistance.

3.4.3 Contractor Technical Assistance

The Director, Bureau of Radiation Protection may, in accordance with policies and procedures contained in the Commonwealth's Contracting for Services Manual, contract the services of an independent contractor for public involvement, technical, administrative, and other support in evaluating the license application. Access and availability of contractor personnel are assured through the terms and conditions established in the agreement with the contractor.

3.4.4 Other Commonwealth Agencies

The Director, Bureau of Radiation Protection may obtain personnel resources from other Commonwealth Agencies. Access and availability of other agency personnel will be acquired and assured through Memoranda of Understanding negotiated between the department and its sister agencies.

3.4.5 Low-Level Waste Advisory Committee

The Low-Level Waste Advisory Committee (LLWAC) consists of 23 members, 19 of whom represent local government, environmental, health, engineering, business, academic, and public interest groups, and four who are members of the General Assembly. Representatives of the host municipality and host county will be added as voting members. At the request of the

Department, LLWAC provides advice on policies and issues related to the implementation of the Act. LLWAC will be invited to participate in the license application review process.

4. MANAGEMENT CONTROL SYSTEM

This section describes the management control system that will be implemented to ensure that the department's responsibilities and activities associated with the license application review process are adequately and effectively carried out.

4.1 LICENSING MANAGEMENT PLAN

The management control system consists of the Licensing Management Plan and its implementing administrative procedures. The Licensing Management Plan describes the department's organizational structure and responsibilities for reviewing the license application. The plan also addresses the functional areas and topics that govern the entire license application review process. Members of the LLRW licensing organization are assigned the responsibility for implementing the various requirements. The Chief, Nuclear Safety Division approves the Licensing Management Plan.

4.2 FUNCTIONAL AREAS AND TOPICS

Functional areas and topics addressed in the Licensing Management Plan include:

- Project Organization: This section describes the function of the LLRW licensing organization and it defines the key responsibilities of project personnel.

- Document Hierarchy and Document Preparation: This section describes the document hierarchy that was created to control activities related to licensing activities. This section also establishes the requirements and assigns the responsibilities for preparing, reviewing, and approving the documents that make up the hierarchy.

- Resource Acquisition: This section establishes the requirements and assigns responsibilities for promptly acquiring the human resources needed to effectively and efficiently review the license application.

- Personnel Qualifications and Training: This section establishes the requirements and assigns the responsibilities for selecting qualified personnel, verifying the education and experience of selected personnel, and conducting general orientation and training.

- Applicant Interface Protocol: This section establishes the requirements and assigns responsibilities for documenting oral and electronic communications, developing and transmitting written correspondence, scheduling technical and management meetings, and arranging site visits.

- Public Interface: This section establishes the requirements and assigns responsibilities for interfacing with the potential host municipality, county, the public, and interested parties from license application receipt through issuance of the licensing decision.

- License Application Receipt and Review: This section establishes the requirements and assigns the responsibilities for receiving, distributing, reviewing, and tracking the license application and related documents.

- Preparing Licensing Documents: This section establishes the requirements and assigns responsibilities for preparing and issuing the Safety Evaluation Report, the Comment and Response document, and the license and license conditions or license denial.

- Records Management: This section establishes the requirements and assigns the responsibilities for generating, transmitting, collecting, storing, preserving, and retrieving records.

- Evaluations: This section establishes the requirements and assigns the responsibilities for independently evaluating compliance with and effectiveness of the administrative controls for the license application review process.

- Regulatory Interpretations: This section establishes the requirements and assigns the responsibilities for preparing and documenting regulatory interpretations.

Administrative procedures supplement the Plan where it is necessary to have written instructions to implement complex requirements. Administrative procedures are controlled and issued to LLRW licensing organization persons involved in implementing the requirements. The Licensing Oversight Function is responsible for assessing compliance with the Licensing Management Plan and the applicable administrative procedures.

5. LICENSE APPLICATION REVIEW PROCESS

Section 5 provides a description of the steps in the license application review process, from application receipt through issuance of the licensing decision. The license application review process is illustrated in Figure 5-1.

5.1 APPLICATION SUBMITTAL AND PUBLIC NOTIFICATION

5.1.1 Application Submittal

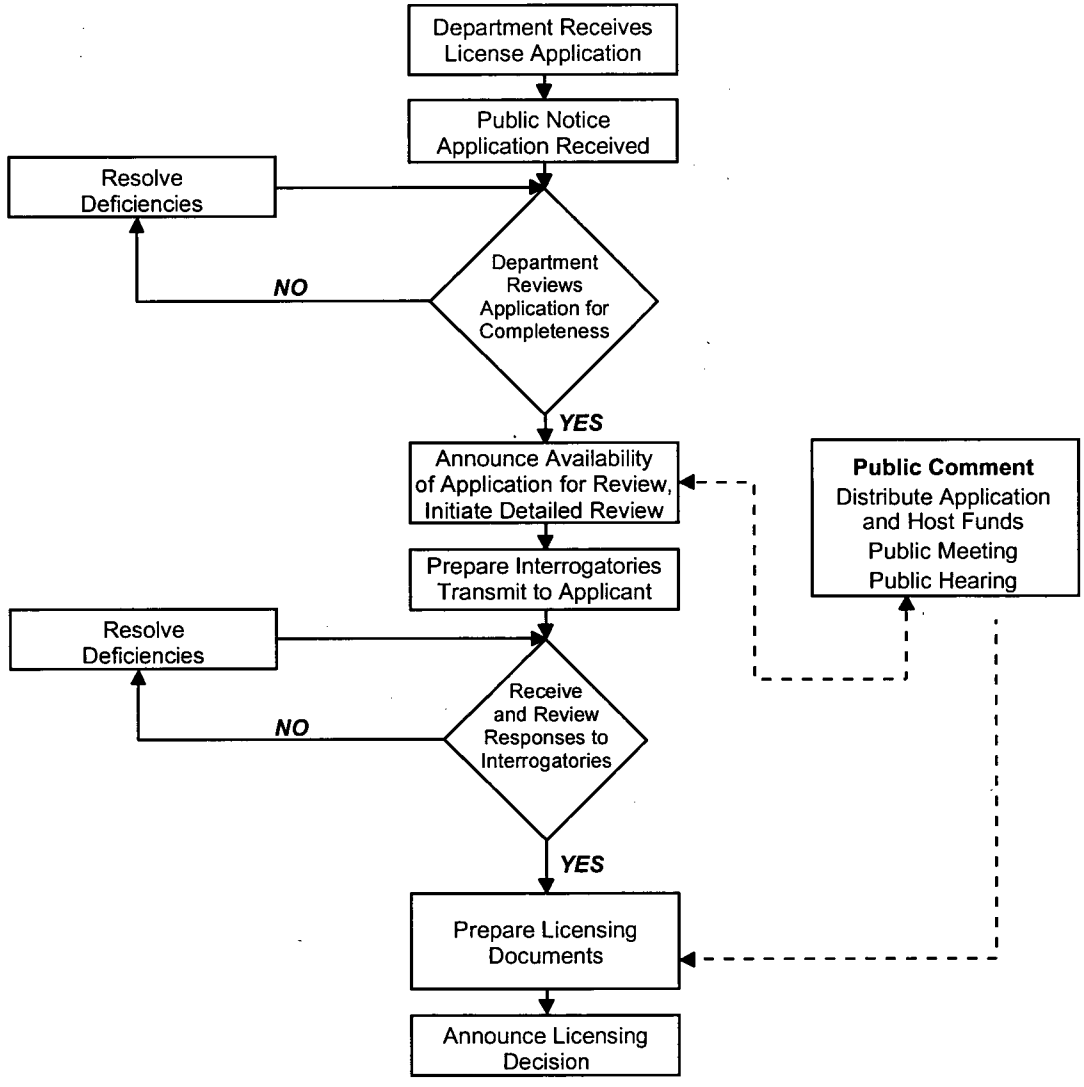
The applicant is required to submit one signed original and 35 copies of the license application package to the Secretary. Sections 236.204 and 212(c) of Chapter 236 state that the application package will consist of the license application (i.e., general information, program plans, a quality assurance/quality control program, specific technical information and technical analyses, institutional control information, and financial information), an impact analysis report, and the department license and permit applications necessary for construction and operation of the disposal facility.

5.1.2 Public Notification

Upon receipt of the license application, the department will notify the applicant, the potential host municipality and county, the LLWAC, other interested parties, and the public that the license application was received. Public notification will be provided through media notifications, mailings, and notices in the Pennsylvania Bulletin, newspapers of wide general circulation, and newspapers in the area where the facility is proposed to be located. The notification will inform the public that the application was received by the department and that the department is reviewing the application to determine if it is complete.

A second public notification will be issued when the license application is determined to be complete. The notification will announce the availability of the application for public review and the duration of the comment period, identify the locations where the application can be reviewed, and provide preliminary information about a public information meeting and a public hearing.

Figure 0-1 Low-Level Radioactive Waste License Application Review Process



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5.2 COMPLETENESS REVIEW

A completeness review will be performed upon receipt of the application to ensure that the necessary information, data, and analyses are included to effectively perform the detailed review.

Each Lead Worker will review his/her assigned section of the license application and determine if the following criteria have been satisfied:

- Is the section organized under the headings and sections corresponding to the Department's Format and Content of the Low-Level Radioactive Waste Disposal Facility License Application, and does the section address each area in sufficient detail to permit an in-depth review?

- Has the department received, or does the application include, all final project data upon which the application relies to reach its conclusions, or which are required in accordance with the requirements of Chapter 236? The application may incorporate by reference separate documents previously submitted to the department.

- Does the section and supporting data/information have adequate legibility and formatting for the detailed review?

Completeness review results will be documented in writing and reviewed and approved with comment resolution documented.

The Chief, Nuclear Safety Division, will make the final decision as to whether the license application is complete enough to begin the detailed review. If the Chief, Nuclear Safety Division, determines that the application is incomplete and requires supplemental information, he/she will prepare a written request to the applicant for supplemental information. The request will instruct the applicant to submit to the department any insert pages, replacement pages, and/or addenda needed as a result of the completeness review. Upon receipt of the supplemental information from the applicant, the supplemental materials will be reviewed for completeness following the same process described above.

When the license application is determined to be complete, the department will distribute the application for public review. The department will commence with a detailed application review at the same time.

5.3 PUBLIC REVIEW AND COMMENT

Upon making the license application available to the public, the department will provide funds, not to exceed $150,000, to the potential host municipality to carry out an independent evaluation of the application. At the request of the potential host county, the department also will provide a reasonable amount of funds, not to exceed $150,000, to the county to carry out an independent evaluation of the application. Within 180 days after distribution of the funding, the potential host municipality and county must present their comments to the department for inclusion in the licensing proceedings.

During the license application review process, the department will hold one public information meeting and one public hearing in the area in which the facility is proposed to be located. The department will issue 30-day public notices to announce the meeting and hearing dates and locations. The notices will be placed in the Pennsylvania Bulletin and in newspapers of general circulation in the area of the proposed host municipality. There will be a minimum of 30 days time between the public information meeting and public hearing.

The public hearing will provide a formal opportunity for the public to submit comments on the license application. A person that wishes to examine witnesses at the hearing must submit to the department a numbered list of contentions. In accordance with Section 236.222(b), these contentions must be limited to failure of the license application and its contents to conform with the Act and Chapter 236. The applicant is required to submit two copies of its testimony two weeks before the hearing date and make its staff available to answer questions. The department may establish the duration for oral testimony and may limit the scope of questioning during the hearing.

The department will accept written comments regarding the application that are submitted within 180 days after the license application was made available to the public. The written comments and transcripts of the hearing will be considered in the Secretary's decision on the application and become part of the public record. The department will provide written responses to comments and the hearing testimony at the time a licensing decision is made.

5.4 DETAILED REVIEW

The detailed review of the license application will begin when the application is deemed complete. Copies of appropriate sections of the license application will be distributed to the Lead Workers according to the applicable requirements and procedures established in the Licensing Management Plan.

5.4.1 Detailed Review Process

The objective of the detailed review is to reach a licensing decision by evaluating the information and analyses presented in the application to determine compliance or noncompliance with Chapter 236 regulatory requirements.

In performing the detailed review, Reviewers will follow the procedures presented in the Licensing Management Plan and guidance presented in, Guidance for Review of the Low-Level Radioactive Waste Disposal Facility License Application to make findings of compliance or noncompliance with regulatory requirements and to describe the basis/rationale for each of these findings. The detailed review will evaluate the adequacy and validity of the data, calculations, analyses, and conclusions of the application through a review of data, models, assumptions, and the applicant's quality assurance records.

LLRW licensing organization personnel may participate in site visits and in periodic technical meetings with the applicant to discuss issues or concerns. Coordination, conduct, and results of meetings and site visits will be documented by a designated member of the LLRW licensing organization in accordance with the procedures presented in the Licensing Management Plan.

If the Reviewer finds the information in his/her assigned section to be acceptable and sufficient to develop regulatory findings and bases, he/she will document "no comments" in writing and submit the documentation to the responsible Lead Worker. The Reviewer will then proceed to prepare regulatory findings.

If the Reviewer finds that additional information, clarification, analysis, or revision is needed to justify a regulatory finding, an interrogatory (i.e., a question or request for supplemental information or revision) will be prepared for submittal to the applicant.

5.4.2 Interrogatory Preparation and Review

The purpose of an interrogatory is to obtain from the applicant additional information to enable the Reviewer to make a determination (i.e., finding) of compliance or noncompliance with applicable regulations and to prepare a description of the bases for these findings.

Reviewers will record their draft interrogatories in a standardized format. The interrogatory will reference the appropriate regulatory requirement and include a justification for requesting the information. The interrogatory will include enough detail to allow the applicant to understand the nature of the information, clarification, justification, or revision requested. Where the interrogatory is based on a disagreement with analyses or conclusions in the application, the

interrogatory will include a description of the reason for the disagreement and why the applicant needs to provide further justification for the conclusions or revise them.

To keep the number of interrogatory rounds to a minimum, an internal review and approval process will be carried out prior to submittal of the interrogatories to the applicant. The Chief LLRW Section, in conjunction with the Integration Team, will review the recommended interrogatories to identify and resolve any inconsistencies or errors and ensure that the interrogatories are directed toward making regulatory findings.

The Integration Team will prepare the interrogatories for those sections of the application in which the applicant summarizes compliance with the performance objectives and technical requirements of Chapter 236. The Integration Team also will consider public comments for inclusion in the interrogatory process. An interrogatory tracking system will be used to ensure that all interrogatories are tracked and addressed.

5.4.3 Interrogatory Transmittal

All approved interrogatories will be submitted to the Director, Bureau of Radiation Protection for formal submittal to the applicant. The submittal will include a request for responses and instructions for submitting additional information (e.g., insert pages, replacement pages, and addenda). The applicant will be requested to provide enough copies of responses and supporting materials for distribution to all persons on the license application distribution list.

5.5 REVIEW OF APPLICANT RESPONSES AND FURTHER INTERROGATORY ROUNDS

Upon receipt of the interrogatory responses and supporting materials from the applicant, each interrogatory response will be entered into the interrogatory tracking system and copies of the interrogatory responses will be distributed to LLRW licensing organization personnel and to all persons on the license application distribution list.

The Reviewers will determine if the applicant's response adequately resolves the concern, and if there is sufficient information to make regulatory findings. The process for reviewing interrogatory responses will be the same as the process described in Section 5.4 (Detailed Review).

If the Reviewer finds the response to the interrogatory to be unacceptable, he/she will prepare a follow-up interrogatory that will undergo the same process as outlined in Section 5.4.2. The new, follow-up interrogatory developed for an inadequate response will be identified as a "derivative" interrogatory (i.e., one derived from a previous interrogatory that is still open).

Preparation of findings and bases will begin when sufficient information is presented in the application to make a regulatory finding. A finding is a determination of compliance or noncompliance with each regulatory requirement. A basis for a finding is a justification that summarizes pertinent supporting data and analyses for the finding. Findings and bases will be documented in a Safety Evaluation Report (SER).

6. PREPARATION OF LICENSING DOCUMENTS

This section describes the preparation, review, and approval of licensing documents including the Safety Evaluation Report (SER), the license and license conditions or the license denial, as applicable, and the Comment and Response document. This section also discusses public notification of the final licensing decision, and distribution of the licensing documents.

6.1 PREPARATION OF SER

The SER will be based on the findings/bases prepared as a result of the detailed review and on evidence presented during the public comment period. The Integration Team, in consultation with the Lead Workers, will develop a detailed outline for the SER. The SER outline will be reviewed and approved by the Chief, LLRW Section. The outline will provide for two SER volumes, as follows:

- Volume I will present an introduction that provides an overview of the proposed facility, the licensee, and the license review process. Volume I also will present integrated findings and bases for compliance with the performance objectives of Sections 236.13 - 236.16, requirements for issuance of a license under Section 236.225, and the integrated technical requirements of Chapter 236, based on the findings in Volume II. Volume I will also include the license and license conditions or notice of denial.

- Each section in Volume II will present findings stating that the pertinent technical requirements in Subchapters B and D through F and the financial arrangements of Subchapter G of Chapter 236 are satisfied, in whole or in part, by the project element reviewed by the Reviewers. Each finding will be supported by a discussion of the basis for compliance with the regulatory requirement.

The SER will be prepared by the Integration Team, and approved for release by the Chief, Nuclear Safety Division and forwarded to the Director, Bureau of Radiation Protection for recommendation of approval or disapproval. Comment resolution will be documented and the necessary revisions will be made by the Integration Team.

6.2 PREPARATION OF LICENSE AND LICENSE CONDITIONS OR NOTICE OF DENIAL

A license will not be issued unless the department has determined that the requirements for issuance of a license under Section 236.225 have been met. If a decision is made to issue a license, it will be prepared by the Integration Team. The license may include the following information:

- Licensee and its address.
- License number.
- Expiration date.
- Issuing agency.
- Limitations on source material, special nuclear material, calibration and check sources, and any other radioactive material that may be received.
- Authorized use of the materials.
- Designation of host and affected municipalities, as required by Section 318(e) of the Act.

The Integration Team also will compile a set of license conditions. At a minimum, the license conditions will include the conditions specified in Section 236.226.
If it is determined that the requirements for issuance of a license under Section 236.225 have not been met, the Integration Team will prepare a notice of intent to deny a license. The notice of intent will document the specific negative regulatory findings/bases that are in the SER.
The draft license and license conditions or draft notice of intent to deny the license will be approved by the Director, Bureau of Radiation Protection. Comment resolution will be documented and the necessary revisions will be made by the Integration Team.

6.3 PREPARATION OF COMMENT AND RESPONSE DOCUMENT

Chapter 236.223(d) requires the department to provide a written response to public comments on the license application and on the testimony from the public hearing. These written responses will be issued by the department as part of the public record at the time the SER is

released. The separate activity of considering public comments as interrogatories is described in Section 5.4.2.

The Public Information Liaison Lead Worker is responsible for compiling all public comments and hearing testimony transcripts, and distributing them to the Chief, Nuclear Safety Division for assignment to responsible Lead Workers for preparation of responses. The Lead Workers will consult with the Reviewers of their section for support in preparing responses, as necessary. Public comments/testimony on application sections addressing compliance with performance objectives and technical requirements and proposed license conditions will be assigned to the Integration Team.

The Lead Workers will submit all of the comments/testimony and their recommended draft responses for their sections of the application to the Chief, LLRW Section for review. The Chief, LLRW Section will direct the Integration Team to review the recommended response for adequacy and appropriateness. The Chief, Nuclear Safety Division will approve Integration Team findings.

A comment response tracking system will be used in order to ensure that public comments are tracked and addressed. Similar public comments/testimony related to a common issue may be grouped into categories with one response prepared for each category. The Public Information Liaison must ensure, however, that each comment/testimony is addressed by a response. Final responses to public comments will be contained in a Comment and Response document and it will be issued in conjunction with the SER.

6.4 LICENSING DECISION AND PUBLIC NOTIFICATION/DISTRIBUTION

The Director, Bureau of Radiation Protection will submit the licensing recommendation, the SER, the license and license conditions or the notice of intent to deny a license and the Comment and Response Document to the Secretary for review. The Secretary's review and decision will be documented and any necessary revisions will be made by the Chief, Nuclear Safety Division with support from the LLRW licensing organization.

The Department will notify the public of its decision to issue or deny the license. The notification will be made in the Pennsylvania Bulletin, local media, newspapers of wide general circulation, and newspapers in the area where the regional facility is located.

If the Secretary determines that the license will be issued, he/she will sign the license and the SER. The Secretary will direct the Director, Bureau of Radiation Protection to distribute the licensing documents to the applicant, the LLWAC, the host municipality and county, and other

parties on the controlled distribution list. Signing of the license and license conditions will constitute the department's approval to begin construction of the facility.

If the Secretary determines that the license will be denied, he/she will sign the notice of intent to deny the license and the SER. The Secretary will direct the Director, Bureau of Radiation Protection to distribute the notice of intent to deny and supporting documentation to the applicant, the LLWAC, the host municipality and county, and other parties on the controlled distribution list. In accordance with Section 236.224(a), if the license application is rejected, the applicant may choose to submit a revised application. The application resubmittal shall be accompanied by a new application fee.

6.5 APPEALING THE LICENSING DECISION

Under Section 307(i) of the Low-Level Radioactive Waste Disposal Act, a citizen of the Commonwealth, a host municipality, or a host county may appeal the issuance of the license to the Environmental Hearing Board, which is required to handle the appeal in an expedited manner. The decision of the Environmental Hearing Board is appealable to the Commonwealth Court.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF
ENVIRONMENTAL PROTECTION

Bureau of Radiation Protection

Prioritization of Licensing Actions

Prepared By:_____**Date**_____

Reviewed By:_____**Date**_____

Approved By:_____**Date**_____

Effective Date_____

Table of Contents

1.0 PURPOSE

1.1 Applicability

The purpose of this procedure is to define the process for prioritizing each licensing action received by the Radioactive Materials Program.

Implementation of this procedure will assure that each licensing action will be processed in a timely and efficient manner.

1.2 References

1.2.1

1.3 Computer Based Letters, Forms and Reports

1.4 Hardcopy Files

1.5 Definitions

1.5.0 Application request means a request for an application for a license from a prospective applicant.

1.5.1 Licensing action means a request or application received from an applicant or a licensee as follows:
a) an application for a license to receive, possess and use licensed radioactive material;
b) an application for renewal of a license;
c) an application for an amendment to a license, e.g., change in administration, authorized use and/or users, RSO, quantity of material, add isotopes, facilities, and etc.; and,
d) a request for termination of a license(s).

1.5.2 Prioritizing means establishing the order and time increment in which the requests or applications are to be processed and completed.

1.5.3 Processing means reviewing the application for license or amendment, requesting additional information, if appropriate, and either issuing or denying the requested license or amendment.

1.5.4 Expedited Renewal means the renewal of a license where the application indicates that there is no change or a very minor change, e.g., change in dosimetry, or leak test vendor, from the previously licensed activity.

1.5.5 Timely Renewal means receipt of an application for renewal of a license, that has been postmarked or received 30 days or more before the license's expiration date. The license remains in effect until processing of the application for renewal has been completed.

2.0 RESPONSIBILITIES

2.1 Licensing RHP

The licensing RHP is responsible for:

- receiving, a renewal or termination request or a new application,
- maintaining the hardcopy and the computer based letters, forms and report files, and
- updating the files, as necessary.

2.2 Licensing RHP

The licensing RHP's are responsible for processing the assigned licensing actions in accordance with the priorities.

2.3 Chief, Radioactive Material Licensing

The Chief, Radioactive Material Licensing is responsible for:

- assigning a priority to a licensing action and
- assigning the licensing action to a licensing RHP for processing.

3.0 PROCEDURE

3.1 Receipt of Application or Request

All applicants for a license, license renewal, or termination request are informed of the receipt of their application.

Appropriate documents such as license applications and appropriate regulatory guides are sent to the requestor. The rule is available at this Internet address:
http://www.dep.state .pa.us

3.2 Licensing Actions - Priorities

Following receipt, each licensing action is assigned a priority that specifies the time allotted for completing the processing of the action. A time increment is assigned each priority.

The priorities for licensing actions follow:

Priority	Time Increment (Days) *Goal*	Licensing Action
R - Rush	As Soon As Possible	As assigned by the Chief New license (MBG-45 days) License Termination License Expiration
H - High	30	New RSO New Authorized User New Use Possible Violations (?)
M - Medium	60	Renewal - In Entirety New Equipment New/Changed Facilities New/Changed Procedures
L - Low	90	Delete AU or RSO Delete Use, Isotopes, Place of Use Expedited Renewal

Applications that do not fit in one of the above categories should be referred to the Chief, Radioactive Materials Licensing for resolution. If it is necessary to request additional information from the applicant/licensee an additional period may be added to the process time.

4.0 RECORDS

4.1 Hardcopy

4.1.1 Requests for applications are maintained in a file.

4.1.2 Applications for license, license renewal or license amendment are maintained in applicable files.

4.2 Computer Based

4.2.1 Appropriate files are updated to record the receipt of applications for license, license renewal and license amendment – L:\Agreement State

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF
ENVIRONMENTAL PROTECTION

Bureau of Radiation Protection

Renewal of Licenses

Prepared By:_____**Date**_____

Reviewed By:_____**Date**_____

Approved By:_____**Date**_____

Effective Date_____

Table of Contents

Section

Renewal of Licenses

1.0 PURPOSE

1.1 Applicability

The purpose of this procedure is to define the steps required for renewal of a specific license. This procedure also defines when an expedited renewal form is allowed rather than renewal in entirety. Timely and untimely applications for renewal are also discussed.

1.2 References

1.3 Computer Based Letters, Forms and Reports

1.3.1 L:/Agreement State\licensing\

1.4 Hardcopy Files

1.5 Definitions

1.5.1 Renewal In Entirety means that based on the review of the application, the inspection history, the current license, or a significant change in the applicable rule, the preparation of a total license revision is warranted. An example is a license that has been amended numerous times since the last renewal, such that the scope of the program has changed.

1.5.2 Expedited Renewal means the renewal of a license where the application, the inspection history and the current license demonstrate that there has not been a significant change in the scope of the licensed program.

1.5.3 Timely Renewal means the receipt of an application for renewal of a license that has been postmarked 30 days or more before the license's expiration date. The license remains in effect until processing of the application for renewal has been completed.

2.0 RESPONSIBILITIES

2.1 Licensing Clerk

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The Licensing Clerk is responsible for notifying a licensee that their license(s) will expire in 90 days and sending appropriate guidance document(s) based on input from the technical staff. The Chief, Radioactive Material Licensing shall be informed of licensees that have not submitted renewal applications at least 30 days prior to expiration and of any licenses that have expired. The Licensing Clerk is responsible for receiving, logging and acknowledging the receipt of an

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application for license renewal and ensuring the applicant is informed that the application is considered to be timely.

Maintains the hardcopy file with renewal documentation.

2.2 Licensing RHP

The Licensing RHP is responsible for reviewing the application to see if it is valid and, with the concurrence of the Chief, Radioactive Material Licensing, signing the letter informing the applicant that the application is considered to be timely, and for processing the application, as assigned.

2.3 Chief, Radioactive Material Licensing

The Chief, Radioactive Material Licensing is responsible for determining if an application for renewal is timely or if the license has expired and should be terminated.

The Chief, Radioactive Material Licensing is responsible for determining if a license should be an expedited renewal form or renewal in entirety and for assigning applications for renewal to a nuclear engineer for processing.

The Chief, Radioactive Material Licensing is responsible for reviewing, approving and signing the license renewal.

2.4 Chief, Radiation Control Division

The Chief, Radiation Control Division is responsible for signing license renewals in the absence of the Chief, Radioactive Material Licensing, once a second review has been performed. The Chief is responsible for approving or disapproving continued operation after the license's expiration date if the application was not deemed timely filed.

3.0 PROCEDURE

The review of an application for renewal of a specific license shall be conducted by a Licensing RHP qualified to conduct such a review.

3.1 License Expiration

Ninety (90) days prior to a license's expiration date, the licensee shall be notified of the pending expiration date and that if an application for renewal is post marked at least 30 days prior to the expiration date, the application will be considered to be timely.

If the renewal application is post marked less than 30 days prior to but not after the expiration date, the Chief, Radioactive Material Licensing shall determine if the application should be considered timely.

If the application is found to be timely, the licensee is informed that activities authorized by the current license may continue until processing of the renewal has been completed.

If a timely application is not received, the licensee is informed that the license is considered to be expired, any activity using licensed radioactive material shall cease and all licensed radioactive material shall be placed in storage or be disposed.

The Chief must approve continued operation under the authority of any license for which the renewal application was submitted after the license's expiration date.

Processing of terminated licenses is covered in License Termination.

3.2 Short Form Renewal

If available, the application for license renewal and the inspection history shall be reviewed.

The application for renewal consists of a completed expedited renewal form.

Expedited renewal of a license may be considered only if the following conditions have been satisfied:

3.2.1 The authorized place of use and facilities are the same.
3.2.2 The program codes for the category-of-use have not changed.
3.2.3 The authorized users have not changed.
3.2.4 The allowable isotopes, quantities, physical form and use have not changed.
3.2.5 The tied down license conditions are the same.
3.2.6 Only instruments that will enhance performance have been added.
3.2.7 No items of noncompliance equal to or greater than Class IV severity have been observed during inspections of the license.

Items of questionable significance that do not satisfy the above requirements, such as adding an authorized user, may be overlooked with concurrence of the Chief, Radioactive Material Licensing.

3.3 Renewal in Entirety

One of the principal reasons for renewing a license in its entirety is to eliminate the confusion that can be caused by multiple amendments to the license and numerous tied down conditions.

The application, all referenced material, prior applications for amendment, and inspection history shall be reviewed. The reviewer shall use, as appropriate, the NURG-1556 Series. If needed, additional information should be requested from the applicant. In particular Pennsylvania specific rule and policy should be reviewed if only NRC guidance was utilized.

The license should contain all information that would be included in an initial license of the same program code(s) including tied down license conditions that are based on a referenced license amendment.

4.0 RECORDS

4.1 Hardcopy

4.1.1 Application for license renewal plus attachments are maintained in the Licensee's file as well as any deficiency letters generated by the technical staff.

4.2 Computer Based

4.2.1 Radioactive Materials Database
4.2.2 Letter for Expired License

5.0 ATTACHMENTS

2.03-1 Sample Renewal Letter for 90 day Notification
2.03-2 Sample Letter for Receipt of Renewal Application-Timely Filed

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF
ENVIRONMENTAL PROTECTION

Bureau of Radiation Protection

License Termination

Prepared By:_____**Date**_____

Reviewed By:_____**Date**_____

Approved By:_____**Date**_____

Effective Date_____

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SECTION

1.0 PURPOSE

1.1 Applicability

This procedure defines the process for terminating a license to possess, use, store and dispose of licensed radioactive material.

This procedure applies to the disposal of licensed material, decommissioning of the site and facilities, and surveys adequate to demonstrate that residual radioactivity is within regulatory limits at such time that a license is terminated.

1.2 References

1.2.1 25 Pa Code
1.2.2 Title 10 Code of Federal Regulations, Part 20, Subpart E - Radiological Criteria for License Termination
1.2.3 NUREG 1727, NMSS Decommissioning Standard Review Plan, October, 2000 (evaluation of License Termination Plans, offers suggestions for evaluation of residual contamination in subsurface soil)
1.2.4 NUREG/BR-0241 NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees (replaced by NUREG 1727, however, Type I, II, III, and IV Decommissioning Types only addressed in this guidance)
1.2.6 NUREG-1575 - EPA 402-R-97-016, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), August, 2000 (evaluation of residual contamination of building surfaces and in surface soil)
1.2.7 NUREG/CR-5849, Manual for Conducting Radiological Surveys in Support of License Termination, December 1993 (replaced by MARSSIM)
1.2.8 Draft Regulatory Guide DG-4006, "Demonstrating Compliance with the Radiological Criteria for License Termination" (replaced by NUREG 1727, however, contains guidance on how to implement MARSSIM)
1.2.9 NUREG-1549, (Draft) "Decision Methods for Dose Assessment to Comply with Radiological Criteria for License Termination" (replaced by NUREG 1727, discusses use of site specific modeling)
1.2.10 D & D, Dose Modeling Code (Buildings)
1.2.11 RESRAD, Dose Modeling Code (Soil Concentration Levels)
1.2.12 RESRAD-Build, Dose Modeling Code (Buildings)
1.2.13 Regulatory Guide 1.86 Termination of Operating Licenses For Nuclear Reactors (1974) (provides values for acceptable levels of surface contamination, however, not dose based)
1.2.14 NUREG-1757-"Consolidated NMSS Decommissioning Guidance"

1.3 Computer Based Letters, Forms and Reports

1.3.1 Standard Termination Letter
1.3.2 Form 314, "Request for Termination of Specific License and Disposition of Radioactive Material"

1.4 Hardcopy Files

1.4.1 Terminated License File

1.5 Definitions

1.5.1 Background radiation means radiation from cosmic sources, naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of a licensee or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by the department.

1.5.2 Critical group means the group of individuals reasonably expected to receive the greatest exposure to radiation for any applicable set of circumstances.

1.5.3 Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license or release of the property under restricted conditions and termination of the license.

1.5.4 Distinguishable from background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

1.5.5 Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental release of radioactive material at the site and previous burials at the site.

1.5.6 Voluntary termination means that a licensee has requested that a license be terminated.

1.5.7 License revocation means a license is terminated because the licensee has allowed the license to expire; did not respond after being informed that the license had expired; and/or, did not request that the license be terminated or renewed.

2.0 RESPONSIBILITIES

2.1 Licensing RHP

The licensing RHP is responsible for:

- identifying those licenses that have expired and for notifying the Chief, Radioactive Materials Licensing
- sending out acknowledgment letters for receipt of termination requests.
- maintaining hardcopy and computer based files.
- processing requests for license termination or for processing expired licenses, as assigned.

2.2 Chief, Decommissioning and Surveillance Division

The chief, decommissioning is responsible for:

- evaluating and/or conducting final decommissioning surveys, as assigned, or
- over-seeing contractors that are conducting, final decommissioning surveys, as assigned.

2.3 Chief, Radioactive Materials Licensing

The chief, radioactive materials licensing is responsible for:

- assigning a request for license termination or an expired license to a licensing RHP for processing. The chief, radioactive materials licensing will instruct the technical staff member in the required scope of the termination or expired license process, i.e., whether the licensee is required to submit a license termination plan (LTP).
- reviewing, approving and signing the license termination.
- in concert with legal counsel, initiating a petition for revocation of the license or other sanction.

2.4 Chief, Radiation Control Division

The Chief is responsible for reviewing and concurring or not concurring in the recommended petition for revocation of the license or other sanctions. The Chief is responsible for approving the implementation of a revocation action and for signing the final order. The initial decision to

proceed with a revocation can be delegated to the Materials Program Supervisor.

3.0 PROCEDURE

3.1 General Provisions

The criteria for termination of a license is listed in 25 Pa Code 215.27 and 25 Pa Code 236.411. The cross-reference to the federal regulation is shown below.

Pa Code	NRC Section	Title
	10 CFR 20.1401	Radiological criteria for license termination
	10 CFR 20.1402	Radiological criteria for unrestricted use
	10 CFR 20.1403	Criteria for license termination under restricted conditions
	10 CFR 20.1404	Alternate criteria for license termination
236.411	10 CFR 20.1406	Minimization of contamination

The licensee shall determine the peak annual TEDE expected within the first 1000 years after decommissioning, when calculating TEDE to the average member of the critical group.

3.2 Request for Termination

Within **5 working days** following the receipt of the request for license termination, the receipt shall be acknowledged and the licensee informed that the Radioactive Materials Program will request additional information.

Following the receipt of a request for termination, a determination of the potential for residual radioactive contamination of the facility shall be made. The license and inspection history shall be reviewed to determine the potential risk of residual radioactive contamination.

The highest risk would be licensees that utilize significant quantities of unsealed radioactive material such as, but not limited to, nuclear pharmacies; waste disposal processing and repackaging services; manufacturing and distribution; nuclear laundries; academic, or medical type A Broad; and, research and development, Type A Broad.

The lowest risk would be licensees that utilize radioactive materials only in the form of sealed sources. Unless there has been a significant leak of a sealed source the probability of residual contamination is essentially zero. NOTE: However, there have been a number of cases of residual contamination resulting from melting sealed sources contained in measuring gauges.

For licenses that authorize both sealed and unsealed sources of radioactive material the highest risk use shall dictate the decommissioning process.

3.3 License Termination - Sealed Sources

Upon the receipt of a request for termination of a license that authorizes the possession and use of radioactive materials only in the form of sealed sources, the following information shall be requested from the licensee:

a) a listing of sealed sources currently or last possessed including type, isotope and quantity, serial number, vendor, date received and use

b) copies of the results of leak tests for each sealed source, if appropriate

c) copies of the records of disposal, decay or transfer to an authorized recipient, for each sealed source

d) copies of periodic inventories, if appropriate

e) a copy of the results of the final survey of the area where sources were used and stored. The record should include the type of instrument used and the last calibration date

f) licensee has submitted a properly completed Form 314, Request for Termination of Specific License and Disposition of Radioactive Material

If the above information, when compared to the license and the inspection history, appears to be accurate and complete, the license shall be terminated.

If the information is incomplete or appears to be inaccurate an inspection of the facility shall be conducted and if warranted, enforcement action taken prior to license termination.

3.4 License Termination - Solid, Liquid, Sealed and Gaseous Sources

Upon receipt of a request for termination of a license(s) that authorizes the possession and use of any radioactive materials in solid, liquid or gaseous form, plus sealed sources, the licensee shall be requested to submit the following information:

a) a listing of licensed radioactive materials currently or last possessed including type, isotope and quantity, serial number, vendor, date received and use, if appropriate

b) copies of the results of leak tests for each sealed source, if appropriate

c) copies of the records of disposal, decay or transfer to an authorized recipient, for each radioactive material listed in a) above

d) copies of periodic inventories, if appropriate

e) a copy of the results of the final survey of the area where radioactive materials were used and stored. The record should include the type of instrument(s) used and the last calibration dates

f) licensee has submitted a properly completed Form 314, "Request for Termination of Specific License and Disposition of Radioactive Material"

If the above information, when compared to the license and the inspection history, appears to be accurate and complete, and with the exception of sealed sources, the licensee has not possessed radioactive material with a half life greater than 30 days, the license(s) shall be terminated.

If the information is incomplete, appears to be inaccurate, the final survey revealed radioactive contamination or the licensee has possessed unsealed radioactive material with a half life greater than 30 days, an inspection of the facility shall be conducted as determined by the Chief, Decommissioning and Environmental Surveillance and/or the Regional Office.

If the inspection reveals that all radioactive material has been properly disposed of and an independent survey reveals no residual activity, the license shall be terminated. However, if items of noncompliance were noted during the inspection enforcement action shall be taken prior to license termination.

If an independent survey reveals possible residual activity the licensee shall be requested to submit a sufficient License Termination Plan (LTP) such that the facility will be decontaminated to levels acceptable for unrestricted use. NUREG-1575 and NUREG/CR-5849 (see sub-Section 1.2 of this procedure) can be used in the development, implementation of the LTP and the termination of the license(s). NUREG 1727 can be used to evaluate the LTP by the Radioactive Materials Program. In addition, other guidance and/or modeling codes may address specific issues and may be used as needed (see sub-Section 1.2 of this procedure).

3.5 Expired License

3.5.1 Licensee Contacted

Within ten (10) working days following the expiration date of a license without the receipt of a request for license termination or license renewal, the licensee shall be contacted by telephone or in person and informed that the license expired. The licensee shall be informed that any activity using radioactive material under the license shall cease, the licensed material shall be placed in storage or disposed of, and an application for license termination shall be submitted within 30 days.

If the licensee intends to continue license operations and states that the failure to submit an application for license renewal was just an oversight, the licensee shall be informed that operations shall cease and that an application for license renewal (extension) should be submitted as quickly as possible. The licensee shall be informed that operation without a current license constitutes noncompliance and that appropriate enforcement action will result.

The licensee shall be informed that only the Chief may authorize continued use of radioactive material without a current license, i.e., grant an exemption.

The above contact shall be recorded in a Confirmatory Action Letter and transmitted to the licensee by Registered Mail, Return Receipt Requested.
(A sample letter is attached to RMPP No. 2.03, License Renewal)

3.5.2 Licensee Not Contacted

If the licensee cannot be contacted either by telephone, visit to the address on the license or all other reasonable efforts, the authorized place of use shall be inspected and surveyed. If no radioactive materials are found and the survey indicates the facility is free of radioactive contamination, necessary legal action may proceed in order to revoke the license.

If residual contamination is discovered, the facility shall be decontaminated by the licensee to levels in the approved decommissioning plan and the license revoked or terminated.

4.0 RECORDS

4.1 Hardcopy

4.1.1 Terminated License File

4.2 Computer Based

4.2.1 Standard Termination Letter
4.2.2 Form 314, "Request for Termination of Specific License and Disposition of Radioactive Material"

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF
ENVIRONMENTAL PROTECTION

Bureau of Radiation Protection

Administrative Licensing Procedures:
Review of an Initial Application for License, Amendment Request, or Termination of a License.

Prepared By:_____ **Date**_____

Reviewed By:_____ **Date**_____

Approved By:_____ **Date**_____

Effective Date: _____

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Section

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<#>Attachment "Conditions, Deficiencies"¶

1.0 PURPOSE

1.1 Applicability

The purpose of this procedure is to define the process for reviewing all types of specific license requests., Standard review plans, checklists and policies that shall be used during the review process will be identified.

The process for issuing a specific license or an amendment to a license and standard license conditions are also provided.

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The process for denying (State's initiative) or abandoning (applicant's or State's initiative) a request for licensing action shall be defined.

The Pennsylvania Agreement State Program will follow the NUREG 1556 procedure for Technical Evaluation of Proposed Uses of Radioactive Material.

The Pennsylvania Decommissioning program will follow NUREG 1757.

In as much as the Commonwealth of Pennsylvania has "incorporated by reference" regulations contained in 10 CFR 19 through 150, the Commonwealth will also utilize the Guidance listed on the "Medical Use Toolkit" including:
"Procedures for Recognizing Certification Process of Specialty Boards"
"Complying with 10 CFR 35.400(a), 35.500(a), and 35.600(a) requirements for licensees to only use sources and devices "as approved in the Sealed Sources and Devices Registry and Sealed Source and Device Registry: Supplement for 10 CFR 35 Users."

"Licensing Guidance for 10 CFR 35.1000 sealed sources and devices included:
Thera spheres and SIRSpheres Yttrium 90 microspheres;
I-125 Iotrex Liquid Brachytherapy Source in Cytyc GliaSite Radiation Therapy System;
Best Vascular, Inc. Beta-Cath Intravascular Brachytherapy (IVB) System;
Nucletron seedSelectron® System, Isotron Brachytherapy Sources and Nucletron FIRST™ System;
Iodine-125 and Palladium 103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions.

1.2 References

1.2.1 10 CFR 19-150
1.2.2 NUREG-1556,"Consolidated Guidance About Materials Licenses".
1.2.3 25 Pa Code 215-232
1.2.4 NUREG-1757
1.2.5 NUREG-1520
1.2.6 NRC Regulatory Guide 4.20
1.2.7 Medical-Use Toolkit

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1.3 Computer Based Letters, Forms and Reports

1.3.1 License application
1.3.2 Links to Guidance and Regulations
1.3.3 Form 3
1.3.4 Deficiency Paragraphs
1.3.5 Transmittal Letter
1.3.6 Microsoft EXCEL Radioactive Material License Database

1.4 Hardcopy Files

1.4.1 Specific License
1.4.2 License Application and/or Amendment Request Submittal
1.4.3 Deficiency Letter
1.4.4 License Transmittal Letter

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1.5 Definitions

Application request means a request for an application for a license from a prospective applicant.

Licensing action means a request or application received from an applicant or a licensee as follows:

a) an application for a license to receive, possess and use licensed radioactive material;
b) an application for renewal of a license;
c) an application for an amendment to a license, e.g., change in administration, authorized use and/or user(s), RSO, quantity of material, add isotopes, facilities, and etc.; and,
d) a request for termination of a license(s).

Processing means reviewing the application for license or amendment, requesting additional information, if appropriate, and either issuing or denying with or without prejudice, the requested license or amendment.

Denying without prejudice means that the application for license was deficient and denied, but that the applicant may reapply after correcting the deficiencies.

Denying with prejudice means that the applicant for license is not qualified and shall not reapply for a license, e.g., a minor applying for a license to possess and use radioactive material or a non medical qualified individual applying for a license to use radioactive material in the diagnosis and/or treatment of humans.

Regulatory Guide means guidance published by the NRC, in which each guide defines an acceptable program or part of a program, for the possession and specific use of radioactive materials. An applicant is not obligated to follow one of these guidance documents when developing their program and applying for a license or amendment; however, if not followed, the applicant must demonstrate that the proposed program is at least equivalent to the one described in the guidance document.

Consolidated Guidance About Materials License means guidance published by the NRC in NUREG-1556 in which each volume defines an acceptable program for a specific type of use of radioactive material.

Licensing checklist report developed to ascertain the completeness of the license application or amendment request.

Deficiency Letter means a letter that in an itemized fashion documents additional information needed to process a licensing request. The problem with the submission, rule or regulatory guidance that is applicable, and the specific action requested of the licensee or applicant is clearly stated.

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2.0 RESPONSIBILITIES

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2.1 Licensing Clerk

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The Licensing Clerk is responsible for receiving and acknowledging receipt of a licensing action request. Acknowledgement can be in the form of surface mail or electronic acknowledgement.
The Licensing Clerk is responsible to assign or verify a client tracking number in the Commonwealth's eFACTS System. The system assigns deadlines for licensing actions
The Licensing Clerk is then responsible for forwarding the request for licensing action to the Licensing Radiation Health Physicist for evaluation.

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2.1 Licensing Radiation Health Physicist

The Licensing Radiation Health Physicist is responsible for receiving the application for a licensing action from the licensing clerk.

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All Materials License Reviewers (aka. Licensing Radiation Health Physicists) shall be authorized to review all radioactive material license types.

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The Licensing Radiation Health Physicist is responsible for maintaining the computer based and hardcopy files and for tracking the applications for license or amendment during processing.

The Licensing Radiation Health Physicist is responsible for responding to requests for license applications by transmitting an application, order form and Internet address of the regulations, and a copy of or reference to specific guidance.

The Licensing Radiation Health Physicist is responsible for reviewing the assigned application, determining if it is complete, requesting additional information as appropriate, and if appropriate, preparing the license or amendment for review and signature by the Chief, Radioactive Materials Licensing. The Licensing Radiation Health Physicist is responsible for recommending whether an application is deficient and should be denied either with or without prejudice.

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The Licensing Radiation Health Physicist will forward a copy of the closeout survey and disposition certificate to the Bureaus's regional office for their evaluation of these records for all licensee's request for license termination or the deletion of a previously licensed site on that specific license. Furthermore, a Decommissioning Project Manager or Technical Reviewer will be involved in all complex license terminations.

All licenses will be reviewed by a second Licensing Radiation Health Physicist prior to being sent to the Chief, Radioactive Material Licensing or in his/her absence, the Chief, Radiation Control for final evaluation and signature.

2.3 Chief, Radioactive Materials Licensing

The Chief, Radioactive Materials Licensing is responsible for assigning a licensing action for processing to a Licensing Radiation Health Physicist.

The Chief, Radioactive Materials Licensing is responsible for final review, approval, and signing licensing actions.

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The Chief, Radioactive Materials Licensing following consultation with and concurrence by the department's Office of Legal Counsel is responsible for denying, with or without prejudice, an application for license or for license amendment.

2.4 Radiation Control Division Chief

The Radioactive Control Division Chief is responsible for final review and signing licensing requests in the absence of the Chief, Radioactive Materials Licensing.

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3.0 PROCEDURE

3.1 Receipt of an Application or Request

Upon the receipt of an application for license or a request for a license amendment the following shall be performed:

3.1.1 Priority

An action priority shall be assigned to the application or request in accordance with the following order: New, Amendment, Termination, Renewal and concurred with by the Chief, Radioactive Materials Licensing.

3.1.2 Assignment of Reviewer

The Chief, Radioactive Materials Licensing shall assign a Licensing Radiation Health Physicist to process the application or request. The review of an application or request shall be conducted by a Licensing Radiation Health Physicist qualified to conduct such a review.

3.2 Processing an Application for License

The application and, all appended and referenced material shall be reviewed using Pennsylvania specific regulations, Consolidated Guidance, Regulatory Guides, Standard Review Plans, Reviewers Evaluation Forms, Licensing Checklists and Technical Assistance Requests as appropriate, by the reviewer to evaluate the applicant and the application.

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Significant portions of the PA review criteria, guides, and other material have been incorporated by reference, adapted, or adopted from NRC material. This being the case, use of NRC material, e.g., NUREG 1556 and NUREG 1757, may be appropriate.

If additional information is needed, a meeting with the applicant and/or a visit to the proposed facility(s) may be requested by the reviewer. If the applicant is licensed to possess and use radioactive materials, appropriate information may be included by reference.

If only NRC guidance is used in the evaluation of the application then Pennsylvania specific rule and policies must be consulted. For example, uses of radioactive materials in medicine are subject to specific Pennsylvania Rule.

The reviewer shall assure that the review of the application includes the following commonly missed items:

a) Application signed by upper management - RSO, only if appropriate,
b) Facility diagrams or sketches, including but not limited to, hoods, shielding, ventilation, work areas, storage areas, location of nearest occupied area, and physical security of radioactive material,
c) Number, type and range of survey instruments including procedures for calibration, checks for operability and maintenance,
d) Training and experience records, preceptor statement for all authorized users,
e) Training and experience records, preceptor statement, delegation of authority and the duties, responsibilities, and if appropriate, the availability of the RSO,
f) Training and experience records for the Radiation Safety Committee Chair if appropriate,
g) Records to be retained and responsibility for records retention assigned. Frequently missed records include training for new employees, annual refresher training, survey instrument calibrations and source checks, and dose calibrator constancy, accuracy, linearity, and geometric variation checks for medical licenses.

h) Procedures for receipt of radioactive material, specifically off-hours and week-ends.

Following the completion of the review of the application by 2 reviewers,and any supplemental material requested by the reviewers, a recommendation to issue a license or deny the application shall be made to the Chief, Radioactive Materials Licensing.

If the recommendation is to issue the license and the Chief, Radioactive Materials Licensing concurs, the reviewer shall prepare the license for the Chief, Radioactive Materials Licensing's signature. A tie-down license condition is used for procedures, radiation detection equipment, use locations, possession limits etc., that are not already specifically identified on the license. For renewal of existing licenses, previous tie-down conditions can be deleted from the license if they are stated in the current application.

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If the recommendation is to deny the application and the Department's Office of Legal Counsel and the Chief, Radioactive Materials Licensing concur, the reviewer in concert with legal shall prepare a notification to the applicant. The notification shall state the reason for denial and if a new application would be accepted from the applicant.

3.3 Processing a Request for License Amendment

A request for an amendment to a specific license need not and probably will not be on a department form. The request may be a letter plus attachments or a formal application. The request shall be signed by the individual in the position, or higher, that signed the application for license or the request shall be returned for proper signature. Alternatively, the licensing action request may be signed by an individual delegated by the person who signed the application or higher.

The initial review of the request for amendment shall determine if the request is so broad that it should be processed as a rewrite of the current license or as a new license. If it's determined that either a rewrite or a new license is appropriate and the Chief, Radioactive Materials Licensing concurs, the request shall be returned to the licensee and an appropriate application shall be requested.

A request from a medical licensee to add a qualified user to their license shall be accompanied by records of the individuals training and qualifications. Records of training shall be signed by the preceptor and shall not be just a letter stating that these procedures had been performed at another licensed facility.
Where appropriate, material previously received for the license may be incorporated by reference.

A request to add an authorized user to a license shall be accompanied by records of the individuals training and qualifications and preceptor statement unless the authorized user has been listed on another radioactive material license. Recentness of training will also be reviewed.

A request to add or replace a Radiation Safety Officer (RSO) or Chair of the Radiation Safety Committee (RSC) shall include training and experience records and duties, responsibilities, and if appropriate, availability when the RSO is a consultant.

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A request to add isotopes, quantities, physical form, use, facilities, instrumentation, or the authorized place of use shall be reviewed in the same way as a request for a specific license for that activity. Requests for sealed sources must include Manufacturer's Name and Model Number of the source/device.

An amendment to a license is normally amended in entirety and includes new tie-down license conditions as appropriate. If approved, the Chief, Radioactive Materials Licensing shall sign the amendment.

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3.4 Writing the License, Second Review, and Documentation

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The Licensing Radiation Health Physicist shall write the license using the templates to develop or modify the license. It is important to specify the type of license, i.e. fee code, so that the appropriate template is selected for a new license. The initial license will have an Amendment Number of "NEW".

The license reviewer shall document the licensing activity on a licensing checklist and submit the file with the license, transmittal letter and checklist to the Chief, Radioactive Material Licensing or designee for the second review.

The second reviewer shall perform a selective review of the licensing request and license. Comments may be documented on the licensing checklist. The second reviewer should discuss issues of concern with the initial license reviewer. When all issues are satisfactorily resolved, the second reviewer documents his/her agreement with the proposed licensing action by signing the licensing checklist and modifying the licensing checklist comments accordingly.

3.5 Signing the License and File Documentation

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The license can then be signed by the Chief, Radioactive Material Licensing, or by the Section Chief, if the Chief, Radioactive Material Licensing is not available. If the Section Chief is signing the license, then both the license reviewer and second reviewer must be qualified license reviewers.

The license file should then be logged documenting the completion of the licensing activity, and inserting the licensing request, deficiency documentation, response(s), transmittal letter, licensing checklist, and license into the PA license file. This information shall be entered into eFACTS as appropriate. A complete copy of the current licensing action will be forwarded to the appropriate regional office for their records.

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All tie-downs should be flagged and should remain in the licensing section of the file. Training documentation and/or other ancillary information that is not considered part of the license may be placed in the back section of the file.

For renewals: the previous licensing information and licenses, and all but the most recent inspection report, can be culled from the file and archived. Training documentation should be maintained for the current authorized users.

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4.0 RECORDS

4.1 Paper

4.1.1 Hardcopy applications for licenses plus attachments are kept in the license file. The entire application package including supporting documentation will be kept, per Commonwealth Records Retention Policy, in the Bureau's file room for future reference.

4.1.2 Requests for amendments are maintained in the appropriate specific license file.

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4.1.1 Applications for license plus attachments are kept in the license file.¶

4.1.3 Requests for Terminations are stored in the "Terminated File".

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4.2 Computer Based

4.2.1 Microsoft Excel Radioactive Material License Database

Spreadsheet contains the following information: License number, licensee name, address, city, state, zip code, fee category, material licensed, county, RCTTF, issue date, expiration date, amendment number, date of current amendment, RSO, Authorized Users, number of sites, priority class.

4.2.2 Bureau's Shared Folder

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Spreadsheet containing the above information is available electronically to the regional Bureau offices for reference. The shared network folders is backed-up per Commonwealth Information Technology Policy.

4.2.3 eFACTS Database

The Commonwealth eFACTS computer system will serve as the license tracking system to track licenses from receipt to completion. This system provides a review process and provides licensing and inspection management reports. The system-assigned client number will serve as the docket number on radiation control correspondence to the licensee. This unique number will remain with the licensee for tracking purposes. Each licensing action is tracked in the eFACTS system. Information includes sites of use, responsible party, radiation safety officer and specific amendments to the license.

5.0 Review Documents

5.1 NUREGs

The Pennsylvania Agreement State Program will follow the NUREG 1556 procedure for Technical Evaluation of Proposed Uses of Radioactive Material.

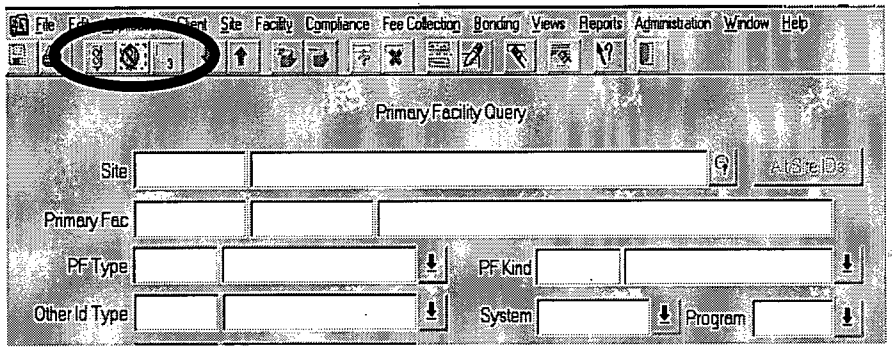
The Pennsylvania Decommissioning program will follow NUREG 1757.

5.2 10 CFR

The Pennsylvania Agreement State Program has adopted by reference much of 10 CFR.

Query Mode

- Indicates the capacity to search the database for information using criteria identified on a eFACTS screen.
- When the system is in query mode you are unable to record data.



What is eFACTS?

- **eFACTS is the Environmental Facility Application Compliance Tracking System.**
- **eFACTS is a Data Integration and System Conversion Project.**
- It contains **integrated:**
  - ⇒ **Client and Site records**
  - ⇒ **Application processing**
  - ⇒ **Program-specific facility details**
  - ⇒ **Compliance (Inspections, Violations, Enforcements, and Penalties)**
  - ⇒ **Licensing**
  - ⇒ **Bonding and Forfeiture Tracking**
  - ⇒ **Self Monitoring**
  - ⇒ **Reporting Functionality**

What is eFACTS? continues

eFACTS allows DEP to collectively focus on and carry out its mission: *"to protect Pennsylvania's air, land, and water from pollution and to provide for the health and safety of its citizens through a cleaner environment."* While historically the agency has had to deal with information in multiple, non-integrated databases and files, DEP now has the ability to access information from multiple programs about a regulated client or site.

To carry out its mission, DEP is responsible for a vast array of diverse programs. These programs include traditional environmental protection programs like air, water, and waste; resource management programs like wetland protection and water resource planning; and other programs as diverse as oil and gas drilling, radiation protection, surface mining, and deep mine safety. Few businesses in Pennsylvania fall outside the scope of DEP's regulatory oversight. Over 1,600 of the DEP regulated businesses must interact with more than one program. Because each program had it's own "stovepiped" data, the agency failed to capitalize on the information it collected. This meant a company might have been in non-compliance across multiple programs, without DEP realizing it. It also put the department at risk for oversights, such as a facility receiving an award from waste minimization from one program, while another program cited the same facility for air quality violations.

Why is the eFACTS needed?

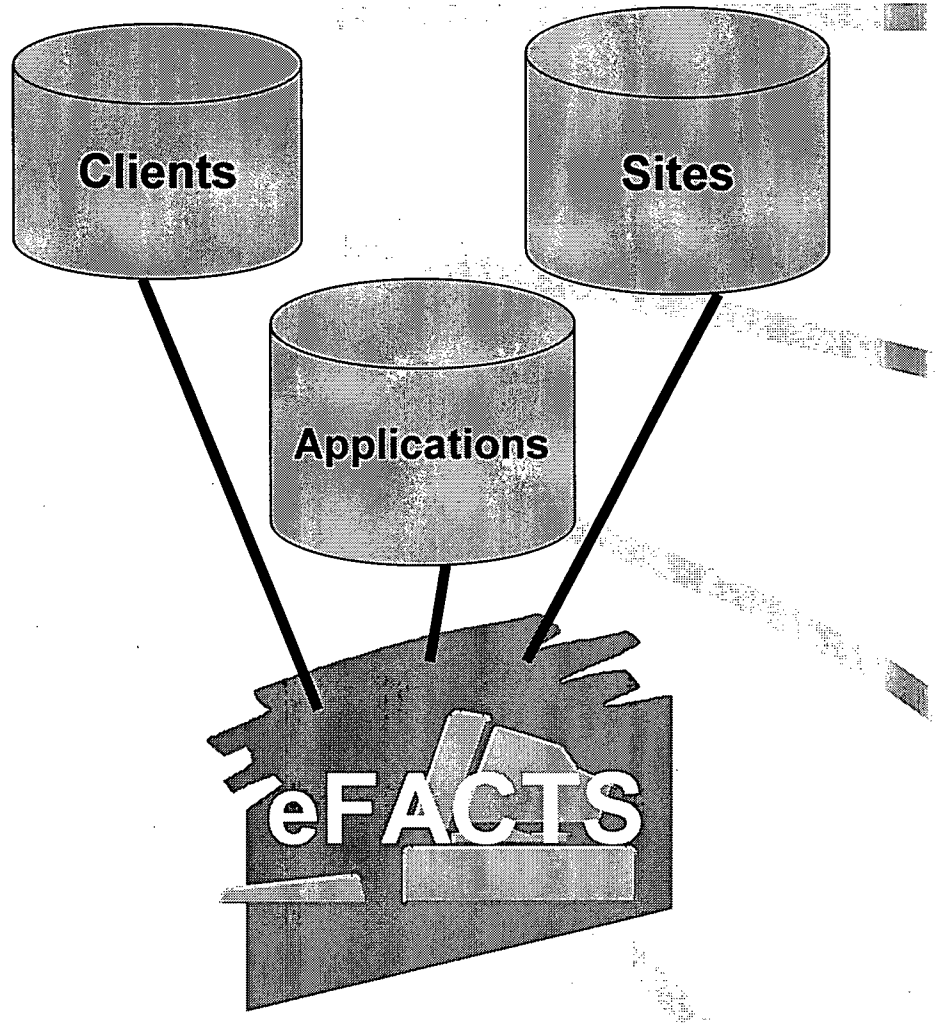
- To foster Cross-Program and Cross-Organizational communication
- To support New Initiatives, support decision making, and better manage DEP Resources
- To better understand facilities regulated by multiple programs
- To foster single authorizations issued by multiple organizations
- To regulate Compliance Issues

Who uses eFACTS?

- People like you, working with the following Bureaus use eFACTS:
  - Land Recycling and Waste Management
  - Mining and Reclamation
  - Oil and Gas Management
  - Radiation Protection
  - Water Quality Protection
  - Air Quality

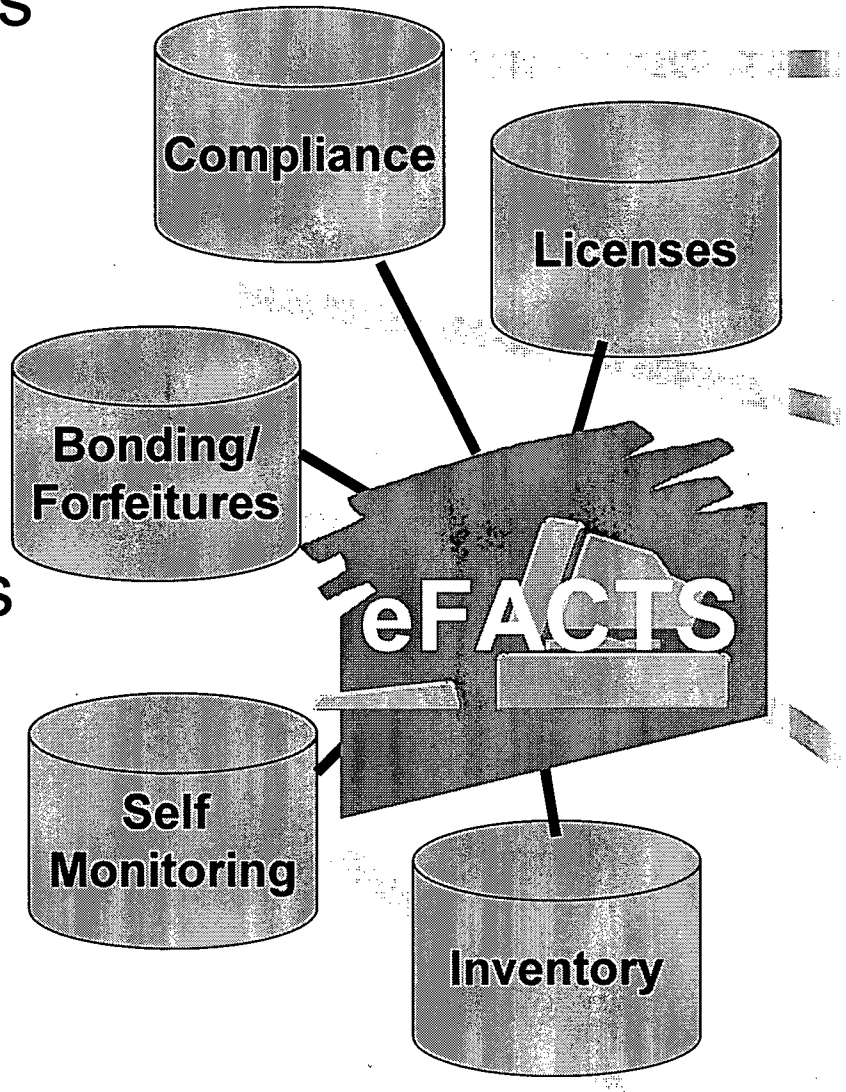
Phase 1

- Application Processing
- Client / Site Systems Conversions
- Data Standardization



Phase 2

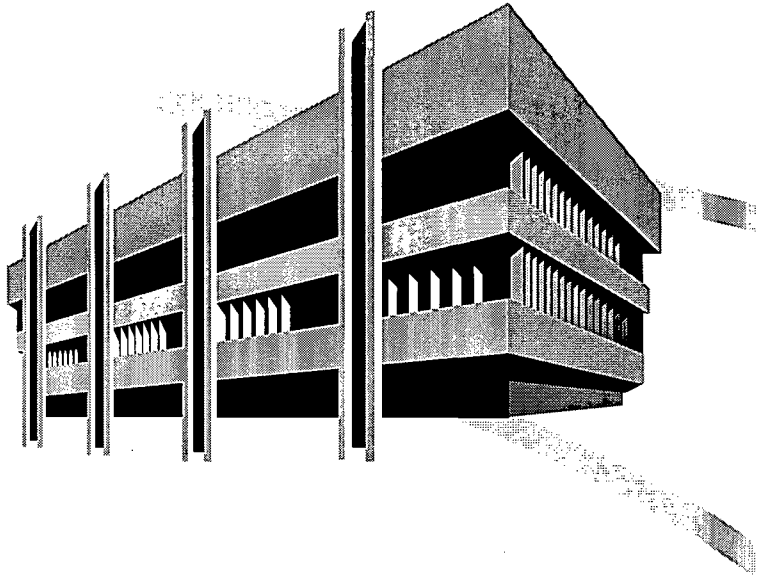
- Program Specific Inventories
  - **BMR**
  - **BWQP**
  - **BLRWM**
  - **BRP**
  - **BOGM**
- Inspections and Violations
- Enforcements and Penalties
- Bonding and Forfeitures
- Self-Monitoring
- Licensing



Client

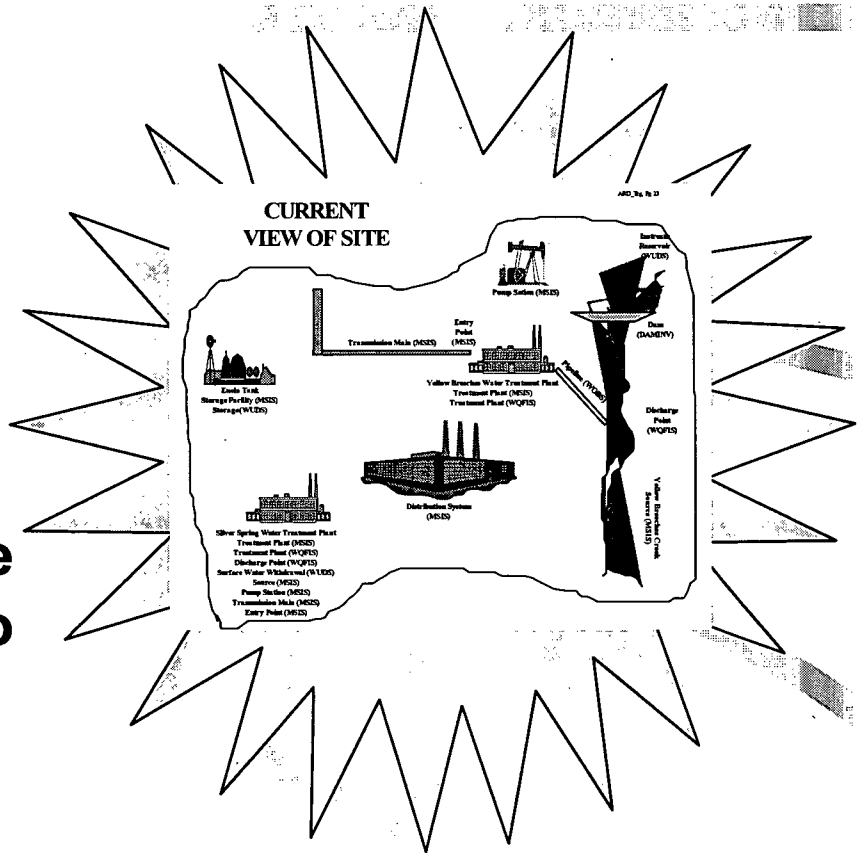
- An applicant;
- An officer within the applicant's organization;
- Any other organization within the applicant's organizational hierarchy;
- An agent representing the applicant;
- An operator working for the applicant;
- A person or organization

  responsible for environmental damage.



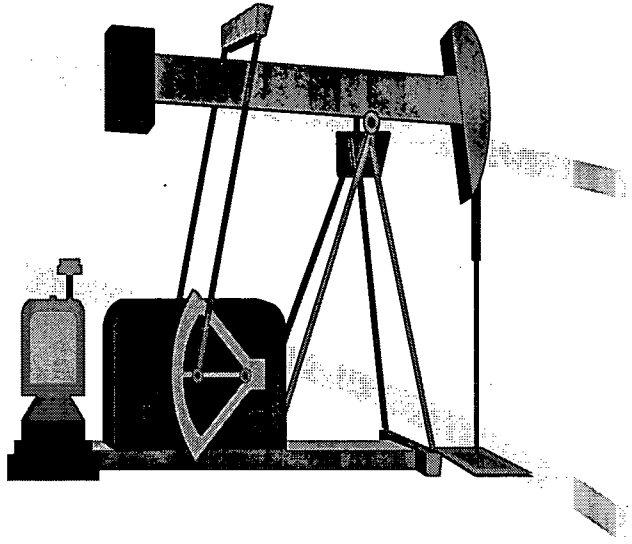
Site

- A site is a physical location(s) of importance to DEP.
- Site is defined by the client/applicant's purpose for doing business, not solely by geographic location.
- This holistic view of site promotes; understanding of the interrelationships of facilities to support pollution prevention; multi-media inspections; a department wide view of compliance; and public understanding and access to information.



Primary Facility

- **A logical bridge between sites and sub facilities that allows DEP to provide a framework for a facility's or an activity's regulation.**

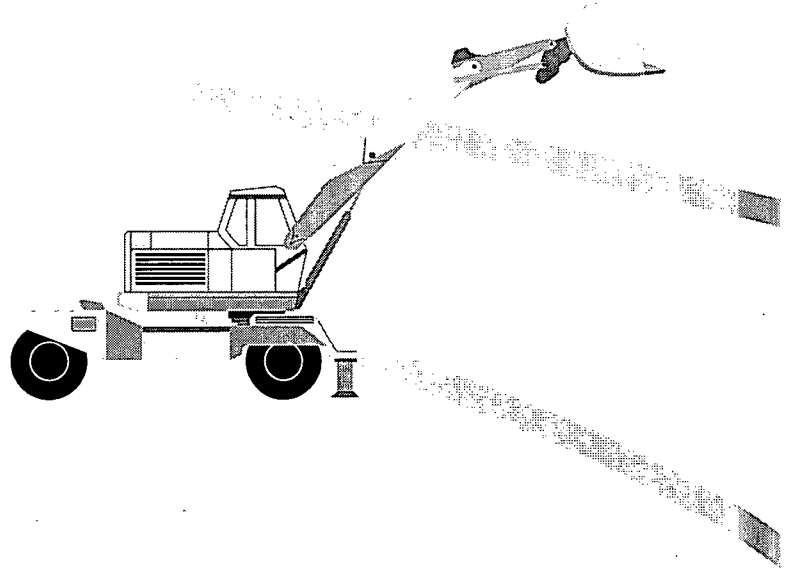


- **Examples:**
  - **Coal Mining Operation**
  - **Oil and Gas Location**
  - **Water Pollution Control Facility**
  - **Radiation Facility**
  - **Captive Hazardous Waste Operation**

Sub Facility

- A physical thing that DEP regulates

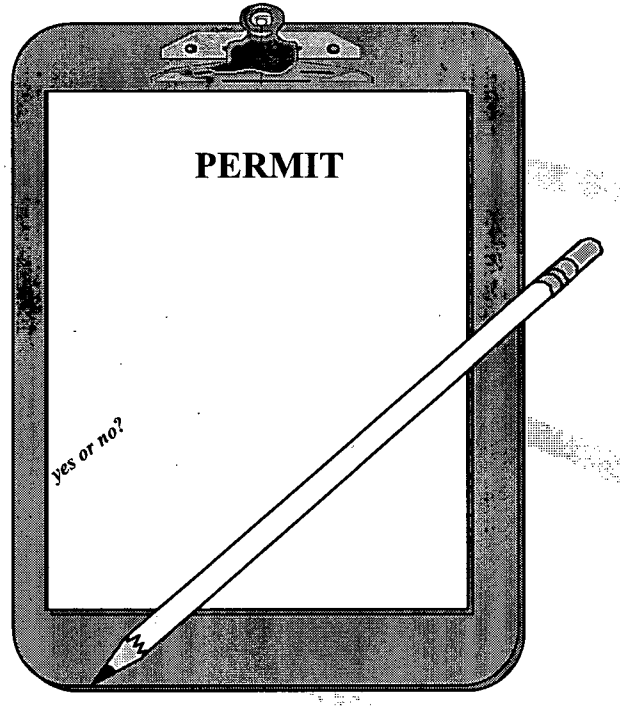
- Examples:
  - Surface Mine
  - Discharge point
  - X-ray machine
  - Treatment plant
  - Oil and gas well



Authorization

- Any DEP approval

- Examples:
  - Permits
  - Certificates
  - Licenses
  - Plans
  - Registrations

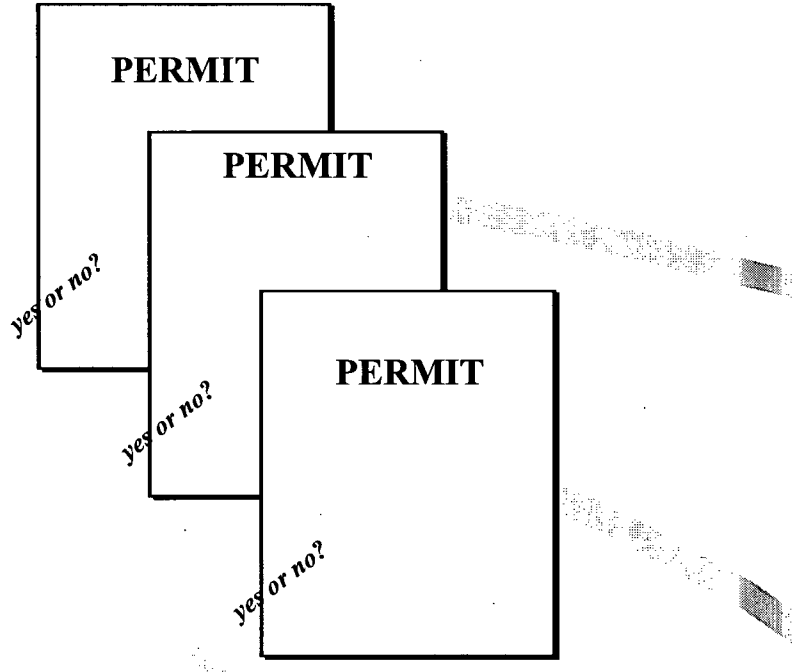


Master Authorization

- **A DEP approval, which will be maintained by continuing renewals, amendments, certifications, reissues, and modifications.**

Project

- **A group of authorizations, potentially including multiple programs, coordinated to support an organization's process or purpose.**

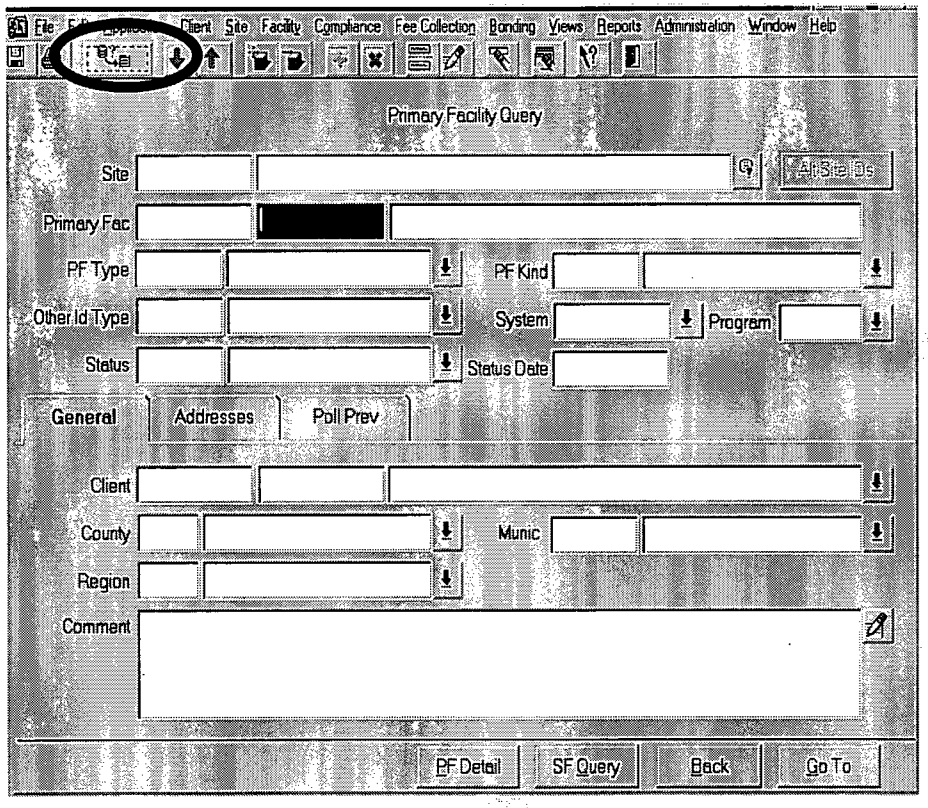


Tasks

- **Assignments that must be completed prior to an authorization's approval.**

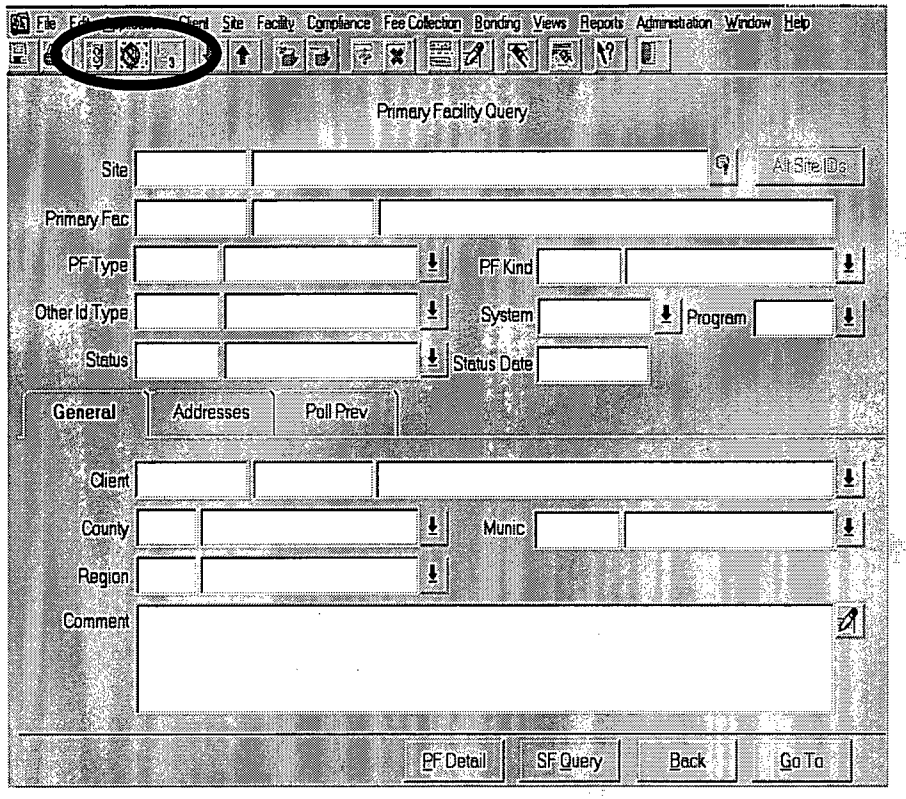
Entry Mode

- **Indicates the capacity to record data in a eFACTS screen.**
- **By default, when a user accesses eFACTS he or she is in entry mode.**



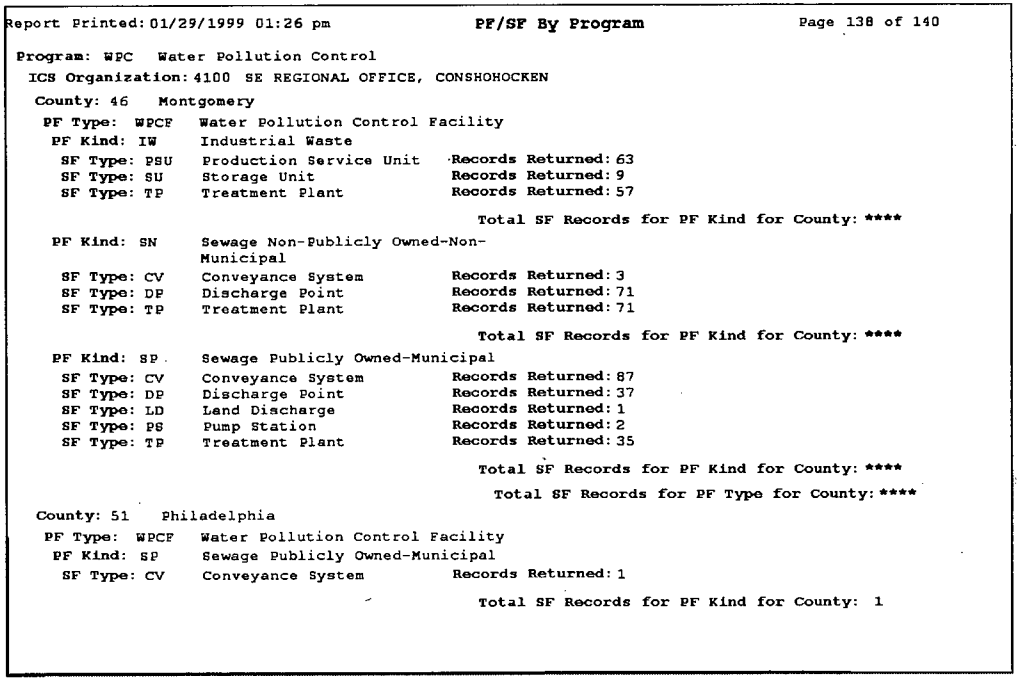
Query Mode

- **Indicates the capacity to search the database for information using criteria identified on a eFACTS screen.**
- **When the system is in query mode you are unable to record data.**



Reports

- Dedicated processes that answer user queries or supply data.
- eFACTS has multiple pre-defined reports available to supply information or statistics.
- Ad-hoc reporting is accomplished when a tool other than eFACTS accesses information contained in eFACTS.



Report Printed: 01/29/1999 01:26 pm **PF/SF By Program** Page 138 of 140

Program: WPC Water Pollution Control
ICS Organization: 4100 SE REGIONAL OFFICE, CONSHOHOCKEN
County: 46 Montgomery
PF Type: WPCF Water Pollution Control Facility
PF Kind: IW Industrial Waste

SF Type: PSU	Production Service Unit	Records Returned: 63
SF Type: SU	Storage Unit	Records Returned: 9
SF Type: TP	Treatment Plant	Records Returned: 57

Total SF Records for PF Kind for County: ****

PF Kind: SN Sewage Non-Publicly Owned-Non-Municipal

SF Type: CV	Conveyance System	Records Returned: 3
SF Type: DP	Discharge Point	Records Returned: 71
SF Type: TP	Treatment Plant	Records Returned: 71

Total SF Records for PF Kind for County: ****

PF Kind: SP Sewage Publicly Owned-Municipal

SF Type: CV	Conveyance System	Records Returned: 87
SF Type: DP	Discharge Point	Records Returned: 37
SF Type: LD	Land Discharge	Records Returned: 1
SF Type: PS	Pump Station	Records Returned: 2
SF Type: TP	Treatment Plant	Records Returned: 35

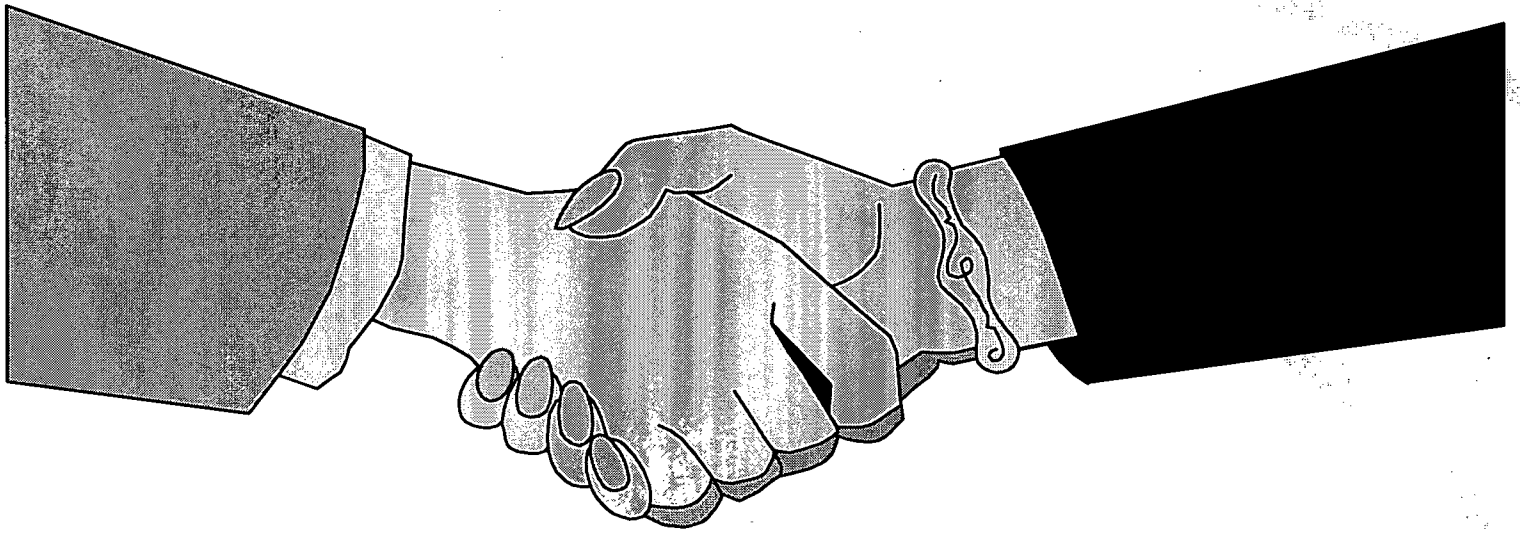
Total SF Records for PF Kind for County: ****
Total SF Records for PF Type for County: ****

County: 51 Philadelphia
PF Type: WPCF Water Pollution Control Facility
PF Kind: SP Sewage Publicly Owned-Municipal
SF Type: CV Conveyance System Records Returned: 1

Total SF Records for PF Kind for County: 1

Moneyback Guarantee

- **A commitment from DEP to process client's applications in a specific time frame or refund the application fee.**



Database

- A structure that is built to hold data that is valuable to an organization that can easily be accessed, managed, and updated.
- An organized collection of information.
- A simple database might be a single file containing many records, each of which contains the same set of fields where each field is a certain fixed width.

Relational Database

- A relational database allows the definition of data structures (how it looks), storage (how it's kept), and retrieval operations and integrity constraints (how and when it can be updated). In such a database the data and relations between them are organized in tables.

- A table is a collection of records and each record in a table contains the same fields. Certain fields may be designated as keys, which means that searches for specific values of that field will use indexing to speed them up.

Client Server

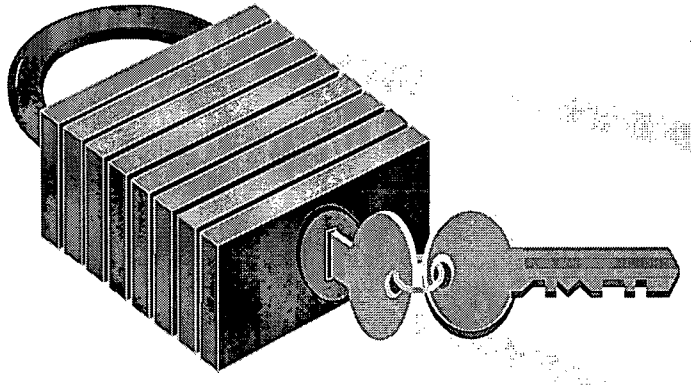
- A common form of distributed system in which software is split between server tasks and client tasks.
- A client (your PC) sends requests to a server, according to some protocol, asking for information or action, and the server responds.
- This is analogous to a customer (client) who sends an order (request) on an order form to a supplier (server) who dispatches the goods and an invoice (response). The order form and invoice are part of the "protocol" used to communicate in this case.

Oracle

- **The database product used to create the Environmental Facility Application Compliance Tracking System (eFACTS).**

Security

- Refers to techniques for ensuring that data stored in a database cannot be compromised.



Security Role

- Refers to the ability of a user to modify (insert, update, or delete) data in eFACTs.
- Examples:
  - Application Processors(APPL)
  - Query Only Rule (Query)
  - Client Verifiers (CLVER)
  - Site Verifiers (STVER)
  - Inspectors (INSP)
  - Enforcement (ENF)
  - Compliance (COMP)
  - Facility Updaters (FACUPD)
  - Data Administrators (DADMN)
  - Program Specific Data Administrators (PRGDA)
  - Certification, Licensing and Bonding Specialist (CLB)
  - Forfeiture Certification, Licensing and Bonding Specialist (FOFRCLB)

eFACTS

Environment, Facility, Application, Compliance Tracking System

Commonwealth of Pennsylvania

Department of Environmental Protection

General Overview User's Guide

Prepared by:	Applications Support Help Desk
Version:	1.8
Date:	April 7, 2006

Table of Contents

Purpose

Welcome to the **pocket-sized guide** for a general overview of **E**nvironment **F**acility **A**pplication **C**ompliance **T**racking **S**ystem (*e*FACTS).

This guide provides instructions on the most commonly performed operations and common components contained in *e*FACTS.

To view the complete 'Basics' User Guides, reference the Basics Section of the Learn About *e*FACTS Page on the *e*FACTS Web Site.

Applications Support Help Desk Team

Help Desk Support Line:

Number: (717) 705-3768

Hours: Monday to Friday 8:00 am to 4:30 pm

Email: ep-efactshelpdeskteam@state.pa.us

Applications Support Help Desk Team:

The Applications Support Help Desk Team is composed of members from Veridyne, Inc. and the DEP. The support team includes help desk specialists, trainers, web masters, on-line help developers and testing engineers working together to provide complete end-user support for *e*FACTS and other applications.

Applications Support Help Desk Team's Services:

- Applications Training
  - Formalized Classroom Training
  - Small Group Training
  - One-on-One Training
- Participate in meetings to provide application guidance
- Telephone Support Help Desk
- Application Web Page Development and Maintenance
- Publish articles identifying solutions to common problems
- Application Testing
- Documentation Development
- Application On-Line Help Development and Maintenance

*e*FACTS Overview

eFACTS

***E**nvironmental **F**acility **A**pplication **C**ompliance **T**racking **S**ystem*

- This system allows DEP to collectively focus on and carry out its mission:

  to protect Pennsylvania's air, land, and water from pollution and to provide for the health and safety of its citizens through a cleaner environment.

- While historically the agency has had to deal with information in multiple, non-integrated databases and files, DEP now has the ability to access information from multiple programs about a regulated client or site.
- To carry out its mission, DEP is responsible for a vast array of diverse programs. These programs include traditional environmental protection programs like air, water, and waste; resource management programs like wetlands protection and water resource planning; and other programs as diverse as oil and gas drilling, radiation protection, a surface mining and deep mine safety.
- Few businesses in Pennsylvania fall outside the scope of DEP's regulatory oversight. Over 1,600 of the DEP regulated businesses must interact with more than one program. Because each program had it's own "stovepiped" data, the agency failed to capitalize on the information it collected. This meant a company might have been in non-compliance across multiple programs, without DEP realizing it. It also put the department at risk for oversights, such as a facility receiving an award for waste minimization from one program, while another program cited the same facility for air quality violations.
- *e*FACTS is a Data Integration and System Conversion Project containing integrated:
  - Client and Site records
  - Application processing functionality
  - Program-specific facility functionality
  - Compliance (Inspections and Enforcements)
  - Licensing
  - Bonding and Forfeiture Tracking
  - Self Monitoring

Why is eFACTS needed?

- To foster Cross-Program and Cross-Organizational communication
- To support New Initiatives
- To better manage DEP Resources
- To better support decision making
- To better understand facilities regulated by multiple programs
- To foster single authorizations issued by multiple organizations
- To regulate Compliance Issues

Phase 1 APSCS (Released February 1997)

- Clients, Sites, Primary Facilities, and Sub Facilities
- Application Processing
- Client/Site Systems Conversions
- Data Standardization

Phase 2 (Released September 1999)

- An extension of Application Processing
- Department-wide Compliance System
- Program Specific Inventories
- Licensing
- Bonding and Forfeiture Tracking
- Self-Monitoring

Phase 3 (Released June 2002)

- Storage Tanks
- Land Recycling
- Fees

Phase 4 (Released ?)

- Abandoned Mines
- Deep Mine Safety

Definitions of Concepts

Client

Any regulated person, company, organization, or government agency.

A client can be any of the following variations:

- An applicant/permittee
- Any officer within the applicant's organizational hierarchy
- Any organization within the applicant's organizational hierarchy
- An agent representing an applicant
- An operator working for an applicant
- A contractor working for an applicant
- A person responsible for environmental damage

Site

A physical location(s) of importance to DEP. Site is not solely defined by geographical location (can span several municipalities and even counties in some cases) but rather by the client/applicant's purpose for doing business.

The Big Picture All DEP Programs involved at a physical location of importance to DEP is grouped under one 'entity', site. This holistic view of site will promote an understanding of the interrelationships of facilities to support pollution prevention; multi-media inspections; a department-wide view of compliance; and public understanding and access to information.

Primary Facility

A physical thing created to serve a particular function. It provides a physical framework to achieve the applicant's business goal. In other words, it is a way to group a specific DEP program's involvement at a site under one heading. For example: the Coal Mining Program groups all of their involvement (regulated entities) under the Primary Facility type of 'Coal Mining Operation'.

Examples:

- Water Pollution Control Facility
- Radiation Facility
- Oil and Gas Location
- Water Resource
- Air Emissions Plant
- Encroachment Location

Sub Facility

Program specific. A sub facility is what DEP regulates. For example: A deep mine is a sub facility of a Coal Mining Operation facility.

Examples:

Water Pollution Control Facility
- ➢ Treatment Plant
- ➢ Discharge Point

Radiation Facility
- ➢ X-ray Machine
- ➢ Radioactive Materials

Oil and Gas Location
- ➢ Well
- ➢ Pit

Water Resource
- ➢ Discharge
- ➢ Groundwater Withdrawal

Air Emissions Plant
- ➢ Incinerator
- ➢ Process

Encroachment Location
- ➢ Bridge
- ➢ Dock

Diagram of the Concept's Relationships (Example 1)

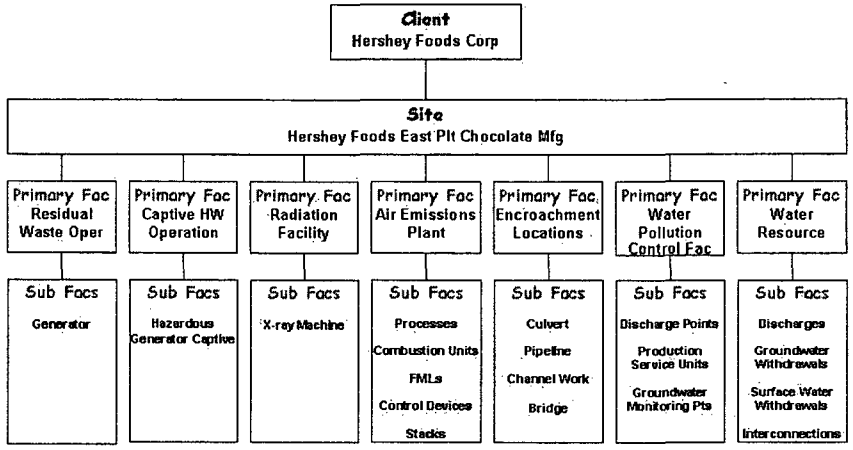
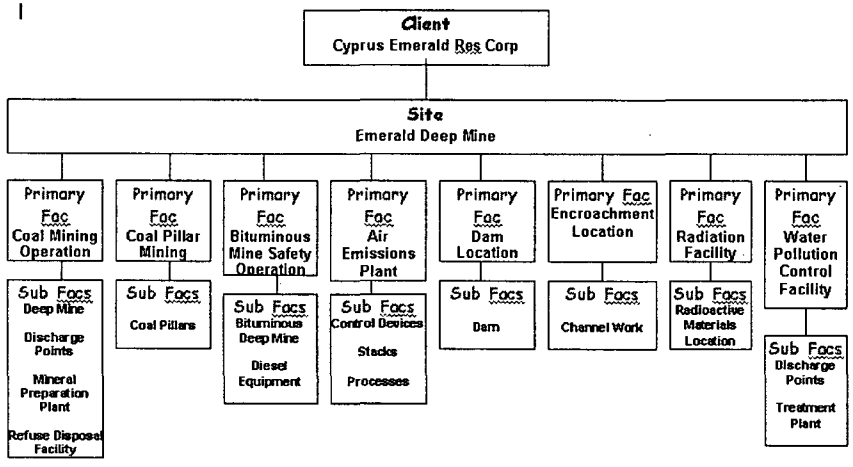


Diagram of the Concept's Relationships (Example 2)



Authorization

Any DEP approval given to a client, site or facility (i.e. permits, certifications, licenses, plans, and regulations, etc.). Also includes notifications to DEP.

Master Authorization

A DEP approval, which will be maintained by continuing renewals, amendments, certifications, reissues, and modifications.

Child Authorization

A renewal, amendment or modification made to a Master Authorization.

Database

A database is a structure that is built to hold data that is valuable to an organization that can easily be accessed, managed, and updated. It is an organized collection of information. A simple database might be a single file containing many records, each of which contains the same set of fields where each field is a certain fixed width.

Relational Database

A relational database allows the definition of data structures (how it looks), storage (how it's kept), and retrieval operations and integrity constraints (how and when it can be updated). In such a database, the data and relations between them are organized in tables. A table is a collection of records, and each record in a table contains the same fields. Certain fields may be designated as keys, which means that searches for specific values of that field will use indexing to speed up searching.

Oracle

The database product used to create *e*FACTS.

Security Role

Refers to the ability of a user to modify (insert, update, or delete) data in *e*FACTS.

Reports

Dedicated processes that answer user queries or supply data. *e*FACTS has multiple pre-defined reports available to supply information or statistics. Ad-hoc reporting is accomplished when a tool other than *e*FACTS accesses information contained in *e*FACTS.

Accessing *e*FACTS

Obtaining eFACTS Security Role(s)

Security in *e*FACTS is based on an individual being assigned a specific security role(s). A security role determines a user's ability to insert, update, or delete information in *e*FACTS. Security is based on a user's specific region/district mining office/area and DEP program.

Part 1: Determining the Type of Security Role Needed:

Before beginning to work in *e*FACTS, a user must apply for an appropriate security role. If you want to learn more about the various security roles in *e*FACTS, access the file using the pathway indicated below or click on one of the links below.

- Security Role Descriptions (\\Epencofs04\PIE\eFACTS\Guidance\security_desc_efacts.doc)
- Security Specifications (\\Epencofs04\PIE\eFACTS_Documentation\Security\eFACTS Security Specification.doc)

Part 2: Completing and Submitting the Necessary Security Application:

After determining the role that you need in *e*FACTS, access the file using the pathway indicated below, or click on the instructions link below and then read the instructions for completing the security application. Once you have read the instructions, click on the DEP program (or access the file) for your appropriate security role, fill out the application, save the file to your hard drive, print a copy of the application, and send the application to the appropriate person in your region.

- **Security Application** (\\Epenscofs04\PIE\eFACTS\Forms\security_requests\efacts)

  Instructions (READ_ME_Security_Requests.doc)
  Air Quality (security_AQ.doc)
  Assistant Regional Director (security_ARD.doc)
  CLB – Certification, Licensing, and Bonding (security_CLB.doc)
  Mining and Reclamation (security_MING.doc)
  Abandoned Mines (security_MING_AMR.doc)
  Deep Mine Safety (security_MING_DMS.doc)
  Oil & Gas (security_OG.doc)
  Pollution Prevention Compliance Assistance (security_PPCA.doc)
  Radiation Protection (security_RP.doc)
  Waste Management (security_WASTE.doc)
  Water Quality (security_WATER.doc)

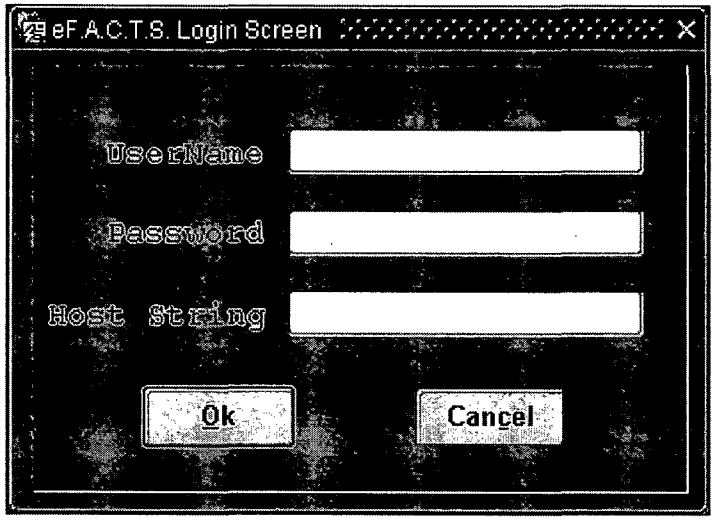
Logging On and Off eFACTS

To log onto the Environmental Facility Application Compliance Tracking System (*e*FACTS), the user **must** have an active security role in *e*FACTS.

Logging Onto *e*FACTS:

1. Click the 

browser icon on your desktop.
2. Click the **Oracle Applications** hyperlink on the **IntraDep Menu**.
3. Click the ***e*FACTS** hyperlink on the **Oracle Web Applications** page.



4. The *e*FACTS Login Screen Pop-Up Window will display. The cursor will be positioned in the *Password* field.
5. If your user name (i.e., your email name) is different from the default user name, click in the *User Name* field and enter your user name.

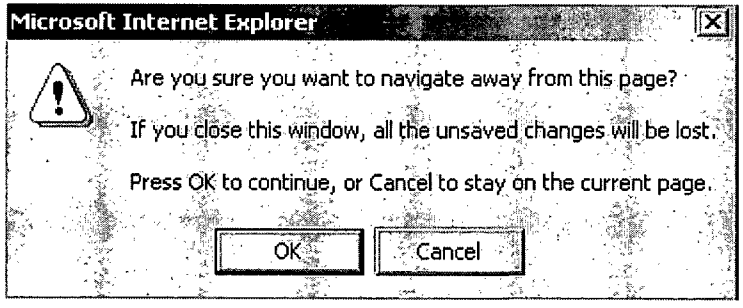
   ***Note:** The user name of the last user to sign into eFACTS on your PC will default.*
6. Click in the *Password* field. Enter your *e*FACTS password.
7. Verify that the Host String is EFACTS or PROD. If not press the [TAB] key once to move to the *Host String* field and update to EFACTS or PROD.

8. Click the OK button if you wish to log onto *e*FACTS or click the CANCEL button if you do not wish to log onto *e*FACTS.
9. If logging into *e*FACTS, the MAIN screen will appear indicating that login was successful.

Logging Off *e*FACTS

1. Click the  button or press the [F10] key to commit any modifications.
2. Click the  button on the toolbar to exit all open screens.

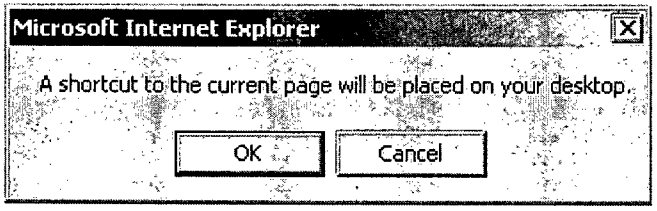
   ***Note:** If more than one screen is open, continue to click the EXIT button until the MAIN Screen displays.*
3. When the MAIN Screen displays, click the **File Menu** and **Exit** command. The screen will become blank.
4. Click the  in the upper right hand corner of the screen. A Logoff Pop-Up Window will display.



5. Click OK on the Pop-Up Window. *e*FACTS will close, and your PC's Desktop will display.

Adding an eFACTS Web Forms Shortcut to Your Desktop

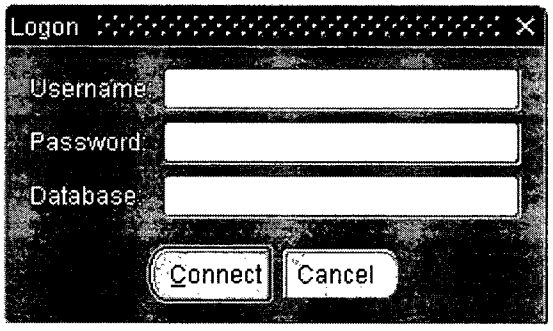
1. Access the **Oracle Web Applications** page.
2. Right click on an area of the page that does not contain text.
3. Select Create Shortcut. A Microsoft Internet Explorer Pop-Up Window displays.



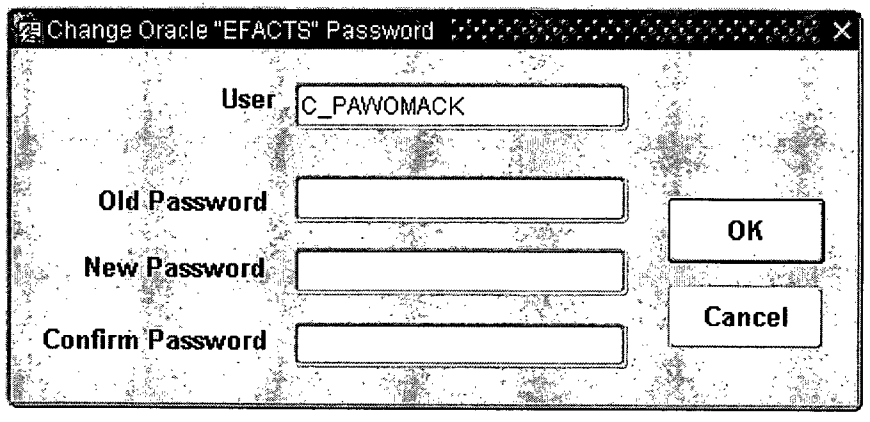
4. Click the OK button. An Main Menu icon will be added to your desktop.
5. If you wish to rename the icon, click once on the icon, pause, and then click once on the text "Main Menu."
6. Type the new name.

Changing your eFACTS Password

1. Click the browser icon on your desktop.
2. Click the **Oracle Applications** hyperlink on the **IntraDep Menu**
3. Click on the Change Oracle Password command on the **Oracle Web Applications** page. The Logon Pop-up Window will display.



4. Enter your user name in the *Username* field. Press the [TAB] key.
5. Enter your current password in the *Password* field. Press the [TAB] key.
6. Enter EFACTS in the *Database* field.
7. Click the CONNECT button.
8. The Change Oracle *e*FACTS Password Pop-Up Window will display.



9. Enter your old password in the *Old Password* field. Press the [TAB] key.
10. Enter your new password in the *New Password* field. Press the [TAB] key.
11. Enter your new password a second time in the *Confirm Password* field to confirm the change.
12. Click the OK button to change the password.

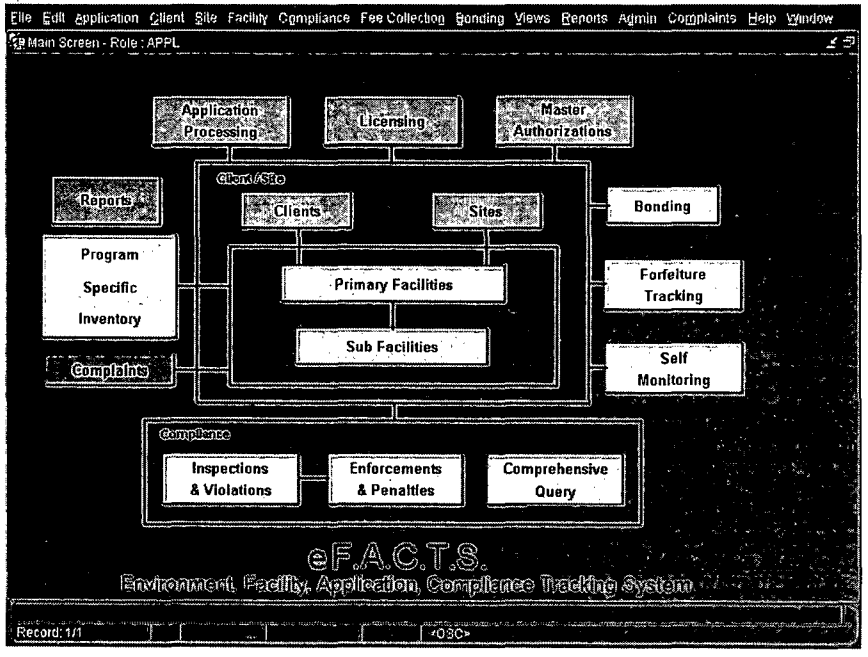
Main Screen (Opening Screen)

The MAIN Screen is the opening screen for the Environmental Facility Application Compliance Tracking System (*e*FACTS). The MAIN Screen automatically displays when the user logs onto *e*FACTS.

The MAIN Screen contains four components:

- *e*FACTS Menu Bar
- Title bar
- Navigational buttons
- System name

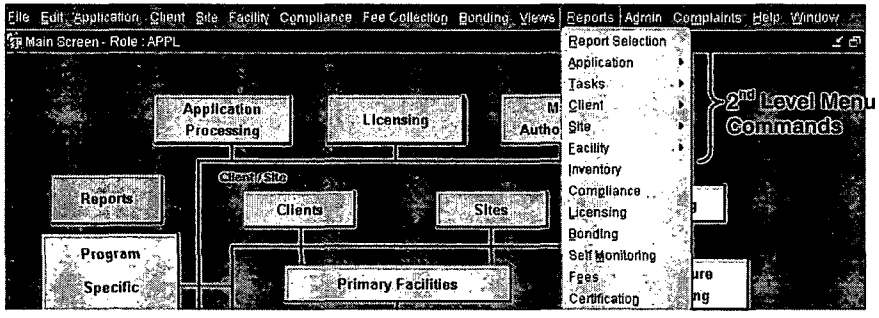
The title bar is displayed on all screens and indicates the name of the active screen, the current security role, and the minimize/maximize/close buttons. The menu bar is displayed directly above the title bar for all screens. The *e*FACTS Menu Bar contains the various menu, command, and sub command options that are used to access the various screens and reports. The navigation buttons display below the title bar and are used to directly access the key screens in *e*FACTS.



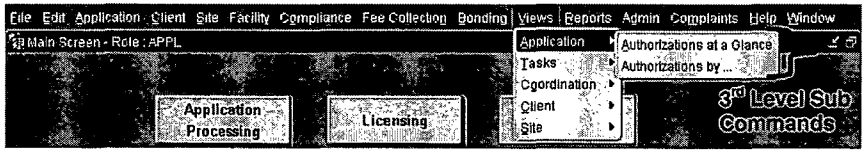
Menu Bar

The *e*FACTS Menu Bar displays on all screens contained within *e*FACTS. The menu bar is located directly above the tool bar at the top of each screen. The *e*FACTS Menu Bar contains the various menus, menu commands, and menu sub commands used to access the various screens and reports contained within *e*FACTS. The *e*FACTS Menu Bar has three levels of options: menu, command, and sub command options. The menu options (i.e., the first level) are always visible on the screen. The menu options do not directly access a screen or report, but clicking the menu option will display the Menu Drop Down List containing a list of commands.

The second level is the command options. The command options are contained on the Menu Drop Down List that display directly below the selected menu option. Clicking a command option will perform an operation (i.e., save, print, etc.), or access a screen or report unless the '►' symbol displays to the right of the command. The left and right arrow indicates that there is a menu of sub commands available.



The third level is the sub command options. The sub commands are displayed on the Menu Command Drop Down List. The sub commands are available if the highlighted command contains the '►' indicator. Clicking the sub command will directly access the associated screen or report.



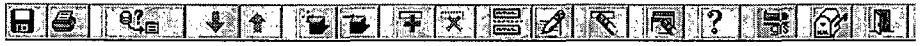
Toolbar

Min/Max/Close Buttons

Every window in *e*FACTS contains a horizontal toolbar positioned in the top left of the window, under the menu bar. The *e*FACTS toolbar displays in two forms: the Entry "Normal" form and the Query form.

Entry "Normal" Mode

The default (Entry Mode) *e*FACTS toolbar is shown below:



The toolbar button descriptions proceed in the order of the toolbar buttons, left to right:

Save (F10)

 Commits (saves) to the database any inserts, updates, or deletes made to the record(s) on the current, active screen. For example: If a user inserts facility details for a particular sub facility, the information is not "permanently" added to the database record until the modifications are committed to the database by clicking the SAVE button.

Print

 Performs a screen print of the current screen. In other words, by clicking the PRINT button, the system prints an exact "picture" of the current screen. When the user clicks the PRINT button, a series of pop-up windows from the program manager will display allowing the user to select a printer, paper format, print orientation, and number of copies.

Enter Query (F7)

 Changes the screen from entry "normal" mode to query mode. Before a user can search for information in *e*FACTS, they **must** click the ENTER QUERY button to place the system into query mode. This button will be displayed when the current, active screen is in entry "normal" mode. When the user clicks on the ENTER QUERY button, the system will "replace" the ENTER QUERY button with the three query mode buttons: EXECUTE QUERY, CANCEL QUERY AND COUNT QUERY. If there are any unsaved updates, the system will display the "Do you want to save the changes?" message before placing the system into query mode, thus providing the user the opportunity to save before continuing. For more information on the three query mode buttons, reference the query mode section following the Entry 'Normal' Mode toolbar button descriptions.

Next Record

 Displays and navigates the cursor to the next record of the **current block**. This button is available, by default, when the user opens a screen and has security access to insert a new record. In addition, when a query is executed and more than one record is retrieved, the NEXT RECORD button is available.

When the user clicks the NEXT RECORD button, the next record will display on the current block until the user reaches the last record. This button is disabled (i.e., grayed out) if there is no next record.

Previous Record

 Displays and navigates the cursor to the previous record of the **current block**. For example: If multiple records are retrieved as the user is "scrolling" through the list of records, the PREVIOUS RECORD button allows the user to go back to the previous record in the list. This button is disabled (i.e., grayed out) if there is no previous record.

Next Block

 Navigates the cursor to the next sequential block. The user can proceed from block to block in the established sequence. This button is available, by default, when the screen is first opened, unless the current active screen contains only one block.

When the user clicks the NEXT BLOCK button, the cursor will navigate to the next block (i.e., group of fields offset by a line, box, or some other visual attribute) on the current active screen. If the screen contains a sequence of tabs, the NEXT RECORD button will move recursively through the blocks on the current active tab but will not proceed to the various tabs.

Previous Block

 Navigates the cursor to the previous sequential block. The user can go back to the previous block in the established sequence. This button is available, by default, when the screen is first open, unless the current active screen contains only one block.

When the user clicks the PREVIOUS BLOCK button, the cursor will navigate to the previous block (i.e., group of fields offset by a line, box, or some other visual attribute) on the current active screen. If the screen contains a sequence of tabs, the PREVIOUS RECORD button will move recursively through the blocks on the current active tab but will not proceed to the various tabs.

Create Record (F6)

 Creates a new blank record. After viewing, inserting, or updating a record, this button for a single block record clears the current screen or for a multi-record block, opens a new blank record below the current record ready for the next record to be added. This button is available, by default, when the screen is first opened and the user has security access to insert a new record on this screen. This button is disabled (i.e., grayed out) if the user does not have insert permission on the current screen.

When the user clicks the CREATE RECORD button, the system opens; and the cursor is placed in a new blank record.

Delete Record (Shift+F6)

 Deletes the current record. This button is available, by default, when the screen is first opened and the user has security access to delete a record on this screen. This button is disabled (i.e., grayed out) if the user does not have delete permission on the current block.

The record is not permanently deleted from the database until the deletion is committed to the database, by clicking the SAVE button.

Duplicate Record (F4)

 Duplicates the previous record into the current, empty record. This button allows the user to enter multiple similar records by inserting a duplicate copy of the current record and then changing the duplicate record by updating the information in the fields that are unique to the new record. This button is available, by default, when the screen is first opened and the user has security access to insert a new record on the current active screen.

When the user clicks the DUPLICATE RECORD button, the system duplicates the previous record into the current, empty record.

Edit Item

 Calls the default editor. The default editor for *e*FACTS is MS Notepad or the Editor. For all free form text fields (i.e., comments, directions, descriptions, etc.) the EDIT button opens Windows Notepad or the Editor. The notepad provides the user with the capability to view, insert, and update the entire contents of the field without scrolling across the field. All updates to the contents of the Notepad will be reflected in the field.

Clear Record

 Clears (does not delete) the current record. This button "removes" the current record from the screen without changing the record and displays the next record in the list.

Clear Form

 Clears the current screen. This button removes **all** records from the current screen without updating the record. If there are any unsaved changes, the "Do you want to save the changes?" message will display, thus providing the user with the capability to save the changes before the form is cleared.

This button is available, by default, except on pop-up windows. When the user clicks the CLEAR FORM button, the screen will display in the same form as when the screen was first opened. All tabs and buttons will return to the same state as when the screen was first opened.

Help

 Displays the context level help for *e*FACTS. The HELP button activates the cursor into "help" mode portrayed by the question mark attached to the cursor. In "help" mode the user can click on any part of the screen, and information will display concerning the selected screen, block, tab, button, or field. For example: If the user needs clarification on a particular field, the user can click the HELP button, move the cursor with the question mark attached, and then click on the field in question. A help pop-up window will display a detailed description of the field.

Caution: *The eFACTS Help File must be installed in order to use the HELP button.*

GIS

 Opens *eMapPA* and displays the GIS MAP SELECTION Screen. The GIS MAP SELECTION Screen displays the client, site, primary facility, and sub facility queried on the *e*FACTS screen (if any).

Correct Address

 For the highlighted address on the original screen, this button displays the Correct Address Pop-Up Window. The Correct Address Pop-Up Window displays the address that has been corrected by Correct Address and allows the user to accept or reject the address.

Exit

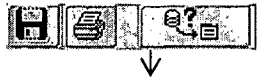
 Exits the current screen. If updates have not been saved, the system will display the "Do you want to save the changes?" message providing the user the opportunity to save any changes that have been made before exiting the screen.

The "Do you want to save the changes?" Pop-Up Window provides three options in the form of buttons. The YES button is used when the user wishes to save the changes before exiting. The NO button is used when the user wishes to exit the screen without saving the changes. The CANCEL button is used when the user wishes to return to the screen without saving the changes or exiting.

Query Mode

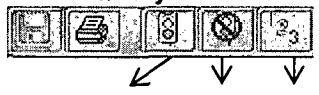
When a form is in entry mode, the system will display the ENTER QUERY button and will 'hide' the EXECUTE QUERY, CANCEL and COUNT QUERY buttons. When the user clicks on the ENTER QUERY button, the system will move the screen into query mode, 'hide' the ENTER QUERY button, and display the EXECUTE QUERY, CANCEL QUERY and COUNT QUERY buttons.

Entry "Normal" Mode



Enter Query

Query Mode



Execute Cancel Count

Execute Query (F8)

 Performs the user's query. The system will retrieve all records that match the user-defined query criteria. Some screens have a restriction on the number of records that may be queried. If the user executes a query which will retrieve more records than the number allowed, the Forms Pop-Up Window will display the message "This query matches (number) records. Enter more restrictive query criteria to select lesser number of records and query again." The user must further define the query before continuing.

Cancel Query

 Cancels the current query by placing the system into entry mode.

Note: *The CANCEL QUERY button does* ***not*** *stop a query that is currently executing (i.e., a running query).*

Count Query (Shift+F2)

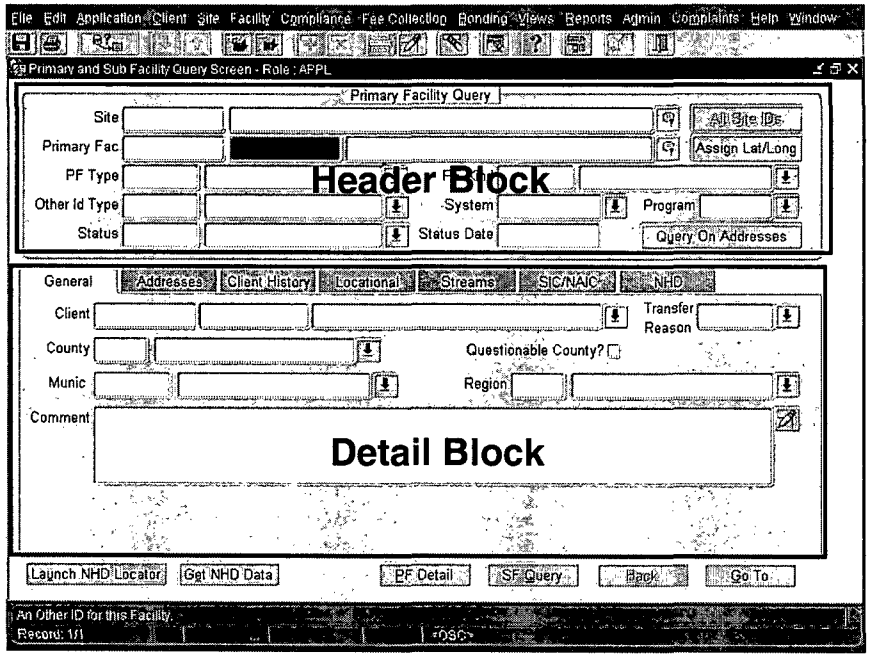
Displays the number of records that match the established query criteria to assist the user in determining whether to execute the query or further qualify the query to reduce the number of records retrieved. The query count displays on the hint line at the bottom left corner of the screen.

Standard Screen Components

Header and Detail Blocks

A **header block** is where information for a screen can be queried. This block will "drive" what information will display on the detail areas of a screen.

A **detail block** will display information in relation to the header block. If query mode is available for a detail block, any queries will be in reference to the queried header record.



Tabs

For the screens that use file tabs, the screen structure involves a header block and attached file tabs. The file tabs are used to display additional information related to the record in the header block. File Tabs can be queried and updated within the context of the header block, except for certain screens where various tabs can be queried to retrieve header information (i.e., most General TABs).

To activate a file tab, click on the file tab name. The header block will remain unchanged, but the activated tab will replace the current tab displayed. The label of the current, active tab will always be displayed in bold type. The labels of the other file tabs will be grayed out if the tab is not relevant for the record in the header block. When retrieving a screen using the GO TO button, the file tabs' accessibility and activation will change depending on the situation and the information retrieved from the "originating" screen.

Before a user activates a file tab, the user must query or insert at least one header record.

Tab labels will display in three different formats that indicate the tab's status.

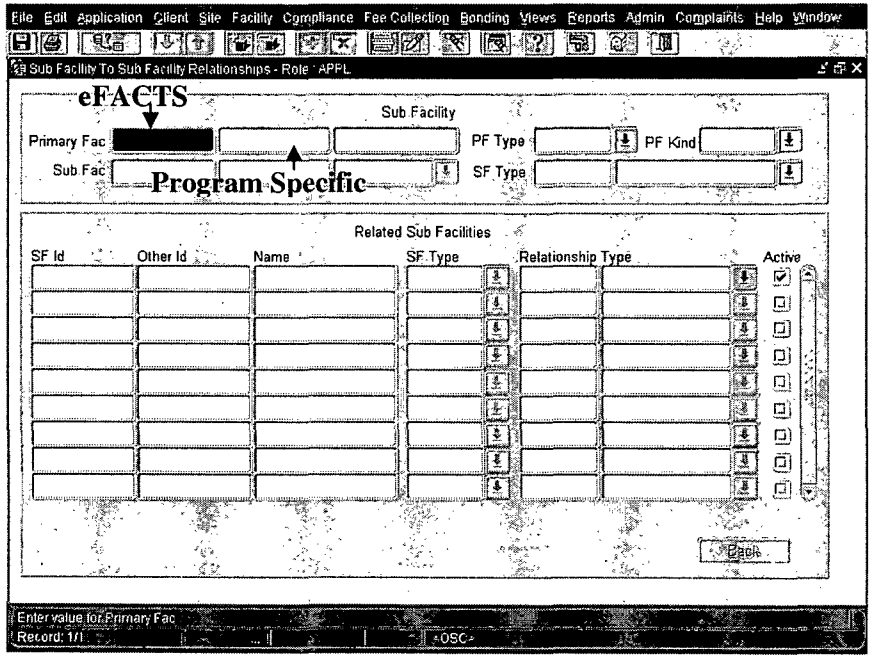
General Light Gray: Indicates the current active tab displayed on the screen.

Rel Clients Dark Gray: Contains available information and can be activated by clicking on the file tab label.

Payments Grayed out: The file tab is inactive and cannot be accessed for the queried record.

Fields

A field is a portion of a record. A field contains information. Various types of fields are available in *e*FACTS. Due to limitations of space on a screen, we were unable to add field labels for each field. To assist the user in easily identifying the unlabeled fields', standard formatting have been applied.



Common field formatting has been applied in the form of four different structures.

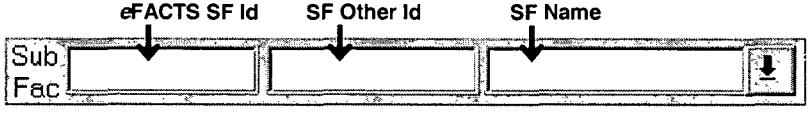
The **first structure** involves the three fields following the primary facility, sub facility, client, or entity field labels.

Primary Facilities (PF)

Primary Facility (Program-Specific) Other Ids:

OG – API Well Number (Permit Number)
Mining – Permit Number
RPX – Registration Number
RPNARM – License Number
WPC –NPDES Id
AQ – AIMS Firm Code
WM – Permit Number
LR – LRP Id
STSTA – Facility Id
WRWOB –WOBS File Id
SDW –Public Water Supply Id
WRDS –DAMINV Dam Id

Sub Facilities (SF)

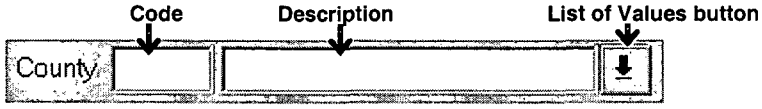


Client

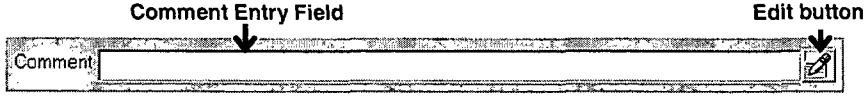
Client (Program-Specific) AKA Ids:

OG – Oil and Gas Operator (OGO) Number
WM – Permit Number
Mining – Permit Number or License Number
WPC – Establishment Id
WRWOB –Water Obstructions Id
SDW –Public Water Supply Id
WRDS – Permit Number
RPX – Registration Number
RPNARM – License Number
AQ – AIMS Firm Code/Tax Id
STSTA – STDS Number or Tank Owner Id

The **second structure** involves fields where there is an available list of codes.



The **third structure** involves free form text fields like comments.

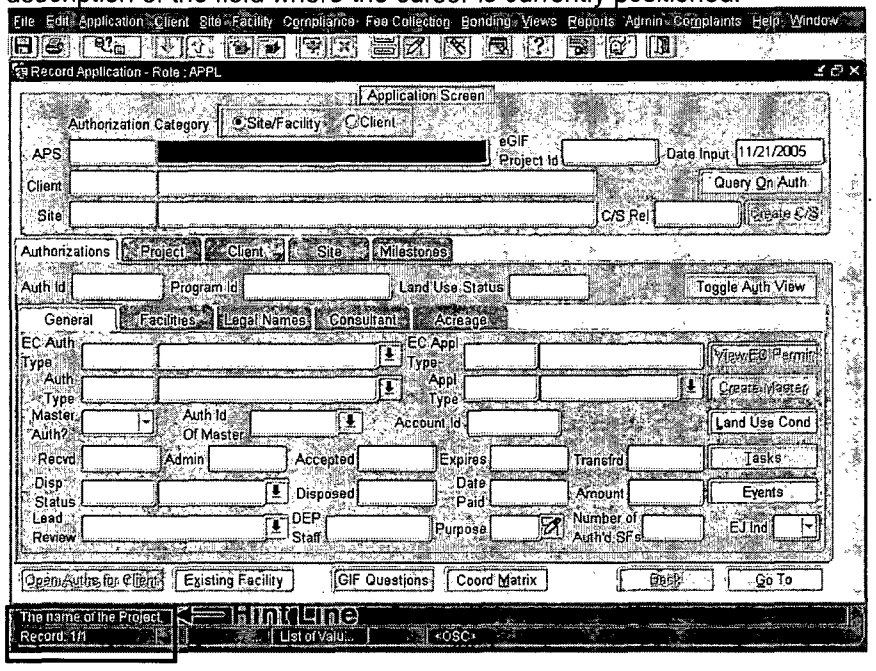


The **fourth structure** involves date fields.

The date can be entered in the format MM/DD/YY or MM/DD/YYYY. In addition to slashes separating the month, days, and year, you can also use a dash, period, or space.

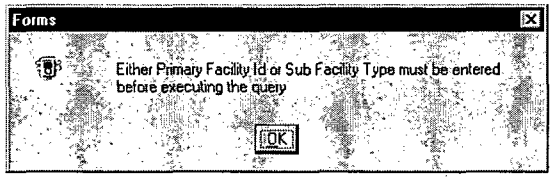
HInt Line

Every window in *e*FACTS (except the MAIN Screen) contains a horizontal bar at the bottom of the screen. The Hint Line is located in the bottom, left corner of the screen. The Hint Line displays information about the screen, an operation in progress, result of an operation, or a description of the field where the cursor is currently positioned.



Pop-Up Messages

Pop-up messages are alerts or warnings produced by the system to identify required or more restrictive information to facilitate system performance. A pop-up message will identify to the user information for the currently active screen. A user should acknowledge the pop-up message by clicking the OK button and enter the identified information to continue with their workflow. The following is an example of a pop-up message in *e*FACTS:

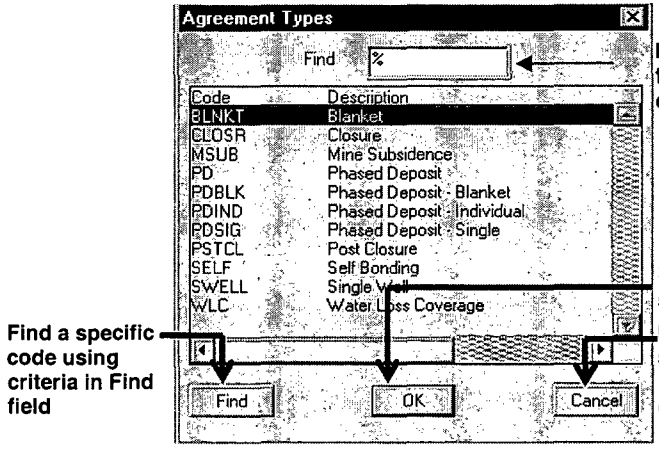


List of Values

The  button displays a list of codes that are available for the field to the left of the button. If the system is in entry mode, the list of values will include only the active codes available for the field. But, if the system is in query mode, the list of values will display all codes that are available for the field regardless of status. The list of values in query mode displays all active and inactive codes so that the user can query historical records that contain a code no longer in use (inactive).

Using the LIST OF VALUES button:

1. Click the LIST OF VALUES button to the right of the field. The List of Values Pop-Up Window will display.



2. Click on the code you wish to select.

   If the list of values contains numerous code values, the list can be restricted by clicking in the *Find* field (top); entering the wildcard (%), part of a code or description, and the wildcard (%); and then clicking the FIND button (bottom of window). Only the codes that match the query criteria selected will display.

3. Click the OK button to select the highlighted code or click the CANCEL button to return to the field without retrieving a code value.

Choice Drop Down List

The  button displays the limited number of options available for the field. This button is to the right of the field and provides a drop down list of a few possible selections.

To select a code value using the CHOICE button:

1. Click the CHOICE button to the right of the field. The Choice Drop Down List will display below the field.

2. Click on the code value you wish to select. The selected code value will display in the field.

Function Keys

If you prefer to use keystrokes instead of the mouse, below are listed the associated keystrokes for *e*FACTS. The keystrokes are assigned commonly used functions. You may also find this information listed under the **Help Menu** and **Keys** command.

Function (A-Z)	Keys
Accept/Save	F10
Application Menu	Ctrl + ,
Cancel	ESC
Clear Block	Shift + F5
Clear Form	Shift + F7
Clear Item	Ctrl + U
Clear Record	Shift + F4
Copy	Ctrl+C
Count Query Hits	Shift + F2
Cut	Ctrl+X
Debug Mode	Ctrl + ?
Delete Backward	Backspace
Delete Record	Shift + F6
Down	Ctrl + I
Down	Down Arrow
Duplicate Item	F3
Duplicate Record	F4
Edit	Ctrl + E
Enter Query	F7
Execute Query	F8
Exit	Ctrl + Q
Help	F1
Insert Record	F6
Left	Left Arrow
List of Values	F9
Main Menu	Ctrl + .
Next Block	Ctrl + Page Down
Next Item	Tab
Next Primary Key	Shift + F3

Function (A-Z)	Keys
Next Record	Shift + Down
Next Set of Records	Ctrl + >
Paste	Ctrl+V
Previous Block	Ctrl + Page Up
Previous Item	Shift + Tab
Previous Menu	Ctrl + Enter
Previous Record	Shift + Up
Print	Shift + F8
Redefine Username/Password	Ctrl + N
Return	Enter
Right	Right Arrow
Scroll Down	Page Down
Scroll Up	Page Up
Show Keys	Ctrl + F1
Toggle Query Mode	F5
Up	Up Arrow
Up	Ctrl + P

Using the Go To and Back Buttons to Navigate the System

Button Descriptions

The Go To button is used to navigate to other related screens within *e*FACTS. The button provides the user the capability to proceed through their workflow without being required to open the next screen via the menu bar and query the record. The GO TO button provides the user the capability of completing a task with a particular record, saving the updates, and then proceeding to the new screen where the record from the previous screen will "automatically" display; saving the user the additional steps of querying the record.

The Back button displays the previous screen used by the user.

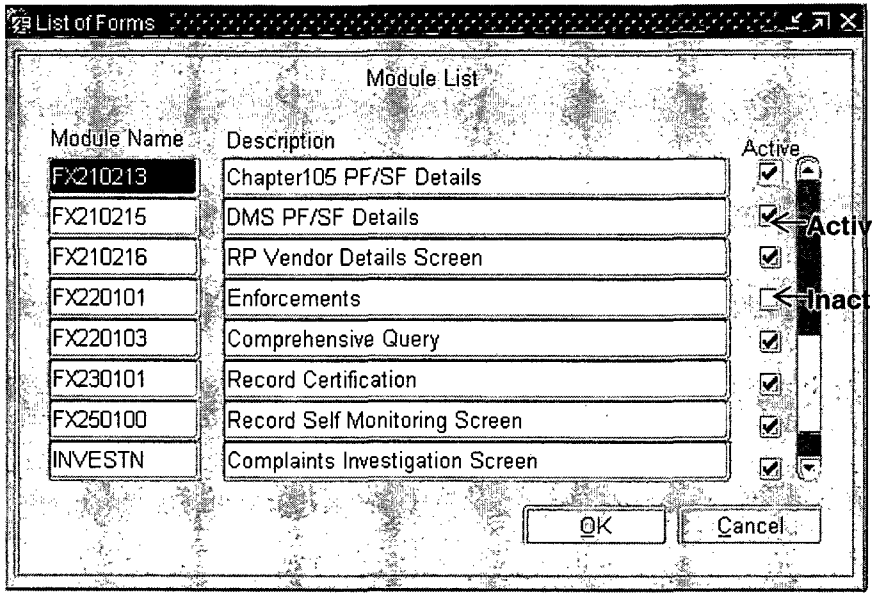
How to use the GO TO and BACK buttons:

1. Open the main screen for your current workflow.
2. Query the record you wish to view or update.
3. Click on the GO TO button at the bottom right corner of the screen. The Module List Pop-up Window will display.

   Warning: *All changes must be saved before clicking the GO TO button.*

   Once a screen has been opened, the GO TO button can only be used twice. For example: If the user queries a record on the RECORD/VERIFY SITE Screen, clicks the GO TO button to proceed to the PRIMARY FACILITY TO CLIENT RELATIONSHIP Screen, and then clicks the GO TO button to proceed to the RECORD/VERIFY CLIENT Screen; the user will not be able to access the GO TO button a third time.

4. Highlight the screen that you want to open. You may only access the screens with an active checkbox ('X' indicator).



5. Click the OK button to open the highlighted screen.
6. The selected screen will display and the details associated with the record from the previous screen will display.

   The displayed information and positioning of the tabs on the new screen is dependent on where the cursor is located in the "originating" screen and the type of record.
7. The user can only use the GO TO button one more time before they are forced to go back at least one screen.

   For example: If the user queries a record on the RECORD/VERIFY SITE Screen, clicks the GO TO button to proceed to the PRIMARY FACILITY TO CLIENT RELATIONSHIP Screen, and then clicks the GO TO button to proceed to the RECORD/VERIFY CLIENT Screen; the user will not be able to access the GO TO button a third time. The user is already two screens "deep." The user must click the BACK button to proceed back at least one screen and then select another screen using the GO TO button.
8. Click the BACK Button to return to the previous screen. If you use the GO TO button to get to a screen, you **must** use the BACK button to return.

Basic Query Rules

A query is a question you ask the system. You ask the question in order to retrieve specific information from the eFACTS database. There are many reasons you may wish to retrieve information from the system. For example: You may wish to view a record, change a record, add information to a record, etc.

Queries (i.e., questions) can be entered in three ways:

- You can ask the system to return a record for single criteria (i.e., *e*FACTS assigned Ids, program specific Ids, etc.).
- You can ask the system to return a record for multiple criteria (a combination of fields). For example: If you wish to know what primary facility records are in the *e*FACTS database, you can ask to see only those primary facilities that are located in Chester County.
- You can ask the system to return a record for a pattern search (using the wildcard '%').

For example: If you want to find a primary facility record, you could execute a query on the primary facility Id and the record would display. If you don't know the primary facility Id, you could still find the record (or similar records) by executing a query using information that you do know, such as primary facility type, related site Id, related client Id, the county where the primary facility is located, the primary facility kind, etc.

It is important to realize that the accuracy and amount of information you supply in a query will affect the number and accuracy of the results to your query. For example: If you execute a query to find a site using the county as the only query criteria, you should expect to receive many sites as a response. However, if you supply the county and municipality, you should expect to see significantly fewer results.

Hints and Tips:

How do I determine the queryable fields? Place the system into query mode. If you can click in a field, it is queryable.

Where should my cursor be positioned before going into query mode? Make sure you can see the field that you want to use as query criteria and click in at least one of the fields. If you follow this rule, your cursor will always be in the right location before querying.

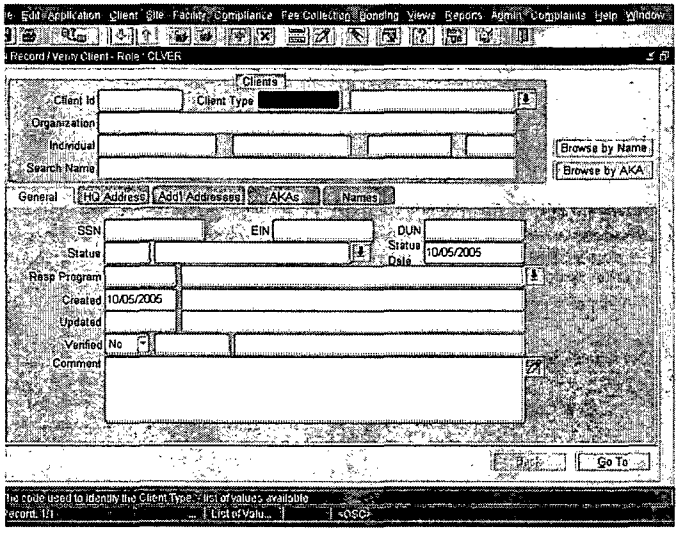
What if I do not know the entire contents of the field? Use the wildcard '%' in the front, middle, or at the end of the information. For Example: If I am searching for a client whose name begins with Brown but I do not know the entire name, I would enter '%Brown%' as the query criteria.

How do I determine the number of records that will be retrieved? Before executing the query, click the COUNT QUERY button or press the [Shift]+[F2] key and view the query count on the hint line (bottom of the screen).

Querying Client Information

There are four recommended queries when attempting to locate an existing client. This section identifies the procedure for locating a client using the name, address, contact, EIN, SSN, AKA Id, and query name.

In addition, this section identifies the information available for a client including the information displayed on the screen and information that can be accessed via the GO TO button.



Querying a Client using the Standard Name

1. Open the RECORD/VERIFY CLIENTS Screen by clicking the CLIENTS button on the MAIN Screen.
2. Click the  button on the toolbar or press the [F7] key to enter query mode.
3. Click in the *Search Name* field.
4. Enter the client's organization or individual name (last first middle suffix).

   Hint: *If you do not know the entire name, use the wildcard in front, in the middle, or at the end of one or two key words in the client name - %one key word%second key word% without spaces.*

   For example: % AMANDAS %GOUR% can be used to find AMANDAS GOURMET COFFEE CO.

   Remember *to use the DEP Data Standards and Naming Conventions.*

5. Click the  button on the toolbar or press the [F8] key to execute the query.

   Caution: *If you are using the wildcard '%' for a pattern search, you may want to click the*  *button on the toolbar to determine the number of results that will be retrieved. To lessen the number of results, revise your pattern search by adding more characters.*
6. The client record will display on the RECORD/VERIFY CLIENTS Screen.
7. Look at the hint line and determine if more than one record was retrieved (bottom left corner of the screen).

   Hint: *Record 1/1 – one record retrieved.*

   Record 1/? – multiple records retrieved.
8. If multiple records are retrieved, use the  button on the toolbar or press the [↓] key to locate the correct record.

Querying a Client using the Address or Contact

1. Open the RECORD/VERIFY CLIENTS Screen by clicking the CLIENTS button on the MAIN Screen.
2. Click on the HQ Address TAB.
3. Click the  button on the toolbar or press the [F7] key to enter query mode.
4. Click in the field that you want to use as query criteria:

   The queryable fields are:

   Address Line 1
   Address Line 2
   City
   State (use the LOV button)
   Zip Code (May enter additional four digits – 17055-6551)
   Country
   Contact Last Name
   Contact First Name
   Contact Middle Name
   Contact Name Suffix
   Contact Title
   Phone (enter 10 digits no dashes – the system defaults dashes)
   Extension
   Fax (enter 10 digits no dashes – the system defaults dashes)
   E-mail

   Hint: *If you do not know the entire address, use the wildcard in front, in the middle, or at the end of one or two key words in the street address.*

   For Example: Enter '%Market' without spaces in Address Line 1 and then enter 'Harrisburg' in the City field to find all clients located on market street in a Harrisburg.
5. Enter the query criteria.
6. Repeat Steps 4 and 5 until you have entered query criteria in every applicable field.
7. Click the  button on the toolbar or press the [F8] key to execute the query.

   Caution: *If are using the wildcard '%' for a pattern search, you may want to click the*  *button on the toolbar to determine the number of results that will be retrieved. To lessen the number of results, revise your pattern search by adding more characters.*

8. The client record will display on the RECORD/VERIFY CLIENTS Screen.
9. Look at the hint line and determine if more than one record was retrieved (bottom left corner of the screen).

   Hint: *Record 1/1 – one record retrieved.*

   Record 1/? – multiple records retrieved.
10. If multiple records are retrieved, use the  button on the toolbar or press the [↓] key to locate the correct record.

Querying a Client using the EIN/SSN

1. Open the RECORD/VERIFY CLIENTS Screen by clicking the CLIENTS button on the MAIN Screen.
2. Click on the General TAB if not displayed.
3. Click the  button on the toolbar or press the [F7] key to enter query mode.
4. Click in the *EIN* field for non-individual clients or the *SSN* field for individual clients.
5. Enter the federal tax Id (EIN) or social security number (SSN) assigned to the client.
6. Click the  button on the toolbar or press the [F8] key to execute the query.
7. The client record(s) will display on the RECORD/VERIFY CLIENTS Screen.
8. Look at the hint line and determine if more than one record was retrieved (bottom left corner of the screen).

   Hint: *Record 1/1 – one record retrieved.*

   Record 1/? – multiple records retrieved.
9. If multiple records are retrieved, use the  button on the toolbar or press the [↓] key to locate the correct record.

Querying a Client using the AKA Id or Query Names

1. Open the RECORD/VERIFY CLIENTS Screen by clicking the CLIENTS button on the MAIN Screen.
2. To query on an AKA Id (program-specific Ids assigned to a client), click the BROWSE BY AKA button (right top corner of screen).

   To query on a query name (previous names for a client, etc.), click the BROWSE BY NAME button (right top corner of the screen).
3. Click the  button on the toolbar or press the [F7] key to enter query mode.
4. Click in the *AKA* or *NAME* field.
5. Enter the program-specific number (AKA) assigned to the client. If searching by name, enter the client query name.

   OG – Oil and Gas Operator (OGO) Number
   WM – Permit Number
   Mining – Permit Number or License Number
   WPC – Establishment Id
   WRWOB –Water Obstructions Id
   SDW –Public Water Supply Id
   WRDS – Permit Number
   RPX – Registration Number
   RPNARM – License Number
   STSTA – STDS Number or Tank Owner Id
   AQ – Tax Id-Plant Code
6. Click the  button on the toolbar or press the [F8] key to execute the query.
7. Verify that the highlighted client is the correct client.
8. Click the OK button.
9. The client record will display on the RECORD/VERIFY CLIENTS Screen.
10. Look at the hint line and determine if more than one record was retrieved (bottom left corner of the screen).

    Hint: *Record 1/1 – one record retrieved.*

    Record 1/? – multiple records retrieved.
11. If multiple records are retrieved, use the  button on the toolbar or press the [↓] key to locate the correct record.

Information Contained in the Client Record

Client Header Block - Displays the main identification information for the client including the unique, system-generated Id (client Id), the type of client, and the DEP standardized and abbreviated name of the client (organization or individual).

The Client Type determines the available information. There are three client types: Individual, Non-Government, and Government.

General TAB - Displays general information regarding the client including EIN/SSN numbers, Dun and Bradstreet Id, status, program responsible for verifying the record, who created and last updated the record, the client verifier that verified the accuracy of the record, and any additional comments.

HQ Address TAB - Displays the address and primary contact for the client's headquarters including address, undeliverable indicator, contact name, title, phone number and extension, fax number, and email.

Add'l Addresses TAB - Displays any addresses in addition to the client's headquarters address by which the client is known.

AKAs TAB - Displays the program-specific Ids assigned to the client. When clients were converted into *e*FACTS from the DEP legacy systems, the Ids from the previous systems were identified as AKA Ids. In addition, a program can assign unique AKA Ids to a client instead of using the system-generated number.

Names TAB – Displays the legal (official registered names) by which the client is known and any names that will assist in querying (previous names, abbreviated names, commonly used name, etc.).

Additional Information Available by using the Go To Button

Client/Client Relationship – Displays a list of clients that are related to the client, their relationship, and begin date and end date of the relationship.

View Authorization Information – Displays a list of client category authorizations linked to the client.

Tank SF Details – Displays details on specific Storage Tank primary facility as well as the related sub facility data for a client.

RP Vendor Details Screen – Displays detail records for a BRP Vendor Client.

Master Authorization Inventory – Displays any client category master authorizations linked to the client.

DMS Equipment Details – Displays the Deep Mine Safety equipment details for the client's master authorization(s).

Inspections – Displays the inspections and violations logged for the client.

Enforcements – Displays the enforcements and penalties taken against a client.

Record Licenses – Displays the Mining and Waste Management Licenses for the client.

Record Certification – Displays certification details for the client.

Record Bonds – Displays the Oil and Gas or Waste Management Bonds for the client.

Record Forfeitures – Displays the forfeiture cases for Oil and Gas or Waste Management Bonds for the client.

Maintain Training Courses – Displays the ST training details for the client.

Record Fee Payments – Displays the screen used to record the receipt of payments for the client's account.

Record Invoices – Displays the fee invoices for the client's account(s).

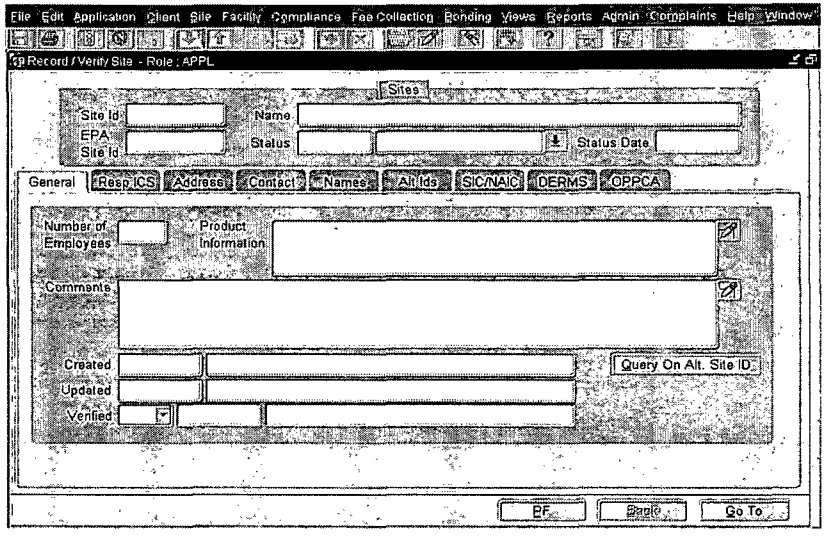
Record Fee Transactions – Displays the fee transactions for the client's account(s).

Comprehensive Fee Details– Display the account, transaction, invoice, and payment details for the client's account(s).

Querying Site Information

There are two primary queries when locating an existing site. This section identifies the procedure for locating a site using the name and the location address.

In addition, this section identifies the information available for a site including the information displayed on the screen and information that can be accessed via the GO TO button.



Querying a Site Using the Name

1. Open the RECORD/VERIFY SITES Screen by clicking the SITES button on the MAIN Screen.
2. Click the  button on the toolbar or press the [F7] key to enter query mode.
3. Enter the Site's Standard Name in the *Name* field.

   Hint: *Use the '%' wildcard if you do not know the entire name. For Example: You can enter %PERRY YACHT CLUB% to find 'COMMODORE PERRY YACHT CLUB MARINA' if you do not know the entire name.*

   Remember *that when working with records that contain regulated site data, specific naming conventions must be applied to the site 'standard' name as well as data standards. See* ***Appendix A*** *for the Site Naming Standards.*

- ***Caution:*** *If are using the wildcard '%' for a pattern search, you may want to click the*  *button on the toolbar to determine the number of results that will be retrieved. To lessen the number of results, revise your pattern search by adding more characters.*

4. Click the  button on the toolbar or press the [F8] key to execute the query.
5. The site record will display on the RECORD/VERIFY SITES Screen.
6. Look at the hint line and determine if more than one record was retrieved (bottom left corner of the screen).

   Hint: *Record 1/1 – one record retrieved.*
   Record 1/? – multiple records retrieved.

7. If multiple records are retrieved, use the  button on the toolbar or press the [↓] key to locate the correct record.

Querying a Site using Location Address

1. Open the RECORD/VERIFY SITES Screen by clicking the SITES button on the MAIN Screen.
2. Click on the Address TAB.
3. Click the  button on the toolbar or press the [F7] key to enter query mode.
4. Click in the field that you want to use as query criteria:

   The queryable fields are:
   Address Line 1
   Address Line 2
   City
   State (use the LOV button)
   ZIP Code (may enter additional four digits—17055-6551)

5. Enter the query criteria.
6. Click the  button on the toolbar or press the [F8] key to execute the query.
7. The site record will display on the RECORD/VERIFY SITES Screen.
8. Look at the hint line and determine if more than one record was retrieved (bottom left corner of the screen).

   Hint: *Record 1/1 – one record retrieved.*
   Record 1/? – multiple records retrieved.

9. If multiple records are retrieved, use the  button on the toolbar or press the [↓] key to locate the correct record.

Information Contained in the Site Record

Site Header Block – Displays the main identification information for the site including system-generated Id, name, EPA site Id, and status.

General TAB – Displays general details about the site including number of employees, product information, additional comments, who created the site, who last updated the site, and the site verifier who verified the accuracy of the site record.

Resp ICS TAB – Displays the location information for the site including the primary county in which the site is located, the priority program and responsible ICS for the site, and the additional counties and municipalities in which the site is located.

Address TAB – Displays the location address and directions for the site.

Contact TAB – Displays the primary contact for the site including name, title, firm, address, phone number and extension, fax number, and email address.

Names TAB – Displays the query names for a site (previous name, commonly used name, etc.).

Alt Ids TAB – For the Oil and Gas Program and Mining Program only, displays the program-specific Ids assigned to the site as an alternate Id to the system-generated number.

SIC/NAIC TAB – Displays the **S**tandard **I**ndustrial **C**lassification (SIC) Codes and **N**orth **A**merican **I**ndustrial **C**lassification (NAIC) Codes that describe the industrial, agricultural, etc. activity(ies) occurring at the site.

DERMS TAB – Displays the DERM file folder numbers (from the Electronic File Management Systems) for the site.

OPPCA TAB – Displays OPPCA's contact at the site.

Query on Alt Site ID BUTTON – Allows user to query on an alternate site id.

Additional Information Available by using the Go To Button

Complaints Maintenance – Displays complaint information for complaints made against a client or site.

Client/Site Relationship – Displays the clients currently related to the site and the clients related to the site in the past including the beginning and end date of the relationship, the type of the relationship, and the client Id and name.

Authorizations by... – Displays a list of authorizations linked to the site.

AML Facility Details – Displays an inventory of abandoned mine Problem Areas and their corresponding Features.

DMS PF/SF Details – Displays detail records for DMS Primary Facilities (PF) and Sub Facilities (SF).

RP Vendor Details Screen - Displays detail records for a BRP Vendor Client.

Master Authorization Inventory – Displays the master authorizations linked to the site.

Transfer Owner – Displays updated detailed information concerning the ownership of a Primary Facility.

Transfer Primary Facilities – Displays detail records for facilities transferred from an existing eFACTS Site record to another eFACTS Site record.

Merge Facilities – Displays detail record of a Primary Facility (PF) or Sub Facility (SF) that has been merged into another.

AML Project – Displays Bureaus of Abandoned Mine Reclamation (BAMR) and Mining and Reclamation (BMR) records that pertain to the tracking of mine reclamation work efforts.

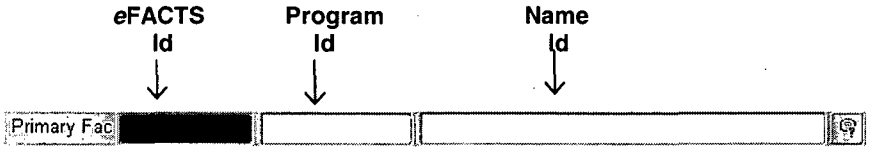
Inspections – Displays the inspections and violations logged for the site.

Record Fee Payments – Displays the screen used to record the receipt of payments for the client's account.

Comprehensive Fee Details– Displays the account, transaction, invoice, and payment details for the client's account(s).

Query Primary and Sub Facility Information

For a primary facility and sub facility, there will be one field label followed by three fields. The three fields contain a standard format.



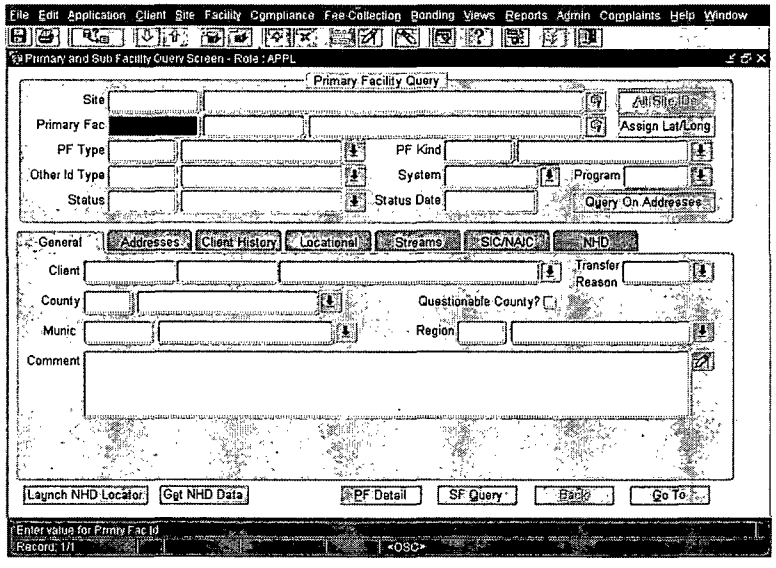
The Program Id is referenced using several different terms including other Id, AKA Id, and program-specific Id.

There are various options for querying an existing primary facility. This section identifies the procedures for querying a primary facility using various fields and querying a primary facility and sub facility using sub facility details.

In addition, this section identifies the information available for a primary facility and sub facility including the information displayed on the screen and information that can be accessed via the GO TO button.

Querying using Primary Facility Information

1. Open the PF/SF QUERY Screen by clicking the PRIMARY FACILITIES button on the MAIN Screen.



2. Click the  button on the toolbar or press the [F7] key to enter query mode.

3. Click in the fields that you want to use as query criteria:

   The following fields are queryable:

   Site Name
   Primary Facility Id
   Primary Fac Other Id
      OG – API Well Number (Permit Number)
      Mining – Permit Number
      RPX – Registration Number
      RPNARM – License Number
      WPC – NPDES Id
      AQ –Tax Id-Plant Code
      WM – Permit Number
      WRWOB –WOBS File Id
      LR – LRP Id
      STSTS – Facility Id
      SDW –Public Water Supply Id
      WRDS –DAMINV Dam Id
   PF Type (use the List of Values)
   PF Kind (use the List of Values)
   Other Id Type (use the List of Values)
   Other Id System (use the List of Values)
   Program (use the List of Values)
   Status Code (use the List of Values)
   Status Date
   Client Id
   Client AKA Id
      OG – Oil and Gas Operator (OGO) Number
      WM – Permit Number
      Mining – Permit Number or License Number
      WPC – Establishment Id
      WRWOB –Water Obstructions Id
      SDW –Public Water Supply Id
      STSTA – STDS Number or Tanks Owner Id
      WRDS – Permit Number
      RPX – Registration Number
      RPNARM – License Number
      AQ – Tax Id-Plant Code
   County (use the List of Values)
   Municipality (use the List of Values)
   Region (use the List of Values)

4. Enter the query criteria.
5. Repeat Steps 3 and 4 until you have entered all desired query criteria.
6. To query on the primary facility address in addition to the other query criteria, click the 

button.

7. Click in the fields that you want to use as query criteria:

   The following fields are queryable:
   Address Line 1
   Address Line 2
   City
   State
   Zip
   Address Type
   Undeliverable

8. Enter the query criteria.
9. Repeat Steps 7 and 8 until you have entered all desired query criteria.
10. Click the  button on the toolbar or press the [F8] key to execute the query.

Caution: If are using the wildcard '%' for a pattern search, you may want to click the  button on the toolbar to determine the number of results that will be retrieved. To lessen the number of results, revise your pattern search by adding more characters.

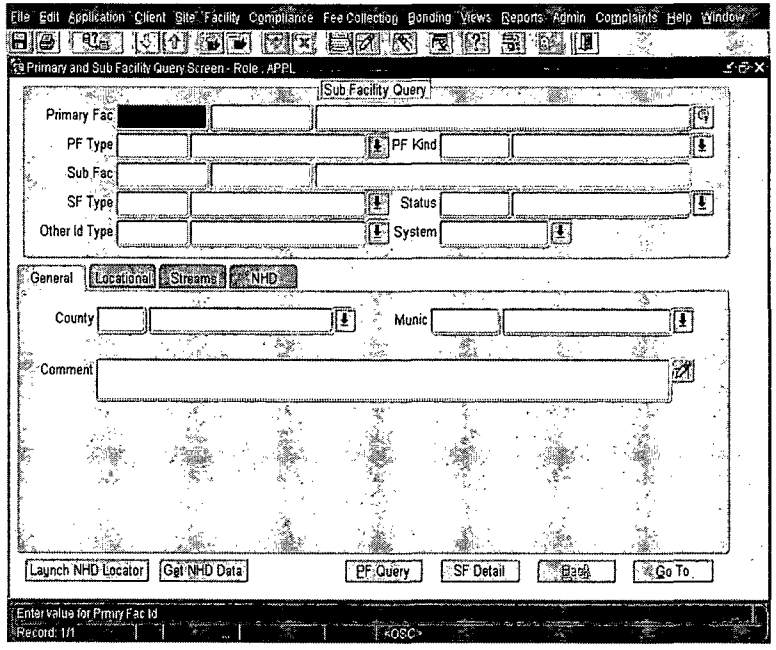
11. The primary facility record will display on the PF/SF QUERY Screen. Look at the hint line and determine if more than one record was retrieved (bottom left corner of the screen).

    Hint: *Record 1/1 – one record retrieved.*
    Record 1/? – multiple records retrieved.

12. If multiple records are retrieved, use the  button on the toolbar or press the [↓] key to locate the correct record.
13. To view the associated sub facilities, click the SF QUERY button at the bottom of the screen.
14. To view or maintain the site record, complete the following steps:
    a. Click the GO TO button at the bottom of the screen (right corner).
    b. The Module List of Values will display. Highlight the RECORD SITE Screen option. Click the OK button (bottom of pop-up window).
    c. The PRIMARY FACILITY DETAILS Screen will display. Click the SITE button (bottom of the screen).
    d. The RECORD/VERIFY SITES Screen will display. The system will 'automatically' query the site.

Querying using Sub Facility Information

1. Open the PF/SF QUERY Screen by clicking the PRIMARY FACILITIES button on the MAIN Screen.
2. Click the SF QUERY button (bottom right corner of the screen).



3. To **query on a combination of the <u>Header Block</u> and the General TAB,** click the General TAB.

   To **query on a combination of the <u>Header Block</u> and the Locational TAB**, click the Locational TAB.

   Note: *Make sure you can see the field that you want to use as query criteria and click in one of the fields before going into query mode.*

4. Click the  button on the toolbar or press the [F7] key to enter query mode.
5. Click in the fields to be used as query criteria:

   The following fields are queryable:
   <u>Header Block</u>
   Primary Facility Id
   Primary Fac Other Id
   OG – API Well Number (Permit Number)
   Mining – Permit Number
   RPX – Registration Number
   RPNARM – License Number

WPC – NPDES Id
AQ – Tax Id-Plant Code
WM – Permit Number
WRWOB –WOBS File Id
SDW –Public Water Supply Id
WRDS –DAMINV Dam Id

PF Type (use the List of Values)
PF Kind (use the List of Values)
Sub Facility Id
Sub Facility Other Id
Sub Facility Type (use the List of Values)
Status Code (use the List of Values)
Other Id Type (use the List of Values)
Other Id System (use the List of Values)

General TAB (if selected in Step 4)
County (use the List of Values)
Municipality (use the List of Values)

Locational TAB (if selected in Step 4)
USGS (use the List of Values)
Map Section
Latitude
Longitude
South Offset (OG only)
West Offset (OG only)
Horizontal Accuracy
Horizontal Accuracy UM
Hor Ref Datum
Hor Coll Method
Reference Point
Altitude
Altitude UM
Altitude Datum
Ver Loc Datum
Geometric Type
Collection Date
Source Map Scale Number
Source Map Scale UM
To
To UM

6. Enter the query criteria.
7. Repeat Steps 5 and 6 until you have entered all desired query criteria.
8. Click the  button on the toolbar or press the [F8] key to execute the query.

9. The sub facility record will display on the SF QUERY Screen. Look at the hint line and determine if more than one record was retrieved (bottom left corner of the screen).

   Hint: *Record 1/1 – one record retrieved.*
   Record 1/? – multiple records retrieved.

10. If multiple records are retrieved, use the  button on the toolbar or press the [↓] key to locate the correct record.
11. To view the associated primary facility, click the PF QUERY button at the bottom of the screen.
12. To view or maintain the site record, complete the following steps:
    a. Click the GO TO button at the bottom of the screen (right corner).
    b. The Module List of Values will display. Highlight the RECORD SITE Screen option. Click the OK button (bottom of pop-up window).
    c. The SUB FACILITY DETAILS Screen will display. Click the SITE button (bottom of the screen).
    d. The RECORD/VERIFY SITES Screen will display. The system will 'automatically' query the site.

Information Contained in the Primary and Sub Facility Records

Primary Facility Record

PF Header Block - Displays main identification information for the primary facility including the Id and name of the site where the primary facility is located, the system-generated and program-specific Ids assigned to the PF, the name of the facility, type of facility, the primary facility kind, and the status of the facility.

General TAB – Displays general information for the primary facility including the client that owns/operates the facility, the county and municipality where the facility is located, the region/district office responsible for regulating the facility, and any additional comments.

Addresses TAB – Displays the various addresses associated with the primary facility (i.e., location address, mailing address, etc.).

Client History TAB – Displays the current client associated with the primary facility and the clients that owned/operated the primary facility in the past including the client identification information and the begin date and end date of the relationship.

Locational TAB – Displays location details for the primary facility including USGS, map section, latitude and longitude, and various other location details (i.e., horizontal accuracy, horizontal reference datum, etc.).

Streams TAB – Displays the streams that the primary facility has the potential to impact environmentally including stream code and name, river mile index, sub basin, watershed, and stream-side.

SIC/NAIC TAB – Displays the **S**tandard **I**ndustrial **C**lassification (SIC) Codes and **N**orth **A**merican **I**ndustrial **C**lassification (NAIC) Codes that describe the industrial, agricultural, etc. activity(ies) occurring at the site.

NHD TAB – Displays the **N**ational **H**ydrography **D**ataset. USGS/EPA created set of digital spatial data that contains information about naturally occurring and constructed bodies of water, natural and artificial paths through which water flows, and related hydrographic entities. Features are combined to form reaches, which provide the framework for linking (or geocoding) water-related data to the NHD surface water drainage network.

Sub Facility Record

SF Header Block - Displays main identification information for the sub facility including details for the primary facility associated with the sub facility (i.e., Id, other Id, name, type, and kind), the system-generated and program-specific Ids assigned to the sub facility, the name of the sub facility, type of sub facility, and the status of the sub facility.

General TAB – Displays general information for the sub facility including the county and municipality where the sub facility is located and any additional comments.

Locational TAB – Displays location details for the sub facility including USGS, map section, latitude and longitude, and various other location details (i.e., horizontal accuracy, horizontal reference datum, etc.).

Streams TAB – Displays the streams that the sub facility has the potential to impact environmentally including stream code and name, river mile index, sub basin, watershed, and stream-side.

NHD TAB – Displays the **N**ational **H**ydrography **D**ataset. USGS/EPA created set of digital spatial data that contains information about naturally occurring and constructed bodies of water, natural and artificial paths through which water flows, and related hydrographic entities. Features are combined to form reaches, which provide the framework for linking (or geocoding) water-related data to the NHD surface water drainage network.

Additional Information Available by using the PF/SF Details Button

BMR Facility Details Screen – Displays the screen containing Bureau of Mining and Reclamation program-specific details for a Coal Mining Operation (CMO) or Industrial Mineral Mining Operation (IMMO) Primary Facility. The BMR FACILITY DETAILS Screen contains:

- General information including acreage details, operational characteristics, various indicators (blast insurance, water loss, etc.), various Ids/numbers (NPDES Id, MSHA Id, etc.), and bond details (current bond amount and final release date).
- Surface Mine sub facility details including the sub facility identification information (Id, other Id, and name of the surface mine), various measurements (ultimate pit floor elevation, ground water elevation, etc.), the minerals mined, and the coal seams mined.
- Deep Mine sub facility details including the sub facility identification information (Id, other Id, and the name of the deep mine), various measurements (permitted underground acres and subsidence control plan acres), the minerals mined, and the coal seams mined.

BOGM Facility Details Screen - Displays the screen containing Bureau of Oil and Gas program-specific details for an Oil and Gas Location (OGL) or Coal Pillar Oil and Gas (CPLOG) Primary Facility. The BOGM FACILITY DETAILS Screen contains:

- Well details including sub facility identification information (Id, API Well number, and name), general information (well number, well status, etc.), well dates for various operations, and well details (surface elevation, UIC Id, etc.).
- Coal Pillar details including sub facility identification information (Id, other Id, and name), date permitted, date revised, coal seam, elevation information, and pillar support information.
- Operator History details including the current client and any previous clients that own(ed)/operate(ed) the primary facility including the client identification information and the begin date and end date of the relationship.

BRP Facility Details Screen – Displays a screen containing Bureau of Radiation Protection program-specific details for a Radiation Facility (RF) Primary Facility. The BRP FACILITY DETAILS Screen contains:

- General information including mailing address, county, area, date issued, RAM category, and RSO.

- X-ray details including sub facility identification information (Id, registration number, and name), compliance status, MQSA details, and tube details.
- RAM details including sub facility identification information (Id, certification number, and name), compliance status, Chapter 224 details, and isotope details.
- Fee details including sub facility identification information (Id, registration/certification number, and name), current account details (balance due, annual fee, etc.), fee invoice details (date invoiced, amount due, transmittal, etc.), and payment details.

BWQP Facility Details Screen – Displays a screen containing Bureau of Water Quality Protection program-specific details for a Water Pollution Control Facility (WPCF) Primary Facility. The BWQP FACILITY DETAILS Screen contains:

- General information including year the last Waste Load Report was received, major/minor indicator, operation certification type required, certified operators, and NAIC codes.
- Program-specific sub facility details for the Conveyance, Discharge Point, Groundwater Monitoring Point, Land Discharge, Pump Station, Storage Unit/Impoundment, and Treatment Plant type sub facilities.

HW Facility Details Screen - Displays a screen containing Hazardous Waste program-specific details for a Captive Hazardous Waste Operation (CAHWO) or a Commercial Hazardous Waste Operation (COHWO) Primary Facility. The BWM HAZARDOUS WASTE FACILITY DETAILS Screen contains program-specific details for BIF, Disposal, Generator, Incinerator, Recycling, Storage, or Treatment Sub Facilities:

- General information including sub facility identification information (Id, other Id, and name), closure and final closure dates, notifications (EPA and PBR), and general sub facility details based on type.
- Process code details.
- Waste details including type of waste, associated measurement, and process codes

RW/MW Facility Details Screen - Displays a screen containing Non-Hazardous Waste program-specific details for a Municipal Waste Operation (MWO) or a Residual Waste Operation (RWO) Primary Facility. The BWM MW/RW FACILITY DETAILS Screen contains:

- Program-specific details for MW type sub facilities (composting, land application, landfill, processing, resource recovery, and transfer) including sub facility identification information (Id, other Id,

and name), volume details, closure and final closure dates, attributes, and various type-specific details.

- Program-specific details for RW type sub facilities (compost, generator, impoundment, incinerator, land application, landfill, processing, and transfer) including sub facility identification information (Id, other Id, and name), volume details, closure and final closure dates, attributes, and various type-specific details.

AML Facility Details Screen - Displays a screen containing Abandoned Mine Land program-specific details. The AML FACILITY DETAILS Screen contains:

- Abandoned Mine Land primary facility (problem area) details and the related sub facility (feature) data. This screen provides functionality to maintain details for the primary facility (ownership data, minerals mined, reason for update, etc.) and related SF facility details (mining details, feature description, keywords, etc.).

DMS Facility Details Screen - Displays a screen containing Deep Mine Safety (DMS) program-specific details for a DMS Bituminous (DMSOB), Anthracite (DMSOA), and Industrial (DMSOI) Primary Facility. The DMS FACILITY DETAILS Screen contains:

- Program-specific details for DMS type sub facilities (deep mine, prep plant, bank, etc.) including sub facility identification information (Id, other Id, and name) and various type-specific details.

Chapter 105 Facility Details Screen - Displays a screen containing Encroachment Location program-specific details for an ENCL Primary Facility. The CHAPTER 105 FACILITY DETAILS Screen contains:

- Program-specific details for ENCL type sub facilities (bridge, culvert, stream restoration, etc.) including sub facility identification information (Id, other Id, and name) and various type-specific details.

Additional Information Available by using Go To Button

Complaints Maintenance – Displays complaint information for complaints made against a client or site.

Record Client – Displays the client associated with the Primary Facility.

Record Site – Displays the site where the Primary Facility and Sub Facility are located.

View Authorization Information – When accessed for a primary facility (PF QUERY Screen), displays a list of authorizations linked to any sub facility associated with the primary facility. When accessed for a sub facility (SF QUERY Screen), displays a list of authorizations linked to the specific sub facility.

Monitoring Point Information – When accessed for a primary facility (PF QUERY Screen), displays a list of monitoring points linked to the primary facility. When accessed for a sub facility (SF QUERY Screen), displays a list of monitoring points linked to the sub facility.

Land Recycling Activities –Used to create, query, and update remedial activity records for a given Primary Facility (PF) under each functional area (Act2, HSCA, Other and Tanks) of the Land Recycling Program (LRP).

Tank Closure – Used to query, create, and update tank closure records for a given Primary Facility (PF). This screen is used to close tanks involved in a cleanup action.

RP Vendor Details Screen – For Radiation Protection, used to create and update one or more detail records for a BRP Vendor Client. Displays information associated with the SF, inspections, fees, hours etc.

SF/SF Relationship – When accessed for a sub facility (SF QUERY Screen), displays a list of sub facilities (usually from other primary facilities) related to the sub facility. This option is inactive when on the PF QUERY Screen.

PF/Client Relationship - When accessed for a primary facility (PF QUERY Screen), displays the additional clients linked to a primary facility (other than the client directly identified on the primary facility record).

Master Authorization Inventory – When accessed for a primary facility (PF QUERY Screen), displays all master authorizations for any associated sub facility. When accessed for a sub facility (SF QUERY Screen), displays the master authorization(s) linked to the specific sub facility.

Transfer Owner – Used to change ownership of a Primary Facility (PF). When the owner of multiple primary facilities changes (a client sells multiple primary facilities it owns to a new client), this screen can be used to change the owner for multiple facilities in one operation. This

screen cannot be used to transfer facilities for Oil and Gas Operators. Oil and Gas Operators must be transferred on the BOGM OPERATOR TRANSFER Screen.

Transfer Primary Facilities – Used to transfer one or more primary facility record(s) and associated sub facilities from an existing site to another site record. The unique PF Id will remain unchanged and all existing data, including Sub Facilities, Compliance, Bonding, Fee Collections, etc. associated with the primary facility will remain intact. The Site Id for the primary facility will be updated with the new Site Id.

Merge Facilities – Used to merge one Primary Facility or Sub Facility into another. In order to merge primary facilities, the primary facilities must belong to the same site and be of the same PF Type. In order to merge sub facilities, both facilities must belong to the same primary facility and be of the same SF Type.

AML Projects – Used to track the Bureau of Abandoned Mine Reclamation (BAMR) mine reclamation work efforts. These efforts, called projects, are aimed at reclaiming environmental and safety concerns that are a result of current or abandoned mining efforts. This screen will be used to create, update, and delete project details.

Active BMR PF Link to AML- Used to maintain links between active Mining Primary Facilities and their Authorizations with the facility that it might impact. This will identify AML locations that may be impacted by mining activities, which will determine if existing or proposed AML projects should be delayed or terminated. Allowable AML Primary Facilities will be Forfeited Mining Primary Facilities and Abandoned Mine Land Locations.

Inspections – When accessed for a primary facility (PF QUERY Screen), displays the inspections conducted at any sub facility associated with the primary facility. When accessed for a sub facility (SF QUERY Screen), displays the inspections linked to the specific sub facility.

Enforcements – Displays the enforcements taken against the client identified for the primary facility.

Record Bonds – When accessed for a primary facility (PF QUERY Screen), displays the bonds for a mining primary facility (CMO or IMMO). When accessed for a sub facility (SF QUERY Screen), displays the bond for a waste management sub facility (CAHWO, COHWO, MWO, or RWO).

Record Forfeitures – When accessed for a primary facility (PF QUERY Screen), displays the forfeiture case details for any bond forfeited by a mining primary facility (CMO or IMMO). When accessed for a sub facility (SF QUERY Screen), displays the forfeiture case details for any bond forfeited by a waste management sub facility (CAHWO, COHWO, MWO, or RWO).

Record Self Monitoring Screen – When accessed for a primary facility (PF QUERY Screen), displays self monitoring reports scheduled, reports due, reports received, and a summary of each type for the primary facility. When accessed for a sub facility (SF QUERY Screen), displays self monitoring reports scheduled, reports due, reports received, and a summary of each type for the sub facility.

Comprehensive Fee Details – Used to query, view, and update the various permitting and facility fee details in one screen. This screen allows the user to retrieve fee details using specified criteria for an Account, Transaction, Invoice or a Payment record.

AIMS Airs Data – For AQ only, displays the AIRS Data for an AQ Air Emission Plant (AEP) primary facility.

AIMS Fuel Material Locations - For AQ only, displays the AQ-specific, sub facility details for an AQ fuel material location sub facility.

AIMS Emission Inventory Data - For AQ only, displays the emission inventory details for an AQ Air Emission Plant (AEP) primary facility.

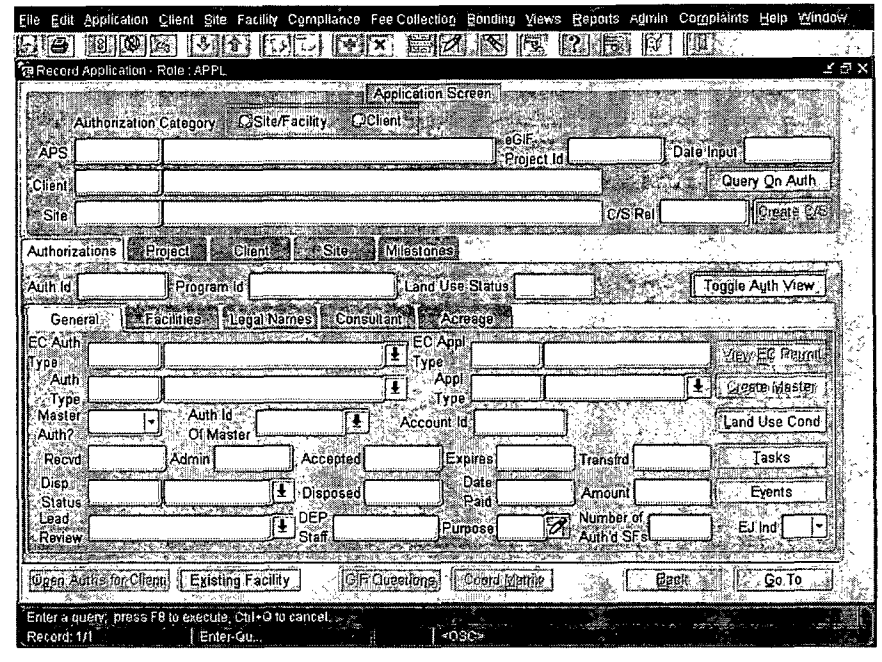
AIMS Primary Facility Update - For AQ only, displays the screen used to update AQ-specific details for an AQ Air Emission Plant (AEP) primary facility.

AIMS Sources - For AQ only, displays the screen used to insert and update AQ-specific details for all AQ sub facilities (processes, incinerators, combustion units, fuel material location, control device, and stacks).

Querying Authorization Information

There are three primary queries when locating an existing application/project/authorization. This section identifies the procedure for locating an application by querying on the APS Id, Client, Site Id, program Id, or Authorization Id.

In addition, this section identifies the information available for an application/project/authorization including the information displayed on the screen and information that can be accessed via the GO TO button.



Using the Program-Specific Id

1. Access the RECORD APPLICATION Screen by clicking the APPLICATION PROCESSING button on the MAIN Screen.
2. Click the Query On Auth button located on the top right corner of the Projects TAB.
3. The Query on Auth Pop-Up Window will display. Click in the *Program Id* field.
4. Enter the program specific Id (permit number, registration number, license number, etc. – the number that your program assigns to an authorization).

5. Click the  button on the toolbar or press the [F8] key to execute the query.
6. The pending application record(s) will display and then the issued authorizations. If more than one application is retrieved, use the  button on the toolbar or press the [↓] key to move through the records.

Using the APS Id, Client Id or Site Id

1. Access the RECORD APPLICATION Screen by clicking the APPLICATION PROCESSING button on the MAN Screen.
2. Click the  button on the toolbar or press the [F7] key to enter query mode.
3. Click in the *APS Id* (first field), *Client Id* (first field after the field label 'Client'), or *Site Id* field (first field after the field label 'Site') depending on the Id that you wish to use as query criteria.
4. Enter the *e*FACTS-assigned Id for the APS, Client, or Site.
5. Click the  button on the toolbar or press the [F8] key to execute the query.
6. The pending application record(s) will display and then the issued authorizations.
7. If more than one application is retrieved, use the  button on the toolbar or press the [↓] key to move through the records.

Using the Authorization Id

1. Access the RECORD APPLICATION Screen by clicking the APPLICATION PROCESSING button on the MAIN Screen.
2. Click the  button located on the top right corner of the Projects TAB.
3. The Query on Auth Pop-Up Window will display. Enter the system-generated Id assigned to an authorization (auth Id).
4. Click the  button on the toolbar or press the [F8] key to execute the query.
5. The application record will display.

Information Contained in the Application Records

Header Block – Displays main identification information for the application including the APS Id and name, the date the application was entered into *e*FACTS, the Id and name of the client requesting the authorization, the Id and name of the site where the activities are being authorized, and the relationship between the client and the site.

Authorizations TAB – Displays the authorizations for the application/project. Displays the main identification information for the authorization including system-generated and program specific Id of the authorization, as well as contains five sub tabs displaying various details for the authorization.

General TAB – Displays the general information for the authorization including the authorization type, application type, various dates (received date, etc.), and the status of the authorization.

Facilities TAB – Displays a list of sub facilities linked to the authorization including system-generated and program-specific Id, name, and latitude/longitude of sub facility.

Legal Names TAB – Displays the official, legal name for the client requesting the authorization instead of the standard client name with DEP data standards and naming conventions applied.

Consultant TAB – Displays the consultant for the authorization including name, title, firm, address, phone number, etc.

Acreage TAB – Displays the type and amount of acreage associated with the Mining permit.

Projects TAB – Displays the address and contact for the project/application.

Client TAB – Displays basic information for the client requesting the authorization.

Site TAB – Displays basic information for the site that is being authorized.

Milestones TAB – Displays the milestones for the project as identified by the client.

GIF QUESTIONS button – Displays coordination questions and land use questions for the application/project.

COORDINATION MATRIX button – Displays ICS codes flagged for potential coordination and their response.

TASKS button – Displays the money back guarantee, standard tasks, and sub task details for the authorization.

EVENTS button – Displays the events (public notification and comment periods) identified for the authorization.

Additional Information Available by using Go To Button

Client/Site Relationship – Displays the clients currently related or previously related to the site including the client identification information (Id and name), begin and end date of the relationship, and the type of relationship.

Maintain/Generate Letters – Displays a list of letters that can be generated for the authorization. The letter template (standard, DEP approved letter) will display in Microsoft Word, and the details from the application/authorization will 'automatically' populate.

Tank SF Details Screen – Displays the Storage Tanks (ST) facility details for a STL sub facility linked to a Tank authorization.

DMS PF/SF Details – For Deep Mine Safety, used to query, create and update one or more detail records for DMS Primary Facilities (PF) and Sub Facilities (SF). User can record detailed information about a mine, DEP inspectors, DEP supervisors, mine employees, addresses for a mine and equipment used at a mine.

RP Vendor Details Screen – For Radiation Protection, used to create and update one or more detail records for a BRP Vendor Client. Displays information associated with the SF, inspections, fees, hours etc.

Master Authorization Inventory – Displays the master authorization details for the authorization.

Transfer BOGM Operator – For Oil and Gas only, displays the BOGM TRANSFER OPERATOR Screen for the Oil and Gas transfer authorization so that a transfer of Oil and Gas Location (OGL) facility from one client to a new client can be processed.

Transfer Owner – Allows the transfer of a primary facilities ownership from one client to a new client (except for OG).

Active BMR PF Link to AML- Used to maintain links between active Mining Primary Facilities and their Authorizations with the facility that it might impact. This will identify AML locations that may be impacted by mining activities, which will determine if existing or proposed AML projects should be delayed or terminated. Allowable AML Primary Facilities will be Forfeited Mining Primary Facilities and Abandoned Mine Land Locations.

Special Waste Approval – For WM only, displays the generating sub facility or client as well as the types and amounts of waste that the receiving sub facility is being authorized to receive.

DMS Equipment Details – Displays information about the equipment used in DMS mining facilities, including the type of equipment, the manufacturer or other applicant and specific details about the equipment as submitted with the approval request. Allows DMS to review the authorizations, which approve the use of the equipment in Pennsylvania mines, and display a list of the mines where the approved equipment is currently in use.

Record Licenses – For WM and Mining only, displays the license details for the authorization (license) including general information, mining-specific license details, insurance details, and waste management-specific license details.

Record Certification– Displays the certifications for the client authorization identified as a certification.

Record Bonds – For WM, Oil and Gas, and Mining only, displays the bond agreements for the client (WM and OG), primary facility (Mining), or sub facility (WM) associated with the authorization.

Record Fee Payments – Displays the screen used to record payments received for the authorizations associated fee transaction.

Record Fee Transactions – Displays the screen used to record transactions for the authorization's account.

Comprehensive Fee Displays – Displays the account, transaction, invoice, or payment details for the authorization's account.

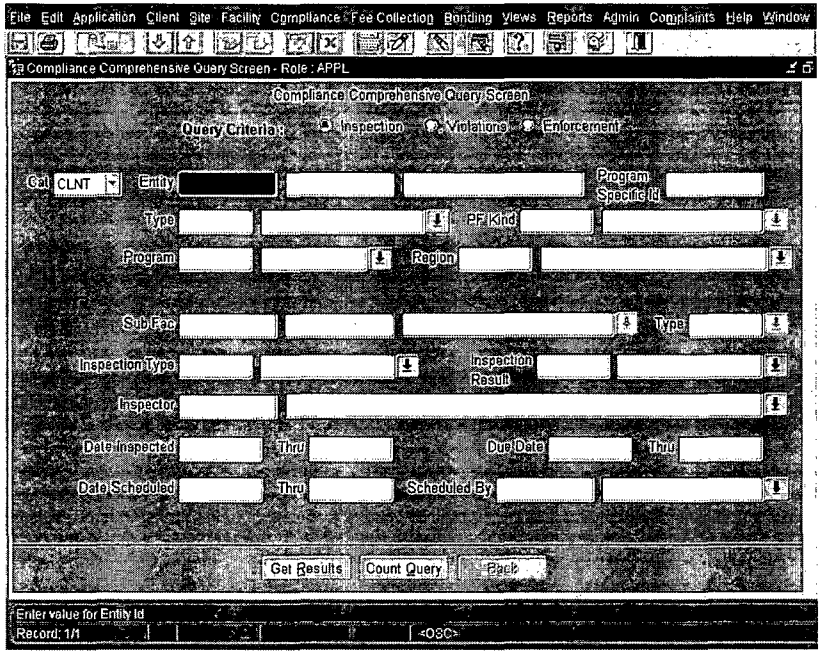
AIMS Permits – For AQ only, displays the screen used to view AQ-specific permit details including applicable requirements, sub facility groups, permit map, etc.

Querying Compliance Information

There are three primary queries when locating compliance information. This section identifies the procedure for locating inspections, violations, and enforcements.

In addition, this section identifies the information available for inspections, violations, enforcements, and penalties including the information displayed on the screens and information that can be accessed via the GO TO button.

1. Open the COMPLIANCE COMPREHENSIVE QUERY Screen by clicking the COMPREHENSIVE QUERY button on the MAIN Screen.



2. Click the appropriate radio button (Inspection, Violations, or Enforcement) that corresponds to the type of records to be retrieved.
3. If you wish to enter query criteria in the first three lines of the screen, use the ▼ button to select the appropriate category.
4. Click in the field that you wish to use as query criteria.

Query Fields for Inspections, Violations, and Enforcements:

- *Entity Id*
- *Entity AKA/Other Id*
- *Program Specific Id PF Kind Code*
- *Entity Type*

- *Program Code*
- *Region Code*

Query Fields for <u>Inspections Only</u>:

- *Sub Fac Id*
- *Sub Fac Other Id*
- *Sub Fac Type*
- *Date Inspected (Range) Begin Date*
- *Date Inspected (Range) Thru Date*
- *Due Date (Range) Begin Date*
- *Due Date (Range) Thru Date*
- *Inspection Type*
- *Inspection Result Code*
- *Date Scheduled (Range) Begin Date*
- *Date Scheduled (Range) Thru Date*
- *Inspector Id*
- *Scheduled By*

Query Fields for <u>Violations Only</u>:

- *Viol Type*
- *Resolution Reason Code*
- *Violation Date (Range) Begin Date*
- *Violation Date (Range) Thru Date*
- *Scheduled Response Date (Range) Begin Date*
- *Scheduled Response Date (Range) Thru Date*
- *Resolution Date (Range) Begin Date*
- *Resolution Date (Range) Thru Date*

Queryable Fields for <u>Enforcements Only</u>:

- *Enf Type*
- *Progress Date*
- *Enf Appeal Status Ind*
- *Enf Appeal Status*
- *Tracking #*
- *Enf Date Final (Range) Begin Date*
- *Enf Date Final (Range) Thru Date*
- *Date Initiated (Range) Begin Date*
- *Date Initiated (Range) Thru Date*
- *Pen Appeal Status*
- *Citation Number*
- *Pen Date Final (Range) Begin Date*
- *Pen Date Final (Range) Thru Date*
- *Pen Final Status*

5. Enter the query criteria in the selected field.
6. Repeat Steps 4 and 5 until you have established query criteria in all fields for which you wish to specify criteria.
7. To **count the number of records** that match the criteria, click the Count Query button. The query count will display on the hint line.

8. To **retrieve and view the inspections, violations, or enforcements** that match the query criteria, click the [Get Results] button.
9. The Retrieved Block will display the inspections, violations, or enforcements matching the query criteria.
10. Locate and highlight the record that you want to view or update.
11. Click the [Go To] button at the bottom of the screen.
12. The Module List of Values Pop-Up Window will display. Highlight the screen on which you want to view details.
13. Click the [OK] button. Review or maintain the displayed details.
14. Click the [Back] button to return to the RETRIEVED Screen.
15. Repeat Steps 10 through 14 to view the details for another inspection, violation or enforcement record.
16. Click the [Criteria] button to return to establish different query criteria.

Information Contained in the Retrieved Records

Inspections – Displays a list of inspections matching the query criteria including system-generated and program-specific Id assigned to the inspection, the type of inspection, the date the inspection was conducted, the result of the inspection, the inspected entity's (PF, Client, or Site) identification information (Id, other Id, and name), and buttons to access a list of inspectors and/or a list of inspected sub facilities.

Violations – Displays a list of violations matching the query criteria including the system-generated and program-specific Id assigned to the violation, the date the violation was identified, the type of violation, indicator identifying if the violation resulted in an enforcement, additional comments, and the sub facility in violation (Id, other Id, and name).

Enforcements– Displays a list of enforcements matching the query criteria including the system-generated and program-specific Id assigned to the enforcement, enforcement type, tracking number, date executed, the client against which the enforcement was taken (Id, AKA Id, and name), date referred, final status, citation number, and penalty details (final status and date, amount due, and amount collected).

Additional Information Available by using Go To Button

Inspections – For a queried inspection, displays the entire inspection record. For a queried violation, displays the entire inspection record for the inspection during which the violation was identified. The inspection record includes the following details:

- Main identification information including the system-generated and program-specific Id, the inspection type, date inspected, and the inspected entity (primary/sub facility, site, or client) details.
- General information including owner/operator of inspected entity, inspector, inspection result, complaint Id, date due or scheduled, inspection result, agency, program and ICS who conducted the inspection, and the county and municipality where the inspected primary facility is located.
- A list of inspected sub facilities.
- A list of violations identified during the inspection including system-generated and program-specific Id, violation type, date of scheduled response, additional comments, resolution date and reason, and sub facility where the violation occurred.
- A list of compliance assistance provided to the inspected entity during the inspection.
- A list of coverage area codes applying to the WM inspection.
- Administrative information including additional comments, who created the enforcement in *e*FACTS, and who last updated the record.

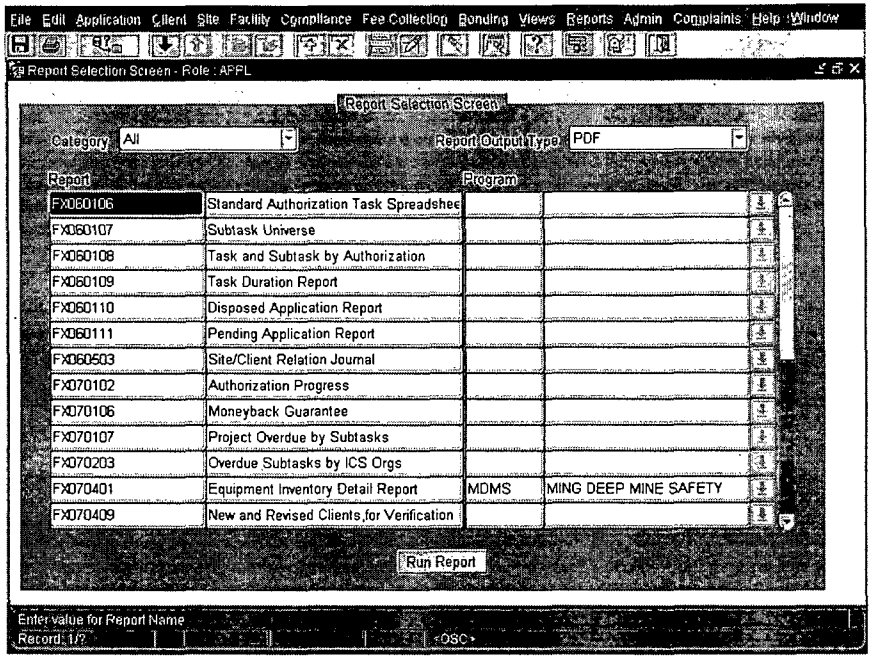
Enforcements – For a queried violation, displays the entire enforcement record that was the result of the queried violation. For a queried enforcement, displays the entire enforcement record. The enforcement record includes the following details:

- Main identification information including the system-generated and program-specific Id, the enforcement type, date executed, and the client against which the enforcement was taken (Id, AKA Id, and name).
- General information including DEP employee assigned the enforcement, date referred, responsible program and ICS, the appeal status of the enforcement and penalty, and the final status of the enforcement and penalty.
- A list of violations including system-generated and program-specific Id, violation type, date of scheduled response, additional comments, resolution date and reason, and sub facility where the violation occurred.

- A list of milestones including the due dates assigned to the client and date that the client completed the milestone.
- A list of related enforcements.
- A list of additional clients included in the enforcement.
- A list of actions taken by DEP to assess the penalty.
- A list of payments scheduled or received regarding the penalty.
- Administrative information including additional comments, who created the enforcement, who last updated the enforcement, and a list of modifications to the enforcement.

How to Run a Report

1. Access the *e*FACTS MAIN Screen.
2. Click on the REPORTS button.
3. The REPORT SELECTION Screen will display.



4. Click the ▼ button to the right of the *Category* field.
5. Highlight the appropriate category.
6. Click on the highlighted category. The report category will display in the *Category* field and the associated reports will display in order by report number.
7. Click the ▼ button to the right of the *Report Output Type* field.
8. Highlight PDF or HTML as the report output type.
9. Click on the highlighted report output type. The report output type will display in the *Report Output Type* field and the report will display/ print in the selected format.
10. Highlight the appropriate report.
11. Click the RUN REPORT button. The RUNTIME PARAMETER Screen will display. The cursor will be positioned in the first parameter field.

12. Select the appropriate criteria by using the  button to the right of the parameter fields or by entering the appropriate code. Press the [TAB] key.
13. If you do not wish to use a parameter to restrict the report output, verify that the field contains the wildcard '%'.

    Note: *If the parameter field is a date range, enter the begin date in the first field, [TAB], and the end date for the range in the second field.*

    Caution: *The dates must be in the format MM/DD/YYYY.*
14. Repeat Steps 12 and 13 until all report criteria has been selected.
15. Click the 

button.
16. The REPORT OUTPUT Screen will display the report details. The total pages of the report will display at the bottom of the screen.
17. Use the  button on the toolbar or the scrollbar to move to the next page of the report.
    - *You may have to use the horizontal and vertical scrollbars to view the entire page of the report.*
    - *To move throughout the report, click the*  *button to move to the previous page, click the*  *button to move to the first page, or click the*  *button to move to the last page of the report.*
    - *The report summary is located at the end of the report.*
18. To print the report click the  button on the toolbar and verify that the page setup is set to appropriate orientation and the margins are accurate and then click the  button to print the report.
19. After you have reviewed all necessary report details, click the  button on the toolbar to close the report previewer.

*e*FACTS Internal Web Site

The internal *e*FACTS Web Site is maintained by the Applications Support Help Desk Team with the sole purpose to provide information regarding *e*FACTS. The web site contains everything from manuals on how to enter a record into *e*FACTS to program-specific guidance.

To access this world of *e*FACTS information, complete the following steps:

1. Access DEP IntraDep.
2. Click on the Data Access Tools Option.
3. Click on the *e*FACTS hyperlink.
4. The *e*FACTS Main Menu will display.

   The following menu options are available:

   Introduction: Provides introductory information about *e*FACTS such as an overview presentation, *e*FACTS movie, and a glossary.

   Getting Started: Provides instructions for a first-time *e*FACTS user on how to get started such as system requirements, installation instructions, security, and logging on and off the system.

   Learn About eFACTS: Provides beginning and veteran employees with information about *e*FACTS such as the basics, brief descriptions of reports and screens, and detailed user guides for each screen and report.

   Enhancement Requests: Provides information about the board that controls the changes made to *e*FACTS as well as provides a form for submitting enhancement requests.

   Help Contacts: Provides information about the *e*FACTS User Support Team including the Help Desk.

   Historical Information: Provides historical information about *e*FACTS.

   Training: Provides a training calendar, course catalog, and a link for requesting training.

   PA Bulletin: Provides general information, department-wide guidance, and program-specific guidance regarding the Pennsylvania Bulletin.

   Guidance: Provides department-wide and program-specific guidance to be followed while working in *e*FACTS.

   Client Verifier Contacts: Provides a listing by program of all DEP Client Verifiers, their location and telephone number.

Policy and Procedure: Provides DEP Policies and procedures to be followed while working in *e*FACTS.

What's New in eFACTS: Provides details about each release of a new version of *e*FACTS screens or reports.

EPA and Other States: Provides information about EPA and other state initiatives (one stop reporting, etc.).

FAQs: Provides answers for frequently asked questions about *e*FACTS.

Submit A Remedy Ticket: Used by the Applications Support Help Desk and the Hewlett Packard *e*FACTS Design, Development and Maintenance Team to submit remedy tickets to the various groups within DEP.

Data Quality: Provides links to pages containing information regarding data quality as it relates to *e*FACTS.

FAQ's Web Forms: Provides answers to the most frequently asked questions regarding eFACTS webforms.

5. Select the appropriate menu option.

*e*FACTS Public Web Site

The public web site provides basic *e*FACTS information to the public regarding clients, sites, facilities, permits, and compliance (inspections, violations, enforcements, and penalties).

To access the *e*FACTS information displayed for the public, complete the following steps:

1. Find the Client Id or Site Id using *e*FACTS (for faster searching).
2. Open DEP's IntraDep.
3. Access DEP's public website by clicking on the www.dep.state.pa.us menu option. Select Permits, Licensing & Certification from the navigation bar beneath the Quick Access heading.
4. Click the *e*FACTS hyperlink at the beginning of the first paragraph. The *e*FACTS page will display.
5. Select a search option or hyperlink: Authorization Search, Client Search, Facility Search, Inspection Search, Name Search, Pollution Prevention, Sites Search or Search by Municipality.
6. Enter the search criteria.
7. Click the SEARCH button.
8. To view the permits, inspections, or detail information, click the appropriate hyperlink.

DEP INSPECTION MANUAL

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INSPECTION PROCEDURE 83822

RADIATION PROTECTION

PROGRAM APPLICABILITY: 2600, 2800

83822-01 INSPECTION OBJECTIVE

To determine whether the licensee's performance is in accordance with regulatory requirements related to radiation protection, and to evaluate the adequacy of certain aspects of the licensee's radiation protection program.

83822-02 INSPECTION REQUIREMENTS

02.01 Radiation Protection Program. Verify that the performance of the radiation protection program, commensurate with the potential risk involved in the licensee's activities, is being implemented and documented. Verify that program performance is being reviewed at least annually, both for content and implementation.

02.02 Radiation Protection Procedures. Verify that performance due to changes in the radiological protection procedures made since the last inspection are consistent with regulations and license requirements.

02.03 Instruments and Equipment. Verify that the performance of radiation protection instruments and equipment is in accordance with license requirements and licensee procedures.

02.04 Exposure Controls

a. External Exposure. Determine that the licensee's performance is in accordance with the following regulatory requirements incorporated by reference:

1. 10 CFR 20.1501 & 20.1502 (surveys and monitoring)
2. 10 CFR 20.1201 (occupational dose limits)
3. 10 CFR 20.1206 (planned special exposures)
4. 10 CFR 20.1207 (exposure of minors)
5. 10 CFR 20.1208 (dose to an embryo/fetus)
6. 10 CFR 20.1203 (external dose from airborne material)
7. 10 CFR 20.2104 (prior occupational dose)
8. 10 CFR 20.2106 (records of monitoring results)

9. 10 CFR 20.2105 (records of planned special exposures)

10. 10 CFR 20.2102 (records of radiation protection program)

11. 10 CFR 20.1301 (dose to the public) Formatted: Bullets and Numbering

12. 10 CFR 20.1101(b) and (d) (ALARA) Formatted: Bullets and Numbering

b. Internal Exposure. Determine that licensee's performance is in accordance with the following regulations:

1. 10 CFR 20.1501 & 20.1502 (surveys and monitoring)

2. 10 CFR 20.1201 (exposure limits)

3. 10 CFR 20.1501(a) & (b) (surveys and monitoring)

4. 10 CFR 20.1701 & 1702 (use of engineering and other controls)

5. 10 CFR 20.1202 (summation of external and internal doses)

6. 10 CFR 1204 (determination of internal dose) Formatted: Bullets and Numbering

7. 10 CFR 20.1302 re:§20.1301 (dose to the public) Formatted: Bullets and Numbering

c. Respiratory Protection. For facilities with a respiratory protection program, determine if licensee's performance is in accordance with 10 CFR 1703.

02.05 Posting, Labeling, and Control

a. Posting and Labeling. Determine if licensee's performance is in accordance with 10 CFR 20.1902, §20.1903, §20.1904, §20.1905 and other posting and labeling requirements specified in the license or licensee procedures.

b. Posting of Notices. Determine if licensee's performance is in accordance with 25 Pa. Code 220.2 and 10 CFR 19.11 incorporated by reference.

c. Control. Determine if licensee's performance is in accordance with the license requirements, licensee procedures, increased controls for risk-significant radioactive sources (NRC Order EA-05-090 equivalent if applicable) and the following regulations:

1. 10 CFR 20.1601 (high radiation area access)

2. 10 CFR 20.1602 (very high radiation area access)

3. 10 CFR 20.1801 (security of stored material)

4. 10 CFR 20.1802 (control of material not in storage)

02.06 Surveys

a. Requirements. Determine if licensee's performance is in accordance with the following regulations:

1. 10 CFR 20.1501(a) & (b) (surveys)

2. 10 CFR 20.2103 (survey records)

b. Leak Tests. Verify if licensee's performance is in accordance with license requirements or other DEP regulations for leak testing of radioactive sealed sources.

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02.07 Notifications and Reports

a. To the DEP. Determine if licensee's performance is in accordance with the following regulations and license requirements incorporated by reference:

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1. 10 CFR 20.2201 & 2202(b) (loss of control or theft of material)

2. 10 CFR 20.2202 & 2203 (incidents, and exposures)

3. 10 CFR 20.2202(a) & 2203 (overexposure)

4. Other radiation protection reports required by the license and by applicable provisions of 10 CFR 30-39, 40and 70,

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b. To the Individual. Determine if licensee's performance is in accordance with 10 CFR 19.13 incorporated by reference.

02.08 As Low As Is Reasonably Achievable (ALARA). Paragraph 20.1101(b) of 10 CFR 20 requires that persons engaged in DEP licensed activities shall, to the extent practicable, maintain occupational doses and doses to members of the public ALARA. During inspections:

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a. Determine if high level management has made a commitment to minimize exposure to workers and has clearly defined procedures and policies to implement the ALARA philosophy.

b. Determine that licensee personnel are made aware of management's commitment to keep occupational exposures ALARA.

c. Ascertain that the radiation protection staffing is sufficient and has been given authority to make certain that ALARA policies are carried out and that workers have been adequately trained to understand the ALARA philosophy and how it should be implemented at their work places.

d. Determine that management and its designees perform periodic (at least annual) audits of its program (special attention should be given to methods to lower internal and external exposure and to determine that effluents released are ALARA.

e. Determine if licensee's performance is in accordance with 10 CFR 19.12 incorporated by reference with respect to workers' understanding of radiation protection in their work place, and how the training received includes an understanding of ALARA as it pertains to the work place.

f. Determine whether modifications to equipment, facilities, and procedures, have been made where practicable to significantly reduce exposures at a reasonable cost. The benefits gained should outweigh the cost of modifications. Also determine if the licensee has considered the ALARA philosophy during the engineering phase for changes in facilities, equipment, or processes and whether an ALARA review was performed during initial implementation of changes.

g. Determine if the RSO and radiation protection staff's performance includes:

1. Identification of the origins of radiation exposures by location and job category and have noted trends in the amounts of radiation at the locations.

2. Consideration of ways to reduce exposures in those locations where exposure to personnel are significant.

3. Periodic review of operating procedures that affect radiation safety and that surveys of operations to identify situations where radiation exposures can be reduced have been made.

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h. Determine if licensee's performance includes a program in which workers can make suggestions on radiation protection (feedback).

i. Determine if licensee's performance includes the use of adequate equipment and supplies in the radiation protection program, and if procedures are available for proper use of these supplies and equipment.

83822-03 INSPECTION GUIDANCE

03.01 Radiation Protection Program. Review the outcome of the licensee's implementation of its radiation protection program to determine if licensee's performance ensures safety and compliance with regulatory requirements. Determine if the program content and implementation are being reviewed at least annually. Inspect the documentation for these reviews.

Review of the licensee's Health Physics (HP) log book or file on HP problems may be useful to identify areas deserving special attention. Particular attention should be directed toward identifying trends and ascertaining whether corrective actions were directed toward the cause and not merely the symptoms.

NRC Regulatory Guides 8.8 and 8.10 may be discussed in terms of providing useful guidance to the licensee regarding ALARA. If the licensee has a documented commitment to ALARA, implementation of the program should be discussed with management. Verify that the ALARA goals are adequate and realistic.

The licensee may have submitted certain of his radiation protection procedures, or his radiation protection manual, along with the license application and, in some cases, those procedures or the manual may be incorporated into license requirements. There are references to licensee procedures throughout this inspection procedure; however, this is not done for all inspection areas. The absence of a notation regarding licensee procedures is not intended to preclude the inspector from inspecting a given area against licensee procedures if there is an applicable license requirement.

03.02 Radiation Protection Procedures. Review any substantive changes to procedures which have been implemented since the last inspection if problems are identified in a specific program area; verify that limits, precautions, controls, etc., specified in the procedures are consistent with regulations and license requirements.

03.03 Instruments and Equipment

a. Randomly select instruments of each major type and examine them to verify operability and proper alarm settings, if alarm settings are applicable. These may

include portable survey instruments, fixed monitoring equipment, constant air monitors, portable air samplers, pocket dosimeters, and alarming dosimeters.

b. Review the most recent calibration records of the instrument(s) selected for inspection to assure that the calibration and surveillance program for these instruments are being accomplished in accordance with license requirements or licensee procedures.

c. Verify that the licensee has a system (a schedule, card file, etc.) which identifies all the instruments and identifies when they are due for calibration or functional testing.

d. Verify that the procedures used to calibrate the instruments selected above contain: review and approval requirements of the licensee's procedural system or license requirements, acceptance criteria including values for trip settings that conform to license requirements, if applicable, and detailed stepwise instructions.

e. Verify that the licensee uses survey instruments that are appropriate for the type and intensity of radiation measured.

03.04 Exposure Controls

a. External Exposure

1. Examine any changes made in procedures for control and use of personnel monitoring equipment; verify that limits, precautions, controls, etc., specified in the procedures are consistent with regulations and license requirements.

   Examine the type of monitoring devices used, the period of use or exchange period, and the number used to determine if these aspects seem consistent with the monitoring program. Determine who the supplier is, and if the service has been changed since the last inspection, determine the reasons for the change. Verify that the personnel dosimetry processor is accredited by NVLAP.

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   For pocket dosimeters or pocket chambers, determine when they are read and recharged, the number used, and review the calibration procedure or leak test procedure.

   Evaluate the adequacy of the licensee's procedures or system for evaluating and using personnel monitoring data to control and minimize exposures. The licensee should account for occupational radiation doses to personnel resulting from exposures to licensed material and other unlicensed radiation sources (e.g. x-ray machines). If applicable, review the implementation of Regulatory issue Summary 2002-06.

2. Review reports of exposure summaries generated since the last inspection to determine that licensee's performance is in accordance with regulatory requirements.

3. Review the records of all persons who received planned special exposures since the last inspection. Determine that exposure histories are on file for these individuals.

4. Determine, by discussion with supervision, if minors have been permitted to work in restricted areas and, if so, determine that licensee's performance is in accordance with 10 CFR 20.1207 by review of exposure records.

5. For licensees who are required to monitor in accordance with 10 CFR 20.1502, review of all "Occupational Dose Record(s) for a Monitoring Period" Forms (NRC Form 5) may be appropriate, depending on the number of monitored personnel. For licensees who are not required to monitor, due to the lack of a likelihood that any worker would receive more than 5 millisieverts in a year, a sampling of Occupational Dose Records (NRC Forms 5) generated as a result of voluntary monitoring may be appropriate. If a licensee is not required to monitor and chooses not to monitor worker exposures, the inspector need only review the licensee's presumptive analysis of exposures and verify the assumptions used in that analysis.

b. Internal Exposure

1. During review of exposure evaluations in 03.03b4 below, verify that the licensee's performance is in accordance with internal exposure limits.

2. Review randomly selected air sampling and bioassay records.

3. By observation, discussion, and review of documentation, verify that engineering controls are considered and used to the extent practicable. Evaluation of process and engineering controls incorporated as part of the facility or equipment as licensed will be performed in the licensing process; the inspection program will evaluate the use of other engineering controls. In situations where a review for licensing is not applicable, such as medical licensees, review these items to the extent practicable to ensure that they comply with descriptions in license applications, or conform to license conditions.

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4. Review documentation of evaluations performed as the result of unplanned exposures. Verify the appropriateness of preventive measures instituted following an unplanned exposure.

c. Respiratory Protection

1. Determine that the equipment is certified by NIOSH/MSHA or otherwise approved by DEP.

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2. Determine proper selection of equipment.

3. Determine by review of records and by discussions that a maintenance and training program is conducted and that it is administered and conducted in accordance with written procedures. Determine by review of records, discussions, and observations that respirator users are individually fitted for respirators and that respiratory equipment is operationally tested immediately prior to each use.

4. Randomly select several control requirements and determine compliance; by review of records, by discussions, or observation.

5. In taking credit for the protection provided by the use of respiratory protective equipment, 10 CFR 20.1703 requires that the protection factor be greater than the multiple by which peak concentrations are expected to exceed the values of Table 1, Appendix B, Column 3 of 10 CFR Part 20, unless ALARA

considerations indicate otherwise. Verify that this criterion is considered in selecting respirators.

03.05 Posting, Labeling, and Control

a. Posting and Labeling. Inspect representative areas to verify compliance; pay particular attention to "temporary" work areas that may be required for maintenance activity, newly established work areas, etc.

Inspect a random sampling of containers in work or storage areas.

b. Control

1. Randomly select high radiation or very high radiation areas to verify that access is controlled in accordance with regulations or license requirements.

2. Inspect areas where radioactive material is located or stored in an unrestricted area.

3. Review a random selection of radiation work permits (RWPs) on file and those currently in effect.

4. Review a random selection of records (e.g., radiation level surveys, interlock tests, audible & visible alarm test results) and inspect work areas to verify licensee's controls ensure the safety of workers and members of the public.

c. Posting of Notices. Determine, by questioning of management, how the licensee performs in accordance with the requirements of 25 Pa. Code 220.2; inspect bulletin boards or other places where notices are posted; question a few individuals to determine if they are aware of the posting of notices.

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03.06 Surveys

a. Requirements. Verify that the licensee has established schedules for periodic surveys of work areas of the plant and facility site; verify that surveys are conducted using approved procedures; review a random selection of survey records to see that surveys are being performed according to schedules; verify that the survey results are reviewed by appropriate supervision; verify that corrective actions have been taken, as appropriate. Attempt to observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys.

Verify specifically that schedule and procedural requirements for surveys appear adequate to demonstrate compliance with the following aspects of the regulations and with pertinent license requirements.

1. 10 CFR 20.1201 (permissible doses)

Determine whether due consideration is given to energy, beta exposure, and extremity exposure, and whether neutron surveys are performed if appropriate.

2. 10 CFR 20.1203 and 20.1204 (exposure to airborne radioactivity)

Determine whether both particulates, non-noble gases and vapors are considered, if appropriate.

3. 10 CFR 20.1902 (posted areas)

4. 10 CFR 20.1301 (radiation in unrestricted areas)

b. Leak Tests. Inspect a random selection of records of leak tests of radioactive sealed sources.

03.07 Notifications and Reports

a. To the DEP. The objective is to determine if the licensee is reporting all the events and data required by the regulations and the license. The inspector should have reviewed those reports submitted since the last inspection; therefore, a determination should be made whether events have occurred which have not been reported. A discussion with management, operating personnel, maintenance, and health physics personnel, and review of RWPs, log books, and other data during the course of the inspection should aid in this determination.

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b. To the Individual. Determine by discussion with individuals selected at random (identified during the course of inspection of other requirements) whether they were notified in accordance with 10 CFR 19.13 incorporated by reference.

03.08 ALARA. For decommissioning licenses, ALARA programs are part of the health and safety plan in the license application. The programs are reviewed periodically by the Department. Materials licensees of high inspection priority should have very active ALARA programs that are identified in the license applications or license conditions, while for lower priority licensees only limited ALARA programs may exist. ALARA programs for GL licensees or those with 7 year inspection frequencies may be nonexistent.

The depth of the ALARA programs will depend on the quantities of radioactive materials possessed and used, and whether the potential for radiation exposures can be significant. For example, licensees such as users of gas chromatographs may have no formal ALARA program because radiation exposures are very small. Nevertheless, even in such cases, consideration should be given to minimizing exposures. The following guidance should be used as applicable or at the inspector's discretion (compare to guidance outlined in Section 02.08).

a. Facility personnel should be made aware of management's commitment to keep exposures to workers ALARA. The commitment should appear in policy statements, instructions to personnel, and similar documents. As a minimum, workers should be familiar with the ALARA commitment so that they can explain what the commitment is, what ALARA means, why it is recommended, and how they have been advised to implement it on their jobs. Examine a selection of policy standards and instructions (if they exist) and interview workers to determine if they understand the ALARA philosophy and what it means at the work place.

b. As a minimum, management should be able to discuss which operating procedures were reviewed, in which locations most exposures are being received, what groups of workers are receiving the highest exposures, what discussions they have had with the radiation protection staff or outside consultants, and what steps have been taken to reduce exposures. Examine a random sample of records and interview personnel to determine what has been done to reduce exposures.

c. No guidance.

d. No guidance.

e. Radiation workers should understand how radiation protection relates to their job and should be retrained at least annually, or as otherwise stated in the license application. Training should be sufficient to ensure that workers can correctly answer questions on radiation protection as it relates to their jobs. Interview workers (consistent with the size of the program) to determine if the workers understand radiation protection as it relates to their jobs and if they have an opportunity to discuss radiation safety with the radiation protection staff.

f. Inquire if modifications have been made to facilities and equipment to reduce exposures. Randomly examine any procedures or records that reflect modifications and attempt to determine the extent of the benefits gained through modifications (for example, modifications may have been beneficial if exposures of 50 mrems/hour were reduced by a factor of 10 to 5 mrems/hour. It may not be beneficial to reduce 1 mrem/hour to 0.1 mrem/hour, considering cost and risk. In both of the above examples, consideration must be given to costs of modification and risk to the population). Verify that ALARA measures do not disproportionately increase the risks from non-radiological hazards, such as industrial hazards.

g. Examine any Radiation Safety Committee records or other records on ALARA policies to determine whether source-term surveys or time motion studies have been conducted and actions taken to reduce significant exposures.

h. No guidance.

i. Examine equipment and supplies to determine if they adequately protect personnel from unnecessary radiation. Such equipment and supplies may include, but are not limited to, decontamination supplies, survey meters, protective clothing, ventilation systems, air sampling equipment, and supplies used for posting areas, such as radiation areas.

END

DEP INSPECTION MANUAL

INSPECTION PROCEDURE 83890

CLOSEOUT INSPECTION AND SURVEY

83890-01 INSPECTION OBJECTIVE

01.01 To ensure that Final Surveys performed at material licenses are conducted as stated in the licensee's decommissioning plan (DP).

01.02 To verify that the sites have been decontaminated to acceptable radiological levels for unrestricted or restricted use and to insure all radioactive sources have been properly dispositioned.

83890-02 INSPECTION REQUIREMENTS

02.01 Preliminary Review. Review the licensee's Decommissioning Plan to determine the scope of site contamination and the licensee's decontamination and final survey program.

02.02 Inspection of Final Surveys and Disposition of Materials

a. Verify, by inspection, the licensee's implementation of the final survey program to confirm the acceptability of the final survey results. See Appendix A, "Final Survey Program Inspection Area," for a detailed inspection checklist for the licensee's final survey program.

b. Confirm, by inspection of records (inventory, transfer, disposal, etc.), that licensed material is being, or has been, transferred to an authorized recipient.

c. Confirm, by inspection of records, that materials and equipment are released in accordance with all applicable regulations and license conditions.

d. Verify, by inspection of the licensee's facility that licensed material and radioactive/contaminated equipment, materials, scrap, etc. are not being used or stored. This should be done following receipt and evaluation of reports of the facility's status as required by 10 CFR 30.36, 40.42, and 70.38.

02.03 Confirmatory Surveys. NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual," (MARSSIM) defines a confirmatory survey as "a type of survey that includes independent (third-party) measurements, sampling, and analyses to verify the findings of a final status survey." Surveys and sampling should be conducted simultaneously with the licensee during the licensee's final status surveys. The inspector should collect side-by-side or split samples with the licensee for comparative purposes, as well as comparing infield instrument readings and sensitivity. Where practical, counting samples previously collected and counted by the licensee is also acceptable. In areas where work-in-process surveys cannot be conducted, or samples collected, after-the-fact confirmatory surveys and sampling may be performed. Sites where DEP's work-in-process surveys and sampling have not identified significant weaknesses in the final survey program may not require after-the-fact surveying and sampling. However, after-the-fact confirmatory surveys may be required for sites where significant unresolved weaknesses were previously identified or where repetitive violations were identified. The goal is to conduct sufficient confirmatory surveys and

sampling so that the DEP can conclude that the licensee's survey program is being implemented in a manner that provides confidence in the results. The in-process approach has resulted in significant savings in cost, assured a more accurate final status survey, and helped the licensee in maintaining its release schedule.

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The lead BRP office for the facility will review each proposed retirement of expired, superseded, or terminated license to determine the necessity of performing a confirmatory survey. The review will be on a case-by-case basis using the following criteria.

a. Those facilities that meet the following criteria do not require a confirmatory survey:

   1. The licensee has conducted an adequate closeout survey.

   2. Use has been limited to small quantities of radionuclides with half-lives of 120 days or less.

   3. The use of sealed sources only (if leak tests have been <0.005 μCi).

   4. The use of limited materials that pose a very low risk to public health and safety.

b. Those facilities that meet the following criteria do require a confirmatory survey:

   1. Partial site release where in-process inspection is not practical.

   2. Repetitive Violations.

   3. Significant lack of Public or Congressional confidence with clean-up efforts at the site.

   4. Significant unresolved weaknesses identified during the inspection of the licensee's final survey program.

02.04 The Conduct of Confirmatory Surveys. If a confirmatory survey is necessary, it should be performed to determine if the licensee's results are accurate and sufficient to demonstrate that the facility meets DEP requirements.

02.05 Reports and Records

a. For licensees subject to the reporting requirements, verify by reviewing records and files that:

   1. Personnel exposure and monitoring reports required by 10 CFR 20.2206 have been submitted to the DEP for the calendar year in which the license has expired or is being terminated, and

   2. Reports of personnel exposures for terminated employees or employees no longer working with radioactive materials required by 10 CFR 19.13 have been submitted to both the DEP and the employee.

b. Determine what plans or arrangements have been made for preserving records required by 10 CFR §§ 20.2102-20.2110.

02.06 Burial of Waste. Determine if waste has been buried onsite. If burial has occurred, review the licensee's actions to historically assess, characterize, survey, and

model the burial site. The licensee should model its former burial sites for compliance with 10 CFR Part 20, Subpart E.

02.07 Final Inspection Report. Prepare a final inspection report which summarizes the actions taken under this inspection procedure and the findings and evaluations of the inspection staff.

83890-03 INSPECTION GUIDANCE

03.01 Preliminary Review. Review the general licensing history of the facility and the regulations for license termination.

03.02 Inspection of Final Survey. Review any license conditions related to decontamination of the facility, the decommissioning plan, any approved final survey programs, and/or final survey reports, as applicable. The inspection of the licensee's final survey program should occur while the licensee is in the process of performing the final survey. The purpose of this "in-process' final survey inspection is to provide confidence that the licensee's survey results are accurate and representative of the condition at the facility. See Appendix A, "Final Survey Program Inspection Area," for detailed inspection checklist for the licensee's final survey program.

03.03 Confirmatory Survey Preparation. Review license records such as the DP for types of radioactive material used onsite, the occurrence of any significant safety issues, and any special concerns about the site expressed by stakeholders. Also review NUREG-1575, MARSSIM.

03.04 Conduct of Confirmatory Surveys. It may be necessary for DEP, or an DEP contractor, to conduct confirmatory measurements to provide supplemental information after the licensee has completed its final survey, in addition to the findings of the in-process inspection, to ensure that the survey results reported by the licensee are accurate and representative of the conditions at the facility. However, comprehensive confirmatory surveys should only be necessary if there is significant doubt about the licensee's final survey results. For example, a confirmatory survey would be needed if an in-process inspection of the licensee's final survey program identifies significant, unresolved weaknesses that are not administrative in nature (i.e., measurement results and/or soil concentration levels in units not comparable to the release criteria, inadequate classification of an area, or improper instrument calibration), licensee has a history of repetitive violations that reduce DEP 's confidence in the survey results; significant lack of public or Congressional confidence in clean-up efforts at the site; or the site is too small (e.g., partial site release) for an in-process inspection. Note that the inspector may perform limited measurements (split samples, "side-by-side," direct measurements, etc.) as part of the in-process inspection of a licensee's ongoing final survey program. During the inspection, buildings, rooms, furniture, systems and equipment; ventilation ducts, filters, sinks, drains, traps and sumps; overhead fixtures, walls and floors, etc., should all be considered as areas to be surveyed.

03.05 Reports and Records. Although certain licensees are not required to report personnel exposures, and the limitations of a license removes the legal obligation to maintain the records required by 10 CFR 20.2101-20.2110, the licensee should be informed that retention of these records is highly recommended. Licensee should be informed the record keeping requirements for decommissioning.

03.06 Final Inspection Report. The final inspection report becomes the official certification of the disposal of licensed material. The final inspection report forms the basis for retiring and eventually disposing of both the licensing and inspection files.

END

APPENDIX A

FINAL SURVEY PROGRAM INSPECTION AREA

I. CONSIDERATION FOR DESIGNING FINAL STATUS SURVEY INSPECTION

A. Has the final survey report been submitted to DEP?

B. Has the licensee final survey program been previously inspected?

C. If the final survey report is not submitted, is the licensee's final survey in-process?

D. Has the final survey plan been submitted and approved by a DEP license reviewer?

II. INSPECTION AREAS FOR LICENSEE FINAL SURVEYS

A. Inspections should be made against commitments in the DP and the licensee's final survey plan (which would have been approved during Decommissioning Plan (DP) review).

B. For facilities that require a significant decontamination effort, all the inspection areas listed below should be inspected while the licensee's final survey program is in progress. For facilities that do not require a significant decontamination effort, only some of the inspection areas below may apply, and it may not be practical to inspect these areas until after the licensee's final survey is completed and the licensee's final survey report has been submitted to DEP.

C. Inspection of a licensee's final survey may include independent confirmatory measurements by the inspector or DEP contractor. The extent of the confirmatory measurements, and whether the use of an DEP contractor is warranted, depends on a number of factors that are discussed in Section II.B. In most cases, limited in-process confirmatory surveys should be sufficient.

D. For each inspection, the inspector should identify which inspections (listed below) are covered.

III. LICENSEE FINAL SURVEY PLANS AND PROCEDURES

A. Determine if all potential contaminants have been identified.

B. Review the Organization and Responsibilities for adequacy/completeness:

1. Survey program documentation

2. Responsibilities and qualifications of the survey staff

C. Review the Quality Assurance/Quality Control program for adequacy / completeness:

1. Organizational structure

2. QA Program

3. Document Control/Records Management program

4. Equipment Maintenance and Control program

5. Audits and Corrective Action program

D. Determine if the laboratory analytical procedures, including QA/QC, are acceptable, and if the results are adequately documented.

E. Determine if the licensee prepared an adequate Final Status Survey (FSS) plan in accordance with guidance documents.

F. Determine if the field and laboratory instrumentation used, or planned to be used, were adequate/appropriate for scanning, direct measurements, and analysis for the radionuclides of concern (ROCs).

G. Determine if the calibration accounted for the ROCs

H. Review ROCs, area classification, survey unit size, estimated mean and standard deviation.

I. Review the methods used to address the impact of multiple ROCs in FSS planning.

J. Review instrument use procedures:

1. Minimum Detectable Concentration (MDC) calculations

2. Actual vs. required scan sensitivity; and

3. Calibration, including accounting for multiple radionuclides and any environmental factors that may influence instrument performance.

K. Select survey units/areas for confirmation:

1. Determine scan coverage based on classification.

2. Review analytical procedures for appropriateness for measuring the ROCs.

3. Cross-check FSS data packages against plan requirements.

L. For soil sampling, determine sampling depth requirements and sampling intervals. At a minimum, samples should be collected from anomalous or other judgmental areas, together with selected licensee-archived samples, for confirmatory analysis. The necessity for, and the specific numbers of, other random/systematic samples should be separately evaluated, using the Data Quality Objectives (DQO) process.

M. For structure surfaces, direct measurements should include, at a minimum, anomalous or judgmental areas and comparative measurement locations. The necessity for, and the specific numbers of, other random/systematic samples should be separately evaluated, using the DQO process.

N. If project documentation is complete, accurate, and represents current radiological conditions relative to the release criteria, then recommend acceptance; if insufficient, then provide technical comments.

O. Calculate action levels to investigate anomalies identified during verification/confirmatory surveys.

P. Evaluate each anomaly identified during verification/confirmatory surveys, for compliance.

1. Is it acceptable relative to size and concentration?

2. Has the licensee adequately addressed it?

3. Is it within the bounds of survey unit classification?

Q. Review if confirmatory analyses or measurements agree with the site's reported results.

R. Review if systematic agreement (randomly selected) and judgmental (location selected using professional judgment based on site knowledge) samples and measurements are less than the Derived Concentration Guidance Level.

IV. DEP CONFIRMATORY SURVEY

A. Review whether or not a confirmatory survey is justified.

1. Significant, unresolved, weaknesses identified during the inspection of the licensee's final survey program.

2. Repetitive violations

3. Significant public, legislative or Congressional interest

4. Partial site release where an in-process inspection is not practical

B. If a confirmatory survey is justified, determine if a DEP Contractor should be used. Meeting one or more of the three criteria listed below will, in general, justify the use of a contractor.

1. Licensee's final survey involves unique or complex technical issues.

2. Confirmatory survey is expected to require more than a person-week effort to complete field surveys and sampling.

3. Confirmatory survey is very high priority project that cannot be completed by DEP staff in a timely manner.

END

NOTE: Some licensees are decommissioning under NUREG/CR-5849. NUREG 1575 Rev.1 should not be applied to these licensees.

DEP INSPECTION MANUAL

INSPECTION PROCEDURE 84850

RADIOACTIVE WASTE MANAGEMENT - INSPECTION OF WASTE GENERATOR REQUIREMENTS OF 25 PA CODE CHAPTERS 219 and 236

PROGRAM APPLICABILITY: 2602 and 2800

84850-01 INSPECTION OBJECTIVE

To determine whether the licensee has established and is maintaining adequate management-controlled procedures and quality assurance that reasonably ensure compliance with the requirements of 25 PA Code Chapter 219 and 25 PA Code Chapter 236 applicable to low-level radioactive waste form, classification, stabilization, and shipment manifests/tracking.

84850-02 INSPECTION REQUIREMENTS

02.01 Management Controls. Review the licensee's written procedures for radioactive waste processing, specifically identifying the primary documentation thereof. Verify that the following aspects are adequately addressed:

a. That the individual(s) and organizational entities that have been assigned the responsibility for radioactive waste processing for low-level land burial have been clearly designated in writing;

b. That there has been a clear delineation of the authorities and responsibilities of those individuals and organizational entities;

c. That written management-approved instructions have been established to carry out the various radioactive waste processing and packaging activities, including authorized changes thereto, and the promulgation/distribution of such instructions to the appropriate line/staff organization.

02.02 Quality Assurance (QA). Verify that the licensee has established and maintains an adequate QA program to ensure compliance with the waste classification and characterization requirements of 10 CFR 61.55 and 61.56 (or 25 Pa. Code Chapter 236 Subchapter F). Verify whether the QA program includes the required audits and management evaluation of such audits. Review the results of the most recent audit and corrective actions [Subsection III.A.3 of Appendix G to 10 CFR Part 20 (or 25 Pa 236.533)].

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02.03 Waste Manifests. Review the licensee's procedures and records to verify that each shipment of radioactive waste intended for offsite disposal to a broker or a licensed land disposal facility is accompanied by a shipment manifest that includes all the required information [10 CFR 20.2006(b) and (c)] (or 25 Pa. Code Chapter 236 Subchapter F if utilizing a licensed land disposal facility in Pennsylvania.)

02.04 Waste Classification. Review the licensee's documentation and records of activities that have been established and are being maintained, to ensure that all low-level radioactive wastes are properly classified according to 10 CFR 61.55 (or 25 Pa. Code Chapter 236 Subchapter F if utilizing a licensed land disposal facility in Pennsylvania.) Verify whether such efforts reasonably ensure that a realistic representation has been accomplished [Subsection III.A.1 of Appendix G to 10 CFR Part 20].

02.05 Waste Form and Characterization. Review the licensee's documentation and records of activities, which have been established and are being maintained, to ensure that all low-level radioactive waste meets the waste characteristics of 10 CFR 61.56 (or 25 Pa. Code Chapter 236 Subchapter F if utilizing a licensed land disposal facility in Pennsylvania.) Verify whether the methods and determinations of the licensee provide reasonable assurance that the waste form requirements are met [Subsection III.A.1 of Appendix G to 10 CFR Part 20].

02.06 Waste Shipment Labeling. Review the licensee's procedures and records to verify that each package of radioactive waste intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of 10 CFR 61.55 [10 CFR 61.57 and Subsection III.A.2 of Appendix G to 10 CFR Part 20] (or 25 Pa. Code Chapter 236 Subchapter F if utilizing a licensed land disposal facility in Pennsylvania.)

02.07 Tracking of Waste Shipments. Review the licensee's procedures and records, to verify that a system has been established to forward to recipients or deliver to waste collectors, at the time of shipment, a copy of the waste manifest. Verify that acknowledgment of receipt of the manifest is obtained. Verify that the licensee has a procedure in place to effect an investigation in any instances wherein acknowledgment of receipt of shipment has not been received within the specified period. Verify that procedures are in place to report such investigations to the appropriate DEP Regional Office and file the required written report. [Subsection III of Appendix G to 10 CFR Part 20 or 25 Pa. Code Section 236.537].

02.08 Disposal Site License Conditions. Review the licensee's procedures and records to verify that the applicable disposal site license conditions are being met. Verify that the licensee has on file a current version of the disposal site license.

84850-03 INSPECTION GUIDANCE

Additional general guidance for inspectors as well as licensees is available through the NRC's Low Level Waste Management Branch (NMSS) in the form of branch technical positions (BTPs) and "topical reports" of licensees that have been reviewed by NMSS. See attached references.

03.01 Specific Guidance

a. Inspection Requirement 02.01, Management Controls. Inspection effort should be directed at verifying that written procedures have been established in a manner approved by management. The procedures should be readily available to any persons having responsibility for low-level waste classification and preparation for transfer of such wastes to land disposal facilities. The inspector should confirm

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that the written procedures include provisions for all of the applicable activities pertaining to Section 84850-02 requirements.

b. Inspection Requirement 02.02, Quality Assurance (QA). The written operating procedures and QA procedures of the licensee collectively are intended to accomplish compliance with the 10 CFR Part 20 and 10 CFR Part 61 regulatory requirements (or 25 Pa 236.533). The nature and scope of the licensee's QA program will vary depending on the nature and complexity of the specific waste stream. Inspectors should observe whether the program and procedures are effective in causing the licensee to perform the required waste form classification and characterizations when changes to the waste stream occur.

c. Inspection Requirement 02.03, Waste Manifests. Inspectors should be aware that it is permissible for the licensee to use the same shipping paper documents that are required to meet U.S. Department of Transportation shipping paper and U.S. Environmental Protection Agency hazardous waste requirements, as the waste-manifest, provided that the combined documentation contains all of the information required by Appendix G to 10 CFR Part 20. Additional waste manifest information may also be required by the operator of the land disposal facility.

d. Inspection Requirement 02.04, Waste Classification. The inspector should review whether the method used by the licensee is adequate to determine radionuclide concentrations, in order to classify his waste. The NRC's NMSS BTP on waste classification describes four acceptable methods for classifying wastes. The inspector may use this BTP as guidance in implementing this inspection requirement.

e. Inspection Requirement 02.05, Waste Form and Characterization. The inspector should determine the test methods and acceptability of such tests used by the licensee to characterize his waste stream. In cases where a "high integrity container" is used to stabilize the waste, the type and acceptability of the specific container should be verified. Waste form and characterization requirements of 25 Pa. Code Chapter 236 Subchapter F must be satisfied if utilizing a licensed land disposal facility in Pennsylvania. Otherwise, the inspector may use the NRC's NMSS BTP on waste form for guidance in implementing this inspection requirement. In addition:

1. Classes B and C solidified waste programs should contain test data on compressive strength, leaching, irradiation stability, biodegradation, and thermal stability. Results of tests should be consistent with the BTP on waste form. Test data packages that do not address all of the above areas may be acceptable, provided that testing is under way to complete the data package. A schedule for completion of the testing should be available for NRC inspection. Solidification media currently being used (cement, vinyl-ester-styrene, asphalt) are acceptable waste forms for shipment and burial, provided that qualification testing is in progress and there are procedures and controls in use to ensure the consistent production of waste capable of existing as a free-standing monolith.

2. The licensee's solidification process control program should incorporate the testing information from the solidification agent stability qualification.

3. NRC-approved topical reports on high integrity containers and solidification agents are acceptable for demonstrating compliance with 10 CFR 61.56(b).

4. A Certificate of Compliance issued by a State for a high integrity container is acceptable for demonstrating compliance for waste shipped to that State.

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Deleted: 1. . For those licensees who use correlation factors for classifying wastes, correlation factors should be based on actual waste stream analysis.¶
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2. . Generic pressurized water reactor (PWR), boiling-water reactor (BWR) or facility scaling factors are acceptable if actual sample analysis data correlate with the generic data base.¶
¶
3. . If generic scaling factors are not appropriate for an individual waste stream, scaling factors should be based on the specific waste stream data.¶
¶
4. . *It is acceptable to base correlation* factors on a single set of analyses, repeated annually.¶
¶
5. . If sample analyses have not been completed, calculational methods for scaling factors are acceptable while analyses are in progress. Samples should be off site for analysis to be considered in progress. After receipt of the sample analyses, calculational methods may continue to be used provided the results correlate with the actual sample analyses.¶
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6. . NRC-approved topical reports for waste classification are acceptable for demonstrating compliance with 10 CFR 61.55.¶
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f. Inspection Requirement 02.06, Waste Shipment Labeling. Inspectors as well as the licensee should be aware that Classes A, B, & C wastes bear no relationship to Types A or B packaging for transport purposes under 49 CFR Part 173 or 10 CFR Part 71. The labeling of waste packages pursuant to this requirement is, therefore, in addition to any other package markings and labels required by the transport regulations.

g. Inspection Requirement 02.07, Tracking of Waste Shipments. In addition to the tracking and acknowledgement requirements of 25 Pa. Code Chapter 236 Subchapter F for land disposal sites in Pennsylvania, inspectors should be aware of the differences in the requirements of Appendix G to 10 CFR Part 20 on waste manifest tracking for shipments by generators to waste collectors, as opposed to shipments directly to land disposal facilities. There are also some differences in the specific requirements of a waste collector who processes the waste before shipping it to the disposal facility, as contrasted with a collector who simply stores the material before transferring it to the land disposal facility.

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84850-04 REFERENCES

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04.01 Regulations

10 CFR 20.1001 - 20.2402 (Incorporated by reference)

10 CFR Part 61 (Referenced through 10 CFR Part 20)

25 Pa. Code Chapter 236 Subchapter F

04.02 Other References

Federal Register, Vol. 48, No. 110, June 7, 1983, NRC Notice, "Low-level Waste Licensing Branch Technical Position Papers on Radioactive Waste Classification and Waste Form; Availability."

Federal Register, Vol. 56, No. 18, January 28, 1991, NRC Notice, "Staff Technical Position on Radioactive Waste Form; Availability."

"Technical Position on Radioactive Waste Classification," mailed to all NRC licensees on May 11, 1983, by NMSS, Low-level Waste Management Branch.

"Waste Form Technical Position Paper, Revision 1," mailed to all NRC licensees on January 24, 1991, by NMSS, Low-level Waste Management Branch.

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Federal Register, Vol. 48, No. 175, Sept. 8, 1983; NRC Notice "Topical Reports in Support of the Implementation of Waste Classification and Waste Form Requirements."

END

DEP INSPECTION MANUAL

INSPECTION PROCEDURE 84900

LOW-LEVEL RADIOACTIVE WASTE STORAGE

PROGRAM APPLICABILITY: 2602 and 2800

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84900-01 INSPECTION OBJECTIVES

To determine whether materials licensees who store low-level radioactive waste (LLW) are doing so safely and in accordance with license conditions. This procedure may be applied to any licensee who stores LLW, regardless of when the storage facility was established.

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84900-02 INSPECTION REQUIREMENTS

02.01 Management Controls and Surveys. Review the license file and identify any special authorizations and requirements for LLW storage. Determine where LLW is being stored. Review how long the LLW has been stored and examine the licensee's accountability and security procedures for the waste. Determine whether the licensee is within the authorized possession limits. Review the licensee's procedures for safe placement, inspection and repackaging of LLW in storage. Determine whether or not the licensee has conducted and properly documented: (1) inspections of LLW packages to assure they maintain integrity; (2) radiation surveys of individual packages and the storage area, in general; and (3) any required effluent sampling. Review the licensee's records for waste placed in storage, and determine whether they are adequate to account for the LLW stored

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02.02 Adequacy of Storage Area. Inspect the storage area(s) to assure its adequacy with respect to:

a. Access control and security.

b. Access to, and housekeeping around waste packages. Adequate lighting should be provided to permit identification of unsafe radiological and non-radiological conditions.

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c. Stable placement of waste or waste packages.

d. Protection from environmental elements, fire and flooding, avoidance of temperature/humidity extremes, and ventilation considerations.

e. Posting and labeling.

02.03 Package Integrity and Labeling. Examine several waste packages to determine whether the packages are adequate for the expected term of storage. Determine whether the type of packaging maintains the package integrity and that the packages are properly labeled.

84900-03 INSPECTION GUIDANCE

General Guidance

As noted in NRC Information Notice 90-09, LLW storage areas or facilities are being added by licensees as interim measures until their States or Regional Compacts construct LLW disposal facilities. Some licensees already have LLW storage facilities. Depending on the specific situation of a State or Compact, LLW may be in storage for anywhere from several months to several years. In general, because the safety hazard of LLW storage facilities--especially for dry LLW storage--is low, extensive inspection efforts are not warranted. The inspection effort, therefore, should be geared toward assuring that licensees who are storing LLW for such periods are in compliance with possession limits and license conditions, and do not develop an "out-of-sight, out-of-mind" attitude. This will best be done by examining the licensee's records to ensure that the required surveys, inspections and accountability checks are being done and then following up with a physical examination of the storage area and waste containers/packages.

Specific Guidance

03.01 Management Controls and Surveys. Determine whether the procedures for placement, inspection and repackaging of LLW are clear and available to all who need to use them, and that they have been approved by management. Confirm that inspections and surveys of stored LLW have been performed at the required frequency and properly documented, and that the licensee has conducted and properly documented all required effluent sampling. Review the results of inspections and surveys of LLW in storage focusing on licensee follow-up actions to problems identified. Check the licensee's records on LLW storage, determine whether the records provide accountability and determine how long LLW has been in storage. Confirm that the licensee is within authorized possession limits. Confirm that any required checks of fire protection systems have been performed.

03.02 Adequacy of Storage Area. Confirm that LLW is stored in a restricted area and is secured against unauthorized removal. Check that waste containers are visible to allow routine inspection and that they are readily accessible to licensee personnel. Confirm that the placement or stacking of containers is stable and that containers are not deformed under load, or likely to fall. Determine that ALARA considerations are used in the placement of the higher activity waste containers in the storage area. Check that the storage area is posted in accordance with 10 CFR Part 20 requirements.

Confirm that the containers are protected from reasonably expected environmental conditions, including fire and flooding, and that the storage location is not subject to extremes of temperature or humidity (i.e., near a boiler room, laundry area, etc.) Check ventilation of the storage area to determine if it is sufficient to prevent build-up of any gases produced by waste decomposition.

03.03 Package Integrity and Labeling. Examine a representative number of packages for signs of swelling, leakage, deformation or deterioration (i.e., rusting or other corrosion which may lead to breach).

Check to determine that the licensee's packages are clearly and properly labeled in accordance with 10 CFR 20.1904 and 20.1905 and that low level radioactive waste is transferred or disposed in accordance with 10 CFR 20.2006.

84900-04 RESOURCES

Most licensees currently have access to a low level waste disposal facility, and it is therefore expected that most of these licensees will not require extended storage of their generated wastes. Therefore, the resources required to implement this procedure are expected to be minimal, unless access to LLW storage facilities becomes unavailable to licensees.

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84900-05 REFERENCES

NRC Information Notice No. 89-13, "Alternative Waste Management Procedures in Case of Denial of Access to Low-Level Waste Disposal Sites," February 8, 1989.

NRC Information Notice No. 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," February 5, 1990.

NRC Information Notice No. 93-50, "Extended Storage of Sealed Sources."

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INSPECTION PROCEDURE 86740

INSPECTION OF TRANSPORTATION ACTIVITIES

PROGRAM APPLICABILITY: 2602 and 2800

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86740-01 INSPECTION OBJECTIVES

To determine whether the licensee has established and is maintaining an effective management-controlled program, to ensure radiological and nuclear safety in the receipt, packaging, delivery to a carrier and, as applicable, the private carriage of licensed radioactive materials; and to determine whether transportation activities are in compliance with 25 Pa. Code Chapter 230 and the applicable PADOT, Nuclear Regulatory Commission (10 CFR Parts 20 and 71) and Department of Transportation (DOT) (49 CFR Parts 171-178) transport regulations incorporated by reference.

This inspection procedure is organized into two sections: Section 1 covers basic transportation requirements found in 10 CFR Part 20, 10 CFR Part 71, Subpart A, and 49 CFR Parts 171-177. Section 2 covers additional transportation requirements found in 10 CFR Part 71, Subparts C, G, and H, and corresponding parts of 49 CFR.

Use Section 1 to inspect all licensees. Determine whether the licensee meets the exemption criteria in 10 CFR Part 71 Subpart B. If the licensee meets the exemption criteria, the inspection may be concluded after conducting Section 1; Section 2 does not apply. If the licensee does not meet the exemption criteria, use both Sections 1 and 2 to conduct the inspection.

86740-02 INSPECTION REQUIREMENTS

SUBSECTION A BASIC REQUIREMENTS

02.01 Preparation of Packages for Shipment. Examine the licensee's written procedures and shipment records. As the situation allows, observe actual package preparations and operations so as to:

a. Preliminary Determinations. Verify that before the initial use of any packaging, the licensee performs the required "preliminary" determinations and quality control relating to construction of the packaging (49 CFR 173.474).

b. Routine Determinations. Verify that before each use of any packaging the licensee performs the required "routine" determinations and quality control (49 CFR 173.475 and 10 CFR 71.87).

c. Liquid Package Requirements

1. Verify that for non-low specific-activity (LSA) Type A packages with liquid contents, the licensee has provided for the required special testing, double containment system, and absorbent material, as appropriate [49 CFR 173.412(k)].

2. Verify that when required for packages containing liquid contents exceeding a Type A quantity and destined for air shipment, a test for leakage is performed on the containment system [49 CFR 173.475(g)].

d. Packaging Marking. Verify that the licensee has marked the package with the applicable general and specific package markings that are required (49 CFR 172.300 - 310). Note that 49 CFR 172.324 addresses reportable quantity (RQ) markings on packages).

e. Package Labeling. Verify that for non-exempted packages, the licensee provides for and accomplishes labeling of each package with the appropriate category of RADIOACTIVE (White-I, Yellow-II, or Yellow-III) label, one each on two opposite sides of the package; and accurately completes the entry of the required information in the blank spaces thereon (49 CFR 172, Subpart E).

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f. Radiation Monitoring. Verify that the licensee provides for and accomplishes monitoring of each completed package, to ensure that external radiation and removable surface contamination are within the allowable limits [49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.475(i), and 10 CFR 71.87(i) and (j)].

02.02 Delivery of Completed Packages to Carriers. Examine the licensee's written procedures, shipment records, and as the situation allows, observe actual transport operations.

a. Shipping Paper Documentation. Verify whether the licensee prepared the required shipping paper documentation, and accurately included all the applicable required elements of information, including the shipper's certificate. [NOTE: for licensee private motor vehicle shipments, the certificate is not required (49 CFR 172.204(b))].

In the case of low-level solid radwaste shipments to licensed land burial sites (10 CFR Part 61), verify that the shipping paper documentation also includes the required additional "waste manifest" information (Appendix G, 10 CFR Part 20).

b. Loading and Placarding Non-Exclusive-Use Shipments. Verify that the licensee provides to a highway carrier, or applies directly to a rail vehicle, the required placards, whenever the licensee delivers any quantity of RADIOACTIVE-Yellow-III labeled packages to such carrier for transport (49 CFR 172.506 and 508).

c. Loading and Placarding Exclusive-Use Shipments

1. Verify that the licensee ensures that the package and vehicle radiation/contamination levels are within the regulatory limits (49 CFR 173.441 and 443).

2. Verify that, except for uranium or thorium ores, the transport vehicle is placarded by the licensee when delivering to a carrier any exclusive-use shipment for which placarding is required [49 CFR Part 172, Subpart F, and 49 CFR 173.427(a)(6)(v)].

3. Verify that shipping paper documentation provided by the licensee to the carrier contains satisfactory instructions for maintenance of exclusive-use shipment controls [49 CFR 173.441(c) and (e) and 49 CFR 173.427(a)(6)(iv)].

4. Verify that for exclusive-use shipments of LSA materials, the licensee has provided for the additional specific requirements [49 CFR 173.427(a), (b), or (c)].

d. HAZMAT Employee Training. Verify that persons involved in the packaging preparation and transport have received proper and adequate training, and that this training has been appropriately documented [49 CFR 172.700 - 704].

02.03 Receipt of Packages. Examine the licensee's procedures and records of incoming shipments to verify compliance with the applicable requirements relating to pickup from a carrier, receiving, and safe opening of packages (10 CFR 20.1906).

02.04 Records and Reports. Review licensee's records and procedures for recordkeeping and reports to verify that a system is in place to:

a. DOT Specification 7A Type A Packaging. Maintain, on file, for at least one year after shipment, the documentation of DOT Spec. 7A safety analysis/testing and/or special form testing [49 CFR 173.415(a), 49 CFR 173.469, and 49 CFR 173.476].

b. Special Form Documentation. Verify that for packages where the licensee relies on a special form determination, to qualify the package as either a limited or Type A quantity, the licensee maintains on file, for at least one year after any shipment, and

provides, on request, the documentation demonstrating that the special form material meets the applicable test requirements (49 CFR 173.469 and 173.476).

c. Incident Reporting. Immediately report to DOT, when transporting licensed material as a private carrier, any incident that occurs in which, as a direct result of the radioactive material, any person is killed, receives injuries requiring hospitalization; property damage exceeds $50,000; or fire, breakage, spillage, or suspected radioactive contamination occurs (49 CFR 171.15 and 49 CFR 171.16).

SUBSECTION B ADDITIONAL REQUIREMENTS

02.05 General License Requirements. Determine which general license(s) in 10 CFR Part 71, Subpart C, the licensee uses to ship radioactive material packages (e.g., 10 CFR 71.12, 71.14, 71.16, etc.). Verify that:

a. The licensee has copies of the specific license, NRC Certificate of Compliance (COC), DOT specification, or other approval of the package.

b. If shipping NRC-certified package(s), has registered with NRC as a user of NRC-certified package(s).

c. Complies with 10 CFR Part 71, Subparts A, G, and H, as applicable.

d. Has a quality assurance (QA) program approval issued by the Commission, as applicable.

e. Complies with other requirements specific to the general license(s) used.

02.06 Management Controls. Review the system of management controls for transportation activities and verify that:

a. Transportation authorities and responsibilities are delineated among individuals and/or organizational entities, and designated in writing.

b. Written management-approved instructions have been established to carry out the various transportation activities, including authorized changes.

02.07 Indoctrination and Training Program. Verify implementation of the indoctrination and training program for persons involved in the licensee's transport activities:

a. Discuss the program with the licensee's representative charged with the responsibility for the training. Identify the major elements of the program: the basis used for selection of personnel to be trained; the schedules and performance of training; and methods used to ensure qualification of competence; and methods to keep people informed of changes in procedures and requirements.

b. Examine records of training completion for all employees involved in transport activities.

c. Discuss the training with one or two supervisors and one to five employees, selected at random, to verify their participation in the training program. In addition to discussions, inspectors may review licensee shipping records, and observe licensee activities to check supervision and/or employee knowledge of licensee-related specific procedural requirements.

02.08 Quality Assurance Program. Review the licensee's documented quality assurance (QA) program, to ensure that the licensee has fulfilled all commitments made in the licensee's QA program application, including development of written QA procedures for transporting radioactive material.

02.09 Audit Program. (10 CFR 71.137). Review the report of the most recent audit of transport activities conducted by the licensee and, if possible, discuss the audit program with one to five employees, selected at random, to check their degree of knowledge of the program and to aid in ensuring that the licensee is conducting an adequate program. Employee knowledge may also be evaluated by review of shipping records and directly observing transportation activities. Verify whether:

a. The most recent audit was conducted in accordance with the licensee's published procedures, and

b. Identified deficiencies (if any) were corrected, or are being corrected, before any more shipments are made.

02.10 Procurement and Selection of Packagings. For packagings that are used by the licensee to transport or to deliver licensed material to a carrier for transport, review the procedures and records for the following:

a. Fabrication of Packagings. Verify, by physical examination and examination of records, whether new packagings have been fabricated in accordance with the approved design (i.e., NRC Certificate of Compliance (COC) or DOT specification). For packagings supplied by, procured leased from a vendor or supplier, verify that the licensee has obtained a written statement from such supplier, certifying that the package has been fabricated in accordance with a NRC-approved quality assurance program.

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b. DOT Revalidation of Foreign-Approved Packagings. Verify that for foreign-approved packagings used by the licensee, such designs have been revalidated by DOT, and the licensee possesses a copy of the applicable foreign certificate, DOT revalidations, and documentation referenced therein, which relate to the use and/or maintenance of the packaging and actions to be taken before shipment (49 CFR 173.473 and 10 CFR 71.16).

02.11 Preparation of Packages for Shipment

a. Package Marking. Verify that, for NRC-certificate packages or DOT-revalidation packages of foreign origin, the outside of the package is durably and legibly marked with the package identification marking indicated in the COC or the DOT Competent Authority Certificate.

b. Advance Notification to Consignee. Verify that the licensee provides, for notification to the consignee before shipment: the dates of shipment and expected arrival, and any special loading/unloading or operating instructions whenever any non-exempt fissile materials and/or packages containing "highway route controlled quantities" are involved [49 CFR 173.22(c) and 10 CFR 71.89].

c. Advance Notification to States. Verify that the licensee provides advance notification to the Governor of a State, or his designee, when required, as described in 10 CFR 71.97.

Deleted: NOTE: This requirement is not the same as that required for safeguards purposes, pursuant to 10 CFR 73.72.

02.12 Periodic Maintenance of Packagings. For reusable NRC-certified, DOT specification, or DOT revalidated foreign-made packagings, examine the licensee's procedures and records for shipments, to verify that, before reuse, all the initial and periodic maintenance required by the certificate, specification, or revalidation has been performed. If possible, observe such maintenance activities (49 CFR 173.474, 49 CFR 173.475, 10 CFR 71.85, and 10 CFR 71.87). For multi-user packages supplied by another party, the licensee-user should obtain written certification that required periodic maintenance and quality control measures have been conducted in accordance with a NRC-approved quality assurance program.

02.13 Records, Reports, and Notifications. Review the licensee's records and procedures for recordkeeping and reports to verify that a system is in place to:

a. Record of Shipment. Maintain on file for three years after any shipment, a record of each shipment of licensed material (which is not exempt therefrom) and that such records contain the required information [10 CFR 71.91(a)].

b. Quality Assurance Records - Components and Services. Maintain, for three years after the life of any packaging, sufficient quality assurance records documenting evidence of the quality of packaging components and those services that are of safety significance, including the results of required preliminary determinations before first use of any packaging [10 CFR 71.85 and 10 CFR 71.91(c)].

c. Quality Assurance Records - Other. Maintain, for three years after the last shipment, sufficient quality assurance records that furnish documented evidence to support the activities affecting quality assurance of transport packages (10 CFR 71.135).

d. Notification of Excess Contamination or Radiation Level. Immediately notify the appropriate regional office and the delivery carrier for instances in which removable radioactive surface contamination and/or external radiation levels on packages received in a shipment exceed the applicable reporting limits [10 CFR 20.1906(d)].

e. Reduction in Package Effectiveness Report. Report to NRC Director, Spent Fuel Project Office (SFPO), Office of Nuclear Material Safety and Safeguards (NMSS), within 30 days, any instances in which there has been a significant reduction in the effectiveness of any packaging during its use, providing additional details of any defects of safety significance to the packaging, after first use, and the means employed to repair such defects, to prevent their recurrence (10 CFR 71.95).

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86740-03 INSPECTION GUIDANCE

03.01 General Guidance. In fulfilling the inspection requirements and objectives of this procedure, the inspector should assess the adequacy of the various aspects of the licensee's program in view of the licensee's total program. That is, he should consider for the various transportation activities such factors as the volume, quantity, and types of radioactive material involved, the inherent potential radiological hazards, the complexity of the packaging required, the number of shipments made and received over a period of time, the number of licensee employees involved in the activities, etc. In other words, a "graded approach" should be used in assessing the adequacy of the licensee's program, with the smaller programs requiring complete but less complex and extensive controls than larger programs. In the same context, the extent and scope of the inspection coverage may be adjusted accordingly. For example, inspection of the transportation program of a licensed processor/supplier of medical isotopes would require much broader inspection coverage: i.e., package procurement, preparation, delivery to carrier, radwaste shipments, etc., as contrasted with the inspection of a radiography user, wherein the primary focus would be on the transport of devices in private carriage. Correspondingly, the transport program of a

typical nuclear utility would focus on the package preparation and delivery to carriers of large volumes of radwaste materials and spent fuel shipments.

03.02 Specific Guidance

SUBSECTION A GUIDANCE FOR BASIC REQUIREMENTS

a. Inspection Requirement 02.01(c). Preparation of Packages for Shipment: Liquid Packaging Requirements. These requirements are very important in examining the packaging configurations used by suppliers of medical and industrial isotopes. Inspectors should verify that in the Type A testing of a given design, the licensee has considered the requirements of 49 CFR 173.412(k) relative to use of absorbent materials and/or a double containment system. For packagings exceeding 50 cc liquid volume, either option is allowed, whereas for less than 50 cc the use of an absorbent material is required. The configuration should be examined visually to verify that the absorbent material is suitably positioned to contact the liquid in the event of leakage. The package testing must also address the results of the additional requirement of 49 CFR 173.466 for liquids, i.e., a 30-ft drop test. For packages containing liquid greater than A_2 and destined for air shipments, the licensee is required to perform a leakage assessment on each package before shipment. Leakage testing methods are described in Regulatory Guide 7.4.

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b. Inspection Requirement 02.01(d). Preparation of Packages for Shipment: Package Marking. The specific requirements for marking of packages include:

1. DOT proper shipping name (49 CFR 172.101 and 49 CFR 172.301).
2. Identification number (e.g., UNXXXX or NAXXXX, 49 CFR 172.101 and 49 CFR 172.301).
3. Gross weight, if greater than 110 pounds, "Type A" or "Type B" as appropriate and radiation symbol for Type B, Type B(U) or Type B(M) packages [49 CFR172.310(a), (b), and (c)].
4. For DOT 7A Type A packages, the words "USA DOT 7A Type A" and "Radioactive Material" [49 CFR 178.350].
5. US NRC packaging approval number [49 CFR 173.471(b)].
6. For DOT specification packages within a nonspecification outer overpack, a statement, such as, "Inside Package(s) Comply with Prescribed Specification(s)" [49 CFR 173.25(a)].
7. "RADIOACTIVE -LSA," or "Radioactive-SCO" in the case of LSA or SCO packages transported as exclusive-use [49 CFR 173.427(a)(6)(vi)].
8. Name and address of the consignee or consignor [49 CFR 172.301(d)].
9. "USA," in conjunction with the NRC-certificate or DOT-specification marking, if the package is destined for export [49 CFR 172.310 (d)].
10. An appropriate arrow symbol to indicate upward positioning, where liquid contents are involved in a combination package [49 CFR 172.312(a)].
11. "RQ" if reportable quantity of hazardous substance [172.324(b)].

The physical requirements for legibility and location of package markings are found in 49 CFR 172.304. Inspectors should not consider marking requirements as a less important requirement, since they constitute a very important element of the Hazardous Materials "Communications" requirements, along with labels, placards, and shipping papers. Marking deficiencies quite often indicate that the licensee is generally unaware of other regulatory requirements and are often accompanied by more serious packaging deficiencies.

c. Inspection Requirement 02.01(e). Preparation of Packages for Shipment: Radiation Monitoring. Licensees who package and offer for transportation large numbers of small medical radiopharmaceuticals often use an "assembly-line" process, in which the loaded package travels past a fixed, preset radiation detector. Inspectors should carefully examine such systems, to ensure that they, in fact, are effective in ensuring compliance with the regulatory limits for radiation levels. Another question that frequently arises is the placement of a specification package (e.g., such as a radiography projector within an outer box or other type of enclosure during transportation). The question involves whether the radiation levels at the surface of the outer box and at 1 meter from the outer box may be used to establish the label requirements for the overall "package." Since DOT regulations do not address this, it is therefore permissible to apply labels, to the outer box, that reflect radiation levels around the outer box. The inner package, which is the authorized package, must be labeled to reflect radiation levels from that package, without the outer box.

Assuming that the inner package (the device) is labeled and marked as a specification package, the outer enclosure would, however, need to be further marked with a statement such as "Inside Packages Complies with Prescribed Specification" (49 CFR 173.25), and labeled as required, based on the radiation levels on the outer enclosure. (See also NRC IE Information Notice 81-02.)

In instances where the licensee consolidates more than one inner package into outer overpacks, such as bags or cartons, certain rules for transport index (TI) determination, label entries, and markings are provided in 49 CFR 173.448(g).

On an open, exclusive use vehicle, a package may not exceed the 200-mrem/ hr surface limit (i.e., a 1000-mrem/hr package must be in a closed transport vehicle [49 CFR 173.441(b)(1)(i) and 177.842(g)]. Inspectors, as well as licensees, should also be aware that the 1000-mrem/hr package limit applies at the surface. Further discussion on radiation limits and other requirements for exclusive-use shipments is provided in NRC IE Information Notice 80-32 (August 29, 1980) and Rev. 1 thereto (February 12, 1982).

Preparation of Packages for Shipment: Contamination Monitoring. In 49 CFR 173.443, Table 11, the expressed limits applicable to a "wipe" sample are stated in terms of the actual limit on the wipe, itself. A "factor of 10" higher limit is allowed for packages shipped as exclusive use. Such packages are required to be at a "factor of 1" (2200 d/m/100 cm^2 beta/gamma) at the start of transportation, but may rise to a "factor of 10" during transportation (22,000 d/m/100 cm^2 beta/gamma). Exclusive-use vehicles in which the "factor of 10" higher-contamination packages are transported must be surveyed.

NOTE: For packages shipped in closed, exclusive-use vehicles dedicated only to radioactive materials shipments and so marked, the "factor of 10" limits may apply at the start of transport [49 CFR 173.443(d) and 177.843(b)]. This provision does not exist in 10 CFR 71.87(i); however, inspectors should be aware that licensees may still apply this provision even though it is not contained in 10 CFR Part 71.

A question sometimes arises concerning the performance of contamination surveys in those cases where a package, such as a cask, is provided with an external heat barrier or screen to achieve compliance with the heat limits of 49 CFR 173.442(b). The question is whether the contamination limits, as measured by wipe tests, may be taken at the surface of the external barrier or at the surface of the cask within the barrier screen. It is DEP's position that the contamination limits must be applied at the package surface (including the surfaces between the package and any removable impact limiter) even though the heat limit is applied at the barrier surface. Monitoring of contamination levels at the outer barrier screen might not disclose the existence of contamination from the package or on the package. Monitoring of the surface contamination of the cask inside the barrier is therefore a regulatory requirement, whereas monitoring of both the cask surface and the outer barrier, would constitute a better health physics practice. (See NRC IE Information Notice 83-10, March 11, 1983.)

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d. Inspection Requirement 02.01(f). Preparation of Packages for Shipment: Package Labeling. If possible, the inspector should examine one or more samples of completed, labeled packages to verify the adequacy of this requirement. The proper category of "RADIOACTIVE" label to be applied to each package is based principally, but not solely, on the measured dose rates at the package surface and at 1 meter (TI). Inspectors are also reminded that the TI assigned to the package label may be assigned on the basis of either nuclear safety for fissile materials or radiation, whichever number is higher. What this means is that in inspecting and surveying a package with a recorded TI, the radiation level reading at 1 meter from a fissile package may not be consistent with the recorded TI on the label. This is not a violation if the TI had been assigned on the basis of the nuclear safety value and is a larger number than it would be based on the actual radiation level at 1 meter. [See also 49 CFR 173.403 Transport Index definition].

Inspectors are also reminded that LSA or SCO packages in other-than-exclusive use are required to be labeled, whereas for exclusive use, they only are required to be marked "RADIOACTIVE-LSA", or "RADIOACTIVE-SCO," as appropriate.

NOTE: The package labeling requirements of 49 CFR Part 172, for purposes of transport, should not be confused with the requirements for marking packaged radwaste as Classes A, B, or C, for purposes of shallow land disposal, pursuant to 10 CFR Part 61. Further, the designators Classes A, B, or C waste bear no direct basis to Types A or B packages, for transport purposes.

e. Inspection Requirement 02.02(a). Delivery of Completed Packages to Carriers: Shipping Paper Documentation. Requirements for shipping paper descriptions constitute a very important part of the hazardous materials regulatory "communications" requirements, the others being labels, marking, and vehicle placards. Generally speaking, as is the case for marking, observation of shipping paper deficiencies may be symptomatic of more serious deficiencies in packaging; therefore, inspectors should be familiar with the detailed shipping paper requirements. Generally speaking, a shipping paper may be any type of transportation document, i.e., bill of lading, shipping invoice, radioactive waste shipment record, etc. However, it must contain the following elements of applicable information [49 CFR 172.201, 172.202, and 172.203 (d)]:

1. The applicable DOT proper shipping name and hazard class, "Radioactive Material," 49 CFR 172.101 (unless the words "Radioactive Material" are already contained in the name). Letters RQ or X in column captioned "HM" [49 CFR 172.203(c)(2)].

2. The applicable identification number (UNXXXX or NAXXXX) from 49 CFR 172.101.

3. The name of each radionuclide. Abbreviations, as taken from 49 CFR 173.435, are authorized.

4. A description of the physical and chemical form of the material. (For special form sources, this description is "SPECIAL FORM.")

5. The activity contained in each package, measured in SI units. Deleted:

6. The category of label applied to each package ("RADIOACTIVE WHITE-I," "RADIOACTIVE YELLOW-II," or "RADIOACTIVE YELLOW-III").

7. The TI (dose rate at 1 meter) assigned to each package bearing "RADIOACTIVE YELLOW-II" or "RADIOACTIVE YELLOW-III" labels.

8. For shipments tendered to a common carrier, the appropriate signed shipper's certification; and for shipments by aircraft, the additional statement as to acceptability for either passenger-carrying or cargo-only aircraft. For shipments by passenger-carrying aircraft, the additional statement of intended use in research or medical diagnosis or treatment must also be included [49 CFR 172.204(a); 49 CFR 172.204(c)(3), 49 CFR 172.204(c)(4), 49 CFR 172.204(d)].

9. The words "Highway Route Controlled Quantity" for any shipments containing such quantity [49 CFR 172.203(d)(4)].

10. Any other descriptive information may be included after the basic description, provided it is not inconsistent therewith [49 CFR 172.201(a)(4)].

    In shipments where both nonhazardous and radioactive materials are described on the same shipping paper, the radioactive materials must appear as the first entry, or be designated by an "X" in columnar fashion, or be highlighted in a contrasting or other distinguishing fashion from the nonhazardous materials.

    NOTE: 10 CFR 20, Appendix G, requires that each shipment of radioactive waste to a land disposal facility be accompanied by a manifest that describes the shipment contents. The waste shipment receiver (e.g., the disposal facility operator) also requires specific additional information. In addition to shipper identification requirements and a certification, the manifests required by 10 CFR 20, Appendix G, must include the following information as a minimum:

    (a) The waste class, pursuant to 10 CFR Part 61;

    (b) A radiological description; and

    (c) A physical and chemical description.

11. Emergency response information that can be used in the mitigation of an incident involving hazardous material. The information includes immediate precautions to be taken in case of an accident or incident (49 CFR 172.602). The information may be on a separate document, but must be maintained in the same manner as the shipping papers.

12. Emergency response telephone number. The number must be monitored at all times that the hazardous material is in transportation, including storage incidental to transportation (49 CFR 172.604).

f. Inspection Requirement 02.02(b). Delivery of Completed Packages to Carriers: Loading and Placarding of Non-Exclusive-Use Shipments. The licensee/shipper's responsibilities in these cases mainly relate to furnishing the required placards

(based on the presence of any "RADIOACTIVE YELLOW-III"-labeled packages) to a highway carrier or applying the placards to a rail vehicle. The basic responsibility for blocking and bracing packages within the vehicle rests with the carrier, as well as storage distance controls based on the TIs. The shipper does, however, have a responsibility not to offer, to a carrier, for placement in a single non-exclusive-use vehicle, packages bearing a total TI value of more than 50 [49 CFR 177.842(a)].

g. Inspection Requirement 02.03. Receipt of Packages. Regulatory Guide 7.3 provides additional guidance on these requirements found in 10 CFR 20.1906, which includes provisions for the following:

1. Arrangements for package receipt or expeditious pickup [10 CFR 20.1906(a)].

2. Monitoring external surfaces and radiation levels for certain packages [10 CFR 20.1906(b), (c) and (f)].

3. Notification of carrier and NRC when package limits or levels are exceeded [10 CFR 20.1906(d)].

4. Requirements for package-opening procedures [10 CFR 20.1906(e)].

h. Inspection Requirement 02.04(a). Procurement and Selection of Packagings: DOT Specification 7A. DOT regulations require that each shipper of a Specification 7A package maintain, on file, a written documentation of the tests and engineering evaluation or comparative data showing that the packaging complies with the specification. If the shipper of a Specification 7A package is not the original designer or user of that package, it is necessary for that shipper to obtain the package evaluation report data from the original supplier/user or to perform the tests himself and document the results.

Further, if a shipper makes any changes to the packaging or its maximum authorized contents, from the description on the original test report furnished by another person, it will be necessary to perform and document a supplemental evaluation, addressing such changes and demonstrating that the package will continue to meet the appropriate performance requirements. In any case, the "bottom line" of the Specification 7A documentation is that the results of how the package meets the applicable environmental and test conditions must be addressed. In this regard, inspectors may find some shippers furnishing and relying on test results and data extracted from several technical reports by the former agency, Energy Research and Development Administration (ERDA), entitled, "Certification of ERDA Contractors Packaging with Respect to DOT Specification 7A Performance Requirements," Report MLM-2228, June 12, 1975, with one Supplement, (April 15, 1976) and MLM-2324 (October 8, 1976). A question may then arise about the sufficiency of the test data from these reports in any given case. Judgment will then have to be exercised in assessing whether the licensee's specific package falls within the parameters of the tests as reported, with respect to such aspects as maximum package weight tested, type of closure, tested content versus actual content, and content limitations. The licensee's documentation should include an evaluation concluding how the package meets the Spec. 7A test requirements based on the recorded data, or any other independent package tests that have been performed. In any case, inspectors should reject any rationale used by the licensee that the marking alone of "DOT Spec. 7A" on the outside of the package is sufficient fulfillment of this requirement.

i. Inspection Requirement 02.04(b). Procurement and Selection of Packagings: Special Form Requirements. Radioactive sealed sources classified as "special form" material must meet the physical integrity requirements, as defined in 49 CFR

173.469 and 49 CFR 173.476. These requirements call for each shipper of a special form source to maintain, on file, a supporting safety analysis or documentation containing the results of the testing performed on the source, to demonstrate that it meets the special form requirements. This does not mean that each shipper has to actually perform the tests, only that he must obtain and retain the documentation of these tests. As a practical matter, each licensee should establish a file of such data for each source design in his inventory. It may be necessary, therefore, for the licensee to procure the required information from the source manufacturer.

In many instances, qualification of the material as special form will have no direct bearing on the type of packaging required, relative to content limit -- for example, where $A_1 = A_2$ (as in the cases of Co-60, Mn-54, and P-32), Type A packaging for A_1 or A_2 quantities is required, regardless of "form." In such cases, when the material has been encapsulated as a sealed source, but is not described on the shipping paper documents as "special form," the documentation of special form testing is not required [49 CFR 173.476(d)]. If the material however, is described as special form, the backup documentation is required.

SUBSECTION B GUIDANCE FOR ADDITIONAL REQUIREMENTS

j. Inspection Requirement 02.06. Management Controls. The inspection effort should be directed at certifying that written procedures have been established in a manner approved by management. The procedures should be readily available to all those having responsibility for any phase of the licensee's transportation activity. The inspector should confirm that the procedures include provisions for all of the applicable transport activities addressed in the Inspection Requirements Section 2 of this procedure.

In reviewing the adequacy of the licensee's program for management controls and associated written documentation thereof, inspectors are reminded to concurrently review, as a cross-check, the licensee's written, approved QA program, which incorporates the elements of 10 CFR Part 71, Subpart H.

In reviewing the program, it will be necessary to review the licensee's procedures that satisfy commitments made in the QA program application.

k. Inspection Requirement 02.08. QA Program. Further guidance on acceptable QA programs for transport packages is provided in NRC Regulatory Guide 7.10. A key factor in verifying this inspection requirement is to ascertain whether the actual QA program reasonably corresponds to that which has been described to, and approved. Questions frequently arise regarding fulfillment of QA requirements in those cases where there are multiple users, as in the case of casks leased from a supplier. The DEP position on this, as stated in NRC IE Information Notice 83-10, March 11, 1983, is restated below, as follows:

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1. Each registered licensee-user should obtain a current certificate from the package owner attesting that the packaging was designed, procured, fabricated, assembled, tested, and is maintained in accordance with an approved QA program.

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2. Each registered licensee-user should provide the owner with a copy of all QA records on maintenance, repair, or modifications to the package, which are conducted under the licensee-user's QA program.

3. Each licensee-user should maintain its own QA program and related records concerning its use/operation and maintenance of the package. The

licensee-user is also encouraged to obtain from the package owner copies of those quality-related documents that may be useful and relevant to the licensee-user's own QA program. (Note: This is not to imply necessarily that the package owner would be expected to provide each user, nor is each user expected to maintain, all of the quality-related documents associated with all of the criteria of 10 CFR Part 71, Subpart H.)

Recognizing the inherent difficulties in maintaining QA records in cases of multi-user packages, it is important to bear in mind that the individual licensee-user is responsible for maintaining as complete a file as possible of the QA records pertaining to package use, and further, to establish mechanisms for exchange of pertinent QA records with the package owner. It remains the responsibility of each licensee-user that his transportation activities meet the requirements of 10 CFR Part 71. As stated above, however, in fulfilling this responsibility, the licensee-user has the prerogative to accept written certifications from package owners and suppliers that certain QA activities, not under the licensee-user's immediate control, were conducted in accordance with an approved QA program.

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l. Inspection Requirement 02.10(a)-(b). Procurement and Selection of Packagings: General Guidance. For Type B, fissile, and certain Type A package designs certified by NRC, a necessary reference is NUREG-0383, "Directory of Certificates of Compliance for Radioactive Materials Packages," which is issued and updated annually by NMSS. DOT Specification Packaging designs are published and listed in 49 CFR Part 178. Authorizations for DOT specifications packagings are found in 49 CFR 173.415, 49 CFR 173.416, and 49 CFR 173.417.

Inspectors should note that some of the regulatory requirements for packaging and transporting packages of LSA or SCO have changed. NUREG-1608, "Categorizing and Transporting Low Specific Activity Materials and Surface Contaminated Objects," provides further guidance on this subject.

m. Inspection Requirement 02.11(a). Preparation of Packages for Shipment: Preliminary and Routine Determinations and Package Marking. Inspection of the required preliminary and routine determinations will have some overlap with the inspection of the licensee's QA activities on transport packages. In reviewing the licensee's preliminary and routine determinations, the following additional guidance is offered.

1. In determining whether a package has any significant damage, the package should be considered to have significant damage if such damage would be likely to preclude the package from meeting the applicable requirements of 10 CFR Part 71 and/or its approved design.

2. In reviewing the adequacy of package closures, closures that involve attempts at sealing with gaskets having visible or obvious imperfections, field splices that are not part of an approved design, caulking, and rusty or dirty sealing surfaces would not be considered to be free from defects.

3. The loading and closing of packages in accordance with written procedures should include a determination that the packaging is authorized for the specific intended contents, and that any lid/closure to the main body is properly aligned, with its bolts properly torqued to the specified values in the prescribed pattern.

4. A record should be established by the licensee for each reusable packaging. Because many packagings are procured in lots and without serial numbers, the record may exist for a large quantity of packagings specified, as in a

purchase order. Special emphasis should be placed on records that show that components important to safety have been inspected for conformance to NRC-approved design. Depending on the type of package, this may include structural, thermal, shielding, containment, closure, and criticality control systems. The records may include visual observations and physical test results.

5. For NRC-certified packaging, the inspector should give special attention to any applicable terms and conditions of the certificate relating to preliminary and routine determinations and routine maintenance.

6. Package-marking requirements include "TYPE " or "TYPE B" as appropriate, and NRC certificate number.

n. Inspection Requirement 02.11(b). Delivery of Completed Packages to Carriers: Loading and Placarding of Exclusive-Use Shipments. The requirements herein will relate very frequently to shipments of low-level radwaste to licensed burial sites, quite frequently as LSA materials. Many of the questions that arise concerning these shipments are addressed in NRC IE Information Notice 80-32 (August 29, 1980) and Rev. 1 (February 12, 1982).

o. Inspection Requirement 02.11. Delivery of Completed Packages to Carriers: Advance Notice to States. A list of the names and mailing addresses of the Governor's designees who are to receive such advance notification of transportation of nuclear waste is published annually in the Federal Register (around June 30). The reporting quantities for the report required by NRC pursuant to 10 CFR 71.97 are currently the same as the quantities designated by DOT as "Highway Route Controlled Quantities."

86740-04 RESOURCE ESTIMATE

Transportation safety inspection resource requirements vary greatly depending on facility size and shipping activity. On-site inspection hours can range from less than 1 hour at material licensee facilities with limited shipping activity, to more than 8 hours at reactor or other large facilities with significant shipments.

86740-05 REFERENCES

05.01 Regulations

a. 49 CFR Parts 100-178, "Hazardous Materials Regulations," of the US Department of Transportation, revised annually, as of October 1.

b. 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

c. US Postal Service Publication No. 6, Dec. 1975 "Radioactive Material," as amended by US Postal Bulletin, June 30, 1982, pp. 2-5.

d. International Atomic Energy Agency, "Regulations for the Safe Transport of Radioactive Material," Safety Series No. 6, 1985(As Amended 1990). IAEA, Vienna, Austria.

05.02 NRC Information Notices

a. 79-21 "Transportation and Commercial Burial of Radioactive Waste," Sept. 7, 1979.

b. 80-24 "Low-Level Waste Burial Criteria," May 30, 1980.

c. 80-25 "Transportation of Pyrophoric Uranium," May 30, 1980.

d. 80-32 "Clarification of Certain Requirements for Exclusive-Use Shipments of Radioactive Materials," Aug. 29, 1980.

e. 80-32 Rev. 1, Feb. 12, 1982.

f. 81-02 "Transportation of Radiography Devices," Jan. 1981.

g. 81-32 "Transfer and/or Disposal of Spent Generators," Oct. 23, 1981.

h. 82-24 "Water Leaking From UF_6 Overpacks," July 20, 1982.

i. 82-47 "Transportation of Type A quantities of Non-Fissile Radioactive Material," Nov. 30, 1982.

j. 83-10 "Clarification of Several Aspects Relating to Use of NRC-Certified Transport Packages," Mar. 11, 1983.

k. 84-14 "Highlights of Recent Transport Regulatory Revisions by DOT and NRC," March 8, 1984.

l. 84-50 "Clarification of Scope of Quality Assurance Programs for Transport Packages Pursuant to 10 CFR 50, Appendix B."

m. 84-72 "Clarification of Conditions for Water Shipments Subject to Hydrogen Gas Generation."

n. 85-46 "Clarification of Several Aspects of Removable Radioactive Surface Contamination Limits for Transport Packages."

o. 86-18 "NRC On-Scene Response during a Major Emergency."

p. 86-67 "Portable Moisture/Density Gauges: Recent Incidents and Common Violations of Requirements for Use, Transportation, and Storage."

q. 86-86 "Clarification of Requirements for Fabrication and Export of Certain Previously Approved Type B Packages."

r. 87-2 "Cracks in Stiffening Rings on 48-inch Diameter UF_6 Cylinders."

s. 87-31 "Blocking, Bracing, and Securing of Radioactive Materials Packages in Transportation."

t. 87-37 "Compliance with the General License Provisions of 10 CFR Part 31."

u. 87-47 "Transportation of Radiography Devices."

v. 87-55 "Portable Moisture/Density Gauges: Recent Incidents of Portable Gauges Being Stolen or Lost."

w. 88-06 "(Bulletin) Actions to be Taken for the Transportation of Model No. SPEC 2-T Radiographic Exposure Device."

x. 88-16 "Identifying Waste Generators in Shipments of Low-Level Waste to Land Disposal Facilities."

y. 88-18 "Malfunction of Lockbox on Radiography Device."

z. 88-33 "Recent Problems Involving the Model SPEC- 2T Radiographic Exposure Device."

aa. 88-62 "Recent Findings Concerning Implementation of Quality Assurance Programs by Suppliers of Transport Packages."

bb. 88-66 "Industrial Radiography Inspection and Enforcement."

cc. 88-101 "Shipment of Contaminated Equipment Between Nuclear Power Stations."

dd. 89-24 "Nuclear Criticality Safety."

ee. 89-74 "Clarification of Transportation Requirements Applicable to Return of Spent Radiopharmacy Dosages from Users to Suppliers."

ff. 90-24 "Transportation of Model SPEC 2-T Radiographic Exposure Device."

gg. 90-27 "Clarification of the Recent Revisions to the Regulatory Requirements for Packaging of Uranium Hexafluoride (UF6) for Transportation."

hh. 90-35 "Transportation of Type A Quantities of Non-Fissile Radioactive Materials."

ii. 90-50 "Minimization of Methane Gas in Plant Systems and Radwaste Shipping Containers."

jj. 90-66 "Incomplete Draining and Drying of Shipping Casks."

kk. 90-82 "Requirements for Use of NRC-Approved Transport Packages for Shipment of Type A Quantities of Radioactive Material."

ll. 91-39 "Compliance with 10 CFR Part 21, "Reporting of Defects and Noncompliance."

05.03 NRC Regulatory Guides

a. 7.1 "Administrative Guide for Packaging and Transporting Radioactive Material," 06/74.

b. 7.2 "Packaging and Transportation of Radioactively Contaminated Biological Material," 06/74.

c. 7.3 "Procedures for Picking Up and Receiving Packages of Radioactive Materials (For Comment)," 06/75.

d. 7.4 "Leakage Tests on Packages for Shipment of Radioactive Materials (For Comment)," 06/75.

e. 7.5 "Administrative Guide for Obtaining Exemptions From Certain NRC Requirements Over Radioactive Material Shipments," 06/75 or 05/77.

f. 7.6 "Design Criteria for the Structural Analysis of Shipping Cask Containment Vessels," 02/77 or 03/78.

g. 7.7 "Administrative Guide for Verifying Compliance With Packaging Requirements for Shipments of Radioactive Materials (For Comment)," 08/77.

h. 7.8 "Load Combinations for the Structural Analysis of Shipping Casks (For Comment)," 05/77.

i. 7.9 "Standard Format and Content of Part 71 Applications for Approval of Packaging of Type B, Large Quantity, and Fissile Radioactive Material," 03/79 or 01/80.

j. 7.10 "Establishing Quality Assurance Programs for Packagings Used in the Transport of Radioactive Material," 01/83.

k. 7.11 "Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Maximum Wall Thickness of 4 Inches (0.1 m)."

l. 7.12 "Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Wall Thickness Greater than 4 Inches (0.1 m) But Not Exceeding 12 Inches (0.3 m)."

05.04 Other Publications

a. U.S. Department of Transportation, " 2000 Emergency Response Guidebook,"

b. U.S. Department of Transportation, "Radioactive Material Regulations Review," RAMREG 001-98.

c. NUREG-1608, "Categorizing and Transporting Low Specific Activity Materials and Surface Contaminated Objects."

d. NUREG-1660, "U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Materials Consigments."

e. Generic Letter 96-07, "Interim Guidance on Transportation of Steam Generators."

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DEP INSPECTION MANUAL

INSPECTION PROCEDURE 87102

MAINTAINING EFFLUENTS FROM MATERIALS FACILITIES AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

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PROGRAM APPLICABILITY: 2800

87102-01 OBJECTIVES

01.01 This procedure is to be implemented at any facility for which accurate and current effluent information is not available, and at all facilities whose effluents are known to exceed 20 percent of 10 CFR Part 20, Appendix B, Table 2 values. Licensees are exempt from this requirement if they do not use unsealed sources, or if they do not possess sufficient amounts of unsealed radioactive materials to cause effluents to exceed the aforementioned 20 percent criterion. Implementation of this procedure, where applicable, is to be at the frequency used for routine inspections at the facility. The objective of the procedure is to determine whether the licensee effectively maintains effluents within applicable limits, constraints, and As Low As Is Reasonably Achievable (ALARA), as is required by 10 CFR20.1101(b), and the constraint on air emissions, as established under 10 CFR 20.1101(d). Effluents include both air and water effluents, but do not include releases to public sewers. Sanitary sewers do not include sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee (see definition in 10 CFR 20.1003).

Comment [D1]: Interesting wording. Caution inspectors not to confuse "sealed sources" with "special form." (I don't think tere will be confusion – LRU)
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87102-02 INSPECTION REQUIREMENTS

02.01 Management Commitment. Review management's written policy statements on ALARA, and the authority of managers and line personnel to implement this policy. Review the methods used by management to supervise implementation of the program. Determine if management and technical personnel are informed of industry developments in the area of ALARA.

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02.02 Audits and Appraisals. Review the results of audits and appraisals of the ALARA program since the last inspection. Determine if effluent ALARA was explicitly considered during these audits and appraisals. Review the adequacy of the licensee's responses to findings.

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02.03 Procedures, Engineering Controls, and Process Controls. Determine the quality of the relevant procedures and the degree to which ALARA techniques are incorporated into them. Determine the extent to which process and engineering controls are used to minimize effluents.

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02.04 Instrumentation. Determine whether effluent monitoring systems

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and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with manufacturers' recommendations and good practices.

02.05 Surveys and Effluent Monitoring. Determine if all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented.

02.06 Worker Training. Determine if the ALARA concept, including its application to effluents, is included in worker training and periodic retraining. Determine if the workers understand their roles and responsibilities in the ALARA program.

02.07 Changes. Review changes in equipment, processes, personnel, and procedures that may have had an effect on effluents, and determine the licensee's understanding of the impact of these changes on effluent ALARA.

87102-03 INSPECTION GUIDANCE

General Guidance

The U.S. Nuclear Regulatory Commission (NRC) Referral Form to the U.S. Environmental Protection Agency (EPA) is provided in the Appendix of this procedure. The form is intended to inform the EPA through the NRC of the inspection and to provide the EPA and the U.S. Nuclear Regulatory Commission (NRC) with data on the magnitude of air emissions from the licensee's facilities. Fill out the form at the end of the inspection and ensure that all the data required in the form are entered. The form is mostly self-explanatory, but the following are some items to note when entering the information. The "Contact" entry in the top box of the form refers to a licensee representative who would be able to answer questions related to the licensee emission information if the NRC or EPA were to contact the licensee for additional information or clarification. In the second box, document the licensee's ALARA goal, as defined in its radiation protection program (typically as a percentage of the Appendix B values in Part 20). If the licensee has an ALARA goal greater than 20 percent of Appendix B, determine if the NRC has approved this goal. Finally, check to determine whether the licensee's air emissions met or exceeded its ALARA goal, and also the ALARA constraint as established under 10 CFR 220.1101 (d). If, for any reason, the licensee is unable to provide the dose to the nearest member of the public, then indicate this in the space provided for insufficient information. Inability to provide the dose may indicate a weakness in the licensee's program because this value is needed to allow evaluation of the extent to which the licensee met their ALARA goal for effluents.

Provide a copy of the completed form to the NRC OSTP regional State/Government Liaison officer.

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EPA Referral in Enforcement Cases. If the inspection findings lead to enforcement action for violations of air emission regulations (e.g., NRC Severity Level I-IV), such as those in 10 CFR 220.1301 - 20.1302, a copy of the inspection report will be provided to the appropriate DEP Bureau of Air Quality regional program staff. A copy of the report will also be sent to the NRC OSTP regional State/Government Liaison officer for possible referral to the EPA.

Specific Guidance

03.01 Management Commitment

a. Determine whether the licensee has incorporated the ALARA philosophy in its radiation protection program supported by a policy statement issued by a level of management sufficient to ensure that the program is properly carried out. The policy statement should make clear that all personnel are responsible for ensuring that the work they supervise or perform is in accordance with ALARA procedures and practices.

b. Review the licensee's ALARA goals, and determine if they are sufficiently challenging yet realistic. Past experience from NRC or DEP licensing and inspection activities, effluent information reported to the DEP or NRC staff, and data provided by the EPA from field studies, all indicate that release goals of less than 20 percent of Appendix B values can be achieved by almost all material facility licensees. Determine if the licensee understands and implements these goals. A licensee that does not achieve these goals should provide reasons for not doing so. Ensure that the reasons provided justify deviation from regulatory guidance. Determine if the licensee has calculated annual doses resulting from air effluents and if the doses are: (i) within the ALARA constraint as required by 210 CFR 20.1101(d); (ii) within the licensee's ALARA goals (as described in its radiation protection program); or (iii) uncertain because there is insufficient information or basis for determination. Review the licensee's history in meeting ALARA goals, and its corrective actions when the goals were not met.

c. Determine if investigation levels for releases are established and used, and the rationale for selecting these levels. The levels chosen to initiate corrective actions are usually those that represent normal and expected releases. Review the investigations initiated when such levels are exceeded, and also review the corrective actions taken.

03.02 Audits and Appraisals

a. Review reports of audits conducted since the last inspection. Assess the quality of the reports and the depth of the audits. Determine

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whether the auditors who performed these audits were qualified for the task.

b. Determine whether the licensee's radiation safety committee (RSC), or radiation safety officer (RSO), if no RSC exists, has conducted periodic or at least annual ALARA effluent reviews as part of the required overall examination of the radiation protection program. If a consultant performs the reviews, determine whether the reviews are examined and approved by the RSC/RSO. The purpose of the ALARA review is to compare operating experience against ALARA goals, and to adjust these goals or operating procedures or equipment, if necessary, to improve performance. Determine if the results of these reviews are sent to senior management with recommendations for changes, and review the responses to these reviews and recommendations. Determine whether the ALARA effluent reviews are considered within the context of the overall site ALARA program and the radiation protection program.

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03.03 Procedures, Engineering Controls, and Process Controls

a. Identify the methods used by the licensee to control and minimize effluents to the environment and whether additional or alternative options were considered. Common control practices for effluents include filtration, encapsulation, adsorption, containment, and the storage of materials for decay. Practices for large, diffuse sources such as contaminated soils or surfaces include covers, wetting during operations, and the application of stabilizers. Verify that, when practicable, unmonitored releases do not exceed 30 percent of the total estimated effluent releases, as suggested in Regulatory Guide 8.37. Verify that, whenever effluent levels were high compared with the desired goals, the licensee considered additional ALARA measures such as recycling process fluids, leakage reduction, and modifications to facilities, operations, and procedures. Verify that the licensee considered collective exposures (i.e., both occupational and general public exposures) and not just effluent levels, when selecting effluent-reduction techniques.

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b. If the licensee rejected a control practice as unreasonable, review the licensee's analysis of the practice. Quantitative or qualitative analyses may be used to justify such practices. For quantitative cost/benefit analyses, $2,000 per person-cSv (person-rem) may be used as a guide to determine whether a change is reasonable. A qualitative analysis is used in situations where assigning monetary values to the various factors involved in the analysis would be very difficult or not meaningful.

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03.04 Instrumentation

a. If continuous effluent monitors are used, ensure that the licensee

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performs calibrations at least annually, or more frequently, if bound by license condition, or if the manufacturer suggests more frequent calibration. Calibrations should be performed according to manufacturer suggested protocols or other written procedures that implement accepted industry good practices. If flow meters are used, ensure that they are calibrated at least annually or according to the manufacturer's recommendations. Ensure that counting efficiencies are appropriate for the samples being counted, and that corrections are applied for the various factors that may distort the results, such as absorption of alpha and beta radiations, filter efficiency, sampling errors, and any other factors that may affect the accuracy of sampling and measurement. Review the licensee's techniques to quantify the releases and verify some of the calculations.

b. Ensure that samples are collected using proper media. Liquid samples should be transferred to a container for counting with the same geometry as the calibration standard. Air samples should be collected using methods appropriate for the type of activity being sampled. If, for any reason, a collection medium's efficiency falls below about 95 percent for the material to be collected, a correction factor should be applied. Charcoal cartridge collection efficiency tables/graphs (i.e., sample flow rate versus collection efficiency) should be available on site. In the case of charcoal cartridges, if the collection efficiency drops below 85 percent, the counting geometry of the cartridge (face-loaded or homogeneous) should be investigated.

c. Ensure that laboratory equipment has been properly calibrated and that the sources and standards used in these calibrations are appropriate for the types of radiations and geometries used at the site. Calibrations should be conducted at least annually, or more frequently if required by a license condition. Calibrations should also be performed after repairs or modifications. Review the licensee's laboratory quality assurance/quality control program.

d. Ensure that laboratory equipment has sufficient sensitivity for the radionuclides being measured. Check that the counting efficiencies, background counts, sample volumes, sample count times, etc. for each measurement protocol permit achievement of the desired or required lower limit of detection (LLD). If LLD values are not clearly specified in the licensee's procedures or clearly displayed in the laboratory, investigate the reasons and verify that the licensee's methods are capable of attaining these limits. Verify that the measurement procedures provide methods to check attainment of the LLDs. Verify that LLD values are routinely checked and recorded. Determine whether the licensee participates in outside programs to periodically verify the accuracy of its methods. These programs usually consist of measuring unknown samples sent to the licensee by an accredited organization, such as the National Institute

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of_Standards and Technology. Review the results of participation in such programs, and enquire as to the reasons_for nonparticipation, if that is the case.

03.05 Surveys and Effluent Monitoring

a. Review effluent release reports for obvious mistakes,_anomalous measurements, omissions, and trends. Identify any_occasions where the licensee exceeded internal investigation_levels. Determine if the licensee identified these events, and review the corrective actions.

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b. Ensure that the licensee has identified the significant sources of radioactive materials that contribute to effluent releases, and also has identified the pathways from these sources to the points of release.

Also ensure that significant release pathways are appropriately monitored.

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c. Determine whether the licensee's sampling procedures are adequate. Ensure that all samples taken are representative._Stack and vent samples should be taken isokinetically, if necessary. Non-isokinetic sampling will not introduce_significant sampling errors if the effluents contain particulates smaller than 5 mm aerodynamic diameter or noble gases. In the case of batch liquid releases, holdup tanks_should be thoroughly mixed before samples are taken._Identify dilution volumes to be used. Ensure that the_licensee knows or has measured the efficiencies of filters or absorbers through which effluents are passed. Note effluent release frequencies, and check whether the licensee has considered possible leakage pathways.

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d. For liquid releases, note that releases to a public sanitary sewer system, in accordance with Part 20 requirements, are_not considered liquid effluents.

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e. Verify that the licensee has considered all reasonably_expected release pathways and identified any potential_unmonitored release pathways. Potential pathways include_doors on exterior walls, open windows, exhaust vents, and unfinished corrugated metal construction. Inquire as to any_releases to storm sewers or runoff from contaminated soil.

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03.06 Worker Training. Verify that ALARA is included in the_annual employee radiation protection training. Verify that_employees have a thorough understanding of the ALARA program's principles and goals. Determine if they understand the role of engineering controls, and their role in the ALARA effort. Do this by conducting interviews with selected employees. Review training

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lesson plans and some examination questions and answers.

03.07 Changes. Tour the facilities and discuss changes in equipment and procedures with cognizant management. Determine whether changes have been made that will affect the types of effluents produced, effluent monitoring, sample collection, or laboratory analyses. Verify that the licensee understands the effects of these changes on effluents and the ALARA program.

87102-04 Resource estimate

For planning purposes, the direct inspection effort to complete this inspection procedure for the first time at a licensee's facility is estimated to average from 2 hours for small licensees to up to 6 hours for larger licensees, such as holders of broad scope licenses. Subsequent implementation of the procedure at the same facility is expected to require less direct inspection effort than the above averages.

87102-05 REFERENCES

U.S. Code of Federal Regulations, Title 10, Part 20

U.S. Code of Federal Regulations, Title 40, Part 61

U.S. Nuclear Regulatory Commission Regulatory Guide 1.109,"Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Compliance with 10 CFR Part50, Appendix I."

U.S. Nuclear Regulatory Commission Regulatory Guide 3.51,"Calculational Models for Estimating Radiation Doses to Man from Uranium Milling Operations."

U.S. Nuclear Regulatory Commission Regulatory Guide 8.25, "Air Sampling in the Workplace."

U.S. Nuclear Regulatory Commission Regulatory Guide 8.37, "ALARA Levels for Effluents From Materials Facilities."

U.S. Environmental Protection Agency, "Background Information Document: Procedures Approved for Demonstrating Compliance with 40CFR Part 61, Subpart I," EPA 520/1-89-001, Office of Radiation Protection Programs, Washington DC, October 1989.

U.S. Environmental Protection Agency, "EPA Guidance Document for Facilities Subject to 40 CFR Part 61, Subpart I: Procedures for Determining Compliance with the Standard and Qualification for Exemption from Reporting," EPA 520/1-89-002, Office of Radiation Protection Programs, Washington DC, October 1989.

U.S. Environmental Protection Agency, "User's Guide for COMPLY,"EPA 520/1-89-003, Office of Radiation Protection Programs, Washington DC, October 1989.

International Commission on Radiological Protection, "Limits for Intakes of Radionuclides by Workers," ICRP No. 30, 1978.

NMSS Licensee Newsletter, "Update on U.S. Environmental Protection Agency's Standard for Radionuclide Emissions from Facilities Licensed by the U.S. Nuclear Regulatory Commission", NUREG/BR-0117,No. 93-4, Dec. '93/Jan. '94.

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APPENDIX

U.S. NUCLEAR REGULATORY COMMISSSION REFERRAL FORM TO THE U.S. ENVIRONMENTAL PROTECTION AGENCY

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APPENDIX

U.S. NUCLEAR REGULATORY COMMISSSION

REFERRAL FORM

TO

ENVIRONMENTAL PROTECTION AGENCY,

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INSPECTION REFERRAL FORM

To: State Programs Liaison Officer, U.S. Nuclear Regulatory Commission Region 1

From: PA Bureau of Radiation Protection, _____ Regional Office

Inspector: _____ Phone: (____) _____

Inspection Dates: _____

License No(s): _____

Licensee: _____

Contact: _____ Phone: (____) _____

Address: _____

_____

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Licensee's ALARA goal if greater than 20 percent of Appendix B, 10CFR Part 20:

___ % Appendix B, Part 20 [_____ mSv (_____ mrem)]

If more than 20 percent Appendix B, has the U.S. Nuclear Regulatory Commission approved this goal? (Yes)____ (No)____

Classification of Effective Dose Equivalent:

Above licensee's ALARA goal? ___ (Yes) ___ (No)

Above 10 CFR 20.1101(d) ALARA constraint requirement? ___ (Yes) ___ (No) [0.1 mSv/yr (10 mrem/yr)]

Insufficient information to estimate dose? ___ (Yes) ___ (No)

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Mr/Ms. _____ .
Radiation Protection Manager .
Region ____ .
¶
U. S. Environmental Protection Agency[Address of EPA Regional Office] .
¶
Dear Mr/Ms. _____¶
In accordance with the 1992 Memorandum Of Understanding between the U.S. Nuclear Regulatory Commission and the U.S. Environmental Protection Agency, I am enclosing the EPA Referral Form(s) on air emissions from ____[licensee names and numbers]___. Should you require any additional information regarding the details of the air emissions, the resulting doses, or the methods used to obtain these doses, please refer these inquiries to the licensee representative indicated in the "Contact" entry on the Form. [In addition, since this inspection found (a) violation(s) of Severity Level ___(I-IV) associated with air or water effluents, we are enclosing a copy of ... [1]

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Mr/Ms._____
Radiation Protection Manager
Region _____

U. S. Environmental Protection Agency[Address of EPA Regional Office]

Dear Mr/Ms. _____

In accordance with the 1992 Memorandum Of Understanding between the U.S. Nuclear Regulatory Commission and the U.S. Environmental Protection Agency, I am enclosing the EPA Referral Form(s) on air emissions from _____[licensee names and numbers]___. Should you require any additional information regarding the details of the air emissions, the resulting doses, or the methods used to obtain these doses, please refer these inquiries to the licensee representative indicated in the "Contact" entry on the Form. [In addition, since this inspection found (a) violation(s) of Severity Level ___(I-IV) associated with air or water effluents, we are enclosing a copy of the inspection report].* Please contact this office at (___) ___-____ if you have any other questions regarding the inspection findings.

Sincerely;

_____, Chief State and Government Affairs
Region ___

Enclosures: 1. EPA Referral Form(s)
2. Inspection Report

cc w/encl:

Deputy Division Director, NMSS

* Add this paragraph only if there are violations of any SeverityLevel (I-IV).

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(See address of regional office on the back of the form.)

Page 10: [3] Deleted **Commonwealth of Pennsylvania** **04/21/2006 1:53:00 PM**

Licensee: _ Contact: _____ Phone:

(____) _____ Address:

Page 10: [4] Comment [D2] **DEP** **01/23/2007 12:48:00 PM**

What prefix is this? I know we're trying to say ___ milli-centi-Sv (10 μSv) increments. (Micro probably didn't translate over, We'll use milli so that doesn't happen – LRU)

Page 10: [5] Comment [D3] **DEP** **01/23/2007 12:48:00 PM**

What prefix is this? I know we're trying to say ___ milli-centi-Sv (10 μSv) increments.

Page 10: [6] Deleted **Commonwealth of Pennsylvania** **04/12/2006 2:39:00 AM**

ADDRESSES OF EPA REGIONAL OFFICES

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EPA Region 8 One Denver Place 999 18th Street, Suite 500 Denver, CO 80202-2466	CO, MT, ND, SD, UT, WY
EPA Region 975 Hawthorne Street San Francisco, CA 94105	AZ, CA, HI, NV, American Samoa, Guam, Trust Territories of the Pacific

EPA Region 101200 6th Avenue Seattle, WA 98101	AK, ID, OR, WA

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Section Break (Next Page)

DEP INSPECTION MANUAL
INSPECTION PROCEDURE 87103

INSPECTION OF MATERIAL LICENSEES INVOLVED IN AN INCIDENT OR BANKRUPTCY FILING

PROGRAM APPLICABILITY: MC 1301

87103-01 INSPECTION OBJECTIVES

01.01 This inspection procedure is applicable to the inspection of incidents that occur at nuclear materials facilities and for those cases where the DEP is concerned that material may not be properly controlled, such as when a licensee files for bankruptcy. DEP management must determine the need to dispatch one or more regional inspectors to conduct a special inspection following occurrence of an incident, either immediately following notification, or before the next routine inspection. This procedure is intended for use in such special inspections. The incidents to be inspected under this procedure include those that are considered serious enough to warrant a special inspection to determine causes and corrective actions, but are not of such a nature as to require an Incident Investigation Team (IIT) or an Augmented Inspection Team (AIT). Typically, the procedure will be used in response to medical events, overexposures, losses or releases of significant quantities of radioactive materials, and situations where DEP is concerned that material may be abandoned, such as in cases where the licensee has filed for bankruptcy, but it is not limited to these type of incidents.

Most of this Inspection Procedure places emphasis on regional inspectors and regional management. Nonetheless, central office inspectors or staff may also be involved in these inspections due to the nature of some type of licensee activities.

01.02 The objective of the procedure is to assist central office or regional inspectors in analyzing the sequence of events leading to the incident, and the conditions that existed at the time these events occurred. This analysis should lead to the identification of contributing factors and root causes, and to the formulation of corrective actions to prevent recurrence. The primary emphasis of the inspection is safety, not compliance. Issues of compliance are addressed after all safety issues and program weaknesses are identified and clearly understood.

01.03 The steps presented in the procedure should be followed in the order they are presented; some of the steps may be repeated in alternating fashion as data accumulates and hypotheses are refined. Experience shows that accidents generally have multiple contributing factors that are interconnected in complex ways. Therefore, a disciplined, organized, and thorough approach to the inspection are essential. Organization and correlation of the findings should start early in the inspection. Charts should be used if the data is complex. The initial organization of the data will necessarily be sketchy and incomplete, but this early start will help direct the inspection and also help identify areas where data is lacking or is inconsistent.

87103-02 DEFINITIONS

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Deleted: In instances where the material has been abandoned, the guidance in Policy and Guidance Directive PG 9-12, "Reviewing Efforts to Dispose of Licensed Material and Requesting DOE Assistance," and Inspection Manual Chapter 1303, "Requesting Emergency Acceptance of Radioactive Material by DOE," should be followed.¶

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02.01 Cause. The action or condition that led to the occurrence of the incident. Causes are labeled, according to their proximity to the incident, as direct, contributing, or root causes.

02.02 Direct Cause. This is the event or failure that led directly to the incident, without any additional intervening action or failure. An example is a technician improperly measuring a dose in a dose calibrator. A possible direct cause for the incorrect dose is improper setting of the radionuclide or energy selection dial on the calibrator.

02.03 Contributing Cause. This is a cause that does not necessarily lead to an incident, but it does make the incident more probable. In the example of the dose calibrator mentioned in the Direct Cause definition, a contributing cause may have been a radionuclide or energy selection dial with illegible markings at the various settings. This does not in itself necessarily lead to errors in measuring doses, since a trained and attentive technician may know from experience where the settings are, without reference to the markings. However, the fact that the markings are not legible makes it much easier to make an error, and hence may be a contributing factor, or cause, when an error does occur.

02.04 Root Cause. This is the cause whose existence establishes the conditions that allow contributing causes to develop and which, in turn, increases the probability of the occurrence of an incident. In the example of the calibrator mentioned in the Direct Cause definition, a root cause may be an organization with a poor maintenance program. The poor maintenance program may be due to an unqualified maintenance manager who fails to set routine maintenance schedules, set maintenance priorities, or respond to maintenance requests. In this case, the root cause may be the presence of the unqualified manager, which results in a poor maintenance program.

87103-03 INSPECTION REQUIREMENT

03.01 Conduct an inspection to: 1) determine the causes of the incident and the corrective actions, taken or planned, to prevent recurrence; or 2) address the accountability and control and health and safety issues associated with a licensee filing for bankruptcy or instances where material may have been abandoned.

87103-04 GENERAL GUIDANCE

04.01 Pre-Inspection Notifications. Regional and Central office management and staff involvement early in the incident assessment is critical in determining the scope of the proposed inspection activities and future actions. Contact should be made with other State and local authorities, Community Relations Coordinators and public affair representatives to coordinate follow-up actions. As soon as the decision is made to inspect the incident, notify the licensee's management that an inspection of the incident is to be conducted. When notifying the licensee, make sure that the incident has been brought under control and that there are no ongoing safety issues. If there are, immediately notify regional management of the situation. Request that the licensee preserve any physical evidence connected with the incident, if that is possible. Request in advance that the licensee be prepared to submit the necessary documents at the initial licensee meeting.

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04.02 Pre-Inspection Preparations. Prepare all materials and documents that may be needed during the inspection, based on your knowledge of the nature of the incident, types of exposures, and the availability of technical support and equipment at the site.

04.03 Initial Licensee Meeting. Meet with the licensee's management as soon as possible upon reaching the site. Explain the purpose of the inspection, the techniques to be used in conducting the inspection, the scope of the work, and the expected duration.

04.04 Facility Inspections. A tour of the facility or a specific area should be performed at the beginning of the inspection since it may be necessary for the inspector to observe proper control of licensed material affected by the incident. If possible have licensee representatives guide the tour, then arrange personnel interviews when the tour is completed. Inspect equipment, tools, work areas, storage areas, and anything else directly or indirectly involved in the incident.

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04.05 Interviews. Interview all personnel directly or indirectly involved in the incident, as well as all levels of management whose area of responsibility is in any way connected with the persons involved in the incident or who have any responsibility for the facilities or equipment connected with the incident.

04.06 Documentation. Obtain copies, or originals if copies are not available, of all documentation that may be needed in the inspection. Ensure that proprietary materials are appropriately safeguarded and original material handled carefully and returned at the end of the inspection. In any case where documentation supports or is needed to support an inspection finding, the inspector must make a copy of the document and include it as an attachment to the inspection report. The licensee should be advised of each document that will be included as part of the report.

04.07 Review of the Data. Review the notes of the interviews and tours, and the relevant documents. Establish a time line for the incident. If the data does not produce a coherent, internally consistent narrative, repeat interviews, tours, and document reviews until all inconsistencies and information gaps are addressed.

04.08 Establishing Causes. Once satisfied that all the relevant information has been obtained, ordered in proper temporal and logical sequence, and verified to be consistent, technically correct, and coherent, identify contributing factors and root causes. Correlate these findings with weaknesses in the licensee's program, and formulate ideas on what the appropriate corrective actions to prevent recurrence should be. Compare with the licensee's corrective actions and evaluate their adequacy. If the licensee's corrective actions are determined to be acceptable, a commitment and schedule for implementation should be made by the licensee and submitted to the regional office.

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04.09 Licensee Briefings. Meet periodically with the licensee's management and key personnel involved in the incident. Review the sequence of events and specify the suspected causes. Provide the licensee with opportunities to modify or correct the data, sequence of events, or conclusions. Obtain further data if warranted by the discussions, and make corrections to the conclusions, as necessary.

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04.10 Event Analysis Data. Make sure that as much as possible any data needed by the NMED database is available to you before the exit meeting (see Section 5.12).

04.11 Exit Meeting. Prepare notes summarizing the sequence of events and the conclusions. Identify possible items of noncompliance. Meet with the licensee's management and present these findings.

04.12 Post Inspection Actions. Any follow-up actions that the inspector takes on a reported incident should be summarized in writing, discussed with his/her supervisor, and maintained in the regional file for the licensee). A formal report of the results of the inspection should be prepared and distributed.

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Inspectors will also meet with Central Office licensing staff when any pertinent licensing issues are raised during the inspection, when inspection findings impact on any licensing actions, or to give feedback on how the licensee has addressed special license amendments or recent licensing actions. This meeting will be documented in the inspection record.

Additionally, in some instances, inspection findings will warrant communication with Bureau of Investigations staff, NRC, or other Federal and State agencies.

The inspector will ensure that inspection findings are clearly documented and reported to the licensee as appropriate. The inspector will also notify the licensee that information that is retained by the inspector is subject to public disclosure and give the licensee the opportunity to request withholding it.

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87103-05 DETAILED GUIDANCE

05.01 Pre-Inspection Notifications. As soon as the decision is made to travel to the licensee's facility to conduct an inspection, call the licensee to notify them of the upcoming inspection. Make sure to speak with a licensee official who is high enough in the organization to ensure prompt execution of any necessary arrangements. During this call, provide the licensee with the following information:

a. Expected time of arrival at the licensee's facility.

b. Purpose of the inspection.

c. Expected duration of the inspection.

d. Request a meeting with appropriate staff, including the responsible licensee management, very soon after the anticipated arrival time.

e. Identify individuals to be interviewed. Have the licensee make arrangements for these persons to be available when needed, and ensure that the radiation safety officer (RSO) will be available. If the licensee uses a consultant, request that the consultant be present during part of the inspection. If that is not possible, then arrangements should be made for him/her to be available by telephone during a specified time period.

f. Specify a time and date on which the exit meeting is expected to be held. Make it clear that this is a rough estimate that depends on the course of the inspection. Also make it clear that the highest level of facility management (e.g., the company president, CEO, or plant manager) is expected at this meeting, including the RSO.

g. Request that copies or, if not possible, originals of all documents that may be needed during the inspection be prepared and ready following the initial meeting. These documents usually include data on surveys and various radiological measurements, log books, calibration and traceability records, training and qualification records, an organization chart, procedures, and any other documents that may seem relevant (see also Section 05.07). If in doubt about the utility of a document, request it anyway. Emphasize the importance of providing all the requested documents as soon as you arrive at the facility.

h. Request that a knowledgeable person be available to accompany you on a tour of the facility.

i. Request that physical evidence connected with the incident be preserved, if possible. Examples of physical evidence may include: a survey instrument that gave erroneous readings or malfunctioned (useful in determining why the instrument malfunctioned); a dosimeter that gave a much higher than expected dose reading (may be tested to determine if the dosimeter is defective); contamination smears and air sample filters (may be recounted or subjected to more sophisticated analysis, if necessary); instrument settings as they were found after the incident, etc.

j. Make sure that access is available to any part of the licensee's facility that is involved in any way, directly or indirectly, with the incident. If there appear to be any difficulties, stress to the licensee that unescorted access must be arranged, escorted if need be. Notify regional management immediately of any potential difficulties in gaining access to areas or information. If a certain level of security clearance is required and you do not have that clearance, or if you do not have the required unescorted access training, immediately inform regional management and request guidance.

05.02 Pre-Inspection Preparations. Before leaving on the inspection, make sure to take all documents, calculators, computer disks, references, radiation safety equipment, etc., that may be needed. A portable computer may be very useful, as would a small hand-held tape recorder to record observations and ideas (not interviews), a camera, video camera or stopwatch. Arrange for regional or Central Office personnel to provide technical assistance over the telephone, in case information that is needed, is not available at the site, or if it is desirable to run a computer program on a regional computer, to check calculations. When preparing for the inspection, consider taking at least the following items:

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a. Writing pads, notebooks, and other stationary needed to record interviews, data, and findings, and to perform calculations and draw charts.

b. Calculator.

c. Computer discs with programs to perform various radiological calculations, if available, and if the licensee can provide the necessary computer, or a portable computer with the necessary software. Word processing software may be helpful if you can type at a reasonably rapid pace.

d. References, handbooks, etc., that contain the basic radiological equations and the values of frequently used constants. For example, if the incident involved external radiation exposures, equations to convert fluence to dose may be needed. A variety of source geometries should be anticipated, such as a point, line, disk, sphere, or cylinder, etc. Quantities normally needed in such calculations include attenuation and energy absorption coefficients at various energies, densities of a variety of materials, buildup factors, organ depths, and so on. Skin dose calculations require skin dose equations applicable to a variety of source geometries. Internal dose calculations will require organ masses, intake retention functions, intake to committed dose conversion factors for organs, and so on. In addition to the technical references, regulatory references should also be taken, including at least 25 PA Code Title 25 Article V and the parts of Chapter I (The parts of Title 10 that pertain to the NRC) that apply to the licensee, as well as other regulations that may apply, such as transportation regulations for transportation-related incidents.

e. Appropriate radiation safety equipment (instrument, dosimetry) to ensure areas are safely controlled.

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05.03 Initial Licensee Meeting. Upon arrival at the site, meet with licensee management. If a sufficiently high level of management commensurate with the severity of the incident is not present, explain the situation to the licensee, terminate the meeting, and contact regional management immediately. Await instructions from the region before proceeding. The importance of this step is that it is necessary to ensure that a licensee representative who has the authority to make changes in the program has first-hand knowledge of the inspection and its findings. During the initial meeting, present the following items briefly, but clearly:

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a. The purpose of the inspection.

b. The expected duration of the inspection.

c. The level of support you expect from the licensee.

Request a brief description of the incident including the names of the personnel directly involved. Request that the licensee make available the personnel to be interviewed. Request that the interviews start immediately after the meeting. Set an approximate time and date for the exit meeting. Make it clear that this is tentative and may change, depending on the progress of the inspection. Request that the licensee provide you with the documents you requested during the pre-inspection telephone conversation described in section 04.01. Find out the name of the person to accompany you on the tours. Request the name of a management person to contact in case you experience difficulties or you do not get the necessary level of support.

05.04 Interviews. Interview everyone connected in any way with the incident, either directly or indirectly. The interviews should follow a widening circle, from the small number of people directly involved, to an increasing number of people less and less directly involved. Persons directly involved are those whose actions directly led to the incident, such as, for example the person who dropped the syringe, or the person who was using the radiography source when it got stuck in the unshielded position. Persons indirectly involved are usually a larger class, but no less important. These include the assistants to the directly involved persons, supervisors of those persons, maintenance people, health physics or safety people, warehouse personnel, drivers, and so on. Also included in persons indirectly involved are the supervisory and management staff whose responsibilities are connected in any way with the persons directly or indirectly involved in the incident or to the facilities, hardware, software, supplies, or anything else involved in the incident. This list can be very long, but the depth of the interviews will vary depending on the closeness of the person's activities or responsibilities to the incident.

Although some of the personnel indirectly involved may not know much about the incident itself, they may contribute invaluable information about the morale of the staff, the quality of management at the facility, the level of training, the degree of attention to detail normally observed at the facility, audit and appraisal practices, involvement of consultants and the quality of their work, the quality of procedures in general, and the degree to which management insists that personnel adhere to applicable procedures. During these interviews, try to get a clear impression of the extent to which the persons interviewed are aware of the circumstances directly or indirectly connected to the incident, and whether their knowledge and awareness are commensurate with their responsibilities in the organization.

When conducting the interviews, observe the following guidelines:

a. Interview only one or, at most, two people at a time. A worker's union representative may be present if the worker requests it. However, unless there is a compelling reason, avoid interviewing people in the presence of the supervisors.

b. Start the interview by stating clearly, but not too specifically, what you expect to learn from the person.

c. Make it clear that the purpose of the interview is not to find fault or assign blame, but to learn what happened and if there were any contributing factors so that any weaknesses in the program may be corrected. Be very courteous and realize that the person being interviewed is helping you in your inspection.

d. Do not interrupt, but ask questions when a statement is not clear. Ask questions that elicit useful details rather than questions that call for yes or no answers. Also, do not ask leading questions, i.e., questions that imply the expected answer, such as "you did follow proper procedure, didn't you?". As long as the person is talking about issues relevant to the incident, let the person talk. Keep the conversation focused and end the interview as soon as it becomes clear that no further useful information can be obtained.

e. Make sure to ask open-ended questions that will produce all the information the person being interviewed is expected to provide. The person interviewed may forget something or may believe that a piece of information is not relevant and may therefore not state it. You must be alert to this selectivity and ask questions to compensate.

f. Write down all information discussed during the interviews, such as times, places, recalled conversations, names of people, equipment, sources, reagents, supplies used, procedures involved, surveys done, and any information presented, even if it does not seem to be very relevant at the time. Keep the notes clear and orderly so that they may be used later to reconstruct the information obtained in the interview.

05.05 Facility Inspections. The purpose of a facility inspection is to help reconstruct the events leading to the incident, to place all items and persons involved in proper spatial perspective, and to attempt to identify any factors, relating to the facility or equipment, that may have contributed to the incident. Have a knowledgeable licensee representative take you on a tour of the facility. Ask that person to point out all relevant items involved in the incident and to show you the path followed by the persons involved, the layout of equipment and materials at the time of the incident, and any equipment settings that may be relevant to the inspection.

Upon arrival at the facility, proceed to make a tour of the facility or the area and remind the licensee of the need to provide unescorted access. Keep in mind that you must abide by all of the licensee's rules and procedures as provided in their site access training. Take time to absorb all detail, and retrace the paths followed by the persons involved in the incident. Remember, however, that this is an event follow-up inspection, and includes only those items that may have a bearing on the event.

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During these tours, look for the following, among other things:

a. Postings and Access Control: Are all radiation areas properly posted with the correct postings? Are radiation postings clearly visible and clean, and do they provide the necessary information? Is access to restricted areas properly controlled? Are dosimeters issued to the proper personnel, and are they worn properly?

b. Equipment and Facilities: Does the equipment, including radiation measuring instruments, look well maintained and properly handled? Do instruments have calibration stickers showing valid calibration dates? Is shielding provided where needed?

05.06 Reenactment of the Incident. Incidents that involved a complicated series of movements may be difficult to visualize on the basis of descriptions provided by the licensee. In this case, a reenactment may prove very helpful. The reenactment consists in having the persons directly involved in the incident go through all the motions that ultimately led to the incident. NRC regional management and staff should encourage the licensee to perform and record on videotape the event reenactment for later and repeat viewing. Prior arrangements and authorizations by the licensee and regional management must be made to record the reenactment on videotape. In any case, where the licensee records the reenactment on videotape, the inspector should obtain a copy of the licensee's videotape.

If the equipment or facility involved in the incident is no longer available, or is unsafe for use in the reenactments, a mockup of the equipment or facility may be used, if warranted. A mockup is a model that is used in place of the equipment during the reenactment. The mockup does not have to be an exact replica of the equipment, but should include the essential features that are significant in determining the outcome of the incident, such as the general shape or size, distances, and the weight if carrying the item was involved.

Reenactments are very important, and sometimes essential, in cases where exposures at high dose rates in complicated configurations were involved. In such cases, differences of a few seconds in the estimated exposure times can result in large differences in the doses assessed for the persons involved. Reenactments, with time-and-motion studies, allow refinement of estimates of exposure times, and also provide the basis for calculating the dose rates at different phases of the incident by observation of the relative positions of the personnel and radiation source during the incident.

If the dose calculations show that any person involved in the incident was exposed to high doses (i.e., above 20 Rem), regional management should contact the appropriate Central office management to consider the need for cytogenetic studies. Such studies may confirm, in some cases, that a high dose was received.

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05.07 Documentation. The documentation needed for the inspection includes documents that indicate the overall quality of the licensee's operation, as well as those that are directly related to the incident. Obtain for review at least the following documents:

a. Procedures for all activities directly and indirectly related to the incident. If applicable, review these procedures and determine their adequacy in terms of clarity of presentation, completeness of information, logical flow of steps to accomplish the desired end, and clarity of decision points. If the procedures are found to be weak, determine who wrote them, the qualifications of those persons, and how the procedures were tested to ensure that they are correct and complete. If availability of procedures appears to be a problem, verify that there are procedures for all of the important activities. Check on the method used by the licensee to keep all procedure copies in the facility updated, and how controlled and uncontrolled procedures are used. Check on the availability of copies of relevant procedures at the locations where they are supposed to be used. Determine the procedure review schedule and verify that procedures were reviewed on schedule by qualified personnel.

b. Training and Qualifications Records. Obtain records of the qualifications of all persons directly or indirectly connected with the incident, including technicians,

safety personnel, supervisors, and managers. Review these records and verify that all personnel meet at least the minimum qualification requirements for their positions and are qualified for their respective functions. Review training records and check the training schedules to verify that they meet minimum training requirements. Verify that persons scheduled for training within the past year or two have attended that training. Review the qualifications of the persons who provide the training, and review some of the lesson plans. Review some examination questions and some answers to these questions.

c. Calibration and Quality Control Records. Check the calibration records and verify that all equipment that should have been calibrated was indeed calibrated. Check that all instruments scheduled for calibration during the past year or two have been calibrated at the proper time, using approved procedures and sources. Check records of traceability of calibration sources or instruments. Verify that personnel performing the calibrations are properly qualified and trained for the job. Check the quality control program and schedules. Verify that daily or periodic quality control checks were made as scheduled, that the results of these checks were recorded, that instruments that did not pass the tests were taken out of service, and that these checks are routinely reviewed and signed by a sufficiently high level of management.

d. Records of the Incident. Obtain and review all records that bear directly and indirectly on activities leading to the incident. These include the names of persons involved, the dates and times they entered and left the relevant areas, the type of dosimetry and the readings of these dosimeters, any protective clothing worn, and any equipment or sources issued to them. Check log books to determine the record of activities that were performed and that eventually led to the incident. Check the records of any radiation surveys that may have been made before, during, or after the incident.

e. Records of Recovery. Obtain all records that show the activities taken to recover from the incident. Check on whom initiated corrective actions, who was notified, who responded and how, who came to the site of the incident, what they did, and when an investigation was initiated. Determine the scope of the licensee's investigation, who was in charge of it and who was involved, who reviewed and approved the results, and what corrective actions were recommended and what actions were actually implemented.

05.08 Review of the Data. A final reconstruction of the incident must now be attempted, and must include all available details. Start as far back in time from the incident as may seem relevant to the ensuing events. Note where the staff members were at the time, what they were doing, and what was said. Proceed forward in this manner until the time of the incident, and then proceed to the recovery phase in the same manner. Note on a time line all relevant detail, such as what doors were open or closed, what postings were in the area, instrument readings, room occupancy, clothing worn, procedures and equipment used, when equipment was turned on or off, and what the thoughts of the persons involved were, relevant to the events that were taking place (e.g., the technician might have thought that the source was in the shield, but, in fact it was not). Try to note why certain actions were taken and certain others were not. For example, the technician did not perform the required survey because he thought the room had been surveyed by someone else, or because the battery in the survey instrument was dead, etc.

At the end of this review, the inspector should understand the incident and relevant factors as well as, if not better than, anyone on site. All detail must fall in place, and the flow of decisions, actions, and responses must be quite clear. If any gaps exist, or if any item is not quite clear, return to the notes or documents, interview more people, or interview again

some of those already interviewed, tour the facility again, or request additional records. If the data and events are complex, consider using charts. Make up your own system or use standard charting techniques, such as those used in event and causal factors analysis.

The inspector can refer to NUREG-1303, "Incident Investigation Manual," as a guide on how to collect data. Although primarily used for an Incident Investigation Team, NUREG-1303 is the reference document based on inspection experience that provides good follow-up information on how to conduct an investigation and interview, collect information, write a preliminary notification, and prepare a report.

05.09 Establishing Causes. Most incidents usually have direct causes, as well as several contributing causes, and one or more root causes. Direct causes are the obvious ones that led directly to the incident. Contributing causes are those that facilitated, or did not prevent, the direct cause. Direct causes usually point to contributing causes which in turn point to root causes. A common direct cause is failure to follow procedures or good practices. Failures to follow procedures may have a number of causes, including, lax discipline, poor management supervision, poorly written procedures, procedures that are difficult or impractical to implement, unavailability of procedures, and so on. These contributing causes may point to other contributing causes, such as poor training, poor morale, no management oversight, etc. For incidents involving a complex interaction of events, or a long sequence of events, charts may prove to be very useful in identifying causes. It should be remembered that causes must be sought not only for the direct causes, but also for every contributing factor. One may view the incident as a series of incidents, each with its own set of causes, and each leading to, or failing to prevent, the subsequent action. All these contributing causes may have one or a few root causes in common, such as, for example, an unqualified program manager, or poor management practices.

After identifying the causes, express them in a logical hierarchy, one leading to the next. State the cause in a manner that suggests how the action should have proceeded if it had been done properly. For example, it is better to say that the bottle slipped out of the technician's hand because the technician was not wearing gloves, causing his or her hand to be slippery, rather than that the bottle slipped because the technician's hand was slippery. The incorrect action is in this way directly tied to the consequence of that action, and at the same time clearly implies the correct action that should have been taken, in this case, to wear gloves. Finally, the inspector should review the direct and root causes against the licensee's causes and corrective actions to determine whether the licensee's response was appropriate.

05.10 Licensee Briefings. Once the events and data are properly ordered and understood, and causes identified, discuss with the licensee, at a preestablished time, the status of findings and communicate the issues as they develop. Schedule a brief meeting that includes all persons directly and indirectly involved in the incident. Ensure that key licensee staff is represented in the meeting, and certainly the supervisory and management personnel directly responsible for the area involved in the incident. If brief meetings are held with the licensee to discuss issues as they develop, reasonable assurance can be made that the licensee will be aware of problematic areas at the time the exit meeting is held.

Present your findings in a clear, and logical order. Review your understanding of the incident, the sequence of events that led to it, the persons involved, their actions, and how these actions contributed to the incident.

After your presentation, which should not last more than 30 minutes for a complex incident, allow the licensee to comment and to express disagreement. Make sure you understand the reasons for the disagreement, and clearly separate those that stem from differences of

opinion from those that arise out of disagreements on matters of fact. For the former, try to understand the licensee's point of view and note it for later consideration. For the latter, ensure that disagreements on fact are resolved, either at the meeting, or later. All factual disagreements must be resolved at this stage. If factual disagreements are extensive, reschedule the meeting and allow time to review and correct any factual errors. This phase of the inspection should not end until all disagreements on matters of fact are resolved to the extent possible and to your satisfaction.

05.11 Management Briefing. Keep regional management informed of the progress of the inspection. Periodically, summarize the findings and call the regional supervisor or manager and discuss the findings. This is especially important if there are, or are expected to be, controversial issues arising from the findings. It is also important to discuss the merits of any items of apparent noncompliance with regional management before discussing them with licensee representatives. Notify regional management of any suspected falsification of records, providing false information to the DEP, or any other willful wrongdoing. If the inspector identifies serious or controversial issues which cannot be immediately resolved then regional management should consider if Central Office or their presence on-site is warranted.

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05.12 Event Analysis Data. DEP collects, reviews, and codes material license event data, and maintains a local database that supplies event data to the NRC's Nuclear Material Events Database (NMED) of non-reactor events. The purpose of collecting operational event data is to identify systemic causes of licensee problems that are significant to licensee and public health and safety. In addition to maintaining this incident database, NRC also provides computer programs to search the database and classify incidents in a variety of ways, depending on the user's needs. For example, incidents may be classified by dose received, body part exposed, type of license, and many other variables. To accomplish this goal, NRC and DEP databases must be provided with a minimum amount of information for each incident. This minimum information is shown in Appendix A in the form of a listing of the variables needed. Review the list and record the data for each variable, as it pertains to the incident. At this stage of the inspection, all listed information should be readily available to you. If not, attempt to obtain any missing information from the licensee before the exit meeting. All documents created related to the event, such as the inspection report, letters to the licensee or trustee, etc., should have the NMED event number in a clearly visible location. This will ensure that all documents related to the event are identified in the database.

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05.13 Exit Meeting. The exit meeting is the concluding meeting of the inspection, and its purpose is to provide the licensee with a summary of the findings and any items of noncompliance. Schedule the meeting for a time just before leaving the site, and leave immediately after the meeting. Make sure the meeting is attended by a sufficiently high level of management, including the RSO. Make sure the meeting is attended by the highest level of facility management (e.g., the company president, CEO, or plant manager), including the RSO. The exit meeting is your meeting, held at your request, and you must conduct the meeting. Open the meeting by explaining the reasons for coming on site, what you did, and what were your findings. Explain what you believe were the causes of the incident and the program weaknesses that they indicate. Present your conclusions regarding contributing and root causes. List the potential violations of regulatory requirements or license conditions, and note that these are apparent violations to be reviewed and approved by regional management. Ask if everything is clear and if there are any questions. Do not enter into any discussions but note any disagreements and inform the licensee that you will convey their disagreements to regional management. Thank the licensee for their cooperation during the inspection, end the meeting, and leave site.

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05.14 Post Inspection Actions. The inspector will review his or her inspection findings with regional management to determine what follow-up actions must be taken. The

inspector should discuss the findings in detail, commensurate with the scope of the licensee's program. Violations, items of concern, and unresolved items should be discussed in sufficient depth for management to make appropriate decisions regarding enforcement actions, referral to other State and Federal agencies, and decisions on the scheduling of future inspections of the licensee's facility.

Discussion of the inspection findings with licensing staff can be particularly useful if the licensee is having its license renewed or has recently submitted a license amendment request. Licensing information requested by the licensee should also be discussed with the licensing staff.

Inspectors should be aware that the information collected may be used as evidence in criminal proceedings.

The inspector will prepare a formal report of the results of the inspection. The findings should be documented in the inspection record, in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement, and when it was violated. Copies of all licensee documents needed to support the violation should be attached to the inspection record. The inspection record should be used to describe what procedures or activities were observed and/or demonstrated by the licensee during the inspection, and any items of concern identified that were not cited as a violation of regulatory requirements.

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87103-06 BIBLIOGRAPHY

Internal Dose Calculations

- ICRP 30 - Limits for Intakes of Radionuclides by Workers.
- Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion, Federal Guidance Report No. 11, EPA-520/1-88-020, September 1988.

External Dose Calculations

- Introduction to Radiological Physics and Radiation Dosimetry, F.H.Attix, John Wiley and Sons, 1986.
- Introduction to Health Physics, H. Cember, Pergamon Press, 1983.
- Table of Isotopes, C. M. Lederer, J. M. Hollander, and Perlman, John Wiley and Sons, 1967 (or later edition).
- Concepts of Radiation Dosimetry, Kase, K.R., and Nelson, W.R., Krieger, New York, 1978.

Skin Dose Calculations

- Radiation Dosimetry, G. J. Hine and G. L. Brownell, Academic Press, 1956

Dosimetry

- Radiation Dosimetry, Volumes I & II, F. H. Attix, W. C. Roesch, and E. Tochilin, Academic Press, 1966.
- Handbook of Radiation Protection and Measurement, Vol. I, Physical Science and Engineering Data, Brodsky, A. ed., CRC Press, Boca Raton, Florida, 1978.
- Handbook of Radiation Protection and Measurement, Vol. II, Biological and Mathematical Information, Brodsky, A. ed., CRC Press, Boca Raton, Florida, 1982.

- The Physics of Radiology, 3rd ed., Johns, H.E. and Cunningham, J. R., Springfield, Ill., 1973.

Bioassay

- NUREG/CR-4884, - Interpretation of Bioassay Measurements.

Biological Effects

- Radiation Biology, A. P. Casarett, Prentice-Hall, 1968.
- Health Effects of Exposure to Low Levels of Ionizing Radiation, Committee on the Biological Effects of Ionizing Radiations, BEIR V, National Academic Press, 1990.
- Manual on Early Medical Treatment of Possible Radiation Injury, IAEA, Vienna, 1978.
- Medical Aspects of Radiation Accidents, Saenger, E.L., ed., U.S. Atomic Energy Commission, Government Printing Office, Washington, D.C., 1980.

Computer Software

- VARSKIN, for skin dose calculations.
- MICROSHIELD, for external dose and shielding calculations.

Deleted: - CINDY, for internal dose calculations.

END

Attachments:

Appendix A, Information Needed For Nuclear Materials Events Database (NMED) Database

Appendix B, Guidance for Inspection of Materials Licensees Who Have Filed for Bankruptcy.

APPENDIX A

INFORMATION NEEDED FOR THE NUCLEAR MATERIALS EVENTS DATABASE (NMED) DATABASE

General Information - All Events

License Number
Additional license numbers, if multiple licenses
PA Event Number
Licensee's name*
Licensee's city of record*
Licensee's county of record*
Licensee's state of record*
Licensee's telephone number*
City where the event occurred
State where the event occurred
Agreement State (Y/N)
NRC region number
Reportable event?
Date event occurred
Date event reported to NRC or state
Time of event
Was a consultant hired to investigate?
License number of additional involved party
Additional licensee's name
Additional licensee's city of record
Additional licensee's county of record
Additional licensee's state of record

* If a non-licensee is involved, note that fact and enter the marked items.

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General Information - All Medical Events

Deleted: Misadministrations

Type of Medical Event (Part 35)
Dose prescribed
Dose received
Percent under prescribed dose
Percent over prescribed dose
Intended target organ or site
Actual target organ or site
Was patient notified of the Medical Event?
Was patient's family notified of the Medical Event?
Was the patient's referring physician notified?
Number of people who received a Medical Event

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Specific Data on Teletherapy Events

Source of radiation prescribed
Source of radiation administered
Model number of teletherapy unit
Manufacturer's name
Serial number of teletherapy unit
Model number of teletherapy unit's source
Manufacturer's name
Serial number of teletherapy unit's source

Teletherapy source activity
Teletherapy source assay date
Teletherapy source radionuclide

Specific Data on Brachytherapy Events

Radionuclide of source prescribed
Radionuclide of source utilized
Activity of source prescribed
Activity of source utilized
Model number of source utilized
Manufacturer's name
Serial number of source utilized

Specific Data on Radiopharmaceutical Events

Radionuclide of pharmaceutical prescribed
Radionuclide of pharmaceutical administered
Activity of pharmaceutical prescribed (mCi)
Activity of pharmaceutical administered (mCi)
Chemical form of pharmaceutical prescribed
Chemical form of pharmaceutical administered
Manufacturer's and/or supplier's name

Specific Data on Radiation Overexposure Events

Number of people who received overexposures
Dose received from the overexposure
Were members of the public overexposed?
Were radiation (occupational) workers overexposed?
Were overexposed persons notified of their exposures?
Source of radiation causing the overexposure
Model number of device causing the overexposure
Manufacturer's name
Serial number of device causing the overexposure
Model number of sealed source causing the overexposure
Manufacturer's name
Radionuclide that caused the overexposure
Activity of the source that caused the overexposure
Assay date of the source

Specific Data on Lost, Abandoned, or Stolen Radioactive Material Events

Model number of the lost or stolen device, instrument, or gauge
Manufacturer's name
Serial number of the lost or stolen device, instrument, or gauge
Model number of the lost, stolen, or abandoned sealed source
Manufacturer's name
Serial number of the lost, stolen, or abandoned sealed source
Radionuclide in the lost, stolen, or abandoned source
Activity in the lost or stolen source
Assay date of source

Specific Data on Leaking Sealed Source Events

Model number of the leaking source

Manufacturer's name
Serial number of the leaking source
Radionuclide of the leaking source
Activity of the leaking source
Assay date of source
Leak test results?
What kind of leak test?

Specific Data on Release of Radioactive Material Events

Radionuclide that was released
Activity of the material released

Specific Data on Radiography Equipment Malfunction or Failure Events

Model number of the equipment that failed or is defective
Manufacturer's name
Serial number of the equipment that failed or is defective
Accessory equipment
Manufacturer's name

Specific Data on Damaged Industrial Gauging Device Events

Model number of the damaged gauge housing
Manufacturer's name
Serial number of the damaged gauge housing
Model number of the sealed source in the damaged gauge
Manufacturer's name
Serial number of the sealed source in the damaged gauge
Activity of the sealed source
Assay date
Source radionuclide

Specific Data on Consultants

Was a consultant hired?
Consultant's name
Name of consultant's company
Who hired the consultant?
What is the consultant's specialty?

Specific Data on Licensee Corrective Actions

Licensee corrective actions

END

APPENDIX B

GUIDANCE FOR INSPECTION OF MATERIALS
LICENSEES WHO HAVE FILED FOR BANKRUPTCY

Note: NUREG-1556, Vol. 15 should be used as guidance for inspection of materials licensees who have filed for bankruptcy.

After receiving a report that a licensee has filed for bankruptcy or that an involuntary petition has been filed against it, DEP licensing staff verify that all licensed material possessed by the licensee is being adequately controlled. If it is determined that licensed material may not be adequately controlled, a special inspection should be conducted. The special inspection should be conducted in accordance with this Inspection Procedure.

Any steps to secure the site should be taken only after consultation with the Office of the General Counsel, to ensure that DEP's rights to compel the debtor to satisfy its public health, safety, and environmental obligations, or to pursue any claim against the assets of the bankruptcy estate would not be unnecessarily prejudiced.

DEP staff performing the assessment of material control and special inspection should take into consideration the following guidance:

1. When determining the adequacy of material control and preparing for an inspection, DEP staff should verify:

   a. the Radiation Safety Officer remains in the position; and
   b. access to the licensed material is under positive control (i.e., the facility has not been abandoned);

   and review DEP license files for:

   a. reports of leaking sealed sources;
   b. disposition of any identified leaking sealed sources;
   c. reports of facility contamination;
   d. reports of possible inventory discrepancies; and
   e. history of violations, specifically those related to performing leak tests, inventories, and facility surveys.

2. While performing the special inspection at the licensee's facility, inspectors should review records for:

   a. definitive inventory of licensed radioactive material;
   b. leak test records;
   c. facility surveys; and
   d. shutter checks of fixed gauges (this will help to determine the status of the device whether locked out or not).

3. While performing the special inspection at the licensee's facility, inspectors should also:

   a. direct an inventory of licensed and unlicensed radioactive material to be performed, as necessary[1];
   b. direct leak tests to be performed, as necessary[2];
   c. direct facility surveys to be performed, as necessary[3]; and
   d. perform a survey.

Deleted: The inspector should be aware that NUREG-1556, Vol.15 "Program-Specific Guidance about changes of control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses,"has been issued in draft form. When this draft report is issued in final form, PG 8-11 "NMSS Procedures for Reviewing Declarations of Bankruptcy," will be considered superseded and

Deleted: Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," requires that, a

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Deleted: Policy and Guidance Directive PG 8-11 also requires that a Bankruptcy Response Team (BRT) be formed. A BRT consists of representatives from various NRC offices, whose purpose is to provide a coordinated response to declarations of bankruptcies, to assess whether there are any current public health and safety concerns at the facility, and to determine any impacts the bankruptcy could have on licensed operations. The results of the special inspection, if conducted, will assist the BRT with their duties.¶
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Inspectors should consider whether control of licensed material has been maintained and will continue to be maintained, especially in cases where operations have ceased or will cease. Considerations of such cases may include:

a. the likelihood of inadvertent releases due to cessation of operations;
b. adequate control of licensed material in the event a closed facility is accessed in an unauthorized manner; and
c. degradation of material control over time in a prolonged shutdown condition.

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Even though the licensee has filed for bankruptcy, the licensee remains responsible for all regulatory requirements. The inspector's role is to make necessary confirmatory measurements. However, if the licensee has abandoned the material and the trustee cannot perform these measurements, the inspector shall perform them to evaluate the health and safety consequences.

Deleted: 4. . Upon completion of the special inspection, the inspector should provide documentation of the findings to the BRT leader.¶
¶

By completing the above actions, all entities involved are aware of the situation and health and safety issues may be resolved before bankruptcy actions are completed.

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[1] If the reviews of files reveal a concern or raise doubts, or if the licensee has a history of not performing inventories, then an inventory should be completed.

[2] If the reviews of files reveal a concern or raise doubts, or if the licensee has a history of not performing leak tests, then the sealed sources should be leak tested. In addition, consideration should be given to leak testing sources that have been in storage for greater than one year. The inspector should consider the former use of the source(s), the current physical condition of the source(s) (e.g., visible damage, corrosion, etc.), and the past history of the licensee's performance of leak testing.

[3] If the reviews of files reveal a concern or raise doubts, or if the licensee has a history of not performing surveys, then a basic facility survey should be conducted.

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DECOMMISSIONING INSPECTION PROCEDURE
FOR MATERIALS LICENSEES

87104-01 INSPECTION OBJECTIVES

01.01 To determine if licensed decommissioning activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed decommissioning programs are being conducted in accordance with DEP requirements.

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01.03 To provide inspection requirements and guidance for facilities needing a significant decommissioning effort and where licensee submittal of a decommissioning plan (DP) for DEP approval may be required.

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87104-02 INSPECTION REQUIREMENTS

A review of the licensed activities will be commensurate with the scope of and the risks associated with the licensee's program. A determination regarding safety and compliance with DEP requirements will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC or DEP, and independent measurements of radiation conditions at the facility, in addition to a review of licensee records.

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All decommissioning activities performed by the licensee and its contractors should be considered for inspection. Inspection findings for contractor activities conducted under the site operator's license and supervision shall be documented against the site operator's program. Inspection findings for contractor activities conducted under the contractor's license and supervision shall be documented against the contractor's program. If it is unclear what radiation safety program governs a contractor activity, that activity shall be viewed as falling under the site operator's license and supervision.

In discussing issues with the licensee and reviewing records, cover the period back to the last inspection. Older records or issues preceding the last inspection should be reviewed if warranted by circumstances such as a history of incidents, non-compliance, or high radiation exposures.

The inspection program should be tailored to each specific licensee. Most materials licensees will not require submittal of a formal DP for DEP review and approval. Some materials licensees, such as medical teletherapists, well loggers, and radiographers, will not require any actual decontamination or dismantlement of facilities. For this type of licensee and licensees requiring limited decontamination, the inspector may use Inspection Procedure (IP) 83890 for the closeout inspection.

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An increased level of DEP inspector oversight is needed for licensees that may require extensive remediation and a detailed final survey, such as manufacturers of radiochemicals and certain academic and research institutions. For these licensees, apply the requirements and guidance in this IP, including the field notes in Appendices A and B.

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02.01 Applicable Inspection Requirements from the Operational Program. The inspector should review all inspection procedures that were applicable to the licensee's operational program, and select those portions that carry over to the licensee's decommissioning program. The inspector should develop an inspection plan that will focus on the adequacy of routine activities that can significantly affect the health and safety of workers and the public and the environment around the licensee's facility.

Deleted: Refer to Inspection Manual Chapter (IMC) 2800 and the IP 87100 series for materials licensees.

Some of the most important inspection elements should include: security and control of contaminated material; radiation protection for workers; radwaste generation, storage, transportation, and disposal; effluent releases and environmental monitoring; management organization and controls; occupational safety and health; essential systems and services to support decommissioning; and final survey.

In addition to the inspection activities described above, the inspector should also use other parts of the DEP Inspection Manual that are routinely used on typical inspections.

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02.02 Inspection of Key Decommissioning Activities. The inspector should develop an inspection plan to observe key decommissioning activities being performed by the licensee and its contractors. Key decommissioning activities, occur in all phases of the decommissioning process. Key decommissioning activities for facilities requiring a significant decommissioning effort, such as building remediation and dismantlement, soil removal, and groundwater remediation, are identified below.

a. Inspections before Dismantlement. This is the decommissioning planning stage after the shutdown of operations and before dismantlement and remediation. Key activities and conditions may include: verification that the DP has been reviewed and approved (if required); identification and demarcation of areas in operation and areas undergoing decommissioning, where only part of a facility is being decommissioned; removal of licensed materials from the facility (if required by license condition); verification that security and control of contaminated material are in compliance with 10 CFR 20.1801 and 20.1802; compliance with decommissioning timeliness requirements; compliance with record keeping requirements for decommissioning; implementation of the licensee's decommissioning organization; site characterization; and construction of site features to support decommissioning.

b. Inspections during Dismantlement and Remediation. This is the stage when the site is actively being decommissioned. Key activities include: maintenance of security and control of contaminated material; decontamination and dismantlement of structures; remediation of soil, sediment, surface waters, and groundwater; survey measurements and analytical methods, waste management and on-site storage; transportation and offsite disposal of wastes; on-site disposal of waste; restoration of the site; and inspection activities identified during the license review of the licensee's DP. Inspectors should consider the use of in-process inspections. In-process inspections have been shown to be more efficient than one-time confirmatory surveys. In-process inspections allow DEP to take side-by-side measurements, collect water and soil samples, and address survey issues early in the decommissioning process.

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c. Inspections After Remediation. Key activities in this stage include: licensee final survey; DEP confirmatory survey; and confirming final site status.

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87104-03 INSPECTION GUIDANCE

General

Observations of licensee decommissioning activities in progress, equipment in use, facilities and use areas, and the implementation of specific license conditions and approved DPs and procedures will be primary indicators of the quality of the licensee's overall radiation safety program.

Review of licensee records related to decommissioning will also contribute to the evaluation of the licensee's program. In reviewing records, look for trends - such as increasing doses, effluent releases, or groundwater contamination - that may indicate areas of potential concern. Records of surveys, waste disposal, effluent release, receipt and transfer of radioactive materials, training, instrument calibrations, source checks, quality assurance/quality control audits, use logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety, such as personnel dose-monitoring records and incident reports, should be examined in greater detail.

The planning and field conduct of an inspection should be coordinated with DEP, Management and any other appropriate Regional or Central Office staff.

A major part of inspection activities will be related to evaluating the licensee's final survey program for release of the site under DEP regulations. For facilities that will require a final survey, the inspector should begin this activity early in the decommissioning process, starting during site characterization, to ensure that the site will be remediated in accordance with DEP requirements and the licensee's approved DP. Confirmatory surveys, by the inspector or an DEP contractor, may be necessary. Inspectors should consider the use of in-process inspections. In-process inspections have been shown to be more efficient than one-time confirmatory surveys. In-process inspections allow DEP to take side-by-side measurements, collect water and soil samples, and address survey issues early in the decommissioning process. The extent of the confirmatory surveys will depend on the inspector's and the Licensing Project Manager's confidence in the quality of the licensee's final survey program. In general, minimal, or no confirmatory surveys are necessary for licensee's that have demonstrated, through DEP inspection or other means, that their final survey program is comprehensive, well-documented, and of high quality.

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Deleted: Many of the inspection activities required during decommissioning are similar to inspection activities conducted at operating facilities. The guidance given in this section, therefore, includes references to other sections of the NRC Inspection Manual that are applicable to materials decommissioning. The inspector should refer to IMC 2602 for general policies and guidance for decommissioning inspections.¶
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03.01 Applicable Inspection Requirements from the Operational Program. Many inspection activities will follow directly from those used during the licensee's operational program. Review the licensee's DP and supporting documents for licensee activities that are similar to those that were performed as part of the operational program. Develop the inspection plan to carry over to decommissioning the applicable inspection activities used during the operational phase of the licensee's program. Tailor the inspection plan to meet licensee-specific conditions.

Some of the operational program's inspection requirements that carry over to decommissioning of licensed activities are described below:

a. Security and Control of Contaminated Material. Security and control of radioactive material at the site shall be maintained, per 10 CFR 20.1801 and 20.1802. Confirm that licensee security and control of contaminated material are in compliance with the DP throughout the decommissioning process. Verify that the posting requirements of 10 CFR 20.1902 are met for any contaminated material. Containers of contaminated materials shall be labeled in accordance with 10 CFR 20.1904 and 20.1905. Contaminated materials in buildings should be secured and controlled by the licensee in such a manner as to prevent unauthorized access or theft of radioactive material.

In some situations, especially for materials licensees, the only way to prevent unauthorized access or theft is to lock all access points to the material. However, mechanisms needed to prevent access are usually dependent upon the nature of the situation at the licensee's facility, such as the physical layout of the facility and the movement patterns of people within that facility. Other possibilities for securing against unauthorized removal include having a person present who could prevent such removal of material. The need to lock access to the licensed material must be determined on a case-by-case basis, after reviewing the details of the licensee's decommissioning program.

At sites undergoing decommissioning, contaminated materials in outside areas may be secured and controlled by fencing (different types, depending on facility location and human populations around the facility, for example), soil covers, or other means. Three-to 4-foot-thick soil covers over contaminated soil, slag, or tailing piles are generally acceptable.

Access to buildings, rooms, or indoor and outdoor areas where contaminated materials are present shall be limited only to individuals having the licensee's permission for access.

b. Radiation Protection for Workers. Inspect the licensee's approved health physics procedures, as implemented in the field, to determine that the approved program is being implemented and to establish the degree of potential for exposures. Tailor subsequent inspections to concentrate on identified areas of risk.

c. Effluent Releases/Environmental Monitoring. Verify that licensee offsite monitoring and sampling locations and frequencies are sufficient to demonstrate that the effluent limits in Appendix B of 10 CFR 20 are being met. The potential for offsite release may be lower during decommissioning than during operations, but inspections for offsite releases should continue to be performed during decommissioning. Verify instrument calibrations are being performed as required.

d. Management Organization and Controls. Review licensee implementation of approved plans and programs, regulatory requirements, and license conditions for the management and control of decommissioning of the facility, including: the licensee organization in place for the decommissioning project; designation and qualification of the radiation safety officer; the QA program and annual review; records control and storage; internal review and audit; safety committee; procedure control for cleanup operations; and the decommissioning procedures to be implemented.

e. Essential Systems and Services to Support Decommissioning. Verify, through observations in the facility and review of licensee records, that the support systems needed for cleanup and dismantlement efforts are functional. These systems include: electrical power; heating, ventilation, and air conditioning systems; water supply; in-plant communications systems; liquid and solid contaminated waste systems; and in-plant lighting.

f. Occupational Health and Safety. Decommissioning activities often involve work practices, such as deep excavating and dismantlement of buildings, that present non-radiological safety hazards. DEP inspectors, although not OSHA inspectors, should be aware of, and identify non-radiological health and safety issues that are caused by licensee decommissioning activities.

g. Documentation of Inspections. Fully document - by the fieldnotes in this IP, the fieldnotes in the applicable 87104 IP for the licensee's operational program, or, if

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necessary for complex sites, a written report - all visits to and inspections of each site undergoing decommissioning. Radioactive materials at the site present potential health and safety hazards until the site is remediated and the license is terminated.

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03.02 Inspection of Key Decommissioning Activities. Identify all significant or key licensee activities of a particular site undergoing decommissioning, including before, during, and after remediation. Develop an inspection plan to focus on activities where potential health and safety problems may occur, especially accounting for high-risk activities. The frequency of inspections should be based on the particular set of decommissioning activities to be performed by the licensee. Typical key decommissioning activities are given below. Complete the checklist of key decommissioning activities in Appendix A as part of your inspection report.

a. Inspections before Dismantlement

1. Facility Conditions. Verify that all requirements preceding actual facility remediation are in place, including: the DP has been reviewed and approved (if required); licensed material used during operations has been removed from the site (if required by license condition); specific license conditions pertaining to the planning and preparation stage of decommissioning have been put in place by the licensee; and essential systems and services to support decommissioning activities are in place.

2. Timeliness Requirements. Verify that decommissioning schedules are consistent with decommissioning timeliness requirements in 10 CFR 30.36, 40.42, and 70.38, or that the licensee has submitted an alternative decommissioning schedule for NRC approval.

3. Recordkeeping Verify that recordkeeping for information important to the safe and effective decommissioning of the facility is consistent with the recordkeeping requirements in 10 CFR 30.35, 40.36, and 70.25.

4. Financial Assurance. Verify that the financial assurance requirements, including financial instruments, are being maintained in accordance with 10 CFR 30.35, 40.36, and 70.25.

5. Site Characterization. Verify that site characterization activities are being conducted in accordance with all applicable radiation protection procedures. The inspector may want to conduct an inspection with the licensee (or licensee's representative) while the licensee is performing characterization. Where possible and warranted, conduct side-by-side measurements with the licensee and take independent measurements for comparison with licensee results. Under special circumstances, the inspector should split samples with the licensee during site characterization, where necessary, to confirm the adequacy and validity of licensee measurements. Evaluate how the results of the planned site characterization will lead to successful site remediation and the licensee's final survey.

   The inspector should request that the licensee review all available historical records of material use, safety event reports, aerial photographs of the site, as-built facility drawings or blueprints, etc., to aid in the identification of activities that may have resulted in contamination at the site. Interviews with employees and former employees may also be useful to identify previous activities and former locations where licensed material was used or disposed.

6. Construction of Site Features to Support Decommissioning. Verify that the construction of new loading docks, roads, rail spurs, drainage ditches, DEP) storm water management units, and other features to support decommissioning, are in accordance with DEP-approved permits (if required) and do not compromise health and safety considerations of workers and the public.

7. Other License Conditions and Approved Plans. Verify that licensee activities conform to specific license conditions, the approved DP, and licensee programs and procedures. Audit licensee performance on high-risk activities, as needed.

8. Hazardous Sites Cleanup Act (HSCA) Facilities. The inspector should be aware of any ongoing Hazardous Sites Cleanup Act (HSCA) investigations to identify potential releases to soil and surface water.

9. Other DEP Programs. The inspector should notify other DEP programs (e.g. Air, Water, Waste) that decommissioning activities may impact.

b. Inspections during Dismantlement and Remediation

1. Decontamination and Dismantlement of Structures. Verify, by field observation and record reviews, that licensee activities to decontaminate and dismantle structures are being performed in accordance with DEP-approved plans. If a decommissioning plan is not required, verify that the remediation activities are being performed in accordance with applicable NRC regulations and guidance incorporated by reference. Structures include buildings, above- and below-ground utilities, treatment lagoons, and other man-made structures used or affected by the licensee.

2. Decontamination and Remediation of Soil, Sediment, Surface Waters, and Groundwater. Verify, by field observation and reviews of licensee records, that decontamination and remediation of soil, sediment, surface waters, and groundwater are being performed in accordance with NRC-approved plans. If a decommissioning plan is not required, verify that the remediation activities are being performed in accordance with applicable DEP regulations and guidance. Inspect licensee activities on-site, and inspect off-site areas that may have been contaminated by licensee operations.

3. Radioactive Waste Management. Confirm that the licensee is maintaining adequate waste management controls related to the release and disposal of liquid, airborne, and solid wastes. Radioactive wastes generated during decommissioning must be disposed of in a manner approved by DEP. Some of the radioactive wastes generated during decommissioning include: building materials; process and facility equipment; concrete rubble; filters, trash, and sludge; material from the waste treatment lagoons; soil and vegetation; groundwater; and surface water. See IP 84850, "Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR 20 and 10 CFR 61."

4. Low-Level Radioactive Waste Storage. During decommissioning, large quantities of low-level waste may be temporarily stored on-site before shipment to a licensed disposal facility. Confirm that the waste is stored in accordance with license conditions and other DEP guidance.

5. Transportation of Wastes. Review the specifics of the licensee's packaging and transportation activities to determine which elements of appropriate DEP,

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IPs will be used during the inspection: For facilities that have large amounts of contaminated materials to ship offsite, transportation of material may continue throughout the decommissioning process. Contaminated materials for off-site disposal must be packaged in accordance with Department of Transportation regulations published in 40 CFR Parts 171-178 and NRC regulations incorporated by reference published in 10 CFR Part 71. NRC Regulatory Guide 7.1 provides guidance for packaging and transporting radioactive materials.

Deleted: IP 86740, "Inspection of Transportation Activities," and IP 84850, "Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR 20 and 10 CFR 61."

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6. Restoration of Site. Verify that the licensee has restored the site to meet license conditions and specifications in NRC-approved plans.

7. Activities Identified during Review of Decommissioning Plan. Plan to inspect any other significant activities or conditions that may have been specified in the licensee's DP or license.

c. Inspections after Remediation

1. Certification of Waste Disposal. Verify that the licensee has submitted information regarding the disposition of all licensed material in accordance with 10 CFR 30.36, 40.42, and 70.38.

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2. Licensee Final Survey Program. There are many elements of the licensee's final survey program that need to be inspected. This inspection should occur while the licensee is in the process of performing the final survey program. The purpose of the "in-process" final survey inspection is to provide confidence that the licensee's survey results are accurate and representative of the conditions at the facility. See Appendix B, "Final Survey Program Inspection Field Notes," for a detailed checklist of inspection items for the licensee's final survey program.

Deleted: See IP 83890, "Closeout Inspection and Survey," for closeout procedures.

3. Confirmatory Survey. It may be necessary for DEP, or a DEP contractor, to conduct confirmatory measurements to provide supplemental information, in addition to the findings of the in-process inspection, to ensure that the survey results reported by the licensee are accurate and representative of the conditions at the facility. However, comprehensive confirmatory surveys should only be necessary if there is significant doubt regarding the licensee's final survey results. For example, a confirmatory survey would be needed if an in-process inspection of the licensee's final survey program identifies multiple weaknesses or a if licensee has a history of violations that reduces the DEP 's confidence in the survey results.

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The inspector may perform limited measurements (split samples, "side-by-side" direct measurements, etc.) as a part of the in-process inspection of a licensee's ongoing final survey program. The scope and number of these measurements should be significantly less than that performed during a "traditional" confirmatory survey performed after the licensee has completed the final survey. In-process inspections will be most effective for medium to large sites. For small sites, it may not be practical to perform an in-process inspection, because the final survey will likely be relatively informal and may only take a few days to complete. In this case, the inspector's close-out inspection would be performed after the licensee has completed the survey and submitted the final survey report. However, the inspection of small sites should still include a review of the licensee's program to the extent practical, augmented by a limited confirmatory survey by DEP staff.

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4. Site Maintenance for Restricted Use. If the site is to be released for restricted use, verify that all conditions limiting use of the site conform to license conditions and approved plans and are in place and functional.

5. Conditions for Release for Unrestricted Use. Verify that the licensee has met all applicable conditions for release of the site for unrestricted use.

87104-04 INSPECTION RESOURCES

The direct on-site inspection hours required to complete this inspection are dependent upon: (1) the licensee's decommissioning activities being inspected; (2) the standard materials health and safety inspection areas covered in the inspection; (3) the overall complexity of decommissioning the facility; and (4) the duration of the licensee's decommissioning program. For facilities needing a significant decommissioning effort, it is estimated that approximately 10 to 40 inspection hours will be needed to complete each inspection of a key decommissioning activity or standard health and safety area from the operational program.

END

Appendices:

A. "Materials Decommissioning Inspection Field Notes for Facilities Needing Significant Decommissioning Effort"

B. "Final Survey Program Inspection Field Notes"

APPENDIX A

MATERIALS DECOMMISSIONING INSPECTION FIELD NOTES FOR FACILITIES NEEDING SIGNIFICANT DECOMMISSIONING EFFORT

Region_____ Inspection Report No._____, License No._____

Licensee (Name & Address)_____

_____

Licensee Contact_____ Telephone No._____

Last Amendment No._____ Date of Amendment_____

Program Code_____

Date of Last Inspection_____

Date of This Inspection_____

Date of Next Inspection_____

Type of Inspection: ( ) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial Decomm. ( ) Reinspection of Decomm.

Level of Inspection: ( ) Normal ( ) Reduced ( ) Extended

Brief Description of Inspection Activities:

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Brief Description of Findings and Action:

_____

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Summary of Findings and Action:

( ) No violations cited
( ) Violation(s), letter issued
( ) Follow-up on previous violations

Inspector:_____ Date_____
_____(Signature)

Approved:_____ Date_____
_____(Signature)

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[Field notes are to be used by the inspector to assist with the performance of the inspection. Note that all areas indicated in the field notes are not required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed") should be made in each section where applicable. Additionally, all areas covered during the inspection should be documented in sufficient detail to describe what activities and/or records the inspector observed. The field notes to the "Decommissioning Inspection Procedure for Materials Licensees" should be supplemented with: (1) the applicable inspection procedures for operating facilities and (2) other written documentation of the inspection, as necessary.]

Deleted: provided in the Inspection Procedure (IP) 87100 series;

1. SUMMARY OF DECOMMISSIONING STATUS

The checklist below is intended to provide, in a written outline format, summary documentation of the status of the licensee's facility in the decommissioning process. This documentation will be filed as part of the inspection report. The inspector should use this information to develop each inspection plan(s) for the various stages of decommissioning, namely, before dismantlement, during dismantlement and site remediation, and after site remediation.

A.	Licensee ceased operational program.	( )Y ( )N
B.	Required decommissioning financial assurance mechanisms in place.	( )Y ( )N
C.	Decommissioning Plan (DP) required.	( )Y ( )N
D.	Licensee final survey required.	( )Y ( )N
E.	NRC confirmatory survey required.	( )Y ( )N
F.	NRC closeout inspection required.	( )Y ( )N
G.	Licensee doing decommissioning planning and preparation before dismantlement.	( )Y ( )N
H.	Licensee actively remediating site.	( )Y ( )N
I.	Licensee completed site remediation.	( )Y ( )N

Description of Facility Status:

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2. INSPECTION OF KEY DECOMMISSIONING ACTIVITIES

The following is a generic checklist of major licensee activities occurring at various stages of decommissioning. From this generic checklist and from facility-specific activities you identify, develop the set of licensee activities to be inspected - for each individual inspection throughout the decommissioning process. Plan to inspect licensee activities that present potential high-risk conditions. Then apply the standard health and safety inspection areas in Section 3 of these field notes (taken from the applicable 87100 series IP for the licensee's operational program) to the specific licensee decommissioning activities that are being inspected.

To complete the licensee activities checklist, the inspector will need to obtain information from the Licensing Project Manager, review the DP, make observations at the licensee's facility, review licensee records, take measurements and samples of contaminants, and undertake other investigative measures, to determine whether the licensee is meeting all regulatory and DP commitments for each decommissioning activity the licensee is performing.

A. LICENSEE ACTIVITIES INSPECTED BEFORE DISMANTLEMENT

1. SNM inventory cleanout/off-site removal of licensed material used in operations has been performed by licensee. ( ) Y ( ) N

2. Facility license conditions are in place and met by licensee. ( ) Y ( ) N

3. Site security and control of contaminated material being maintained in compliance with 10 CFR 20.1801 and 20.1802. ( ) Y ( ) N

4. Support systems and services (e.g., lighting, water supply) are in place. ( ) Y ( ) N

5. Decommissioning schedules are consistent with timeliness requirements in 10 CFR 30.36, 40.42, and 70.38. ( ) Y ( ) N

6. Licensee's record keeping is consistent with 10 CFR 30.35, 40.36, and 70.25. ( ) Y ( ) N

7. Financial assurance requirements are being maintained in accordance with 10 CFR 30.35, 40.36, and 70.25. ( ) Y ( ) N

8. Licensee is conducting site characterization in accordance with applicable radiation protection procedures. ( ) Y ( ) N

9. Construction of new site features (e.g., roads, rail spurs, staging areas, sediment control ponds) conforms to DP and does not compromise health and safety of workers and public. ( ) Y ( ) N

10. Licensee activities conform to specific license conditions and licensee programs and procedures. ( ) Y ( ) N

11. Other licensee activities: ( ) Y ( ) N

Basis for Findings:

B. LICENSEE ACTIVITIES INSPECTED DURING DECONTAMINATION, DISMANTLEMENT, AND SITE REMEDIATION

1. Site security and control of contaminated material being maintained in compliance with 10 CFR 20.1801 and 20.1802. ( ) Y ( ) N

2. Decontamination and dismantlement of structures are being performed consistent with DP and sound industry practice (structures include buildings, utilities, treatment lagoons, etc.). ( ) Y ( ) N

3. Decontamination and remediation of the following are being performed consistent with DP and sound industry practice:
   a. Soil. ( ) Y ( ) N
   b. Sediment. ( ) Y ( ) N
   c. Surface waters. ( ) Y ( ) N
   d. Groundwater. ( ) Y ( ) N
   e. Other mediums: ( ) Y ( ) N

4. Licensee release and disposal of decommissioning wastes are consistent with DP and approved by DEP for:
   a. Liquid wastes (e.g., groundwater, surface water, liquid from treatment ponds, process liquids). ( ) Y ( ) N
   b. Solid wastes (e.g., building materials, process and other facility equipment, concrete rubble, soil). ( ) Y ( ) N
   c. Other wastes: ( ) Y ( ) N

5. Temporary, onsite storage of low-level radioactive wastes from decommissioning meets license conditions. ( ) Y ( ) N

6. Packaging and shipment of radioactive waste materials meet requirements in 40 CFR Parts 171-178 and 10 CFR Part 71 ( ) Y ( ) N

7. Restoration of Site - Licensee has restored site to meet license conditions and DEP approved plans. ( ) Y ( ) N

8. Licensee survey of material and equipment for free release sufficient to demonstrate compliance with release criteria. ( ) Y ( ) N

9. Other licensee activities: ( ) Y ( ) N

Basis for Findings:

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¶
1. . SNM inventory cleanout/off-site removal of licensed material used in operations has been performed by licensee. . ( )Y ( )N¶
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. 2. . Facility license conditions are in place and met by licensee. . ( )Y ( )N¶
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3. . Site security and control of contaminated material being maintained in compliance with 10 CFR 20.1801 and 20.1802.( )Y ( )N¶
¶
. 4. . Support systems and services (e.g., lighting, water supply) are in place. . . . . ( )Y ( )N¶
¶
. 5. . Decommissioning schedules are consistent with timeliness requirements in 10 CFR 30.36, 40.42, and 70.38. ( )Y ( )N¶
¶
. 6. . Licensee's recordkeeping is consistent with 10 CFR 30.35, 40.36, and 70.25. . . . . ( )Y ( )N¶
¶
. 7. . Financial assurance requirements are being maintained in accordance with 10 CFR 30.35, 40.36, and 70.25. ( )Y ( )N¶
¶
. 8. . Licensee is conducting site characterization in accordance with applicable radiation protection procedures. ( )Y ( )N¶
¶
. 9. . Construction of new site features (e.g., roads, rail spurs, staging areas, sediment control ponds) conforms to DP and does not compromise health and safety of workers and public. ( )Y ( )N¶
¶
. 10. . Licensee activities conform to specific license conditions and licensee programs and procedures. . . . . ( )Y ( )N¶
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11. . Other licensee activities: . . . . . ( )Y ( )N¶
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Basis for Findings: . ¶
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C. LICENSEE ACTIVITIES INSPECTED AFTER COMPLETION OF SITE REMEDIATION

1. Licensee has submitted the proper forms for disposition of licensed material in accordance with 10 CFR 30.36, 40.42, and 70.38. ( ) Y ( ) N

2. Licensee's final survey program is acceptable (see Appendix B for inspection items for final surveys). ( ) Y ( ) N

3. DEP confirmatory survey performed. ( ) Y ( ) N

4. Site maintenance activities (if any, for restricted use) conform to license conditions and DEP approved plans and are in place and functional. ( ) Y ( ) N

5. Other licensee activities: ( ) Y ( ) N

Basis for Findings:

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3. INSPECTION OF STANDARD HEALTH AND SAFETY AREAS FROM THE OPERATIONAL INSPECTION PROGRAM

Identify the standard inspection areas (from the inspection program of the licensee's operational program) to be covered during each decommissioning inspection. Then identify the new activities within the standard inspection areas undertaken by the licensee during decommissioning. Some of the new activities given below, as well as any other activities the inspector identifies, should be considered inspection items under the general set of health and safety inspection areas used in the applicable IP.

Minimum inspection areas for the initial decommissioning inspection: decommissioning organization; decommissioning activities in compliance with a regulatory-approved DP; licensee procedures for implementing the DP; Radiation Safety Committee (RSC) and Radiation Safety Officer (RSO) responsibilities; and the licensee's decommissioning training program.

A. GENERAL OVERVIEW

1. Describe the licensee's decommissioning organizational structure:

   a. Licensee is performing decommissioning activities in compliance with its approved decommissioning plan. ( ) Y ( ) N

   b. Licensee has implementing procedures for the decommissioning activities identified in the DP. ( ) Y ( ) N

   c. The RSC and RSO fulfill license requirements to deal with all decommissioning activities. ( ) Y ( ) N

Basis for Findings:

B. FACILITIES

1. Describe, from field observation, the licensee-identified facilities and outdoor areas to be decommissioned:

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2. The licensee's remediation plan includes all the contaminated facilities and areas on-site and off-site. ( ) Y ( ) N

3. All essential systems and services (e.g., electrical power, water supply, communications systems) are in place and functional for the planned decommissioning activities. ( ) Y ( ) N

4. Licensee's emergency plan is in place and operative for the duration of decommissioning. ( ) Y ( ) N

5. For complex sites needing site characterization, describe the key site characterization activities to be performed by the licensee to determine the nature and extent of contamination:

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6. Licensee's characterization activities performed in conformance with good industry practice. ( ) Y ( ) N

Basis for Findings:

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C. EQUIPMENT AND INSTRUMENTATION

1. Survey instruments are applicable to contaminants of interest. ( ) Y ( ) N

2. Use of survey instruments appropriate for site. ( ) Y ( ) N

Basis for Findings:

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D. MATERIALS

1. Radioactive materials licensed during operations have been removed offsite; residual quantities conform to license conditions. ( ) Y ( ) N

2. Security and control of licensed materials, including contaminated areas, are being maintained. ( ) Y ( ) N

Basis for Findings:

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E. TRAINING

1. Licensee has developed training program for new decommissioning activities (e.g., demolition of structures, excavation of soil); program is adequate. ( ) Y ( ) N

2. Training program being effectively implemented. ( ) Y ( ) N

Basis for Findings:

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F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

1. Area surveys are being performed in areas being decommissioned. ( ) Y ( ) N

2. Where active remediation (e.g., demolition of structures, excavation of soil) is being performed, radiation levels in unrestricted areas do not exceed 2 mrem in any one hour. ( ) Y ( ) N

Basis for Findings:

G. RADIATION PROTECTION

1. The licensee's approved health physics program is being implemented in the field for new decommissioning activities. ( ) Y ( ) N

2. Site security and control of contaminated material are in compliance with 10 CFR 20.1801 and 20.1802. ( ) Y ( ) N

Basis for Findings:

H. RADIOACTIVE WASTE MANAGEMENT/EFFLUENTS/ENVIRONMENTAL MONITORING

1. Offsite disposal of decommissioning wastes conforms to free release criteria and disposal site requirements. ( ) Y ( ) N

2. All new effluent releases conform to DP and applicable regulations. ( ) Y ( ) N

3. The licensee's environmental monitoring program is being implemented in conformance with the DP and all applicable limits are being met. ( ) Y ( ) N

4. Temporary storage/staging areas for radioactive wastes from building demolition, equipment dismantlement, soil excavation, etc., are adequately posted and protected. ( ) Y ( ) N

Basis for Findings:

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I. RECORDKEEPING FOR DECOMMISSIONING

1. Copies of the licensee's decommissioning cost estimates and funding methods are on file. ( ) Y ( ) N

2. Licensee has adequate records for decommissioning activities performed (e.g., for decontamination and dismantlement of structures; decontamination and remediation of soil, sediment, surface waters, groundwater; surveys of remediated facilities). ( ) Y ( ) N

3. Licensee's financial assurance conforms to the financial assurance requirements of DEP approved possession limits and DEP regulations. ( ) Y ( ) N

Basis for Findings:

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J. TRANSPORTATION

1. Describe the licensee's program to package and ship decommissioning waste materials:

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2. Licensee's program meets all applicable 10 CFR and 49 CFR requirements for marking labeling, placarding, and shipping paper requirements for radioactive waste shipments. ( ) Y ( ) N

Basis for Findings:

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K. POSTING AND LABELING

1. All contaminated areas, waste processing areas, and waste handling areas are posted in conformance with regulations. ( ) Y ( ) N

2. Packaged radioactive waste materials are labeled in accordance with regulations. ( ) Y ( ) N

Basis for Findings:

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L. OCCUPATIONAL HEALTH AND SAFETY

1. Describe the occupational health and safety observations made at the licensee's facilities:

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2. Licensee and Occupational Safety and Health Administration were informed of occupational health and safety issues observed during the inspection. ( ) Y ( ) N

Basis for Findings:

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4. VIOLATIONS, NON-CITED VIOLATIONS, FOLLOW-UP ITEMS, AND OTHER ISSUES

Briefly state (1) the requirements and (2) how and when the licensee violated the requirement. For non-cited violations, indicate why the violation was not cited. Briefly describe follow-up items and other issues.

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END

APPENDIX B

FINAL SURVEY PROGRAM INSPECTION FIELD NOTES

1. STATUS OF LICENSEE FINAL SURVEY

A.	Final survey report submitted to DEP/BRP.	( ) Y ( ) N
B.	Previous inspection(s) of licensee final survey program conducted.	( ) Y ( ) N
C.	Final survey report not submitted, licensee final survey in progress.	( ) Y ( ) N
D.	Final survey plan submitted and approved by DEP.	( ) Y ( ) N

Basis for Findings:

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2. INSPECTION AREAS FOR LICENSEE FINAL SURVEYS

NOTES:

(1) For facilities where an approved decommissioning plan (DP) is required, inspections should be made against commitments in the DP and the licensee's final survey plan (which would have been approved by DEP during license review). For facilities where a DP is not required, inspections should be made against appropriate regulations, and license conditions.

(2) For facilities that require a significant decommissioning effort, all the inspection areas listed below should be inspected while the licensee's final survey program is in progress. For small, licensed facilities that do not require a significant decommissioning effort, only some of the inspection areas below may apply, and it may not be practicable to inspect these areas until after the licensee's final survey is completed and the licensee's final survey report has been submitted to DEP.

(3) Inspection of a licensee's final survey may include independent confirmatory measurements by the inspector or DEP contractor. The extent of the confirmatory measurements, and whether the use of a DEP contractor is warranted, depends on a number factors that are discussed in Section 2.C. In most cases, minimal confirmatory surveys should be sufficient.

(4) The inspector should identify which inspection areas listed below are performed during each inspection.

A. SITE CONDITIONS AT TIME OF LICENSEE FINAL SURVEY

1. Site has been decontaminated/remediated in accordance with DP or site procedures. ( ) Y ( ) N

Basis for Findings:

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B. LICENSEE FINAL SURVEY PLANS AND PROCEDURES

1. Contaminants:

   a. Licensee has identified all potential contaminants ( ) Y ( ) N

   b. Licensee has specified acceptable release criteria. ( ) Y ( ) N

   c. Licensee has clearly documented the basis for any alternate criteria, if applicable. ( ) Y ( ) N

2. Organization and Responsibilities:

   a. Survey program documented. ( ) Y ( ) N

   b. Survey staff responsibilities and qualifications documented. ( ) Y ( ) N

3. Quality Assurance/Quality Control:

   a. Organization ( ) Y ( ) N

   b. QA Program ( ) Y ( ) N

   c. Operational Procedures ( ) Y ( ) N

   d. Document Control/Records Management ( ) Y ( ) N

   e. Equipment Maintenance and Control ( ) Y ( ) N

   f. Audits and Corrective Action ( ) Y ( ) N

   g. Independent third party measurement QC ( ) Y ( ) N

4. Laboratory analytical procedures, including QA/QC, acceptable, and results adequately documented. ( ) Y ( ) N

5. Field Survey Instrumentation:

   a. Survey instrumentation is appropriate for contaminants of interest and site conditions. ( ) Y ( ) N

   b. Licensee has properly calibrated survey instrumentation. ( ) Y ( ) N

   c. Instrument operational procedures adequate ( ) Y ( ) N

   Basis for Findings:

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6. Licensee is performing the survey in conformance with the approved survey plan :

   a. All potentially contaminated locations on-site and off-site have been properly classified as "impacted" or "non-impacted" areas. ( ) Y ( ) N

   b. "Survey Units" have been properly selected. ( ) Y ( ) N

   c. Background determination acceptable. ( ) Y ( ) N

   d. Number and location of measurements and samples in each "survey unit" is acceptable. ( ) Y ( ) N

   e. Surface scan procedures and percent coverage acceptable. ( ) Y ( ) N

   f. Surface activity measurement procedures acceptable.
      (1) Direct ( ) Y ( ) N
      (2) Removable ( ) Y ( ) N

   g. Exposure rate measurement procedures acceptable. ( ) Y ( ) N

h. Surveying and sampling of the following media conducted as appropriate:

(1) Soil and sediment, surface and subsurface	( ) Y ( ) N
(2) Groundwater	( ) Y ( ) N
(3) Surface water	( ) Y ( ) N
(4) Buildings, interiors and exteriors	( ) Y ( ) N
(5) Equipment and systems	( ) Y ( ) N
(6) Grounds	( ) Y ( ) N
(7) Other media:	( ) Y ( ) N

Basis for Findings:

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7. Licensee's Final Survey report sufficient to demonstrate that release criteria have been met.

NOTE: The final survey report will, in general, not be available for review at the time of an "in-process" inspection of a final survey program. However, at the end of the survey project, after the final survey report has been submitted, the inspector should ensure that appropriate DEP personnel have reviewed these areas. If questions remain as to whether these areas have been satisfied by the licensee, or the final survey report has not been reviewed, the areas listed below should be addressed during the inspection.

a. Survey results demonstrate, with 95% confidence, that average residual contamination in each "survey unit" is less than release criteria. ( ) Y ( ) N

b. Survey results demonstrate that the hot-spot criteria in NUREG-1575, Rev. 1 have been satisfied. ( ) Y ( ) N

c. Elevated survey results investigated by licensee. ( ) Y ( ) N

d. "Survey Units" reclassified, as necessary, based on survey results. ( ) Y ( ) N

e. Reclassified "survey units" surveyed with proper number and location of samples and proper percentage of the surface scanned. ( ) Y ( ) N

f. Survey report provides sufficient documentation of procedures and QA/QC. ( ) Y ( ) N

g. Survey report provides diagrams or other documentation identifying survey locations. ( ) Y ( ) N

Basis for Findings:

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NOTE: Some licensees are performing their final survey using NUREG/CR-5849. NUREG-1575 Rev. 1 should not be applied to those licensees.

C. DEP/BRP CONFIRMATORY SURVEY

1. Evaluate whether a confirmatory survey is justified.

   a. Significant, unresolved, weaknesses identified during the inspection of the licensee's final survey program. ( ) Y ( ) N

   b. Repetitive violations. ( ) Y ( ) N

   c. Significant public or Congressional interest. ( ) Y ( ) N

   d. Small site where an in-process inspection not practical. ( ) Y ( ) N

2. If a confirmatory survey is justified, determine if a DEP contractor should be used. Meeting one or more of the three criteria listed below will, in general, justify the use of a contractor.

   a. Licensee's final survey involves unique or complex technical issues. ( ) Y ( ) N

   b. Confirmatory survey is expected to require more than a man-week effort to complete field surveys and sampling. ( ) Y ( ) N

   c. Confirmatory survey is very high priority that cannot be completed by DEP/BRP staff in a timely manner. ( ) Y ( ) N

END

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DEP INSPECTION MANUAL

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INSPECTION PROCEDURE 87121

INDUSTRIAL RADIOGRAPHY PROGRAMS

PROGRAM APPLICABILITY: 2800

87121-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with Department of Environmental Protection (DEP) requirements.

Deleted: U.S. Nuclear Regulatory Commission (NRC)

The scope of this program is limited to activities and programs utilizing licensed radioactive materials for the performance of industrial radiography.

87121-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by DEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

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The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective industrial radiography radiation safety program:

02.01 FE-1: The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

02.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4: The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 FE-6: The licensee should ensure that workers are:

a. knowledgeable of radiation uses and safety practices;
b. skilled in radiation safety practices under normal and accident conditions; and,
c. empowered to implement the radiation safety program.

02.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;
b. that audits for ALARA practices are performed; and,
c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

Usually the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, repetitive violations, or high radiation exposures.

87121-03 INSPECTION GUIDANCE

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection.

Common elements to all inspections include entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Each of the following areas should be reviewed during each inspection of all industrial radiography licensees.

03.01 FE-1: The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

a. Security. Through direct observation and licensee staff interviews, determine that all entrances to radiographic facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to radiographic storage facilities, etc.

1. If any entrance or area is found to be unsecured, determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

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2. If entrances or other areas are found to be unsecured, examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be under constant surveillance or physically secured.

b. Facilities. Through direct observation and licensee staff interviews, verify that any permanent radiographic installation is configured in accordance with the design and performance requirements found in 10 CFR Part 34. Specifically, verify that the facility has an operable independent entrance control or visible-audible alarm system pursuant to 10 CFR 34.33. Observe staff tests of the entrance controls and/or radiation warning signals, to confirm operability during the inspection.

Verify that permanent radiographic facilities are shielded so that the radiation levels in adjacent areas, including the roof, do not exceed 0.02 millisievert (mSv) (2 millirem [mrem]) in any 1 hour. This evaluation should consider the maximum allowable source quantity and any other limitations on positioning within the facility.

c. Receipt and Transfer of Licensed Material. Through observation and interviews, verify that the licensee receives packages and makes transfers of licensed material in accordance with DEP and applicable U.S. Department of Transportation (DOT) regulations and license conditions. Through discussions with licensee personnel, determine how the licensee ensures that transfers are made to authorized recipients. Focus on how the licensee receives packages, opens packages, and how and when package radiation surveys are performed (including wipe tests). Also determine what actions the licensee takes (or should take) when surveys reveal packages that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection,

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the inspector should, when practical, observe personnel performing the package receipt surveys.

d. Physical Inventory. Through interviews and review of records, verify that, as required by 10 CFR 34.29(a), the licensee conducts quarterly physical inventories to account for all licensed material received and possessed under the license. Verify that inventory records are maintained in accordance with 10 CFR 34.69. Verify that sealed sources, and radiographic exposure devices used by the licensee are in accordance with sealed source and device (SS&D) registrations sheets issued by the DEP, NRC or an Agreement State. In order to make an assessment in this area, the inspector may ask the licensee how they ensure that they only use registered sources and devices. If practical, the inspector should verify that the inventory includes all radiographic exposure devices and storage containers containing depleted uranium and calibrators used for calibrating survey instruments.

e. Material Security and Control. Examine areas where radioactive materials are stored. Storage areas should be locked and have limited and controlled access. Radiographic exposure devices and storage containers must be physically secured to prevent access or removal by unauthorized personnel. Transport packages (including overpacks) containing licensed material must be locked and physically secure in the transport vehicle.

The inspector should make every reasonable effort to perform a "field inspection" at a temporary job site of the licensee. This inspection should be unannounced. If possible, make some of the observations of the licensee's operations before announcing your presence. During the field inspection, verify that the boundaries of the restricted area are controlled and posted; the radiation levels at the boundary of the restricted area do not exceed 0.02 mSv (2 mrem) in any 1 hour; and that the operations are conducted by at least two qualified individuals. Ask the licensee how they ensure that the radiation level limits (0.02 mSv [2 mrem] in any 1 hour) are complied with, and make an assessment of the adequacy of the methods. Verify that the high radiation area is under constant surveillance, as required by 10 CFR 34.51.

At job sites where other workers are present, interview them to determine their understanding of the licensee's access control. Although these workers may not have or need any knowledge of the licensee's operations, if they were informed of the licensee's operations, this would be an indication of the licensee's good safety practices. Inspectors should keep in mind that, as non-licensees, such individuals have no obligation to cooperate with the DEP.

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f. Area Surveys. The inspector should verify that radiation levels at the boundary of the restricted area do not exceed 0.02 mSv (2 mrem) in any one hour. This will require the inspector to determine the instantaneous exposure rate and the number of radiographic exposures performed by the

licensee. The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation. However, the inspector should use DEP's instruments for independent verification of the licensee's measurements. The inspector should use a survey instrument that has been calibrated within the last 12 months. This will enhance the credibility of the inspector's survey results if there is any disagreement between the readings obtained from the licensee's instruments and the inspector's (DEP's). Ensure that the licensee's survey meters are operational and have been calibrated within the last 6 months.

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The inspector should verify that the radiographer or radiographer's assistant performs a survey of the exposure device and guide tube after each exposure of the source. The survey must be sufficient to confirm that the source has returned to its shielded position. If practical, observe how licensee conducts surveys, to determine the adequacy of surveys. (See FE-5)

g. Leak Tests. Through interviews with licensee staff and review of records, verify that required leak tests are performed at the required interval. Determine if the licensee exchanges or returns their iridium-192 sources to the vendor less than six months from the date that they were received, negating the need to perform periodic (six months) leak tests.

1. If the licensee performs leak tests, verify that the wipe of a sealed source is taken from the nearest accessible surface to the sealed source where contamination might accumulate (i.e., the point on the camera or source exchanger where the guide tube or transfer tube connects) and at intervals not to exceed 6 months.

2. Verify that devices containing depleted uranium are leak tested annually, to verify the integrity of the "s" tube.

3. The licensee should verify that the licensee's leak test analyses (or that of it's leak test services vendor) has sufficient sensitivity to measure 185 becquerels (0.005 microcurie) for each type of isotope present on its license. Through discussions with licensee personnel and/or review of pertinent records, determine if the licensee had a leaking source or indication that the integrity of any "s" tubes was compromised. If leak test results show contamination in excess of the regulatory limits, verify that the licensee made appropriate notifications, evaluations, and removed the source from service.

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h. Waste Storage and Disposal. Determine if the licensee possesses any industrial radiographic sources or other licensed sources that have been removed from service. Verify that the sources are stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed the limits of 10 CFR 20.1301, "Dose Limits for Individual Members of the Public."

In the rare case where a licensee may have transferred a source to a burial site for offsite disposal, review the licensee's procedures and records to verify that each shipment is accompanied by a shipment manifest that includes all the required information. Also review the licensee's procedures and records to verify that each package intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of 10 CFR 61.55 [Subsection III.A.2 of Appendix G to Part 20].

i. Incidents and Unusual Occurrences. Review and evaluate any incident or unusual occurrence that took place since the last inspection. Verify if incidents were required to be reported, and, if so, that proper reporting procedures were followed. For incidents or unusual occurrences not required to be reported, determine that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

a. Equipment. Through interviews with key licensee personnel, verify that the types and quantities possessed by the licensee are within any applicable license limits (including SS&D registry limits) and that the licensee is using approved combinations of sources and devices. Verify that all sealed sources (source assemblies), radiography devices (cameras), and source changers used by the licensee (unless specifically exempted) meet 10 CFR 34.20 requirements. Confirm that licensees are aware that associated equipment needs to comply with 10 CFR 34.20. Refer to Regulatory Issue Summary 2005-10, "Performance–Based Approach for Associated Equipment in 10 CFR 34.20," (ML051590049) for additional information about acceptable methods to demonstrate that associated equipment complies with 10 CFR 34.20.

If the associated equipment appears to be modified or defective (defective equipment may be an indication of a modification), the inspector should verify whether or not the licensee had developed and implemented a testing program to demonstrate that modified components meet the performance criteria in 10 CFR 34.20. The inspector should alert the inspection supervisor who may extend the inspection and request an SS&D reviewer to evaluate the licensee's modification of the equipment. The expectation is that the design safety features of the industrial radiography system were not compromised by a replacement component of associated equipment that was modified by the licensee. Before using a modified system, the licensee is required to demonstrate that the replacement component meets the

performance criteria in 10 CFR 34.20(a)(1) and (2), (b)(3), (c)(5) and (8), and (e).

b. Routine and Non-Routine Maintenance. Through direct examination, assess the condition of licensee equipment, i.e., cameras, drive cables, source changers, etc. The examination should be sufficiently thorough to detect any of the following conditions: excessive or uneven wearing, fraying, unraveling, nicks, kinks or bends, loss of flexibility (abnormal stiffness), excessive grit or dirt, and stretching. The inspector may refer to Appendix O, "Daily Maintenance Check of Radiographic Equipment," NUREG-1556, Vol. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Industrial Radiography Licenses" (August, 1998).

1. Should a defect, such as a damaged cable, be found in use, notify an appropriate licensee representative and then expand the scope of the examination. Monitor actions, if any, taken by the licensee in response to this discovery. Should the licensee elect to not take action, the inspector should consult with regional management.

2. Verify that the licensee has an inspection and maintenance program that complies with 10 CFR 34.31(a) and provides for visual and operability checks of radiographic equipment, survey meters, transport containers, associated equipment, and source changers before use and quarterly to ensure that the equipment is in good working condition.

3. Verify that the licensee's inspection and maintenance program ensures that the sources are adequately shielded, and that the required labeling is present.

The inspector should verify that the licensee is aware of the requirements contained in 10 CFR Part 21 and 10 CFR 34.101(a), and has procedures in place for reporting defects and certain equipment failures.

03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

1. Operational Limits. Verify that industrial radiography devices (and sources) are used in accordance with any operational limits described in the applicable SSD sheet. Through observation and discussions with the licensee, assess that: (1) storage conditions for the devices that should be protected from fire and the elements, (2) package integrity is appropriately

maintained, and that (3) controls are in effect to minimize the risk from other hazardous materials.

2. Temporary Job Site Hazards. During inspections of licensed activities at temporary job sites, verify that licensee personnel ensure that devices are protected from heavy construction equipment, welding equipment, high voltage lines, and other industrial hazards.

3. Fire Protection. Materials licensees are not required by DEP regulations to implement a fire protection program. However, in many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. Determine if licensees have a plan in place for preventing fires and combating fires that might occur. Any perceived problems/deficiencies (i.e., improper storage of combustible or flammable material, fire extinguishers out of service, lack of fire alarm or detection system, lack of fire suppression system) noted by the inspector should be brought to the licensee's attention and discussed with regional management. Proper fire protection systems can be evidenced by the licensee's involvement with the local fire department.

4. Transportation. Through direct observation, verify that the licensee properly transports radiographic devices. Examine packages (including overpacks) for proper labeling, review associated certification documentation. Examine vehicles for proper blocking and bracing of shipping containers. Verify that shipping papers are complete and available. Survey packages and vehicles to verify compliance with 10 CFR Part 71 and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.

   Through interviews of licensee staff, determine if there were any incidents required to be reported to the DOT. For further inspection guidance, refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer to "Hazard Communications for Class 7 (Radioactive) Materials." These field reference charts, related to hazard communications for transportation of radioactive materials, are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings. They also contain references to the DOT regulatory requirements.

03.04 FE-4: The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

1. Through observation, verify that personnel dosimetry devices (film badges, TLDs, or OSDs) are worn by appropriate licensee personnel, including all radiographers and radiographer's assistants. Also verify that direct reading dosimeters and alarm ratemeters are also worn by appropriate personnel. Note that alarm ratemeters are not required to be worn when radiography is being performed at permanent radiographic installations. Dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields, must be issued to licensee personnel. Verify that any dosimeters, that require processing to determine the radiation dose, are processed by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited processor.

2. Verify that, pursuant to 10 CFR 19.13(b), the licensee advises each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to the provisions of 10 CFR 20.2106, "Records of individual monitoring results." Verify that this has been done by asking workers and management if the written report requiring this information has been provided to each of them within the last year. The report must include external doses from routine operations, accidents, and emergencies. The report to the individual must contain all of the information required in 10 CFR 19.13(a).

   Verify that, pursuant to 10 CFR 20.2206(c), the licensee submits annual reports of individual monitoring, on or before April 30 of each year (covering the previous year) to the Department.

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3. Verify that an evaluation has been performed that demonstrates that the use and storage of sealed sources will not likely result in exposures to members of the public or radiation levels in unrestricted areas that are in excess of the regulatory limits. For storage areas that are located adjacent to unrestricted areas, licensees must ensure (through measurement or calculation) that doses in the unrestricted areas do not exceed 0.02 mSv [2 mrem] in any one hour or 1 mSv [100 mrem] in a year to the maximally exposed member of the public.

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

a. Through observation, verify that survey instrumentation has the appropriate range of use. Also verify that the survey instruments are properly calibrated at 6-month intervals. Verify that all survey instruments, pocket dosimeters, and alarming rate meters, in use, have current calibrations. The technical adequacy of calibration procedures at facilities that perform their own calibrations should be examined. Verify that the licensee performs an appropriate operability check before use on each day the equipment is used.

b. If the licensee is authorized both to collect and analyze leak test samples, determine if the type of counting equipment is appropriate for the samples being analyzed and the sensitivity required. Also determine if the laboratory instrumentation is calibrated for the appropriate geometries of the samples to be analyzed and is routinely checked for proper operation. The licensee should maintain calibration records, control charts, and maintenance and repair records, to demonstrate proper operation of laboratory instrumentation.

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03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

a. Certification. Through review of records, verify that radiographers are certified by a recognized certifying entity. Ask to see the radiographer's certificate, or verify through other appropriate means that all radiographers, observed performing in that role are, in fact, certified.

b. General Training. Interview one or more radiographers and/or radiographers' assistants to determine that they possess the adequate knowledge and understanding of the licensee's operating and emergency procedures. The interviews should include discussions about actual or hypothetical emergency conditions in order to assess the worker's response to such conditions. Whenever practical, observe licensed activities in progress to assess the worker's understanding of the radiation protection requirements associated with their assigned activities.

Verify that all industrial radiography personnel understand the mechanism for raising safety concerns and the proper response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and radioactive material. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements.

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1. If the licensee provides their own training, determine that instructors who provide classroom training to individuals in the principles of radiation and radiation safety have knowledge and understanding of the principles beyond those obtainable in a course similar to the one given to prospective radiographers.

2. Individuals who provide instruction in the hands-on use of radiography equipment should be qualified radiographers with at least 1 year of experience in performing radiography or possess a thorough understanding of the operation of radiographic equipment (e.g., manufacturers' service representatives).

Observe related activities (i.e., transportation of licensed materials, surveys and equipment checks, and maintenance activities) and interview personnel

to assure that appropriate training was actually received by these individuals. Note that if a radiographer or radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months, they must demonstrate knowledge of training requirements by a practical examination, before these individuals can participate in a radiographic operation. Verify that radiographers understand that they must directly supervise radiographic operations and that radiographers' assistants are aware that they can operate radiographic equipment only under the direct supervision (direct observation) of radiographers.

Verify that licensees are performing refresher training, for radiographers and radiographers' assistants, at least every 12 months.

c. Operating and Emergency Procedures. Verify that licensee personnel are knowledgeable of the operational procedures by observing the performance of tasks at selected work stations and by a comparison of their performance with established procedures. Also examine the licensee's emergency procedures to determine that these procedures are as approved by or described to DEP. Through discussions with workers, verify that licensee personnel understand and implement the established procedures and are aware of procedural revisions.

Some licensees may have agreements with other agencies (i.e., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

d. Posting and Labeling. Verify that proper caution signs are being used at access points to areas containing licensed materials, radiation areas, and high radiation areas. (Note: The exemptions under 10 CFR 20.1903 do not apply to radiographic operations.) Also spot-check labeling on packages or other containers to determine that proper information (e.g., radionuclide, quantity, and date of measurement) is recorded.

Verify that storage areas, radiation areas, and high radiation areas at temporary job sites are conspicuously posted as required. Depending on the associated hazard and licensing requirements, controls may include tape, rope, or structural barriers to prevent access into the restricted area.

Examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits

for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

The DEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding DEP regulations and license provisions and to terminate unsafe activities involving byproduct material.

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Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining DEP's prior written consent before transferring control of the license.
- Notifying the Department in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).
- Assuring the appropriate response, when applicable, to generic communications from the NRC or DEP.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities. (10 CFR 30.35).
- Notifying the DEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (10 CFR 30.36).
- Notifying the DEP of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21.
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

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a. RSC (where required or used) - Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the

conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

b. RSO -Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

1. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

2. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.

c. Audits - Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to

deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

1. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

2. Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

87121-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

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DEP INSPECTION MANUAL

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INSPECTION PROCEDURE 87122

IRRADIATOR PROGRAMS

PROGRAM APPLICABILITY: 2800

87122-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with Department (DEP) requirements.

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While this inspection procedure can be used for construction inspections, Manual Chapter 2815, "Construction and Preoperational Inspection of Panoramic, Wet-Source-Storage Gamma Irradiators," is also available for that type of irradiator.

87122-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by the Department, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

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The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective irradiator radiation safety program:

02.01 FE-1. The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

02.02 FE-2. The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3. The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4. The licensee should implement a radiation dosimetry program to measure and record accurately radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5. The licensee should provide radiation instrumentation in sufficient number, condition, and location to monitor accurately radiation levels in areas where licensed material is used and stored.

02.06 FE-6. The licensee should ensure that workers are:

a. knowledgeable of radiation uses and safety practices;
b. skilled in radiation safety practices under normal and accident conditions; and,
c. empowered to implement the radiation safety program.

02.07 FE-7. The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;
b. that audits for ALARA practices are performed; and,
c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

Usually the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, repetitive violations, or high radiation exposures.

87122-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. Each of the following elements should be reviewed as appropriate, during each irradiator inspection. If the inspector identifies a concern while reviewing any of the following elements, he/she should closely examine the licensee's actual implementation of that respective portion of the radiation safety program to identify any potential violations or other regulatory concerns. If the inspector has not identified any concerns relating to the items described in the following sub-elements, the inspector may conclude that the licensee's performance is adequate for that particular element. The inspector has the flexibility, and is expected to, examine other related aspects of the licensee's program if, during the examination of these elements, the inspector develops an additional radiation safety concern. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection.

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Common elements to all inspections include inspection preparation, entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys,

and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Some of the following areas may not be applicable to all irradiator licensees. In particular, many of the following elements and requirements will not be applicable to self-contained dry-source-storage irradiator licensees. Also, references to 10 CFR 36 requirements only apply to irradiators for which the dose rates exceed 5 gray (500 rad) per hour at 1 meter from the radioactive sealed sources.

Specific Guidance

03.01 FE-1:The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits

a. Security. Through direct observation and licensee staff interviews, determine that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

   1. If any entrance or area is found to be unsecured, determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

   2. If entrances or other areas are found to be unsecured, examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be under constant surveillance or physically secured.

b. Facilities. Through direct observation and licensee staff interviews, verify that the irradiator facility is configured in accordance with the design and performance requirements found in Subpart C of 10 CFR Part 36. Specifically, verify by the performance of interlock checks that access to the irradiator is controlled pursuant to 10 CFR 36.23.

   NOTE: Some irradiator licensees, in particular those using converted teletherapy units, have received exemptions from some of the safety systems described in Subpart C of Part 36. Usually these exemptions are granted based on administrative procedures committed to by the licensee. Inspectors should check the license to ensure that the administrative commitments on which these exemptions were granted are actually implemented by the licensee and are effective.

   Verify that the mechanisms to control source movement meet each of the requirements of 10 CFR 36.31. If the product moves on a conveyor system, verify that the source rack and movement mechanism are protected by a barrier or guide, as required by 10 CFR 36.35.

Verify that sealed sources installed after July 1, 1993, meet the performance criteria of 10 CFR 36.21. This may be performed by a review of the sealed source registration certificate. Verify that irradiator pools initially licensed after July 1, 1993, meet the requirements of 10 CFR 36.33. Visual observation of the pool is acceptable verification. Verify that the facility complies with the design requirements of 10 CFR 36.39 and that the licensee performed the pre-source-loading construction monitoring and acceptance testing requirements of 10 CFR 36.41. These verifications involve reviewing the licensee's records on the required design checks, construction monitoring, and acceptance testing.

c. Receipt and Transfer of Licensed Material. Through direct observation and licensee staff interviews, assess the adequacy of the licensee's package receipt practices implemented in accordance with 10 CFR 20.1906(e). Irradiator facilities do not receive or transfer licensed material on a routine basis. Such activities are usually limited to source loadings or exchanges.

If the inspector is present at the time of the receipt of sources:

1. Determine that packages received at the licensee's facility are properly secured at all times in accordance with 10 CFR 20.1801 and 20.1802.

2. Assess, through observation of actual or simulated surveys, the adequacy of the licensee's performance of radiation measurements, that required wipe tests are properly evaluated and that the licensee has procedures for handling packages where survey results are above regulatory limits.

3. Determine that the incoming packages are checked for damage, and that the licensee has appropriate procedures for the handling of damaged packages.

4. Verify that the licensee is receiving packages and making transfers of licensed material in accordance with DEP and applicable U.S. Department of Transportation (DOT) regulations and license conditions.

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d. Authorized Uses. Through the observation of licensed activities:

1. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license. Note that pursuant to 10 CFR 36.69, irradiation of explosive material is prohibited (unless authorized in writing by the Department or previously authorized by NRC) and that irradiation of more than small quantities of flammable material is prohibited in panoramic irradiators (unless authorized in writing by the Department or previously authorized by NRC).

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2. Physically examine the inventory of radioactive material on hand (e.g., check for any sources that may have fallen off the source rack). To the extent practical, ensure by physical confirmation that the licensee's inventory is complete and accurate.

3. If the inspector believes that there is reason to suspect that all irradiator sources have not been accounted for, perform a more detailed assessment of the licensee's accounting system. For example, a beam-type facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a facility with a pool irradiator with multiple sources will need a sophisticated accounting system, for all licensed material, that provides accurate information on the receipt, location, the quantity used and disposed of, and the amount transferred to other laboratories operating under the same license. In both types of accounting systems, the licensee should perform routine physical audits to ensure the accuracy of the system.

e. Loading, Unloading, and Repositioning of Sources. Verify that loading, unloading, and repositioning the sources are performed by either the licensee or an organization specifically authorized by the Department, NRC, or an Agreement State to perform these operations, per the requirements in 10 CFR 36.13(g). If the licensee performs these operations, the procedures used must be authorized in the license. If the licensee loads, unloads, or repositions sources, interview personnel who are authorized to perform the operations, to determine that contamination surveys of the shipping cask, radiation monitoring during operations, and (not a 10 CFR Part 36 requirement) recording of the location of each individual source placed in the source rack are performed. Review the survey records to confirm that the surveys were performed.

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f. Leak Tests. Verify that tests for leaking sources are performed in accordance with the manufacturer's recommendations, the requirements of 10 CFR 36.59, and/or the license. Verify that the leak test is analyzed in accordance with the license.

1. If there has been any indication of a leaking source, verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination, in accordance with 10 CFR 36.59(c). Consider taking confirmatory pool-water samples.

2. Ensure that the licensee has performed the following: 1) cleanup and cooling system operated as required by license; 2) demineralizers are operated and maintained in accordance with license conditions; 3) pool-water level and quality are maintained in accordance with license conditions; and 4) radiation monitor activates alarm [10 CFR 36.59(b)].

03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment

a. Shielding. Verify that the shielding meets the requirements of 10 CFR 36.25. Several independent measurements to confirm the licensee's survey data are acceptable verifications. Special emphasis should be given to areas where ducting or wireways pass through shielding, edges of walls and doors where shielding overlaps, and where visible defects/cracks appear in the walls. Shield surveys should be completed before initial operation, after source exchange or

modification, and at intervals not to exceed 3 years [10 CFR 36.57(a)]. Verify that dose rates conform to the requirements specified in 10 CFR 36.25(a) and (b).

Verify that the licensee has established and implemented procedures to identify and report safety component defects per the requirements of 10 CFR Part 21.

b. Area Surveys. Verify, during observations and by direct measurements, that the radiation dose rates around the facility are within the limits of Part 20 and 10 CFR 36.25. The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation. However, the inspector must use DEP instruments for independent verification of the licensee's measurements. If practical, observe how licensees conduct surveys, to determine the adequacy of surveys. Also, note the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured. The survey activities should be at a specified frequency in accordance with the related licensee procedures.

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c. Equipment. Verify that equipment and procedures comply with the requirements in 10 CFR 36.23, 36.31, and 36.37. Verify that equipment and instrumentation are appropriate, operable, calibrated, adequately maintained, and conform to those described in the license.

1. If it is determined that equipment is not operable or appears to be inadequately maintained, verify that the licensee has established procedures to perform the inspection and maintenance requirements of 10 CFR 36.61. Verify that non-routine operations (e.g., repairs) are performed by authorized personnel (licensee or others). Procedures and their implementation (practices) must be consistent with license commitments.

2. Equipment and instrumentation should be appropriate to the scope of the licensed program. All sampling and monitoring instruments should have current calibrations appropriate to the types and energies of radiation to be detected. The technical adequacy of calibration procedures at facilities that perform their own calibrations should be examined. Processing equipment, ventilation, and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use. An operable, calibrated, conductivity meter should be available.

3. Verify that the licensee has procedures to perform the inspection and maintenance requirements of 10 CFR 36.61. The licensee should have a procedures manual for performing the inspections, as well as a logbook, of the outcomes of the inspections, that can be reviewed. Procedures, as well as practices (as determined by review of records and interviews of staff), for maintenance, repair, modification, or replacement of equipment affecting safe operation of the facility must be consistent with licensee commitments regarding what will be done by licensee personnel (and the training to be provided for such activities) and what functions will be conducted by outside personnel (equipment manufacturers or others).

03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

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a. Fire Protection. Verify that the fire protection requirements of 10 CFR 36.27 are met. Discussions with the operators regarding the systems and procedures in the event of fire, and observations of the detectors, alarms, and fire extinguishing systems are acceptable verifications.

b. Ozone. The inspector should be aware of the potential health hazard of ozone within the radiation facility. Irradiators with large sources are typically equipped with ventilation systems to exhaust ozone (and nitrogen oxides), produced by irradiation of air. Such facilities could be expected to also have operative ozone monitors as well as procedures to restrict access of personnel to areas when ozone concentrations exceed limits established by the Occupational Safety and Health Administration (OSHA). Also, note that ozone can be detected by odor at a concentration which is 15% of the OSHA concentration limit; ozone odor does not necessarily indicate that an air concentration of ozone warranting concern is present. Concerns in this area should be referred to OSHA.

c. Transportation. The inspector should review: the licensee's hazardous material training; packages and associated documentation; vehicles (including placarding, cargo blocking, and bracing, etc.); shipping papers; and any incidents reported to Department of Transportation (DOT). Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with 10 CFR Part 71 and DOT regulations for transportation of radioactive materials.

NOTE: For further inspection guidance, refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the NRC field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

03.04 FE-4: The licensee should implement a radiation dosimetry program to measure and record accurately radiation doses received by workers or members of the public as a result of licensed operations

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed

materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

a. Personnel Dosimeters. Through observation, verify that personnel dosimetry devices are worn by appropriate licensee personnel in accordance with 10 CFR 36.55. Dosimetry devices appropriate to the type, energy, and the anticipated radiation fields must be issued to licensee personnel. Verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited processor. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

b. Radiation Doses. Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

1. If any such incident or unusual occurrence took place, review and evaluate the licensee's actions. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the Department.

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2. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed a sufficient investigation to identify the cause of the incident, and took appropriate corrective actions to prevent recurrence of the situation leading to the incident or unusual occurrence.

c. Reports. Part 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose as shown in dose records maintained by the licensee. Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

d. Public Doses. Examine the licensee's evaluation or documentation to demonstrate compliance with dose limits for individual members of the public. [10 CFR 20.1302]

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored

a. Instruments. Radiation protection instrumentation should be appropriate to the scope of the licensed program. Verify that portable survey instruments are available, have the appropriate range of use and are used in accordance with the requirements of Part 36. Verify that area radiation monitors required by 10 CFR 36.23 (c), 36.29, 36.39 (e), 36.41 (e), and 36.59 (b) are appropriate, operable;

have the proper alarm settings (if applicable), are adequately maintained and conform to the requirements of Part 36.

b. Calibrations. Verify that the survey instruments are calibrated at least annually and in accordance with the requirements in 10 CFR 36.57(c). All survey, sampling, and monitoring instruments should have current calibrations appropriate to the types and energies of radiation to be detected. Survey instruments must be calibrated and checked for appropriate response in accordance with 10 CFR 36.55(b) and 36.57(c) and licensee procedures. The inspector may choose to examine the instrument calibration records (efficiency checks, lower-limit-of-detection calculations, etc.); physical location of counting instruments; methods of detection; and pool-water-sample locations.

c. Inspection and maintenance. Verify that the licensee has established procedures to perform the inspection and maintenance requirements of 10 CFR 36.61 with regard to radiation monitors. Verify that non-routine operations (e.g., repairs) are performed by authorized personnel (licensee or others). Procedures and their implementation (practices) must be consistent with license commitments.

03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program

a. Authorized Operators. Verify through observations and interviews that the operators have knowledge commensurate with operational duties. (An example of an activity to observe is entering and leaving the radiation room, with requirements of this activity listed in 10 CFR 36.67.) Authorized operators should be trained in accordance with the approved license criteria. The instruction, testing, training, periodic safety reviews and safety performance evaluations required for individuals operating an irradiator without a supervisor present are listed in 10 CFR 36.51. Also listed in that section are training requirements for individuals permitted unescorted access to irradiators and for individuals who must be prepared to respond to alarms.

1. If, during the course of observations or interviews, a situation develops that causes the inspector to question the quality the staff's knowledge, verify that appropriate training and initial instructions have been accomplished as specified in the license and/or regulations.

2. Review examples of tests and scoring to determine that relevant topics of 10 CFR 36.51 are effectively covered in the training program. Ascertain the licensee's method of reinstructing and retesting those operators who do not initially pass the testing.

3. Also, verify that the licensee is conducting operator safety reviews and safety performance evaluations at least annually as required by 10 CFR 36.51(d) and 36.51(e).

Non-authorized operators may operate the irradiator only in the presence of a supervisor who is an experienced authorized user. Determine that the authorized

operators are personally performing or, if permitted in the license, supervising the work of non-authorized operators.

b. General Training. Also interview workers other than operators to verify that, pursuant to 10 CFR 19.12, instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Individuals should understand the radiation protection requirements associated with their assigned activities. Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

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If any concerns are identified regarding the level of knowledge of staff, examine records of training and attendant examinations or tests (if applicable) to the extent that the inspector is satisfied that the training program is being implemented as required. Where examinations are required, read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities.

c. Operating and Emergency Procedures. Verify that operational procedures are being followed by observing licensee personnel perform tasks at selected work stations and by a comparison of their activities with established procedures.

1. If concerns are identified regarding a specific procedure or task, examine the licensee's written procedures to determine that these procedures are as approved by the Department.

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2. With regard to emergency procedures, verify that licensee personnel understand and implement the established procedures and are aware of any procedural revisions. The licensee can revise these procedures, without Department approval, if the conditions of 10 CFR 36.53(c) are met. Verify that the conditions were met for any revisions of these procedures made without DEP approval.

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When applicable, discuss with the licensee's representatives, or observe, the conduct of periodic tests and drills, especially for scenarios involving fires and large releases of radioactive material. Some licensees may have agreements with other agencies (i.e., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

d. Posting and Labeling. Verify that proper caution signs are being used at access points to areas containing licensed materials and radiation areas as required by 10 CFR 20.1902. Also randomly examine signals and alarms to determine operability

and audibility at occupied locations, per 10 CFR 36.23(b). [Note: Do not perform tests of systems that may result in unnecessary radiation exposure to DEP or licensee personnel. Instead of actual tests, look for evidence of radiation effects damage to wiring and warning lights.]

Also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded. Examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed

DEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions and to terminate unsafe activities involving byproduct material.

Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining prior written consent from DEP before transferring control of the license;
- Notifying the Department in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).
- Assuring the appropriate response, when applicable, to generic communications from DEP.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities. (10 CFR 30.35)
- Notifying DEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (10 CFR 30.36)
- Notifying the DEP of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21.

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- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

a. RSC (where required or used). Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

b. RSO. Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

1. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

2. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.

c. Audits. Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The

results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

1. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

2. Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

87122-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

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INSPECTION PROCEDURE 87123

WELL LOGGING PROGRAMS

PROGRAM APPLICABILITY: 2800

87123-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with Department (DEP) requirements.

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87123-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by DEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

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The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective well logging radiation safety program:

02.01 FE-1. The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

02.02 FE-2. The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3. The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4. The licensee should implement a radiation dosimetry program to measure accurately and record radiation doses received by workers or members of the public as a result of licensed operations.

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02.05 FE-5. The licensee should provide radiation instrumentation in sufficient number, condition, and location to monitor accurately radiation levels in areas where licensed material is used and stored.

02.06 FE-6. The licensee should ensure that workers are:

a. knowledgeable of radiation uses and safety practices;
b. skilled in radiation safety practices under normal and accident conditions; and,
c. empowered to implement the radiation safety program.

02.07 FE-7. The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;
b. that audits for ALARA practices are performed; and,
c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

Usually the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, repetitive violations, or high radiation exposures.

87123-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within DEP's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem. For additional information relating to the evaluation of radiation safety programs, inspectors should refer to Inspection Procedure (IP) 83822, "Radiation Protection."

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Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, observations, and demonstrations rather than exclusive reliance on review of records. An examination of the licensee's records should not be considered the primary part of the inspection program.

In the records reviewed, look for trends such as increasing doses. Records such as surveys, waste disposal, receipt and transfer of licensed materials/ other radiation sources, training, and utilization logs, may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely

related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail.

Common elements to all inspections include preparation, entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Each of the following Focus Elements should be reviewed during each inspection of all well logging licensees. Inspectors should select sub-elements for review that are representative of the licensee's scope of use. If the licensee is using byproduct material at a temporary job site, then the inspector should consider those activities for the review of each Focus Element.

Specific Guidance

03.01 FE-1:The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits

Facilities

a. Through direct observation, verify that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities (if the licensee has used unsealed materials for subsurface tracer studies), etc.

    1. If any entrance or area is unsecured, determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

    2. If entrances or other areas are unsecured, examine areas where radioactive materials are used and stored. Storage areas must be locked and have limited and controlled access. Radioactive material use areas must be under constant surveillance or physically secured.

b. Through observations, verify that use and storage areas, including radioactive waste storage facilities (if the licensee has used unsealed materials for subsurface tracer studies), are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas must be physically secured when unattended.

c. Observe the licensee's operation at a temporary job site. This inspection should be unannounced. If possible, make arrangements with licensee management or the licensee's client to observe the licensee's field operations before announcing your presence.

Through interviews of other workers who are present at the field site, determine their understanding of the licensee's access control. Although these workers may not have or need any knowledge of the licensee's operations, if they were informed of the licensee's operations, i.e., to maintain a practical safe distance from licensed operations, this would be an indication of the licensee's good safety practices. As non-licensees, such individuals have no obligation to cooperate with the DEP.

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1. If other workers are unaware of basic radiation safety practices, determine if the licensee failed to provide instructions. Assess the role of other workers at the field site and the potential for radiation exposures of unacceptable consequence to other workers.

Receipt and Transfer of Licensed Materials

a. Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and receiving areas; 2) inspects packages for damage; 3) performs appropriate package receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If you are unable to observe the receipt of packages, request that personnel who normally receive packages for the licensee to demonstrate package receipt processes and surveys.

1. If packages are left unattended, assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

2. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in Focus Element 5 (Section 03.05, below).

b. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Physical Inventory.

a. Through observation, physically examine the inventory of radioactive material on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license, including Sealed Source and Device (SSD) registry limits.

1. Assess how the licensee ensures that only registered SSD combinations are used.

2. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license. For example, a licensee may not use sealed sources in a well without a surface casing or inject licensed material into a fresh water aquifer except as specifically authorized by the Commission.

3. Verify that the inventory, including radioactive markers (10 CFR 39.37, 39.47) is complete.

b. Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.

1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the DEP.

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2. For incidents or unusual occurrences that were not required to be reported, determine that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

3. Verify that the licensee has adequate procedures in place for the abandonment of irretrievable sources. Verify that the licensee has a written agreement with the well owner/operator for recovery or abandonment of sources (10 CFR 39.15).

03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment

Routine and Non-Routine Maintenance

Through interviews of licensee staff and observation of the licensee's equipment, verify that the licensee has inspection and maintenance programs required under 10 CFR 39.43 and that associated records of defects are available. The equipment items involved in the program should include source holders, logging tools, uranium sinker bars, source-handling tools, storage containers, and transport containers. The program should ensure that no physical damage is visible and that the required labeling is legible. Physically examine a representative sample of source handling tools to determine their condition and their ability to adequately secure a source during transfer to and from its source storage container. Physically examine source storage containers to ensure that they are in good condition and that design safety features function as intended.

a. If licensee staff did not check well logging equipment each day before use and semiannually or if physical damage is evident or illegible labels are apparent, assess the licensee's process for completing the checks. Determine how the licensee failed to implement the written procedure.

b. If unauthorized individuals removed sealed sources from source holders or logging tools, assess the licensee's process for dismantling well logging equipment and the potential for radiation exposures. Determine how the licensee failed to implement the written procedure.

c. If individuals were not specifically approved by DEP, NRC, or an Agreement State to open, remove, or modify a sealed source or to remove (e.g., chisel, drill, or cut) a stuck sealed source from the source holder, assess the licensee's process for performing the operation and the potential for radiation exposures. Determine how the licensee failed to obtain approval from DEP, NRC, or an Agreement State.

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Area Radiation Surveys

Through interviews of selected licensee personnel, including the RSO, verify specifically that schedule and procedural requirements for surveys are adequate to demonstrate compliance with the regulations and with pertinent license requirements. Determine whether due consideration is given to gamma and neutron emissions from the radionuclides involved, and to total body exposure and extremity exposure.

Verify that the licensee has established schedules for periodic surveys of work and storage areas of the facility site. Observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys. Review a random selection of survey records to verify that surveys are performed according to schedules; assess that the survey results are reviewed by an appropriate supervisor and that corrective actions have been taken, as appropriate.

Request that licensee personnel spot-check radiation levels in selected areas using the licensee's instrumentation. Compare the results with those obtained using DEP's instruments.

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03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material

The inspector should be attentive to potential industrial safety hazards for referral to the U.S. Department of Labor's Occupational Safety and Health Administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

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Operational Limits

Verify that well logging sources are used in accordance with any operational limits described in the applicable SSD sheet. Sources have limits for temperature, pressure, corrosive chemical exposure, etc. Also, inspectors should assess that sources in storage

are protected from fire (see "Fire Protection," below) and the elements, that package integrity is appropriately maintained, and that controls are in effect to minimize the risk from other hazardous materials.

Temporary Job Site Hazards

During inspections of licensed activities at temporary job sites, verify that licensee personnel ensure that sources are protected from heavy equipment such as cranes, drill pipe, etc.; welding equipment; high voltage lines; and other industrial hazards.

Fire Protection

In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensee's facilities, be alert to potential fire hazards. An effective licensee fire protection program should (1) prevent fires from starting, (2) rapidly detect, control, and extinguish those fires that do occur, and (3) provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to control licensed material safely and prevent the spread of contamination and unnecessary exposures to workers or the public.

Through observation and discussion with the licensee, while touring the facilities, assess firesafe conditions and equipment, i.e., that: (1) work areas are generally uncluttered and free of combustible debris, (2) incompatible materials (i.e., materials labeled as "corrosive", "flammable", or "oxidizer") are isolated from each other and enclosed by fire resistant barriers, (3) fire detection systems are operable, (4) fire suppression systems are operable, (5) portable fire extinguishers are unexpired (check maintenance tags), (6) electric switches and electric motors are explosion-proof, arc welders or open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive chemicals, and that (7) the local fire department is involved with the licensee's fire protection program.

Through observations and discussions with licensee staff, assess that: (1) radioactive waste is protected from fire and the elements, (2) package integrity is appropriately maintained, (3) the storage area is ventilated, and (4) controls are in effect to minimize the risk from other hazardous materials.

Any problems/deficiencies noted should be promptly brought to the licensee's attention and discussed with Regional management.

Licensees should be practical in approaching the safety of the device in the event of fire. They should not endanger themselves to protect the source, but should be able to provide radiological hazard information to emergency medical and fire personnel who respond to the fire.

Industrial/Chemical Hazards

Through observations and interviews of licensee personnel, determine that the licensee controls the use/storage of hazardous (corrosive or combustible) chemicals near well logging equipment that could degrade performance or render safety features inoperable. If the licensee is required to implement an emergency plan, verify that the plan includes these hazards, as appropriate, as initiating events.

Transportation

Verify that licensed material is packaged and transported (or offered for transport) in accordance with 10 CFR Part 71 and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials. The inspector should refer to IP 86740, "Inspection of Transportation Activities" for further inspection guidance. Also the field reference charts, "Hazard Communications for Class 7 (Radioactive) Materials," are useful for determining compliance with the transportation requirements for minimum packaging, shipping papers, marking and labeling packages, placarding vehicles, and package and vehicle radiation limits and contamination limits.

a. Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers.

b. If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

c. Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COC) issued by the NRC. The licensee must maintain copies of the COC for the packages that it has used and ensure that it follows the instructions and limitations of the COC when preparing the packages for shipment.

d. If the licensee reported any transportation incidents, review the licensee's actions in response to the incidents.

e. In the case where a licensee may have transferred a source to a burial site for offsite disposal, review the licensee's procedures and records to verify that each shipment is accompanied by a shipment manifest that includes all the required information. Also review the licensee's procedures and records to verify that each package intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of 10 CFR 61.55 [Subsection III.A.2 of Appendix G to Part 20]. Verify that records are maintained that demonstrate compliance with the requirements for the disposal of licensed material made under 10 CFR 20.2002-2005, 10 CFR Part 61, and disposal by burial in soil. For further inspection

guidance, refer to IP 84850, "Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61."

03.04 FE-4: The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams. For additional guidance relating to personnel dosimetry, refer to Inspection Procedure (IP) 83822, "Radiation Protection."

Personnel Dosimetry

a. Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes.

b. If the licensee monitors worker exposures (internal and external), notwithstanding a prospective analysis indicating that monitoring was not required, review selected reports of monitoring results. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

    1. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one worker consistently receives significantly more exposure than all other workers each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.

    2. Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.

c. Through interviews of workers and observations of activities in progress, verify that radiation monitors are worn appropriately and are recording the highest dose for which they are intended.

    1. If monitors are not (or cannot be) worn in the most appropriate location to record the highest dose received by the individual(s), through interviews of the RSO, verify that the licensee has performed assessments (through surveys, calculation, or both) of occupational exposures received and adjusted the dose of record for the worker(s).

    2. Review the results of the licensee's assessment and verify the assumptions and outcomes. Verify that the dose of record for the affected worker(s) has

been adjusted and that the adjusted dose is within the applicable regulatory limit and ALARA.

d. Through interviews of the RSO and review of records of external monitoring results, determine whether processing (collection, process, and assessment) of monitoring devices is being performed in a timely manner.

e. Through interviews of the RSO and workers who handle volatile radionuclides (e.g., radioiodine), verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies. [Note–the unsealed radionuclides used for subsurface tracer studies are generally non-volatile.]

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f. Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the DEP.

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2. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

Contamination Control

Through interviews of selected licensee staff, including the RSO, the inspector should verify that personnel have an adequate understanding of the procedures to be followed in the event that the licensee's sources are ruptured or licensed materials have caused contamination. Occasionally, well logging tools containing sources become lodged, or otherwise immobilized in the well. When this happens, operations are initiated to retrieve the tools from the well. The inspector should verify that the drilling fluids (mud) are monitored for radioactive materials whenever retrieval operations are ongoing.

Note that, in accordance with 10 CFR 39.67, the licensee is required to make radiation surveys of each area where licensed materials are used and stored. In particular, the licensee is required to perform a radiation survey at temporary job sites before and after each subsurface tracer study, to confirm the absence of contamination. Licensees must be authorized to knowingly inject radioactive materials into fresh water aquifers. If practical, observe how licensees conduct surveys to determine the adequacy of such surveys. Also,

note the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

The inspector should determine if workers take smears or instrument readings in areas that are potentially contaminated and accessible to facility personnel. Particular attention should be given to well heads and storage areas. The inspector should also perform independent measurements, as needed, to verify licensee assumptions or measurements.

Leak Tests

Through discussions with licensee personnel and/or by demonstration of leak test procedures, verify that leak tests are performed in accordance with the manufacturer's recommendations and/or license. In accordance with 10 CFR 39.35, verify that the wipe of a sealed source is taken from the nearest accessible point to the sealed source where contamination might accumulate, at intervals not to exceed 6 months (or other frequencies in accordance with the sealed source and device evaluation certificate).

Verify that the licensee's leak test analyses (or that of it's leak test services vendor) has sufficient sensitivity to measure 185 becquerel (0.005 microcurie) for each type of isotope present on its license. Through discussions with licensee staff and/or review of pertinent records, determine if the licensee had a leaking source. If leak test results show contamination in excess of the regulatory limits, verify that the licensee made appropriate notifications, evaluations, and removed the source from service.

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to monitor accurately radiation levels in areas where licensed material is used and stored

Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (i.e., area and transportation surveys; bioassay and leak test analyses) have been routinely calibrated and maintained.

Survey Instruments

a. Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to the DEP instrument. Verify that licensee's instrument response is comparable (i.e., ± 20%) to the DEP instrument.

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b. Through interviews of the RSO and workers, and by observation, determine whether the licensee has a system for tagging out inoperable and out-of-service survey instruments.

Instrument Calibration and Maintenance

a. If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO, that the vendor is authorized by the DEP, NRC or an Agreement State to perform that service.

b. Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Assess that calibrations include a determination of "as found" condition before adjustments are made. Assess that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.

c. If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."

Bioassay Instruments

Through observations and interviews of the RSO and workers, verify that the licensee's instrumentation for performing in vivo bioassay measurements is adequate for those measurements. Determine that bioassay probes and scalers are compatible. Determine that licensee staff perform a response check using appropriate sources (such as a barium-133 source to simulate iodine-131) and a suitable background measurement before taking bioassay measurements.

Leak Test Analysis

If the licensee is authorized to both collect and analyze leak test samples, the inspector should determine if the type of counting equipment is appropriate for the samples being analyzed and the sensitivity required. The inspector should determine if the laboratory instrumentation is calibrated for the appropriate geometries of the samples to be analyzed and is routinely checked for proper operation. The licensee should maintain calibration records, control charts, and maintenance and repair records, to demonstrate proper operation of laboratory instrumentation.

03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program

a. Authorized Users. Authorized users (logging supervisors and logging assistants) may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties.

Through observations and interviews of logging supervisors and logging assistants, assess implementation of radiation safety practices for well logging activities (i.e.,

loading of sources into tools, leak-testing procedures, maintenance activities). Verify their ability to recognize unsafe radiological conditions and to respond appropriately to emergency situations. Also verify that logging supervisors and logging assistants understand the mechanism for raising safety concerns to licensee managers.

Review selected training records to determine that examinations or tests (if applicable) have been implemented and are appropriate. Read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities.

Note that, at a minimum, the licensee is required to provide safety reviews, as defined in 10 CFR 39.2, for logging supervisors and logging assistants at least once during each calendar year.

b. General Training. Verify, pursuant to 10 CFR 19.12, that initial instructions have been given to workers who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of the storage, transfer, or use of radiation and/or radioactive material; health protection problems associated with exposure to radiation; precautions or procedures to minimize exposure; and the purposes and functions of protective devices employed. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements.

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c. Operating and Emergency Procedures. Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures. The emergency procedures will be approved by DEP, and reviewed and updated by the licensee. Any revision requires an amendment to the license.

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Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that those agencies (involved in such agreements) understand their roles in emergency responses.

Verify that licensee personnel are knowledgeable of the operational procedures by observing the performance of tasks at selected work stations and by a comparison of their performance with established procedures. Determine that the licensee's emergency procedures have been approved by or described to DEP. Through discussions with workers, assess that licensee personnel understand and implement the established procedures and are aware of procedural revisions. Determine the licensee has adequate procedures in place for handling irretrievable, abandoned sources.

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Through discussions with licensee staff, assess the licensee's handling of tracer materials. Verify, when practical (and when required), that well logging personnel

wear appropriate protective clothing during their work activities. Requirements for protective clothing may be found in the licensee's procedures. Assess that all waste items (e.g., empty vials, gloves, napkins, cans, etc.) are appropriately packaged, labeled, and transported from the job site to the licensee's waste storage location, and that the licensee has appropriate methods to track the items in storage.

d. Posting and Labeling. Determine that proper caution signs are being used at access points to areas containing licensed materials and radiation areas. Section 20.1903 provides exceptions to posting caution signs. The inspector should also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

Observe locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed

DEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding DEP regulations and license provisions and to terminate unsafe activities involving byproduct material.

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Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining prior written consent from DEP before transferring control of the license;
- Notifying the Department in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).

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- Assuring the appropriate response, when applicable, to generic communications from the NRC and Department.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities. (10 CFR 30.35)
- Notifying DEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (10 CFR 30.36)
- Notifying the DEP of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR Part 21.
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

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a. RSC (where required or used). Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been effective in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

b. RSO. Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

1. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

2. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.

c. Audits. Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

1. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

2. Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

87123-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

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DEP INSPECTION MANUAL

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INSPECTION PROCEDURE 87124

FIXED AND PORTABLE GAUGE PROGRAMS

PROGRAM APPLICABILITY: 2800

87124-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with Department of Environmental Protection (DEP) requirements.

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87124-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by DEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

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The inspector should determine if the licensee possesses licensed material as authorized by a general license. If so, the inspector should also assess the adequacy of licensee's program for management and oversight of the generally licensed material.

The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective fixed or portable gauge radiation safety program:

02.01 FE-1. The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

02.02 FE-2. The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3. The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4. The licensee should implement a radiation dosimetry program to measure and record accurately radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5. The licensee should provide radiation instrumentation in sufficient number, condition, and location to monitor accurately radiation levels in areas where licensed material is used and stored.

02.06 FE-6. The licensee should ensure that workers are:

a. knowledgeable of radiation uses and safety practices;
b. skilled in radiation safety practices under normal and accident conditions; and,
c. empowered to implement the radiation safety program.

02.07 FE-7. The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;
b. that audits for ALARA practices are performed; and,
c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

87124-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the DEP's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem.

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An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records alone.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of licensed materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail.

Common elements to all inspections include entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Each of the following elements should be reviewed as appropriate, during each inspection of a fixed and portable gauge licensee.

Specific Guidance

03.01 FE-1: The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits

Facilities

a. Through direct observation, verify that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

    1. If any entrance or area is unsecured, determine, through interviews of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

    2. If entrances or other areas are unsecured, observe other areas where radioactive materials are used and stored and verify that they are locked and have limited and controlled access. Radioactive material use areas must be under constant surveillance or physically secured.

b. Through observations, verify that use and storage areas are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas should be physically secured when unattended.

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c. Evaluate licensee practices regarding access controls including control of keys and access codes to ensure that only currently authorized individuals have access to licensed materials.

d. Licensed material in use must be controlled and under constant surveillance. Portable gauges must be under constant surveillance when at a temporary job site. For fixed gauges in use, constant surveillance is not required, provided that the licensee has adequate facility security and effective procedures for ensuring that gauges are not removed by unauthorized individuals. Determine the adequacy of the licensee's procedures for securing licensed materials at temporary job sites. Evaluate licensee's procedures for securing gauges that are not in use at temporary job sites. Evaluate how the licensee secures gauges that are in transport, including securing gauges in a licensee vehicle (or a vehicle of an individual employed by the licensee) when that vehicle is parked in a restaurant, hotel, or similar facility. Verify that either the gauge's transport case or operating handle is locked when the device is packaged for transport.

Receipt and Transfer of Licensed Materials

Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and receiving areas; 2) inspects gauge shipping containers for damage; 3) performs appropriate receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If possible, observe the receipt of packages. Otherwise, request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

a. If packages are left unattended, then assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

b. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, then interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in Focus Element 5.

Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Inventory Control

Through observation, physically examine the inventory of gauges on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license. Compare the possession of gauges with inventory records. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license.

Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.

a. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the Department.

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b. For incidents or unusual occurrences that were not required to be reported, determine whether the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment

a. Equipment. The SSD sheet specifies the type of safety features installed on the device and specifies the frequency at which these features should be inspected for proper operation. Fixed gauges operated in high temperature environments may require supplemental cooling systems that have inspection and maintenance requirements. Ensure devices are used in accordance with any operating limits (such as temperature and vibration limits) described on the applicable SSD sheet. Verify that engineered safety features (such as shutters, locking mechanisms, or interlocks) are appropriate, operable, calibrated, adequately maintained, and conform to the description in the applicable SSD sheet. Ensure that the facility provides protection of shield integrity, including fire protection. Licensees should have copies of or access to these SSD Certificates, in addition to the manufacturers' manuals for operation and maintenance.

b. Process or Other Engineering Controls. Verify that, where applicable, that the licensee uses processes or other engineering controls to maintain doses as low as is reasonably achievable (ALARA). For example, fixed gauge licensees may install protective cages around the area where a gauge is mounted to prevent inadvertent access to the radiation beam.

c. Routine and Non-Routine Maintenance. Confirm that any maintenance of gauges is performed in accordance with the applicable manufacturer's maintenance procedures. Maintenance procedures must include ALARA provisions, and ensure that the gauge functions as designed and the source integrity is not compromised. For portable gauges, routine maintenance may include the cleaning and lubrication of the source rod and shutter mechanism (e.g., to remove caked dirt, mud, asphalt, or residues from the source rod; lubricate the shutter mechanism). For fixed gauges, routine maintenance is normally limited to cleaning of the gauge housings to ensure that required labels remain legible.

More extensive maintenance or servicing (beyond routine cleaning and lubrication) that involves detaching the source or source rod from portable gauges must be performed by the gauge manufacturer or a person specifically authorized by the Department, the NRC or an Agreement State. Persons performing installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed source, and non-routine maintenance or repair of components related to the radiological safety of fixed gauges (i.e., the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, shielding) must be authorized by the Department, the NRC or an Agreement State. The license will contain a condition if the licensee is authorized to perform these activities.

03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

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a. Operational Limits. Verify that gauges are operated in accordance with any operating limits (i.e., heat, vibration, corrosive materials, or other industrial or environmental hazards) described on the applicable SSD sheet. Determine whether if fixed gauge are installed in accordance with the limiting conditions described in the sealed source and device catalog certificate and by the device manufacturer (i.e.: temperature, vibration, etc.). Verify that gauges in storage are protected from fire and the elements and that adequate controls are in effect to minimize the risk from other hazardous materials.

   Verify that radiological labeling is clearly visible and legible.

b. Temporary Job Site Hazards. During inspections of licensed activities at temporary job sites, verify that licensee personnel ensure that devices are protected from heavy construction equipment, welding equipment, high voltage lines, and other industrial hazards.

c. Fire Protection. Materials licensees are not required by DEP regulations to implement a fire protection program. However, in many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. Determine if licensees have a plan in place for preventing fires and combating fires that might occur. Any perceived problems/deficiencies (i.e., improper storage of combustible or flammable material, fire extinguishers out of service, lack of fire alarm or detection system, lack of fire suppression system) noted by the inspector should be brought to the licensee's attention and discussed with regional management. Proper fire protection systems can be evidenced by the licensee's involvement with the local fire department.

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d. Transportation. Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with 10 CFR

Part 71 and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.
Examine: packages and the associated certification documentation; vehicles (including cargo blocking and bracing, and gauge security); and, shipping papers. Review any incidents required to be reported to the DOT.

NOTE: For further inspection guidance refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer to "Hazard Communications for Class 7 (Radioactive) Materials." These field reference charts, related to hazard communications for transportation of radioactive materials, are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings. They also contain references to the DOT regulatory requirements.

03.04 FE-4: The licensee should implement a radiation dosimetry program to measure and record accurately radiation doses received by workers or members of the public as a result of licensed operations

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include, for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

Verify that the licensee has performed adequate surveys to show compliance with public dose limits and that conditions in controlled areas and unrestricted areas meet the requirements specified for these areas.

a. For most fixed and portable gauge licensees, occupationally exposed workers are not likely to receive annual doses in excess of ten percent of the applicable limit in 10 CFR Part 20. Therefore, these licensees are not normally required to implement a radiation dosimetry program. In these instances, evaluate the licensee's demonstration that personnel are not likely to receive in excess of ten percent of the Part 20 occupational dose limit. In all cases, if a licensee does not provide personnel monitoring devices, it must have a documented prospective evaluation of occupational exposure that demonstrates that monitoring is not required.

   Dosimetry devices must be appropriate to the type, energy, and the anticipated radiation fields, must be issued to licensee personnel, when monitoring is required. Verify that any dosimeters that require processing to determine the radiation dose, are processed by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited processor.

b. Verify that the licensee annually advises each worker who is required to be monitored of the worker's dose, as shown in records maintained by the licensee.

c. For most fixed and portable gauge licensees, extensive evaluations of doses received by members of the public from licensed activities may not be necessary. Verify that the use and storage of gauges will not likely result in exposures to members of the public or radiation levels in unrestricted areas that are in excess of the regulatory limits. For storage areas that located adjacent to unrestricted areas, licensees must ensure (through measurement or calculation) that doses in the unrestricted areas do not exceed 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) in a year to the maximally exposed member of the public.

d. Area Surveys. Most fixed and portable gauge licensees are not required to perform routine surveys. Surveys of fixed gauges are required when the licensee (or its licensed contractor) installs, removes, or relocates a gauge. Generally, portable gauge licensees are only required to perform surveys if they are authorized to perform maintenance involving the removal of the source rod, or the device's shielding.

If practical, observe how licensees conduct any required surveys to determine the adequacy of such surveys. Note the types of any instruments used, and whether they are designed and calibrated for the type of radiation being measured. (See FE-5)

e. Leak Tests. Verify that leak tests of sealed sources are performed at the required frequency. Also verify that leak test samples are analyzed in accordance with the license requirements.

1. If records of leak test results show contamination in excess of the regulatory requirements, then verify that the licensee made appropriate notifications and removed the source from service.

f. Storage and Disposal of Gauges Removed From Service. Determine if the licensee has gauges that have been removed from service. Verify that the gauges are stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed the limits of 10 CFR 20.1301, "Dose Limits for Individual Members of the Public."

Licensee personnel should be aware of the presence of the device and the need to prevent unauthorized disposal or abandonment.

Typically, gauge licensees dispose of devices either by returning the device to the manufacturer or by transfer to another appropriately licensed person. Verify that any person to whom the licensee has transferred gauges was properly licensed to receive them.

If the licensee transfers gauges to a burial site for offsite disposal, assess the licensee's procedures and records to verify that each shipment is accompanied by a shipment manifest that includes all the required information. Also assess the licensee's procedures and records to verify that each package intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it

as Class A, B, or C waste in accordance with the classification criteria of 10 CFR 61.55 [Subsection III.A.2 of Appendix G to Part 20].

For additional guidance relating to the evaluation of radiation safety programs and personnel dosimetry, refer to Inspection Procedure (IP) 83822, "Radiation Protection."

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to monitor accurately radiation levels in areas where licensed material is used and stored

Gauge licensees should either possess, or have access to, radiation survey equipment. Equipment and instrumentation should be appropriate to the scope of the licensed program.

a. Verify that the instrumentation has the appropriate range of use. Also verify that the survey instruments are calibrated at the appropriate frequency and checked for operability before use. Survey and monitoring instruments must be appropriately calibrated for the types and energies of radiation to be detected.

03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program

Authorized Users

Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties. Typically, successful completion of one of the following is considered as evidence of adequate training and experience for operating gauging devices:

- Gauge manufacturer's course for users; or

- Equivalent course that meets Appendix D criteria in either NUREG 1556, volume 1, Program-Specific Guidance About Portable Gauge Licenses" or NUREG 1556, volume 4, Program-Specific Guidance About Fixed Gauge Licenses"

Authorized users are required to either be physically present or to otherwise supervise the use of gauges. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of...," For some licenses that have the condition "... under the direct supervision of ... ," the authorized user must be physically present at the facility for easy contact or to observe the individual(s) working. Another phrase used is " ... may only be used by ... ". Finally, "... under the direct supervision and physical presence of ... " means the authorized user must directly supervise and be present at the work station. Considering the many license condition phrases, the inspector must exercise judgment to interpret the role of the authorized users.

When the wording of the license condition is " ... used by or under the supervision of ... ," an authorized user named on the license is considered to be supervising the use of licensed materials when he or she directs personnel in the conduct of operations involving the licensed material. This does not imply that the authorized user must be present at all times during the use of such materials. The authorized user is responsible for assuring that personnel under his/her supervision have been properly trained and instructed and is responsible for the supervision of operations involving the use of licensed materials, whether he or she is present or absent.

General Training

Determine that appropriate training and initial instructions are being accomplished as specified in the license and/or regulations. The inspector must verify that appropriate training is provided to authorized users (including the RSO), other persons using licensed materials, and other licensee employees who may have unescorted access to licensed materials or to restricted areas.

The requirements for certain kinds of training and instruction are found in the regulations, while the procedures for their implementation are generally found in the procedures included in the license's "tie-down" condition. Discuss with the licensee how, and by whom, training is conducted, and the content of the training provided to workers (generally found in the license application).

Generally, most gauge licensee employees are not likely to receive an occupational dose of more than 1 mSv (100 mrem) in a year. The only exception would likely be a licensee that performs an extensive amount of maintenance on it own gauges. Verify that initial instructions have been given to workers, if any, who are likely to receive more than 1 mSv (100 mrem) in a year. For this kind of training, it is the licensee management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

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Through interview of one or more users of radioactive materials (other than the RSO) determine that they possess the adequate knowledge and understanding of the licensee's operating and emergency procedures. The interviews should include discussions about actual or hypothetical emergency conditions in order to assess the worker's response to such conditions. Observe licensed activities in progress or a demonstration of activities to assess the worker's understanding of the radiation protection requirements associated with their assigned activities.

Operating and Emergency Procedures

Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for lower-inspection-priority

licenses. The emergency procedures will be approved by the DEP, and reviewed and updated by the licensee. Any revision requires an amendment to the license.

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Verify that licensee personnel are knowledgeable of the operational procedures by observing the performance of tasks at selected work stations and by a comparison of their performance with established procedures. Assess the licensee's emergency procedures to determine that these procedures are as approved by or described to DEP. Through interview of workers, verify that licensee personnel understand and implement the established procedures and are aware of procedural revisions.

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Licensees should be aware of relative radiological risks and not try to protect the device to the extent that they would be subjected to fire or other life-threatening situations (e.g., attempting to rescue a portable gauge from the path of approaching soil compacting equipment.)

Some licensees may have agreements with other agencies (i.e., fire, law enforcement, and medical organizations) regarding response to emergencies. Through interviews of licensee officials, determine what actions the licensee has taken to ensure that such agencies (involved in such agreements) understand their roles in emergency responses.

Posting and Labeling

Through observation, verify that proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. Through observation of labeling on packages or other containers, verify that the proper information (e.g., isotope, quantity, and date of measurement) is recorded. Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902.

Through observation, verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed

The DEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding DEP regulations and license provisions and to terminate unsafe activities involving byproduct material.

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Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining prior written consent from the Department before transferring control of the license.
- Notifying the Department in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).
- Assuring the appropriate response, when applicable, to generic communications from DEP.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities (10 CFR 30.35).
- Notifying DEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place (10 CFR 30.36).
- Notifying DEP of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21.
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

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a. RSC (where required or used). Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

b, RSO. Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

1. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

2. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.

c. Audits. Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

1. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

2. Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

87124-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

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DEP INSPECTION MANUAL

INSPECTION PROCEDURE 87125

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MATERIALS PROCESSOR/MANUFACTURER PROGRAMS

PROGRAM APPLICABILITY: 2800

87125-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with Department of Environmental Protection (DEP) requirements.

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01.03 To determine if the licensee is manufacturing sources or devices in accordance with statements made to DEP.

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87125-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspections of materials processor/manufacturers. For the purpose of this IP, materials processor/manufacturers are those licensees that process raw material and/or sources and distribute those processed materials and sources to users as finished products. Examples are major radiopharmaceutical processor/manufacturers (not radiopharmacies), sealed source fabricators, device manufacturers, and other manufacturing licensees that use irradiated bulk quantities of raw materials or sources. This IP does not apply to inspection of distributors that are not involved in the processing of raw materials or sources, nor manufacturing of devices.

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by DEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. Inspections of materials processors/manufacturers differ from other materials inspections in a significant manner. In addition to the routine objectives of an inspection, these inspections also ensure that sources and devices manufactured by the licensee conform to the provisions of the registration certificate and the commitments made in the application at the time the source or device was registered (by NRC or an Agreement State). The inspection is the main source of information to the Department that the manufacturer is still making

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sources and devices as authorized in the license and registration certificate. The inspection should determine whether the licensee is deviating from the provisions of the registration certificate and the processes and procedures, as described in the references listed in the source or device registration certificates. The manufacturer must have copies of the registration certificate as well as the references available in order to be able to meet the provisions of the certificate and the commitments that the licensee made in the application. The inspector should use these documents to supplement the directions in the Inspection Procedure with product specific information.

The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective materials processor/manufacturer radiation safety program:

02.01 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

02.02 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 The licensee should ensure that workers are:

a. knowledgeable of radiation uses and safety practices;
b. skilled in radiation safety practices under normal and accident conditions; and,
c. empowered to implement the radiation safety program.

02.07 The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;
b. that audits for ALARA practices are performed; and,
c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

Usually the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if

warranted by circumstances, such as incidents, repetitive violations, or high radiation exposures.

87125-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection.

Common elements to all inspections include preparation, entrance and exit meetings with appropriate licensee management, including radiation safety committee (RSC) members and the radiation safety officer (RSO), observations of facilities and work in progress, independent and confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Each of the following areas should be reviewed during each inspection of all large materials processor/manufacturers.

Specific Guidance

03.01 FE-1:The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits

Facilities

a. Through direct observation, verify that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

    1. If any entrance or area is unsecured, determine, through interviews of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

    2. If entrances or other areas are unsecured, observe other areas where radioactive materials are used and stored and verify that they are locked and have limited and controlled access. Radioactive material use areas must be under constant surveillance or physically secured.

b. Through observations, verify that use and storage areas are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas should be physically secured when unattended.

Receipt and Transfer of Licensed Materials

a. Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and receiving areas; 2) inspects packages for damage; 3) performs appropriate package receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If possible, observe the receipt of packages. Otherwise, request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

1. If packages are left unattended, assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

2. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in Focus Element 5 (Section 03.05, below).

b. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Inventory Control

a. Through observation, physically examine the inventory of radioactive material on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license. Compare the possession of selected sealed sources with inventory records. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license.

b. Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.

1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the Department.

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2. For incidents or unusual occurrences that were not required to be reported, determine whether the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

NOTE: Item c. below only applies to those licensees authorized to possess sufficient quantities of source or special nuclear materials that the licensee is required to report the receipt, transfer or disposal of these materials to NRC's Nuclear Materials Management and Safeguards System (NMMSS). IMC 2800, Enclosure 7 contains specific guidance.

c. Through interviews of the RSO or other responsible licensee personnel, along with the review of relevant records, verify that the licensee has fulfilled the applicable reporting requirements relating to the NMMSS.

1. Discuss the location of all subject material possessed by the licensee. Compare the licensee's most recent record of physical inventory performed with the information documented in the licensee's NMMSS account on the DOE/NRC Form 742, "Material Balance Report."

2. Review the licensee's records documenting the receipt, transfer or disposal of NMMSS-reportable materials. Compare these records to the NMMSS TJ-45 report. Verify that each set of records properly documents and accounts for any receipt, transfer or disposal of NMMSS-reportable materials that may have occurred subsequently to the most recent filing of the DOE/NRC Form 742 by the licensee.

3. Verify the information listed on the licensee's inventory record by walking down the licensee's facility and (if practicable) visually identifying, at a minimum, a representative sample of the materials that the licensee reported to NMMSS on the most recently submitted DOE/NRC Form 742. If appropriate, verify the presence of the subject material with a radiation survey instrument.

NOTE: The inspector should not ask licensee personnel to open any container or otherwise change the container's shielding to facilitate this survey.

4. Review administrative information listed in the NMMSS Report D-3 with licensee personnel to ensure that the information is up to date. Verify that licensee personnel are cognizant of the need to make any required changes and the processes available for making any needed corrections.

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03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment

Process and Engineering Controls

Through observations, interviews of licensee personnel, and independent and confirmatory surveys, assess the adequacy of glove boxes, hot cells, remote-handling devices, shields and shielding devices, and other engineered safeguards to assure that they are adequate for the purposes for which they are intended. Specifically:

a. For hot cells, determine that the licensee controls: the entry of personnel to hot cells; the removal of material from process enclosures; and contamination originating within the hot cells.

    1. If any weaknesses in hot cell operations are identified, review the records of radiation surveys and/or air monitoring around the hot cell area.

    2. If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of FE 03.04.

b. For glove boxes, determine that the licensee: periodically checks the integrity of gloves and replaces gloves as necessary; controls the removal of material from process enclosures; and controls contamination originating within the glove boxes.

    1. If any weaknesses in glove box operations are identified, review the records of surveys around the glove box area and extremity monitoring records of individuals who work in the area.

    2. If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of FE 03.04.

c. For temporary or portable shielding, verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.

d. For all processes where shielding is used, assess the adequacy of shielding during maximum loading of hot cells and glove boxes. Determine, by surveying the areas near manufacturing processes, the continued adequacy of shielding. If the licensee initiates new processes in existing hot cells or glove boxes, determine whether the licensee has evaluated the adequacy of existing shielding before beginning the new process.

Product Shielding

Ambient radiation levels should be determined for areas normally occupied by workers. If higher than expected readings are found, determine the source of the higher dose rates.

a. Through direct observations, interviews of licensee personnel, and independent measurements, verify that large quantities of stock or bulk radioactive materials are adequately shielded. Verify that such shielding cannot be easily removed or opened. Determine whether the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads.

b. Through direct observations and interviews of licensee personnel, verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials, such as individual vials and manufactured sealed sources, and that licensee personnel use the shields when handling the containers/sources. Verify that unit shields are adequate for the quantities of radioactive materials typically contained in them.

c. Randomly select a number of finished products/devices that are ready for distribution and verify that the external radiation levels are consistent with expected values.

    1. If higher than expected levels are noted, verify that the shielding included in prepared, distributed products conforms to that described in the license documents, as appropriate.

    2. Verify that the licensee has not made changes to the size, shape, or contents (i.e., lead versus stainless steel) of the shielding materials without prior approval of the Department, NRC or an Agreement State. Deleted:

Routine and Non-Routine Maintenance

By interviewing selected maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine that maintenance personnel verify, either through their own or health physics staff surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from process equipment, entering rooms or areas (such as bunkers or hot cells) normally posted as high radiation or very high radiation areas, or entering tanks or vessels that normally contain or have contained radioactive materials. Verify that shielding removed for maintenance and opened manways are properly replaced prior to lifting of maintenance holds when equipment is returned to service.

For maintenance activities that include potentially significant radiological conditions, such as high dose rates (>100 millirem [1 mSv] per hour general area or > 1 rem [10 mSv] per hour contact) or contamination levels (>100,000 disintegrations per minute [1667 Bq] per 100 square centimeters), determine whether the licensee has established more stringent requirements, such as more detailed pre-job briefing of personnel, additional protective clothing, and/or constant job coverage by a health physics technician.

Area Radiation Surveys

Through interviews of selected licensee personnel, including the RSO, verify that the licensee has established schedules for periodic surveys of work and storage areas of the

facility site; verify that surveys are conducted using approved procedures; review a random selection of survey records to verify that surveys are performed according to schedules; verify that the survey results are reviewed by appropriate supervision; and verify that corrective actions have been taken, as appropriate. Attempt to observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys. Verify specifically that schedule and procedural requirements for surveys are adequate to demonstrate compliance with the regulations and with pertinent license requirements. Determine whether due consideration is given to energy, beta exposure, and extremity exposure, and whether neutron surveys are performed if appropriate.

Request that licensee personnel spot-check radiation levels in selected areas using the licensee's instrumentation. Compare the results with those obtained using the Department's instruments.

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03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration (see Manual Chapter 1007). The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

a. Fire Protection. In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensee's facilities, be alert to potential fire hazards. An effective licensee fire protection program should (1) prevent fires from starting, (2) rapidly detect, control, and extinguish those fires that do occur, and (3) provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public.

   Through observation and discussion with the licensee, while touring the facilities, assess firesafe conditions and equipment, i.e., that: (1) work areas are generally uncluttered and free of combustible debris, (2) incompatible materials (i.e., materials labeled as "corrosive", "flammable", or "oxidizer") are isolated from each other and enclosed by fire resistant barriers, (3) fire detection systems are operable, (4) fire suppression systems are operable, (5) portable fire extinguishers are unexpired (check maintenance tags), (6) electric switches and electric motors are explosion-proof, arc welders or open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive chemicals, and that (7) the local fire department is involved with the licensee's fire protection program.

   Any problems/deficiencies noted should be promptly brought to the licensee's attention and discussed with Regional management.

b. Industrial/Chemical Hazards. Through observations and interviews of licensee personnel, determine that the licensee controls the use/storage of hazardous (corrosive or combustible) chemicals near process equipment which could degrade their performance or render safety features inoperable. If the licensee is required to implement an emergency plan, verify that the plan includes these hazards, as appropriate, as initiating events.

c. Transportation. Verify that licensed material is packaged and transported (or offered for transport) in accordance with 10 CFR Part 71 and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.

1. Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers.

2. If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

3. Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs) issued by the NRC. The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

4. If the licensee reported any transportation incidents, review the licensee's actions in response to the incidents.

d. Operational Limits. Verify that the licensee operates process equipment within the equipment manufacturer's or industry consensus operational limits. Such limits may include temperature, humidity, vibration, or radiological considerations. In addition, such equipment may be subject to periodic preventative maintenance requirements/recommendations. If so, verify that such maintenance is performed.

03.04 FE-4: The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

a. Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes.

b. If the licensee monitors worker exposures (internal and external), notwithstanding a prospective analysis indicating that monitoring was not required, review selected reports of monitoring results. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

    1. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one worker consistently receives significantly more exposure than all other workers each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.

    2. Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.

c. Through interviews of workers and observations of activities in progress, verify that radiation monitors are worn appropriately and are recording the highest dose for which they are intended.

    1. If monitors are not (or cannot be) worn in the most appropriate location to record the highest dose received by the individual(s), through interviews of the RSO, verify that the licensee has performed assessments (through surveys, calculation, or both) of occupational exposures received and adjusted the dose of record for the worker(s).

    2. Review the results of the licensee's assessment and verify the assumptions and outcomes. Verify that the dose of record for the affected worker(s) has been adjusted and that the adjusted dose is within the applicable regulatory limit and ALARA.

d. Through interviews of the RSO and review of records of external monitoring results, determine whether processing (collection, process, and assessment) of monitoring devices is being performed in a timely manner.

e. Through interviews of the RSO and workers who handle volatile radionuclides (e.g., radioiodine), verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials.

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Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies.

f. Through observations of facilities and activities in progress, interviews of the RSO and workers, independent and confirmatory measurements, and reviews of records of licensee evaluations, verify that the licensee effectively uses procedures and engineering controls to maintain doses to members of the public and radiation levels in unrestricted areas within regulatory limits and ALARA.

g. Through observations of facilities and activities in progress, interviews of the RSO and workers, and reviews of records of air monitoring results and licensee evaluations, verify that licensee releases of gaseous radioactive effluents to unrestricted areas are within the constraint value. Verify that air sampling equipment is calibrated and operational, and that sampling lines are intact and draw from their intended collection points.

h. Through observations, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors in-line ventilation filtration systems for saturation. Determine whether filter systems are monitored for differential pressure to ensure that there is no bypass of the filters, including perforations/channels and worn or degraded seals.

i. Through observations, independent measurements, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors the flow rates of fume and laminar flow hoods used to process licensed materials. Verify that licensee staff use calibrated instruments to measure flow rates. Verify that hood flow rates are adequate to prevent outflow of volatile, gaseous, and particulate materials into work areas, including the prevention of high eddy currents originating from excessive hood flow rates.

j. Through observations, verify that respiratory protection equipment is certified by NIOSH/MSHA or otherwise approved by the Department. Determine that the licensee has selected the proper equipment for its licensed operations. Through interviews of the RSO, determine that the licensee has established a maintenance and training program for the use of respiratory protection equipment. Through interviews of selected workers who have used, or are designated/approved to use, respiratory protection equipment, determine that they are individually fitted for the type of respirators that they are expected to use and that respiratory equipment is operationally tested immediately prior to each use.

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k. Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the Department.

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2. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored

a. Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated.

b. If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the Department, NRC or an Agreement State to perform that service.

c. Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Verify that calibrations include a determination of "as found" condition before adjustments are made. Verify that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.

d. If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."

e. Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to DEP's instrument. Verify that licensee's instrument response is comparable to DEP's instrument (±20%).

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f. Through interviews of the RSO and workers, and by observation, determine that licensee has a system for tagging out inoperable and out-of-service survey instruments.

g. Through observations and interviews of the RSO and workers, verify that the licensee's instrumentation for performing *in vivo* bioassay measurements is

adequate for those measurements. Determine that bioassay probes and scalers are compatible. Determine that licensee staff perform a response check using appropriate sources (such as a barium-133 source to simulate iodine-131) and a suitable background measurement before taking bioassay measurements.

h. Through observations and interviews of selected licensee personnel, determine the type and quantity of radiation laboratory instrumentation used by the licensee, such as liquid scintillation counters, alpha/beta counters, and gamma counting systems. Determine if the types of laboratory equipment are appropriate for the samples being analyzed and the sensitivity required. Determine if the laboratory instrumentation is calibrated for the appropriate geometries of the samples to be analyzed and is routinely checked for proper operation. Determine whether the licensee maintains calibration records, control charts, and maintenance and repair records to demonstrate proper operation of laboratory instrumentation.

03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program

a. Authorized Users. Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify through interviews that the authorized user has knowledge commensurate with operational duties. In cases where users are specified by license condition, determine that the licensed materials they use conform to the license condition.

Determine that the authorized users are personally performing or, if permitted in the license, supervising, the authorized work, rather than someone else not named in the license. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of ...." For other types of licensees, supervision is defined in the regulations. For some licenses that have the condition "... under the direct supervision of ..," the authorized user must be physically present at the facility, for easy contact or to observe the individual(s) working. Another phrase used is "... may only be used by ...." Finally, "... under the direct supervision and physical presence of ..." means the authorized user must directly supervise and be present at the work station. **CAUTION:** Considering the many license condition phrases and regulations, exercise judgment when assessing the role of the authorized users.

When the wording of the license condition is "... used by or under the supervision of ...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

b. General Training. Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).

1. 10 CFR Part 19-Required Training. Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP's regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

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2. Training Required by License Commitments. Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. Through interviews of one or more users of radioactive materials, assess their understanding of the training that they have received, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

Through observation of related activities and discussions with selected licensee personnel, verify that they actually received radiation safety training. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee.

Determine, by observing and interviewing workers, if training and experience are adequate to enable users to safely undertake activities authorized by the license and whether they are aware of the risks involved. Examine the licensee's program for on-the-job training of new workers. Determine if there is adequate retraining for workers to cover regulation changes and/or

radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

c. Operating and Emergency Procedures. Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures may be approved by DEP and reviewed and updated by the licensee. However, licensees who follow the guidance in the appropriate NUREG 1556 series will likely develop procedures, including emergency procedures that have not received specific DEP review and approval.

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Review and assess the licensee's process for controlling documents (procedures) and making revisions to procedures. Revisions to operating procedures should be reviewed by licensee health physics staff to ensure that the revisions do not adversely affect radiological safety. Select a sample of operating or process areas and determine that pertinent procedures are available to personnel, are current, and are in use in those selected areas. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities. Determine whether process activities use procedures for reference or are required to be used "in-hand."

During interviews of selected licensee personnel, assess the worker's knowledge and understanding of the licensee's emergency procedures, through proposed hypothetical emergency scenarios (i.e., "what if" questions). The scenarios should include those types of accidents appropriate to the licensee's program (e.g., contaminated packages identified during receipt surveys, fires, contamination events involving large quantities (100 millicuries [3.7 GBq] of iodine-131 or 1 curie [37 GBq] of technetium-99m)).

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If the licensee is required to have and implement an emergency plan, assess in-plant procedures for handling accidents including evacuation, prevention of spread of contamination, securing sources, handling accident victims, and any other major portions of the emergency plan. Verify, by discussions with workers, and review of procedures, that the emergency plan has been implemented and is being maintained. Verify that lines of communication with outside organizations that may be called on to assist in an emergency are current and tested. Ensure that biennial emergency plan drills and/or exercises include observation by DEP staff.

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Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

d. Posting and Labeling. Determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. Section 20.1903 provides exceptions to posting caution signs. When applicable, randomly examine signals and alarms to determine proper operation. Observe labeling on

randomly selected packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile radioactive materials are used in an area, such an area should be controlled for airborne contamination. High radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

Examine locations where notices to workers are posted. Applicable documents, notices, or forms must be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed

The Department holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding DEP regulations and license provisions and to terminate unsafe activities involving byproduct material.

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Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.

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- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.

- Obtaining the DEP's prior written consent before transferring control of the license;
- Notifying the Department's central office, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).
- Assuring the appropriate response, when applicable, to generic communications from the Department or NRC.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities. (10 CFR 30.35)
- Notifying the Department of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (10 CFR 30.36)
- Notifying the Department of defects or other radiation safety equipment malfunctions in accordance with license condition where applicable.
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

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a. RSC (where required or used). Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

   Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

b. RSO. Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or

licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

1. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

2. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.

c. Audits. Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

1. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

2. Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Source or Device Review. Through discussions with licensee management and workers, and by observing licensee practices, determine whether the licensee is manufacturing any sources or devices differently since the product was reviewed by the NRC or an Agreement State and listed in Sealed Source and Device Registry. In particular, ask whether recent models of a device have been changed from previous versions (includes any changes, whether or not they affect safety), and, if so, whether the new models were reviewed by the NRC or an Agreement State and recorded in the registry. Verify that the devices being manufactured conform to the registration certificate. Check to see whether the devices match those entered into the sealed source and device registry.

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1. If any devices: 1) do not have a registration certificate; 2) have been changed since the device was registered, with no update on the registration certificate; or 3) are not entered in the sealed source and device registry, immediately contact the inspection supervisor.

2. Through observations and interviews of licensee personnel, determine the nature of any unapproved device changes or unregistered devices.

Determine the licensee's basis for making the change or not registering the device.

3. The region should then contact the NRC Materials Safety and Inspection Branch (MSIB) of the Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS), for further guidance. If possible, the region should make the contact with IMNS while the inspector is still on site, so that he/she may follow up during the remaining course of the inspection.

Verify that the licensee submits its transfer reports (quarterly for generally licensed devices/sources, and every five years for exempt materials) at the required frequency. Examine selected transfer reports and verify that they contain the required information.

Verify that distributed products include affixed, durable, and clearly visible labels that conform to those described in the license application as well as in the sealed sources and device registration.

e. Quality Assurance and Quality Control (QA and QC). If the licensee manufactures sources or devices using licensed material, the licensee will have committed to programs for QA and QC in either its license or in the device registration documentation. Verify that the licensee is using those QA and QC programs.

Discuss the QA/QC program with members of the QA staff or management, to determine if they are familiar with their responsibilities. Determine whether the QA/QC program is being implemented.

Most QA/QC programs will generate audit or inspection reports. On a sampling basis, spot-check some of these reports. If deficiencies in the licensed program (including the source or device manufacturing process) were noted, ask the licensee how they followed up and what corrective actions were taken to address the deficiencies. Determine whether the corrective actions were successful in addressing the deficiencies. Determine whether the licensee has an effective internal program for assuring quality in the final product and identifying problems in its own processes.

87125-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

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NRC INSPECTION MANUAL

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INSPECTION PROCEDURE 87126

INDUSTRIAL/ACADEMIC/RESEARCH PROGRAMS

PROGRAM APPLICABILITY: 2800

87126-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with Department of Environmental Protection, requirements.

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87126-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspections of licensees authorized for academic, research and development, and industrial uses of limited scope (ARDL) and for non-medical broad scope licenses. IP 87125 should be followed for inspection of materials processors/manufacturers and IP 87127 should be followed for radiopharmacies.

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by DEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

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The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective materials radiation safety program:

02.01 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

02.02 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 The licensee should implement a radiation dosimetry program to measure and record accurately radiation doses received by workers or members of the public as a result of licensed operations.

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02.05 The licensee should provide radiation instrumentation in sufficient number, condition, and location to monitor radiation levels accurately in areas where licensed material is used and stored.

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02.06 The licensee should ensure that workers are:

a. knowledgeable of radiation uses and safety practices;
b. skilled in radiation safety practices under normal and accident conditions; and,
c. empowered to implement the radiation safety program.

02.07 The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;
b. that audits for ALARA practices are performed; and,
c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

87126-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the DEP's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem.

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Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, observations, and demonstrations. An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress,

equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records alone.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of licensed materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail.

Common elements to all inspections include entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent and confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Each of the following focus elements should be reviewed as appropriate, during each inspection of an ARDL-licensee or broad-scope licensee.

Specific Guidance

03.01 FE-1: The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits

Facilities

a. Through direct observation, determine that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

    1. If the inspector finds any entrance or area to be unsecured, the inspector should determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. The inspector should determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. The inspector should determine if the licensee's facility is configured to separate working areas from unrestricted areas.

    2. If the inspector finds entrances or other areas unsecured, the inspector should examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be under constant surveillance or physically secured.

b. Through observations, verify that use and storage areas are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when

licensee personnel are present or physically secured against unauthorized access. Storage areas should be physically secured when unattended.

c. Evaluate licensee practices regarding access controls including control of keys and access codes to ensure only currently authorized individuals have access to licensed materials.

d. Ensure licensee practices include testing of interlock systems, as applicable (such as for hot cells).

e. Examine airflow patterns and building air intakes for potential of spreading contamination, and for releases or doses in excess of regulatory limits.

Receipt and Transfer of Licensed Materials

a. Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and receiving areas; 2) inspects packages for damage; 3) performs appropriate package receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If the inspector is unable to observe the receipt of packages, the inspector should request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

   1. If packages are left unattended, the inspector should assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

   2. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, the inspector should interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in Focus Element 5 (Section 03.05, below).

b. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive the forms and quantities of such materials.

Inventory Control

a. Through observation, the inspector should physically examine the inventory of radioactive material on hand and selected records of receipt and transfer to determine that quantities and forms are as authorized on the license. The inspector should compare the possession of selected sealed sources with inventory records. The inspector should verify that the licensee is limiting its possession and use of licensed materials to the isotopes, forms and quantities

specified in the license. Examine the adequacy of methods used by the licensee to demonstrate compliance with license possession limits.

(Note: The licensee should have an accounting system that suits the type of licensed program. For example, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility will need a sophisticated accounting system for all licensed material that provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other facilities operating under the same license, and the amount remaining after decay. The accounting systems should also consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees.

b. Through interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving lost, missing, or stolen licensed materials.

1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the DEP.

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2. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

NOTE: Item c. below only applies to those licensees authorized to possess sufficient quantities of source or special nuclear materials that the licensee is required to report the receipt, transfer or disposal of these materials to the NRC Nuclear Materials Management and Safeguards System (NMMSS). IMC 2800, Enclosure 6 contains specific guidance.

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c. Through interviews of the RSO or other responsible licensee personnel, along with the review of relevant records, verify that the licensee has fulfilled the applicable reporting requirements relating to the NRC NMMSS.

1. Discuss the location of all subject material possessed by the licensee. Compare the licensee's most recent record of physical inventory performed with the information documented in the licensee's NMMSS account on the DOE/NRC Form 742, "Material Balance Report."

2. Review the licensee's records documenting the receipt, transfer or disposal of NMMSS-reportable materials. Compare these records to the NMMSS TJ-45 report. Verify that each set of records properly documents and accounts for any receipt, transfer or disposal of NMMSS-reportable materials that may have occurred subsequently to the most recent filing of the DOE/NRC Form 742 by the licensee.

3. Verify the information listed on the licensee's inventory record by walking down the licensee's facility and (if practicable) visually identifying, at a minimum, a representative sample of the materials that the licensee reports possession of to NMMSS. If appropriate, verify the presence of the subject material with a radiation survey instrument.

NOTE: The inspector should not ask licensee personnel to open any container or otherwise change the container's shielding to facilitate this survey.

4. Review administrative information listed in the NRC NMMSS Report D-3 with licensee personnel to ensure that the information is up to date. Verify that licensee personnel are cognizant of the need to make any required changes and the processes available for making any needed corrections.

03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment

a. Process and Engineering Controls

Through observations, interviews of licensee personnel, and independent and confirmatory surveys, assess the adequacy of glove boxes, hot cells, remote-handling devices, shields and shielding devices, ventilation systems and other engineered safeguards to assure that they are adequate for the purposes for which they are intended. Specifically:

1. Hot Cells. Verify that the licensee controls: the entry of personnel into hot cells; the removal of material from process enclosures; and contamination originating within the hot cells.

   (a) If any weaknesses are identified in hot cell operations, then review the records of radiation surveys and/or air monitoring around the hot cell area.

   (b) If records indicate elevated radiation or airborne contamination levels, then review the personnel monitoring records of individuals who worked in the area.

For all processes where shielding is used, assess the adequacy of shielding during maximum loading of hot cells and ensure the licensee verified the adequacy of shielding before beginning new processes.

2. Glove Boxes. Verify that the licensee: periodically checks the integrity of gloves and replaces gloves as necessary; controls the removal of material from process enclosures; and controls contamination originating within the glove boxes.

(a) If any weaknesses are identified in glove box operations, then review the records of surveys around the glove box area and extremity monitoring records of individuals who work in the area.

For all processes where shielding is used, assess the adequacy of shielding during maximum loading of glove boxes and ensure the licensee verified the adequacy of shielding before beginning new processes.

b. Shielding

1. Temporary or Portable Shielding. Verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.

2. Bulk Product Shielding. Verify that the licensee maintains large quantities of stock or bulk radioactive materials in adequate shielding. Verify that such shielding cannot be easily removed or opened. Verify that the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads. Ensure that licensee personnel are aware of lifting equipment load limitations and that the limitations are not exceeded.

3. Unit Shielding. Verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials (i.e., vials, syringes, individual sources, etc.) and that licensee personnel use the shields when handling the containers. Unshielded containers of hard-beta[1]- and gamma-emitting radionuclides should not be directly handled by personnel. Verify that unit shields are adequate for the quantities of radioactive materials typically contained therein.

4. Shipped Product Shielding. Verify that the shielding included in packaging of materials that are transferred to a carrier for transport/transfer to an off site location conforms to that described in the SSD registry or license documents, as appropriate. The licensee may not make changes to the size, shape, or contents (e.g., lead versus stainless steel) of the shielding materials without prior approval of the NRC or the Agreement State that approved the registry, as applicable. Observe packages that are ready for shipment and verify that the external radiation levels are consistent with the registry sheet/license document. Otherwise, determine that DOT requirements for shielding are met.

c. Sealed Sources and Devices

Through discussions with licensee management and workers, and by observing licensee practices, determine whether the licensee is manufacturing any different sources or devices since the product was registered with NRC or an Agreement State. In particular, ask whether recent models of a device have been changed

1 "Hard Beta-emitting" radionuclides are those where the average β energy is 0.5 MeV or greater.

from previous versions (includes any changes, whether or not they affect safety), and, if so, whether the new models were registered with NRC or an Agreement State. Verify that the devices being manufactured conform to the registration certificate. Check to see whether the devices are entered into the sealed source and device registry. If the inspector finds any devices that: 1) do not have a registration certificate; 2) have been changed since the device was registered, with no update on the registration certificate; or 3) are not entered in the sealed source and device registry, immediately contact the inspection supervisor at the regional office, who will notify central office. Upon notification, central office will then contact the NRC Materials Safety and Inspection Branch (MSIB) of the Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS), for further guidance. If possible, central office should make the contact with IMNS while the inspector is still on site, so that he/she may follow up during the remaining course of the inspection.

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d. Routine and Non-Routine Maintenance. By interviewing selected maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine that maintenance personnel verify, either through their own or health physics staff surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from equipment, entering rooms or areas (such as bunkers or hot cells) normally posted as high radiation or very high radiation areas, or entering tanks or vessels that normally contain or have contained radioactive materials. Verify that shielding removed for maintenance and opened access panels are properly replaced prior to lifting of maintenance holds when equipment is returned to service.

For maintenance activities that include potentially significant radiological conditions, such as high dose rates (> 1 mSv ([100 millirem] per hour general area or > 100 mSv [1 rem] per hour contact) or contamination levels (> 100,000 disintegrations per minute [1667 Bq] per 100 cm^2), determine whether the licensee has established more stringent radiation work permit (RWP) requirements, such as more detailed pre-job briefing of personnel, appropriate protective clothing, and/or constant job coverage by a health physics technician.

03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material

The inspector should be attentive to potential industrial safety hazards, for possible referral to the U.S. Department of Labor's Occupational Safety and Health Administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

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a. Operational Limits. Through observation, discussions with licensee staff and review of product specification information, verify that the licensee operates process equipment within the equipment manufacturer's or industry consensus operational limits. Such limits may include temperature, humidity, vibration, or radiological considerations. In addition, such equipment may be subject to periodic

preventative maintenance requirements/recommendations. If so, verify that such maintenance is performed.

b. Industrial/Chemical Hazards. Verify that the licensee controls the use/storage of hazardous (corrosive or combustible) chemicals near process equipment which could degrade their performance or render safety features inoperable. If the licensee is required to implement an emergency plan, verify that the plan includes these hazards, as appropriate, as initiating events.

c. Fire Protection. In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensee's facilities, the inspector should be alert to potential fire hazards. An effective licensee fire protection program should (1) prevent fires from starting, (2) rapidly detect, control, and extinguish those fires that do occur, and (3) provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public.

Through observation and discussion with the licensee, while touring the facilities, assess firesafe conditions and equipment, i.e., that: (1) work areas are generally uncluttered and free of combustible debris, (2) incompatible materials (i.e., materials labeled as "corrosive", "flammable", or "oxidizer") are isolated from each other and enclosed by fire resistant barriers, (3) fire detection systems are operable, (4) fire suppression systems are operable, (5) portable fire extinguishers are unexpired (check maintenance tags), (6) electric switches and electric motors are explosion-proof, arc welders or open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive chemicals, and that (7) the local fire department is involved with the licensee's fire protection program.

Problems/deficiencies noted by the inspector should be promptly brought to the licensee's attention and discussed with Regional management.

d. Natural Hazards. Depending on the licensee's geographic location, it could be susceptible to natural hazards, such as tornadoes, flooding, and earthquakes. Verify that those licensee's have considered the impact of such hazards in the design and modification of areas critical to safety; the selection and location of facilities for the storage of large quantities of radioactive materials, including radioactive waste storage facilities; and in the development of emergency procedures and contingency plans, when applicable.

e. Transportation. Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is packaged and transported (or offered for transport) in accordance with 10 CFR Part 71 and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.

Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers. Examine any incidents that were required to be reported to the DOT.

If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs) issued by the NRC. The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

For further inspection guidance refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer to "Hazard Communications for Class 7 (Radioactive) Materials." These field reference charts, related to hazard communications for transportation of radioactive materials, are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings. They also contain references to the DOT regulatory requirements.

03.04 FE-4: The licensee should implement a radiation dosimetry program to measure and record accurately radiation doses received by workers or members of the public as a result of licensed operations

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include, for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

Verify that the licensee has performed adequate surveys to show compliance with public dose limits and that conditions in controlled areas and unrestricted areas meet the requirements specified for these areas.

a. Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

1. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (e.g., one worker consistently receives significantly more exposure than all other workers each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.

2. Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.

b. External Exposure Controls. Examine any changes made for control and use of personnel monitoring equipment; verify that limits, precautions, controls, etc., established by the licensee are consistent with regulations and license requirements.

Examine the type of monitoring devices used, the period of use or exchange period, and the number used to determine if these aspects seem consistent with the monitoring program. Determine who the supplier is, and if the service has been changed since the last inspection, determine the reasons for the change. Verify that the personnel dosimetry processor is accredited by National Voluntary Laboratory Accreditation Program (NVLAP). NOTE: If the licensee operates its own dosimetry program, ensure that it has received the appropriate NVLAP accreditation and that the accreditation includes the type, energy, and intensity of radiations applicable to the licensee's operations.

For pocket dosimeters or pocket chambers, determine when they are read and recharged, the number used, and review the calibration procedure or charge leakage test procedure.

For electronic dosimeters, determine that the energy response and alarm set points are appropriate for the radiological conditions present during licensee operations. Verify that the licensee has established a calibration procedure and frequency for the dosimeters. Examine a random sample of electronic dosimeters that are available for use and verify that they have been calibrated in accordance with the procedures and stated frequency.

For all personnel monitoring devices used (whole body and extremity monitors, pocket chambers, electronic dosimeters), verify that the licensee has provided appropriate guidance to personnel regarding the wearing and placement of monitors. During observations of activities in progress, verify that dosimeters are properly worn, paying particular attention to physical manipulations of containers of radioactive materials (i.e., vials, syringes, etc.), whether or not they are shielded, and verify that extremity monitors are located so that they record the maximum dose.

Evaluate the adequacy of the licensee's procedures or system for evaluating and using personnel monitoring data to control and minimize exposures. The licensee should account for occupational radiation doses to personnel resulting from

exposures to licensed material and all other radiation sources (e.g., accelerators) subject to licensing or registration.

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Review reports of exposure summaries generated since the last inspection to determine that licensee's performance is in accordance with regulatory requirements.

Determine, through discussion with authorized users and the RSO, if minors have been permitted to work in restricted areas and, if so, determine that licensee's performance is in accordance with 10 CFR 20.1207 by review of exposure records.

For licensees who are not required to monitor, due to the lack of a likelihood that any worker would receive more than 5 millisievert (500 millirem) in a year, a sampling of NRC (DEP) Forms 5 generated as a result of voluntary monitoring may be appropriate. If a licensee is not required to monitor and chooses not to monitor worker exposures, the inspector need only review the licensee's presumptive analysis of exposures and verify the assumptions used in that analysis.

c. Internal Exposure. *During review of exposure evaluations, verify that the licensee's* performance is in accordance with internal exposure limits.

Review randomly selected air sampling and bioassay records. Determine if the licensee has established appropriate action levels and verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies.

By observation, discussion, and review of documentation, verify that engineering controls are considered and used to the extent practicable. Evaluate process and engineering controls incorporated as part of the facility or equipment.

Review documentation of evaluations performed as the result of unplanned exposures. Discuss these intakes with exposed personnel and licensee health physics staff and evaluate the circumstances of the incidents. Verify the appropriateness of preventive measures instituted following an unplanned exposure.

d. Area Radiation and Contamination Control

1. Area Surveys. Through direct observation of surveys and interviews of licensee personnel, evaluate the licensee's area radiation survey program. The inspector should:

   - Determine if the licensee's schedule for performing periodic surveys of work areas and unrestricted areas complies with license requirements.

- Determine surveys are conducted using approved procedures.
- Review a random sample of survey records and determine whether surveys are being performed according to schedules.
- Verify that survey results are reviewed by appropriate supervision.
- Verify that corrective actions have been taken, as appropriate.
- Determine whether survey is adequate for type (α, β, γ, or neutron) and energy of radiation to be detected and measured.
- Determine whether both particulate, non-noble gases and vapors are considered, if appropriate.
- Determine if workers take smears or instrument readings in areas that are readily accessible to facility personnel such as bench tops, sinks used for disposal, and storage areas.
- Ask licensee to spot-check radiation levels in selected areas using the licensee's own instrumentation. Compare measurements with a DEP instrument.

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Note: The inspector must use DEP's instruments calibrated according to DEP policy for independent verification of the licensee's measurements. DEP instruments should also be used to make measurements in support of violations to be cited. There may be up to a 20% difference between instruments if one reads 10% high and the other 10% low.

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e. Leak Tests and Sealed Source Inventories. Through direct observation and licensee staff interviews, assess the adequacy of the licensee's implementation of its leak test and inventory procedures. The inspector should:

- Verify that leak tests are performed at the frequency specified in the license.
- Verify that leak test samples are collected in accordance with either licensee or leak test vendor procedures.
- Verify that the licensee's leak test analyses (or that of it's leak test services vendor) have sufficient sensitivity to measure 185 becquerels (0.005 microcurie) for each type of isotope present on its license. Through discussions with licensee staff and/or review of pertinent records, determine if the licensee had a leaking source. If leak test results show contamination in excess of the regulatory limits, verify that the licensee made appropriate notifications, evaluations, and removed the source from service.

- If the licensee analyzes leak tests on sealed sources as a service to other licensees, it is important that the licensee demonstrate to the inspector an adequate method of performing and analyzing leak tests.

- Determine if sealed source inventories are performed at the required frequency.

- Evaluate the licensee's inventory methods to ensure that they could detect missing or unaccounted radiation sources.

f. Contamination Control. Verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination. When appropriate, consider taking confirmatory wipe samples.

g. Protective Clothing. If practical, observe the use of protective clothing worn by research lab personnel or other applicable staff during their work activities should provide the inspector with an acceptable means of reviewing this requirement. Requirements for protective clothing may be found in the licensee's procedures or as posted by the licensee.

h. Process Controls. By observation, determine compliance with license requirements for repair, tagging, opening, modification, and replacement of sealed sources and devices. Ensure that the licensee has methods or procedures to minimize exposure during maintenance on devices. Verify through discussions with workers and by reviewing procedures that, when maintenance or modification is performed, controls are in place and are effective to warn workers of radiological hazards, prevent unnecessary exposure, and prevent the spread of contamination.

i. Waste Management

1. Waste Storage and Disposal. Verify that the waste is protected from fire and the elements, that package integrity is adequately maintained, that the storage area is properly ventilated, and that adequate controls are in effect to minimize the risk from other hazardous materials. Verify that the licensee has appropriate methods to track the items in storage.

   Inspection effort should be directed at verifying that written procedures have been established in a manner approved by management. The procedures should be readily available to any persons having responsibility for low-level waste classification and preparation for transfer of such wastes to land disposal facilities.

   Verify that storage for decay is not causing elevated radiation doses to waste processing workers. If applicable, confirm that the resident time of waste at the facility does not exceed the time limit authorized in the license. For licensees who have implemented an interim waste storage program, verify that the program is consistent with the license. For further guidance on interim waste storage, see Information Notice 90-09, "Extended Interim

Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees."

Examine monitoring systems. Review and evaluate a sample of the procedures and other administrative and physical controls for the release and disposal of radioactive waste.

The inspector should determine whether radioactive material labels have been removed or defaced from discarded materials, being careful to not endanger him or herself to biological, chemical, or physically hazardous waste (e.g., sharp objects). Ensure that wastes prepared for shipment to a disposal site comply with applicable standards and regulations regarding chemical and physical form, stability, type of container, and labeling. Also ensure that the licensee implements an adequate QC program as required by Appendix F of 10 CFR Part 20 to ensure compliance with applicable regulations.

For further inspection guidance, refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61."

2. Effluents. Examine the waste release records generated since the last inspection, all annual or semiannual reports, all pertinent non-routine event reports, and a random selection of liquid and airborne waste release records. Randomly select procedures for both liquid and airborne systems and verify that the licensee's procedures are being followed. The verification can be made by observations of an operation, a review of selected records, interviews with workers, etc.

   For liquid wastes, determine if the licensee has: identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complied with the regulatory requirements for disposal in the publicly-owned sanitary sewerage system. If the licensee disposes of liquid wastes to surface waters, ground waters, or a private sanitary sewerage treatment system, determine whether the licensee is in compliance with the regulations and all applicable license restrictions.

   For airborne radioactivity, determine if the licensee has identified all routes of airborne releases to the environment and complies with the regulations and all applicable license restrictions. For a licensee authorized to dispose of radioactive material by incineration, determine compliance with 10 CFR 20.2004 and license requirements, and discuss with the licensee its methods for evaluating concentrations in the ash.

   Determine compliance with license conditions relating to environmental monitoring. If applicable, observe sampling stations and equipment for adequacy. Review a sample of procedures, records, and reports to verify that the licensee has established and is maintaining an environmental monitoring program, if required in the license.

Review the licensee's ALARA goals, where applicable, and determine if the licensee has implemented these goals. Determine if the licensee has calculated annual doses resulting from air effluents and if the doses: (1) are within the licensee's ALARA goals (as described in its radiation protection program); (2) exceed the licensee's ALARA goals; or (3) are uncertain because there is insufficient information or basis for determination. Review the licensee's history in meeting ALARA goals, and its corrective actions when the goals were not met.

Verify that the licensee's air effluents, excluding Radon-222 and its daughters, have not exceeded the constraint limit in 10 CFR 20.1101. Information on evaluating air effluents is available in Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors." If the licensee estimated or measured a dose greater than 0.1 millisievert (10 mrem) per year, from air emissions, to the nearest individual member of the public, the licensee should have notified the Department [10 CFR 20.2203(a)(2)(vi)]. If the licensee has notified DEP that its air effluents have exceeded the constraint level, the inspector should review the effectiveness and timeliness of the licensee's corrective actions. Records of the results of measurements and calculations needed to evaluate the release of radioactive effluents to the environment are required pursuant to 10 CFR 20.2103(b)(4).

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For further inspection guidance, refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Reasonably Achievable (ALARA).

j. Respiratory Protection. Through observations, verify that respiratory protection equipment is certified by NIOSH/MSHA or otherwise approved by NRC. Determine that the licensee has selected the proper equipment for its licensed operations. Through interviews of the RSO, determine that the licensee has established a maintenance and training program for the use of respiratory protection equipment. Through interviews of selected workers who have used, or are designated/approved to use, respiratory protection equipment, determine that they are individually fitted for the type of respirators that they are expected to use and that respiratory equipment is operationally tested immediately prior to each use.

In taking credit for the protection provided by the use of respiratory protective equipment, 10 CFR 20.1703 requires that the protection factor be greater than the multiple by which peak concentrations are expected to exceed the values of Table 1, Appendix B, Column 3 of 10 CFR Part 20, unless ALARA considerations indicate otherwise. Verify that this criterion is considered in selecting respirators.

k. Reports to Workers. 10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses

annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

I. ALARA. The licensee should, in addition to complying with regulatory requirements and license conditions, make reasonable efforts to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas ALARA. This can be accomplished by the implementation of good radiation planning and practices, and by the commitment, from management and workers, to policies that prevent departure from ALARA practices. Also, licensees are required to keep occupational doses and doses to members of the public ALARA, in 10 CFR 20.1101(b).

Assess the licensee's ALARA practices, and verify implementation of any ALARA commitments in licensing documents, by reviewing:

1. A written commitment by high-level management to minimize worker exposure by the implementation of clearly defined procedures and policies;

2. That licensee personnel are made aware of management's commitment to keep occupational exposures ALARA;

3. That the radiation safety staff have been given authority to assure ALARA procedures and policies are carried out;

4. That workers are adequately trained, not only in the radiation safety procedures, but also in the ALARA philosophy;

5. That management and its designees perform periodic audits to find out how exposures and effluent releases might be lowered;

6. That modifications to procedures, equipment, and facilities have been made to reduce exposures at reasonable costs, where possible;

7. That the licensee has QA and QC programs, where applicable; and

8. That the licensee has a functioning and effective preventive maintenance program, where applicable.

Review and evaluate engineering controls to assure that, for example, exhausts from ventilated enclosures are adequately treated to reduce emissions to the out-of-plant environs to the lowest reasonably achievable levels within regulatory limits. Evaluate ventilated enclosures to assure that they are adequate to minimize internal exposures. Review shielding and the use of remote handling tools to assure that facilities and equipment are adequate to reduce exposure (both

internal and external) to the lowest reasonably achievable levels within regulatory limits.

m. Event Evaluation. Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

- Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the Department.

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- For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored

a. Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated at the required frequency.

b. If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the DEP, the NRC or an Agreement State to perform that service.

c. Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Verify that calibrations include a determination of "as found" condition before adjustments are made. Verify that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.

d. If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."

e. Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee

instrument readings to DEP instrument. Verify that licensee's instrument response is comparable to the DEP instrument (±20%).

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f. Through interviews of the RSO and workers, and by observation, verify that licensee has a system for tagging out inoperable and out-of-service survey instruments.

g. Through observations and interviews of the RSO and workers, determine whether the licensee's instrumentation for performing bioassay measurements is adequate for those measurements. Verify that bioassay probes and scalers are compatible. Verify that licensee staff perform a response check using appropriate sources and a suitable background measurement before taking bioassay measurements.

h. Through observations and interviews of the RSO and workers, assess the procedures and methods, and equipment used by the licensee to assure compliance with air-monitoring and air-handling commitments requirements (such as flow rates into hoods, air flows in ventilation systems, differential pressures in cells, in glove boxes, and across filter systems).

i. Assess the equipment used by the licensee to satisfy these measurements. If appropriate, verify that air measurement equipment is functional and calibrated at the required frequency. Examine a representative sample of sampling gauges and data recorders and verify that it is operating within its design specifications. Using a properly calibrated hand-held anemometer, spot-check the linear airflow rate (corrected for altitude, when necessary) at the face of several hoods to verify that it meets the commitments made in the license. Using smoke tubes, visualize the airflow at the hood face to ensure that no excessive turbulence is present that may result in the spread of radioactive contamination.

03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program

a. Authorized Users. Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify through interviews that the authorized user has knowledge commensurate with operational duties. In cases where users are specified by license condition, determine that the licensed materials they use conform to the license condition.

Determine that the authorized users are personally performing or, if permitted in the license, supervising, the authorized work, rather than someone else not named in the license. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of ...." For other types of licensees, supervision is defined in the regulations. For some licenses that have the condition "... under the direct supervision of .." the authorized user must be physically present at the facility, for easy contact or to observe the individual(s) working. Another phrase used is "... may only be used by ...." Finally, "... under the direct supervision and physical

presence of ..." means the authorized user must directly supervise and be present at the work station. Considering the many license condition phrases and regulations, the inspector must exercise judgment when assessing the role of the authorized users.

When the wording of the license condition is "... used by or under the supervision of ...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

b. General Training. Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).

1. 10 CFR Part 19-Required Training. Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

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2. Training Required by License Commitments. Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. One or more users of radioactive materials should be interviewed to determine their understanding of the training that they have received, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

The inspector should also observe related activities and discuss the radiation safety training received by selected individuals to assure that appropriate training was actually received by these individuals. Authorized users and

supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee.

Determine, by observing and interviewing workers, if training and experience are adequate to enable users to safely undertake activities authorized by the license and whether they are aware of the risks involved. Examine the licensee's program for on-the-job training of new workers. Determine if there is adequate retraining for workers to cover regulation changes and/or radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

c. Operating and Emergency Procedures. Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures may be approved by DEP and reviewed and updated by the licensee. However, licensees who follow the guidance in the appropriate NUREG 1556 series will likely develop procedures, including emergency procedures that have not received specific DEP review and approval.

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Review and evaluate the licensee's process for controlling documents (procedures) and making revisions to procedures. Revisions to operating procedures should be reviewed by licensee health physics staff to ensure that the revisions do not adversely affect radiological safety. Select a sample of operating or process areas and verify that pertinent procedures are available to personnel, are current, and are in use in those selected areas. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities. Determine whether process activities use procedures for reference or are required to be used "in-hand."

During interviews of selected licensee personnel, propose hypothetical emergency scenarios (i.e., "what if" questions) to assess the worker's knowledge and understanding of the licensee's emergency procedures. The scenarios should include those types of accidents appropriate to the licensee's program (i.e., contaminated packages identified during receipt surveys, fires, contamination events involving large quantities of licensed materials.

If the licensee is required to have and implement an emergency plan, evaluate in-plant procedures for handling accidents including evacuation, prevention of spread of contamination, securing sources, handling accident victims, and any other major portions of the emergency plan. Verify, by discussions with workers, and review of procedures, that the emergency plan has been implemented and is being maintained. Verify that lines of communication with outside organizations that may

be called on to assist in an emergency are current and tested. Ensure that biennial emergency plan drills and/or exercises include observation by DEP staff. Deleted: NRC

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that those agencies (involved in such agreements) understand their roles in emergency responses.

d. Posting and Labeling. The inspector should determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. Section 20.1903 provides exceptions to posting caution signs. When applicable, the inspector should also randomly examine signals and alarms to determine proper operation. The inspector should also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile radioactive materials are used in an area, such as area should be controlled for airborne contamination. High-radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

The inspector should also examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed

The Department holds the licensee responsible for the radiation protection program; Deleted: NRC
therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding DEP regulations and license provisions Deleted: NRC
and to terminate unsafe activities involving byproduct material..

Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining the Department's prior written consent before transferring control of the license; Deleted: NRC's
- Notifying the Department in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)). Deleted: appropriate NRC regional administrator
- Assuring the appropriate response, when applicable, to generic communications from the Department. Deleted: NRC
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities. (10 CFR 30.35)
- Notifying the Department of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (10 CFR 30.36) Deleted: NRC
- Notifying the Department of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21. Deleted: NRC
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

a. RSC (where required or used). Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

b. RSO. Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

- If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

- If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.

c. Audits. Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

- If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

- Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

87126-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

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DEP INSPECTION MANUAL

INSPECTION PROCEDURE 87127

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RADIOPHARMACY PROGRAMS

PROGRAM APPLICABILITY: 2800

87127-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with Pennsylvania Department of Environmental Protection (DEP) requirements.

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87127-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by DEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

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The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective radiopharmacy radiation safety program:
02.01 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

02.02 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 The licensee should ensure that workers are:

a. knowledgeable of radiation uses and safety practices;
b. skilled in radiation safety practices under normal and accident conditions; and,
c. empowered to implement the radiation safety program.

02.07 The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;
b. that audits for ALARA practices are performed; and,
c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

87127-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the DEP's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem.

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Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, observations, and demonstrations.

An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records, alone.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of licensed materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail.

Common elements to all inspections include preparation, entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent and confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Specific Guidance

Each of the following areas should be reviewed during each inspection of a radiopharmacy

03.01 FE-1:The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits

Facilities

a. Through direct observation, verify that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

    1. If any entrance or area is unsecured, determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

    2. If entrances or other areas are unsecured, examine areas where radioactive materials are used and stored. Storage areas must be locked and have limited and controlled access. Radioactive material use areas must be under constant surveillance or physically secured.

b. Through observations, verify that use and storage areas, including radioactive waste storage facilities, are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas must be physically secured when unattended.

Receipt and Transfer of Licensed Materials

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a. Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and receiving areas; 2) inspects packages for damage; 3) performs appropriate package receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If unable to observe the receipt of packages, request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

   1. If packages are left unattended, assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

   2. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in Focus Element 5 (Section 03.05, below).

b. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Inventory Control

a. Through observation, physically examine the inventory of radioactive material on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license. Compare the possession of selected sealed sources with inventory records. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license.

b. Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.

   1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the DEP.

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   2. For incidents or unusual occurrences that were not required to be reported, determine that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment

Process and Engineering Controls

Through observations, interviews of licensee personnel, and independent and confirmatory surveys, assess the adequacy of glove boxes, hot cells, remote-handling devices, shields and shielding devices, and other engineered safeguards to assure that they are adequate for the purposes for which they are intended. Specifically:

a. For hot cells, determine that the licensee controls: the entry of personnel to hot cells; the removal of material from process enclosures; and contamination originating within the hot cells.

    1. If any weaknesses in hot cell operations are identified, review the records of radiation surveys and/or air monitoring around the hot cell area.

    2. If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of FE 03.04.

b. For glove boxes, determine that the licensee: periodically checks the integrity of gloves and replaces gloves as necessary; controls the removal of material from process enclosures; and controls contamination originating within the glove boxes.

    1. If any weaknesses in glove box operations are identified, review the records of surveys around the glove box area and extremity monitoring records of individuals who work in the area.

    2. If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of FE 03.04.

c. For temporary or portable shielding, verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.

d. For all processes where shielding is used, assess the adequacy of shielding during maximum loading of hot cells and glove boxes. Determine, by surveying the areas near manufacturing processes to ensure the continued adequacy of shielding. If the licensee initiates new processes in existing hot cells or glove boxes, determine whether the licensee has evaluated the adequacy of existing shielding before beginning the new process.

Product Shielding

Ambient radiation levels should be determined for areas normally occupied by workers. If higher than expected readings are found, the inspector should determine the source of the higher dose rates.

a. Through direct observations, interviews of licensee personnel, and independent measurements, verify that large quantities of stock or bulk radioactive materials are adequately shielded. Verify that such shielding cannot be easily removed or opened. Determine whether the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads.

b. Through direct observations and interviews of licensee personnel, verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials, such as unit dose vials and syringes, and that licensee personnel use the shields when handling the containers. Verify that unit shields are adequate for the quantities of radioactive materials typically contained in them.

c. Randomly select a number of finished products that are ready for distribution and verify that the external radiation levels are consistent with expected values.

    1. If higher than expected levels are noted, verify that the shielding included in prepared, distributed products conforms to that described in the license documents, as appropriate.

    2. Verify that the licensee has not made changes to the size, shape, or contents (i.e., lead versus stainless steel) of the shielding materials without prior approval of the DEP, NRC or an Agreement State.

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Routine and Non-Routine Maintenance

By interviewing selected maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine that maintenance personnel verify, either through their own or health physics staff surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from process equipment, entering rooms or areas (such as bunkers or hot cells) normally posted as high radiation or very high radiation areas, or entering tanks or vessels that normally contain or have contained radioactive materials. Verify that shielding removed for maintenance and opened manways are properly replaced prior to lifting of maintenance holds when equipment is returned to service.

For maintenance activities that include potentially significant radiological conditions, such as high dose rates (>100 millirem per hour general area or > 1 rem per hour contact) or contamination levels (>100,000 disintegrations per minute per 100 square centimeters), determine whether the licensee has established more stringent requirements, such as more detailed pre-job briefing of personnel, additional protective clothing, and/or constant job coverage by a health physics technician.

Area Radiation Surveys

Through interviews of selected licensee personnel, including the RSO, verify that the licensee has established schedules for periodic surveys of work and storage areas of the facility site; verify that surveys are conducted using approved procedures; review a random selection of survey records to verify that surveys are performed according to schedules; verify that the survey results are reviewed by appropriate supervision; and verify that corrective actions have been taken, as appropriate. Attempt to observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys. Verify specifically that schedule and procedural requirements for surveys are adequate to demonstrate compliance with the regulations and with pertinent license requirements. Determine whether due consideration is given to energy, beta exposure, and extremity exposure.

Request that licensee personnel spot-check radiation levels in selected areas using the licensee's instrumentation. Compare the results with those obtained using the DEP's instruments. Deleted: NRC

03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material

The inspector should be attentive to potential industrial safety hazards, for possible referral to the U.S. Department of Labor's Occupational Safety and Health Administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

a. Fire Protection. In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensees facilities, be alert to potential fire hazards. An effective licensee fire protection program should (1) prevent fires from starting, (2) rapidly detect, control, and extinguish those fires that do occur, and (3) provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public.

   Through observation and discussion with the licensee, while touring the facilities, assess firesafe conditions and equipment, i.e., that: (1) work areas are generally uncluttered and free of combustible debris, (2) incompatible materials (i.e., materials labeled as "corrosive", "flammable", or "oxidizer") are isolated from each other and enclosed by fire resistant barriers, (3) fire detection systems are operable, (4) fire suppression systems are operable, (5) portable fire extinguishers are unexpired (check maintenance tags), (6) electric switches and electric motors are explosion-proof and open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive

chemicals, and that (7) the local fire department is involved with the licensee's fire protection program.
Any problems/deficiencies noted should be promptly brought to the licensee's attention and discussed with Regional management.

d. Industrial/Chemical Hazards. Through observations and interviews of licensee personnel, determine that the licensee controls the use/storage of hazardous (corrosive or combustible) chemicals near process equipment which could degrade their performance or render safety features inoperable. If the licensee is required to implement an emergency plan, verify that the plan includes these hazards, as appropriate, as initiating events.

e. Transportation. Verify that licensed material is packaged and transported (or offered for transport) in accordance with 10 CFR Part 71 and U. S. Department of Transportation (DOT) regulations and Pennsylvania Department of Transportation (PA DOT) regulations for transportation of radioactive materials.

1. Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers.

2. If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

3. Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs) issued by the NRC. The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

4. If the licensee reported any transportation incidents, review the licensee's actions in response to the incidents.

03.04 FE-4: The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed

materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

a. Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes.

b. If the licensee monitors worker exposures (internal and external), notwithstanding a prospective analysis indicating that monitoring was not required, review selected reports of monitoring results. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

    1. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one pharmacist consistently receives significantly more exposure than all other pharmacists each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.

    2. Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.

c. Through interviews of workers and observations of activities in progress, verify that radiation monitors are worn appropriately and are recording the highest dose for which they are intended.

    1. If monitors are not (or cannot be) worn in the most appropriate location to record the highest dose received by the individual(s), through interviews of the RSO, verify that the licensee has performed assessments (through surveys, calculation, or both) of occupational exposures received and adjusted the dose of record for the worker(s).

    2. Review the results of the licensee's assessment and verify the assumptions and outcomes. Verify that the dose of record for the affected worker(s) has been adjusted and that the adjusted dose is within the applicable regulatory limit and ALARA.

d. Through interviews of the RSO and review of records of external monitoring results, determine whether processing (collection, process, and assessment) of monitoring devices is being performed in a timely manner.

e. Through interviews of the RSO and workers who handle volatile radionuclides (e.g., radioiodine), verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes.

Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies.

f. Through observations of facilities and activities in progress, interviews of the RSO and workers, independent and confirmatory measurements, and reviews of records of licensee evaluations, verify that the licensee effectively uses procedures and engineering controls to maintain doses to members of the public and radiation levels in unrestricted areas within regulatory limits and ALARA.

g. Through observations of facilities and activities in progress, interviews of the RSO and workers, and reviews of records of air monitoring results and licensee evaluations, verify that licensee releases of gaseous radioactive effluents to unrestricted areas are within the constraint value. Verify that air sampling equipment is calibrated and operational, and that sampling lines are intact and draw from their intended collection points.

h. Through observations, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors in-line ventilation filtration systems for saturation. Determine whether filter systems are monitored for differential pressure to ensure that there is no bypass of the filters, including perforations/channels and worn or degraded seals.

i. Through observations, independent measurements, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors the flow rates of fume and laminar flow hoods used to process licensed materials. Verify that licensee staff use calibrated instruments to measure flow rates. Verify that hood flow rates are adequate to prevent outflow of volatile, gaseous, and particulate materials into work areas, including the prevention of high eddy currents originating from excessive hood flow rates.

j. Through observations, verify that respiratory protection equipment is certified by NIOSH/MSHA or otherwise approved by DEP. Determine that the licensee has selected the proper equipment for its licensed operations. Through interviews of the RSO, determine that the licensee has established a maintenance and training program for the use of respiratory protection equipment. Through interviews of selected workers who have used, or are designated/approved to use, respiratory protection equipment, determine that they are individually fitted for the type of respirators that they are expected to use and that respiratory equipment is operationally tested immediately prior to each use.

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k. Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

   1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be

reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the DEP.

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2. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored

a. Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated.

b. If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the DEP, NRC or an Agreement State to perform that service.

c. Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Verify that calibrations include a determination of "as found" condition before adjustments are made. Verify that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.

d. If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."

e. Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to DEP instrument. Verify that licensee's instrument response is comparable to DEP instrument (±20%).

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f. Through interviews of the RSO and workers, and by observation, determine whether the licensee has a system for tagging out inoperable and out-of-service survey instruments.

g. Through observations and interviews of the RSO and workers, verify that the licensee's instrumentation for performing *in vivo* bioassay measurements is adequate for those measurements. Determine that bioassay probes and scalers are compatible. Determine that licensee staff perform a response check using

appropriate sources (such as a barium-133 source to simulate iodine-131) and a suitable background measurement before taking bioassay measurements.

h. *Through interviews of pharmacy staff and review of selected records, verify that* the licensee performs appropriate checks and tests on each dose calibrator used to dispense dosages for distribution. Such checks and tests include constancy (to verify reproducible instrument response), linearity (to verify instrument response over the range of activities dispensed), accuracy (to verify appropriate energy response), and geometry dependence (to verify instrument response over the range of volumes and containers used to dispense radioactive materials). Verify that the licensee has established acceptance levels for each dose calibrator check and test, and that personnel performing the checks and tests are aware of them and understand the appropriate response if acceptance levels are not met. Determine whether any dose calibrators have been identified that failed a check or test and verify that licensee's response was appropriate. The inspector should request that licensee personnel demonstrate a dose calibrator constancy check.

i. For each dose calibrator used to measure and dispense beta-emitters, verify through observations, interviews, and reviews of selected records, that the licensee has performed geometry dependence testing for each source/container configuration used and that the licensee has established appropriate calibration factors for each configuration used.

03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program

a. Authorized Users. Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify through interviews that the authorized user has knowledge commensurate with operational duties. In cases where users are specified by license condition, *determine that the licensed materials they use conform to the license condition.*

Determine that the authorized users are personally performing or, if permitted in the license, supervising, the authorized work, rather than someone else not named in the license. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of...." For other types of licensees, supervision is defined in the regulations. For some licenses that have the condition "... under the direct supervision of...," the authorized user must be physically present at the facility, for easy contact or to observe the individual(s) working. Another phrase used is "... may only be used by...." Finally, "... under the direct supervision and physical presence of..." means the authorized user must directly supervise and be present at the work station. **CAUTION:** Considering the many license condition phrases and regulations, exercise judgment when assessing the role of the authorized users.

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When the wording of the license condition is "... used by or under the supervision of...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

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b. Authorized Nuclear Pharmacists (ANPs). ANPs may either be named on the license or appointed by the licensee. For those appointed by the licensee, verify that these individuals are qualified as ANPs in accordance with 10 CFR 32.72 (b) and have knowledge commensurate with their operational duties.

The regulations in 10 CFR 32.72(b)(2) permit the nuclear pharmacy licensee to have an individual "under the supervision of" an authorized nuclear pharmacist prepare radioactive drugs for medical use. These regulations do not specifically require that the authorized user be present at all times during the use of such materials. However, the authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.27(b), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

c. General Training. Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).

1. 10 CFR Part 19-Required Training. Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

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2. Training Required by License Commitments. Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. Through interviews of one or more users of radioactive materials, assess their understanding of the training that they have received, both in the basic instructions and that specified in the license application.

For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

Through observation of related activities and discussions with selected licensee personnel, verify that they actually received radiation safety training. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee.

Determine, by observing and interviewing workers, if training and experience are adequate to enable users to safely undertake activities authorized by the license and whether they are aware of the risks involved. Examine the licensee's program for on-the-job training of new workers. Determine if there is adequate retraining for workers to cover regulation changes and/or radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

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d. Operating and Emergency Procedures. Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures may be approved by DEP and reviewed and updated by the licensee. However, licensees who follow the guidance in the appropriate NUREG 1556 series will likely develop procedures, including emergency procedures that have not received specific DEP review and approval.

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Review and evaluate the licensee's process for controlling documents (procedures) and making revisions to procedures. Revisions to operating procedures should be reviewed by licensee health physics staff to ensure that the revisions do not adversely affect radiological safety. Select a sample of operating or process areas and verify that pertinent procedures are available to personnel, are current, and are in use in those selected areas. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities. Determine whether process activities use procedures for reference or are required to be used "in-hand."

During interviews of selected licensee personnel, assess the worker's knowledge and understanding of the licensee's emergency procedures, through proposed hypothetical emergency scenarios (i.e., "what if" questions). The scenarios should include those types of accidents appropriate to the licensee's program (i.e., contaminated packages identified during receipt surveys, fires, contamination

events involving large quantities (100 millicuries of iodine-131 or 1 curie of technetium-99m)).

If the licensee is required to have and implement an emergency plan, assess procedures for handling accidents including evacuation, prevention of spread of contamination, securing sources, handling accident victims, and any other major portions of the emergency plan. Verify, by discussions with workers, and review of procedures, that the emergency plan has been implemented and is being maintained. Verify that lines of communication with outside organizations that may be called on to assist in an emergency are current and tested. Ensure that biennial emergency plan drills and/or exercises include observation by DEP staff. Deleted: NRC

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

e. Posting and Labeling. Determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. Section 20.1903 provides exceptions to posting caution signs. When applicable, randomly examine signals and alarms to determine proper operation. Observe labeling on randomly selected packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile radioactive materials are used in an area, such an area should be controlled for airborne contamination. High radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

Examine locations where notices to workers are posted. Applicable documents, notices, or forms must be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed

The DEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding DEP regulations and license provisions and to terminate unsafe activities involving byproduct material.

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Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining the DEP's prior written consent before transferring control of the license;
- Notifying the appropriate DEP Central Office in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).
- Assuring the appropriate response, when applicable, to generic communications from the DEP.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities. (10 CFR 30.35)
- Notifying the DEP Central Office of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (10 CFR 30.36)
- Notifying the DEP of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21.
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

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a. RSC (where required or used). Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

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Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

b. RSO. Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

1. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

2. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.

c. Audits. Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

1. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

2. Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

87127-04 REFERENCES

A listing of IMCs and IPs applicable to the inspection program for materials licensees can be found in IMC 2800. Inspectors are to use these documents as guidelines in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

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INSPECTION PROCEDURE 87130

NUCLEAR MEDICINE PROGRAMS,
WRITTEN DIRECTIVE NOT REQUIRED

PROGRAM APPLICABILITY: 2800

87130-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with Pennsylvania Department of Environmental Protection (DEP) requirements.

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87130-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The DEP Inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or a patient's privacy.

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Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable, the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

02.01 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below DEP regulatory limits.

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02.02 Shielding of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records, that the licensee's performance has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has ensured that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, ALARA practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with DEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35, if the licensee has submitted the information required by 10 CFR 35.12(b) through (d), and the licensee has received written approval from the DEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the DEP considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used that have not been specifically amended to a licensee's license. If an inspector encounters such activity and uses, the inspector should contact DEP regional management as soon as practicable to independently verify that such use is authorized under DEP regulatory requirements. If further verification of such use is needed, the region should contact the Central Office Licensing Section for further guidance.

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87130-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with DEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by DEP, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

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Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records reviewed the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses. Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for those areas of concerns, the records may or may not substantiate his/her concerns. If the inspector substantiates a significant safety concern regarding a particular matter, it may be more appropriate to discuss this matter with DEP regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation the radiation safety program for that particular element of a focus area.

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If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (e.g., licensee materials inventories), or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information.

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The inspector should keep the licensee apprized of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

Whenever possible the inspector should keep DEP regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate DEP guidance under such circumstances.

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03.01 Security and Control of Licensed Material

a. Adequate and Authorized Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition as submitted by the licensee in accordance with 10 CFR 35.13. Based on direct observations made during tours of the licensee's

facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

b. Adequate Equipment and Instrumentation

1. Through discussion with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee is appropriate to the scope of the licensed program. The inspector should independently verify through direct observations that survey instruments have been calibrated in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected.

2. If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects.

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c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with DEP, NRC and applicable U.S. Department of Transportation (DOT) and Pennsylvania Dept. of Transportation (PA DOT) regulations and license conditions.

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Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has methods for picking up, receiving, and opening packages that address how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are taken if surveys reveal that packages are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should observe, when practical, personnel performing the package receipt surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may need a sophisticated accounting system which provides accurate information on the

receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with DEP, PA DOT and DOT regulatory requirements for transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported. For further inspection guidance, the inspector should refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the DEP field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

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e. Material Security and Control. Through direct observations made during tours of the licensee's facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee has maintained adequate security and control of licensed material. From those observations, the inspector should note areas where radioactive materials are used and stored. From further observations and discussions, the inspector should verify that licensed material in storage, in controlled or unrestricted areas, is secured from unauthorized removal or access. Also, the inspector should verify that the storage areas are locked and have limited and controlled access. For licensed material not in storage, in controlled or unrestricted areas, the inspector should verify that such material is controlled and under constant surveillance or physically secured. Controls may include a utilization log to indicate when, in what amount, and by whom, radioactive material is taken from and returned to storage areas. In addition, the inspector should verify that access to restricted areas is limited by the licensee.

f. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas.

During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. The inspector should determine that areas occupied by radiation workers for long periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply in accordance with 10 CFR 19.11, 20.1902, and 21.6.

g. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources in accordance with 10 CFR 35.67(g). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

h. Waste Storage and Disposal. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that radioactive waste is stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed DEP regulatory limits. Through further discussions, observations, and reviews, if necessary, the inspector should verify that disposals of decay-in-storage waste are performed in accordance with DEP regulatory requirements.

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The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less (300 days for NARM sealed sources) and can be decayed in storage until surveys are indistinguishable from background, then be disposed of as non-radioactive waste.

Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify the following areas, when appropriate:

1. Waste disposed in accordance with 10 CFR 35.92;

2. Waste compacted in accordance with license conditions;

3. Waste storage containers properly labeled and area properly posted in accordance with 10 CFR 20.1902 and 20.1904; and

4. Waste was returned from a landfill due to radioactive contamination.

For further inspection guidance, the inspector should refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61" and Information Notice (IN) 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20."

i. Effluents. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that releases into a public sanitary sewerage system and septic tanks, if any, are consistent with the form and quantity restrictions of DEP regulatory requirements. If the inspector determines that a review of selected records is necessary, the inspector should pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water. If a review of selected records is necessary, the inspector should examine the waste release records generated since the last inspection, annual or semiannual reports, pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records.

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For liquid wastes, the inspector should determine through further discussions, observations and reviews, if necessary, if the licensee has identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complies with the regulatory requirements for disposal into sanitary sewerage.

Through further discussions, direct observations made during tours of the licensee's facility, and reviews, if necessary, the inspector should verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within DEP regulatory requirements and are ALARA (This should include xenon or other gas waste, also).

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In addition, from those discussions, observations and reviews, if necessary, the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with the manufacturer's recommendations.

Furthermore, from those discussions, observations and reviews, if necessary, the inspector should verify that all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented by the licensee.

For further inspection guidance, the inspector should refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)."

03.02 Shielding of Licensed Material

In the application for the license, the licensee committed to develop and implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301. Through observations and interviews, the inspector should assess the actual implementation of ALARA procedures which include shielding of licensed material.

a. Syringe and Vial Shields. Determine a sufficient number, type, and condition of syringe and vial shields are being used to protect workers and members of the public from unnecessary radiation. Verify labeling of syringe and vial shields required by 10 CFR 35.69.

b. Other Shielding. Determine use of shielding for waste receptacles, storage containers, and work areas to protect workers in the hot lab.

If shielding is not evident, then the inspector should assess the licensee's evaluation of radiation doses to workers and members of the public respectively under 10 CFR 20.1201 and 1301. The licensee may have determined that shielding was not needed. The inspector should verify that the licensee instructed workers under 10 CFR 19.12 about shielding.

03.03 Comprehensive Safety Measures

During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration or the Pennsylvania Department of Labor and Industry.

During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.04 Radiation Dosimetry Program

The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

a. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.

b. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within DEP regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and discussions the

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inspector determines that a worker had exceeded an DEP regulatory limit, the inspector should immediately contact DEP regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

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10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor.

Through discussions with cognizant licensee representatives and a review of selected records, the inspector should evaluate the adequacy of the licensee's methods used to assess the SDE to the portion of the skin of the extremity expected to have received the highest dose. The inspector should give particular attention to the distance between the location that is likely to have received the highest dose when sources are manipulated manually (even when shields are used) and where the extremity monitor is worn.

d. Internal Dosimetry Through interviews with cognizant licensee representatives, and records review, if appropriate, verify that measurements for internal deposition of licensed materials are performed and evaluated in accordance with 10 CFR 20.1501.

03.05 Radiation Instrumentation, Surveys, and Leak Tests

a. Equipment and Instrumentation

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with DEP regulatory requirements and the manufacturer's recommendations. The inspector should verify that:

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(a) the radiation survey instruments have been calibrated in accordance with10 CFR 35.61;

(b) the instruments used to measure the activity of unsealed byproduct material meet the requirements of 10 CFR 35.60;

(c) licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with 10 CFR 35.204, to ensure that humans are not administered a pharmaceutical containing more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m.

The inspector should independently verify through direct observations that survey instruments have been calibrated at the required frequency in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee's that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee's calibration procedures.

2. When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects in accordance with Part 21. This will vary dependent upon the scope of the licensee's program.

b. Area Radiation Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within DEP regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. However, the inspector must use DEP radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the DEP regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

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If practical and when appropriate, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

c. Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed or contained sources are performed at the required frequency found in 10 CFR 35.67(b) or license conditions. Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review

of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.67(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels) or approved level included in a license condition, the inspector should verify that the licensee made the appropriate notifications per 10 CFR 35.67(e) and removed the source from service.

03.06 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). The inspector should note that it is the licensee's management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

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Of the training program elements, training given to authorized users and nuclear pharmacists, and those individuals under the supervision of authorized users and nuclear pharmacists, is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users, authorized nuclear pharmacists and supervised individuals understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

b. Operating and Emergency Procedures. During the conduct of the inspection, the inspector should verify through direct observations of licensed activities, if practical, licensee personnel perform tasks at selected work stations to verify that such licensed activities are performed in accordance with the licensee's operating procedures. Through discussions with cognizant licensee staff, the inspector should verify that for those individuals interviewed understand and implement procedures establish by the licensee and are aware of procedural revisions. If appropriate, the inspector should review the licensee's emergency procedures to determine that these procedures are adequate to ensure compliance to DEP regulatory requirements.

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Discuss with cognizant licensee representatives, or if practicable, observe licensee personnel conduct periodic tests, especially for scenarios involving events that would require reporting to the DEP under 10 CFR 20.2202.

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Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. The inspector should discuss with cognizant licensee representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

c. Protective Clothing. Through direct observations of licensed activities and discussions with cognizant licensee representatives, the inspector should verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed. The observation of the protective clothing that licensee staff wear during their work activities should provide the inspector with an acceptable means of reviewing this requirement. If the inspector identifies a concern with this practice, the inspector should discuss this practice with appropriate licensee representatives to ensure that licensee staff are following licensee procedures for wearing adequate protective clothing.

03.07 Management Oversight

The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management and the RSO. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the

license have changed, the inspector should determine whether the licensee has submitted appropriate notification to DEP. This information must be provided whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have taken place. If there have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and DEP regional staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

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Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials Inspection Program," and regional policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with DEP regulatory requirements and the licensee's license.

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In reviewing the scope of the licensee's program in this area, the inspector should discuss information that includes lab personnel, locations of use, human research and medical use activities, mobile nuclear medicine services, distribution of pharmaceuticals under 10 CFR Part 35 license, and principal types and quantities of licensed materials used.

c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the

licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify that, when deficiencies are identified, the RSO has sufficient authority to implement corrective actions, including termination of operations that pose a threat to health and safety.

2. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Authorized Users. Authorized users (physicians, nuclear pharmacists, and medical physicists) are named on the license. The inspector should note that the regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. Also, these regulations do not specifically require that the authorized user be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.27(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

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e. Authorized Uses. The inspector should determine from observing the use of licensed material, discussing the activities with cognizant licensee personnel, and if necessary, from a review of selected records, that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license. From those observations, discussions, and reviews, if necessary, the inspector should verify that the total activity of licensed material does not exceed the maximum activity authorized either in the license or in the design specifications of the device's sealed source device registration certificate.

f. Financial Assurance and Decommissioning. The decommissioning recordkeeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100%), to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have been received radiation exposures that exceeded DEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded DEP regulatory limits, the inspector should immediately contact DEP regional management for further guidance.

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Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify DEP. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to DEP. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to DEP. If conditions have changed and the adequacy of the

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financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact regional management as soon as practicable from the licensee's site to discuss the situation.

Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

g. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply.

The inspector should note that the requirements of 10 CFR 30.36, 40.42 and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The Decommissioning Timeliness Rule became effective on September 15, 2001 through incorporation by reference of 10 CFR. If the license has expired or been revoked, or if the licensee has made a decision to permanently cease principal activities, and the licensee provided DEP notification before September 15, 2001, then September 15, 2001, is considered to be the date for initiating the decommissioning calendar (i.e., date of notification). If there has been a 24-month duration in which no principal activities have been conducted at the location before the effective date of the rule, but the licensee did not notify DEP, then the 24-month time period of inactivity is considered to be initiated on September 15, 2001, and the licensee must provide notification to DEP within either 30 or 60 days of September 15, 2003 (depending on whether the licensee requests a delay).

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The inspector should note that the DEP has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failure to notify DEP, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

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Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should contact DEP Central Office management as soon as practicable for further guidance.

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For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG/BR-0241. "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees."

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, , etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these DEP communications, when a response is required.

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i, Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Department. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embryo/fetus or a nursing child, etc.

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From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to DEP and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for follow up and compliance to the appropriate DEP regulatory requirements.

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j. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of equipment for nonmedical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular DEP requirement.

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k. Research Involving Human Subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and 3) the

licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. The licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the DEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the DEP considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee's license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently verify that such use is authorized under the regulations. If further verification of such use is needed, the region should contact the Central Office Licensing Section for further guidance.

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For further inspection guidance, refer to MC 2800.

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DEP INSPECTION MANUAL

INSPECTION PROCEDURE 87131

NUCLEAR MEDICINE PROGRAMS,
WRITTEN DIRECTIVE REQUIRED

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PROGRAM APPLICABILITY: 2800

87131-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with Pennsylvania Department of Environmental Protection (DEP) requirements.

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87131-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The DEP Inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or a patient's privacy.

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Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable, the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

02.01 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below DEP regulatory limits.

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02.02 Shielding of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records, that the licensee's performance has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has ensured that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, ALARA practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with DEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35, if the licensee has submitted the information required by 10 CFR 35.12(b) through (d), and the licensee has received written approval from the DEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the DEP considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used that have not been specifically amended to a licensee's license. If an inspector encounters such activity and uses, the inspector should contact DEP regional management as soon as practicable to independently verify that such use is authorized under DEP regulatory requirements. If further verification of such use is needed, the region should contact the Central Office Licensing Section for further guidance.

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87131-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with DEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by DEP, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

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Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be

appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records reviewed the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses. Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for *those areas of concerns, the records may or may not substantiate his/her concerns. If the* inspector substantiates a significant safety concern regarding a particular matter, it may be more appropriate to discuss this matter with DEP regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation the radiation safety program for that particular element of a focus area.

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If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (e.g., licensee materials inventories), or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information.

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The inspector should keep the licensee apprised of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

Whenever possible the inspector should keep DEP regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate DEP guidance under such circumstances.

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03.01 Security and Control of Licensed Material

a. Adequate and Authorized Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition as submitted by the licensee in accordance with 10 CFR 35.13. Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

b. Adequate Equipment and Instrumentation

1. Through discussion with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee is appropriate to the scope of the licensed program. The inspector should independently verify through direct observations that survey instruments have been calibrated in accordance with 10 CFR 35.61.

The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected.

2. If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects in accordance with 10 CFR 21

c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with DEP and applicable U.S. Department of Transportation (DOT) and Pennsylvania Dept. of Transportation (PA DOT) regulations and license conditions.

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Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has methods for picking up, receiving, and opening packages that address how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are taken if surveys reveal that packages are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should observe, when practical, personnel performing the package receipt surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with DEP, PA DOT and DOT regulatory requirements for transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported. For further inspection guidance, the inspector should refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the DEP field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

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e. Material Security and Control. Through direct observations made during tours of the licensee's facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee has maintained adequate security and control of licensed material. From those observations, the inspector should note areas where radioactive materials are used and stored. From further observations and discussions, the inspector should verify that licensed material in storage, in controlled or unrestricted areas, is secured from unauthorized removal or access. Also, the inspector should verify that the storage areas are locked and have limited and controlled access. For licensed material not in storage, in controlled or unrestricted areas, the inspector should verify that such material is controlled and under constant surveillance or physically secured. Controls may include a utilization log to indicate when, in what amount, and by whom, radioactive material is taken from and returned to storage areas. In addition, the inspector should verify that access to restricted areas is limited by the licensee.

f. Written Directives. During the onsite inspection, the inspector should observe and interview individuals as they perform applicable duties to determine that individuals are knowledgeable about the need for written directives and if the licensee's written directives, as implemented, effectively ensure that radiation from byproduct material will be administered as directed by the authorized user in accordance with 10 CFR 35.40. The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with 10 CFR 35.41.

g. Patient Release. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected records, the inspector should determine if a licensee is knowledgeable about patient release criteria and that a process exists to establish that a patient administered radiopharmaceuticals or therapeutic quantities of radioactive material is releasable from control in accordance with 10 CFR 35.75.

1. The inspector should note that the patient release criteria permits licensees to release individuals from control if the TEDE for any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee

representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with 10 CFR 35.75.

2. Through further discussions the inspector should verify that the licensee is familiar with the requirements in 10 CFR 35.75(b) to provide instructions to released individuals if the dose to any other individual is likely to exceed 0.1 rem. The inspector should note that, in general, the licensee is required to give instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable. The inspector may determine how the licensee is demonstrating compliance with this requirement by discussing the content of the instructions with appropriate licensee staff. If concerns are identified from those discussions, the inspector may find it necessary to review the sample instructions given to patients. If the licensee is required by the rule to provide instructions to breast-feeding women, the inspector should verify through further discussions and reviews, if necessary, that the instructions include guidance on the interruption or discontinuation of breast-feeding and information on the potential consequences of failure to follow the guidance.

3. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that if the TEDE to a breast-feeding child could exceed 0.5 rem if the breast-feeding were continued, the licensee has maintained documentation that instructions were provided in accordance with 10 CFR 35.75(d).

h. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by DEP regulatory requirements. If necessary, the inspector should conduct a review of selected records to independently verify those discussions with such individuals. If from those reviews a previously unidentified medical event is identified by the inspector, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045, "Report and notification of a medical event" or 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child" and 2) Upon identification of such an event, the inspector should notify DEP regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

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i. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. The inspector should determine that areas occupied by radiation workers for long periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply in accordance with 10 CFR 19.11, 20.1902, and 21.6.

j. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources in accordance with 10 CFR 35.67(g). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

k. Waste Storage and Disposal. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that radioactive waste is stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed DEP regulatory limits. Through further discussions, observations, and reviews, if necessary, the inspector should verify that disposals of decay-in-storage waste are performed in accordance with DEP regulatory requirements.

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The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less (300 days for NARM sealed sources) and can be decayed in storage until surveys are indistinguishable from background, then be disposed of as non-radioactive waste.

Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify the following areas, when appropriate:

1. Waste disposed in accordance with 10 CFR 35.92;

2. Waste compacted in accordance with license conditions;

3. Waste storage containers properly labeled and area properly posted in accordance with 10 CFR 20.1902 and 20.1904; and

4. Waste was returned from a landfill due to radioactive contamination.

For further inspection guidance, the inspector should refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61" and Information Notice (IN) 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20."

l. Effluents. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that releases into a public sanitary sewerage system and septic tanks, if any, are consistent with the form and quantity restrictions of DEP regulatory requirements. If the inspector

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determines that a review of selected records is necessary, the inspector should pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water. If a review of selected records is necessary, the inspector should examine the waste release records generated since the last inspection, annual or semiannual reports, pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records.

For liquid wastes, the inspector should determine through further discussions, observations and reviews, if necessary, if the licensee has identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complies with the regulatory requirements for disposal into sanitary sewerage.

Through further discussions, direct observations made during tours of the licensee's facility, and reviews, if necessary, the inspector should verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within DEP regulatory requirements and are ALARA (This should include xenon or other gas waste, also).

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In addition, from those discussions, observations and reviews, if necessary, the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with the manufacturer's recommendations.

Furthermore, from those discussions, observations and reviews, if necessary, the inspector should verify that all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented by the licensee.

For further inspection guidance, the inspector should refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)".

03.02 Shielding of Licensed Material

In an application for a license, a licensee must commit to develop, implement, and maintain procedures under 10 CFR 20.1101 and 10 CFR 20.1301 for safe use of unsealed byproduct material. Through observations and interviews, the inspector should assess the actual implementation of ALARA procedures which include shielding of licensed material.

a. Syringe and Vial Shields. Determine a sufficient number, type, and condition of syringe and vial shields are being used to protect workers and members of the public from unnecessary radiation. Verify labeling of syringe and vial shields required by 10 CFR 35.69.

b. Shielding in the Hot Lab. Determine use of shielding for waste receptacles, storage containers, generator systems, and work areas to protect workers in the hot lab.

c. Shielding for Nuclear Medicine Therapy. Determine use of shielding for administration of therapeutic quantities of byproduct material to protect workers

and family members of the patient who may be present. To limit doses to workers and individual members of the public, a licensee may use portable shielding in patient rooms or the licensee may have installed permanent shielding in certain patient rooms designated for patients that cannot be released under 10 CFR 35.75. In an application for a license, the applicant would have described the shielding along with calculations to estimate dose levels. For portable shields, an applicant would also commit to develop administrative procedures for proper use and placement of the shields within a patient room.

If shielding is not evident, then the inspector should assess the licensee's procedure and further evaluation of radiation doses to workers and members of the public respectively under 10 CFR 20.1201, 20.1301, and 20.1302. The inspector should verify that the licensee instructed workers under 10 CFR 19.12 about shielding. The licensee may have determined that shielding was not indicated under certain conditions to protect the patient or human research subject from a non-radiological hazard which has significant health and safety consequences to the patient or human research subject.

03.03 Comprehensive Safety Measures

During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration or the Pennsylvania Department of Labor and Industry.

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During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.04 Radiation Dosimetry Program

The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

a. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.

b. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within DEP regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and discussions the inspector determines that a worker had exceeded an DEP regulatory limit, the inspector should immediately contact DEP regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

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10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through

discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor.

Through discussions with cognizant licensee representatives and a review of selected records, the inspector should evaluate the adequacy of the licensee's methods used to assess the SDE to the portion of the skin of the extremity expected to have received the highest dose. The inspector should give particular attention to the distance between the location that is likely to have received the highest dose when sources are manipulated manually (even when shields are used) and where the extremity monitor is worn.

d. Internal Dosimetry. Through interviews with cognizant licensee representatives, and records review, if appropriate, verify that measurements for internal deposition of licensed materials are performed and evaluated in accordance with 10 CFR 20.1501.

03.05 Radiation Instrumentation and Surveys

a. Equipment and Instrumentation

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with DEP regulatory requirements and the manufacturer's recommendations. The inspector should verify that:

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(a) The radiation survey instruments have been calibrated in accordance with10 CFR 35.61;
(b) The instruments used to measure the activity of unsealed byproduct material meet the requirements of 10 CFR 35.60;

(c) Licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with 10 CFR 35.204, to ensure that humans are

not administered a pharmaceutical containing more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m.

The inspector should independently verify through direct observations that survey instruments have been calibrated at the required frequency in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee's that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee's calibration procedures.

2. When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects.

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b. Area Radiation Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within DEP regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. However, the inspector must use DEP radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the DEP regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

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If practical and when appropriate, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

c. Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed or contained sources are performed at the required frequency found in 10 CFR 35.67(b) or license conditions. Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.67(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels) or approved level included in a license condition, the inspector should verify that the licensee made the appropriate notifications per 10 CFR 35.67 (e) and removed the source from service.

03.06 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). The inspector should note that it is the licensee's management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

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Of the training program elements, training given to authorized users and nuclear pharmacists, and those individuals under the supervision of authorized users and nuclear pharmacists is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users, authorized nuclear pharmacists and supervised individuals understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, "dry runs" for more complex or hazardous operations, and authorized nuclear pharmacists instruction in the preparation of drugs.

b. Operating and Emergency Procedures. During the conduct of the inspection, the inspector should verify through direct observations of licensed activities, if practical, licensee personnel perform tasks at selected work stations to verify that such licensed activities are performed in accordance with the licensee's operating procedures. Through discussions with cognizant licensee staff, the inspector should verify that for those individuals interviewed understand and implement procedures establish by the licensee and are aware of procedural revisions. If appropriate, the inspector should review the licensee's emergency procedures to determine that these procedures are adequate to ensure compliance to DEP regulatory requirements.

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Discuss with cognizant licensee representatives, or if practicable, observe licensee personnel conduct periodic tests, especially for scenarios involving events that would require reporting to the DEP under 10 CFR 20.2202.

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Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. The

inspector should discuss with cognizant licensee representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

c. Safety Instruction for Personnel Caring for Non-Releasable Patients. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee provides radiation safety instruction for all personnel caring for patients who cannot be released under 10 CFR 35.75, in accordance with10 CFR 35.310. The inspector should note that radiation safety instruction must be conducted initially and at least annually an be commensurate with the duties of the personnel.

d. Protective Clothing. Through direct observations of licensed activities and discussions with cognizant licensee representatives, the inspector should verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed. The observation of the protective clothing that licensee staff wear during their work activities should provide the inspector with an acceptable means of reviewing this requirement. If the inspector identifies a concern with this practice, the inspector should discuss this practice with appropriate licensee representatives to ensure that licensee staff are following licensee procedures for wearing adequate protective clothing.

03.07 Management Oversight

The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management and the RSO. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to DEP. This information must be provided whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have taken place. If there have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and DEP Central Office staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

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Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials Inspection Program," and regional policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with DEP regulatory requirements and the licensee's license.

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In reviewing the scope of the licensee's program in this area, the inspector should discuss information that includes lab personnel, locations of use, human research and medical use activities, mobile nuclear medicine services, distribution of pharmaceuticals under 10 CFR Part 35 license, and principal types and quantities of licensed materials used.

c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify that, when deficiencies are identified, the RSO

has sufficient authority to implement corrective actions, including termination of operations that pose a threat to health and safety.

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2. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Authorized Users. Authorized users (physicians, nuclear pharmacists, and medical physicists) are named on the license. The inspector should note that the regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. Also, these regulations do not specifically require that the authorized user be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.27(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

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e. Authorized Uses. The inspector should determine from observing the use of licensed material, discussing the activities with cognizant licensee personnel, and if necessary, from a review of selected records, that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license. From those observations, discussions, and reviews, if necessary, the inspector should verify that the total activity of licensed material does not exceed the maximum activity authorized either in the license or in the design specifications of the device's sealed source device registration certificate.

f. Financial Assurance and Decommissioning. The decommissioning recordkeeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100%), to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have been received radiation exposures that exceeded DEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded DEP regulatory limits, the inspector should immediately contact DEP regional management for further guidance.

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Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify DEP. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to DEP. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to DEP. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact regional management as soon as practicable from the licensee's site to discuss the situation.

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Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

g. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal

activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply.

The inspector should note that the requirements of 10 CFR 30.36, 40.42 and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The Decommissioning Timeliness Rule became effective on September 15, 2001 through incorporation by reference of 10 CFR. If the license has expired or been revoked, or if the licensee has made a decision to permanently cease principal activities, and the licensee provided DEP notification before September 15, 2001, then September 15, 2001, is considered to be the date for initiating the decommissioning calendar (i.e., date of notification). If there has been a 24-month duration in which no principal activities have been conducted at the location before the effective date of the rule, but the licensee did not notify DEP, then the 24-month time period of inactivity is considered to be initiated on September 15, 2001, and the licensee must provide notification to DEP within either 30 or 60 days of September 15, 2003 (depending on whether the licensee requests a delay).

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The inspector should note that the DEP has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failure to notify DEP, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

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Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should contact DEP Central Office management as soon as practicable for further guidance.

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For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG/BR-0241. "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees."

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these DEP communications, when a response is required.

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i. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Department. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embryo/fetus or a nursing child, etc. Deleted: Commission

From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to DEP and individuals, if applicable. Deleted: NRC If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for follow-up and compliance to the appropriate DEP regulatory requirements. Deleted: NRC

j. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of equipment for non-medical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular DEP requirement. Deleted: NRC

k. Research Involving Human Subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and 3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. The licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the DEP in a license or license amendment Deleted: NRC and uses the material in accordance with the regulations and specific conditions the DEP Deleted: NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee's license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently verify that such use is authorized under the regulations. If further verification of such use is needed, the region should contact the Central Office Licensing Section, for further guidance. Deleted: NMSS

For further inspection guidance, refer to MC 2800.

END

DEP INSPECTION MANUAL

INSPECTION PROCEDURE 87132

BRACHYTHERAPY PROGRAMS

PROGRAM APPLICABILITY: 2800

87132-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with Pennsylvania Dept. of Environmental Protection (DEP) requirements.

87132-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The DEP Inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or a patient's privacy.

Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable,

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the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

This inspection procedure is applicable to all forms of brachytherapy (temporary and permanent implants, remote afterloaders, eye applicators and plaques, etc.). However, all the following areas may not be applicable to each brachytherapy program.

02.01 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below DEP regulatory limits.

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02.02 Shielding of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has ensured that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to

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ensure awareness of the radiation protection program, ALARA practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with DEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35, if the licensee has submitted the information required by 10 CFR 35.12(b) through (d), and the licensee has received written approval from the DEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the DEP considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used that have not been specifically amended to a licensee's license. If an inspector encounters such activity and use, the inspector should contact DEP regional management as soon as practicable to independently verify that such use is authorized under DEP regulatory requirements. If further verification of such use is needed, the region should contact the Central Office Licensing Section for further guidance.

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87132-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with DEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by DEP, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

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Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records reviewed the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses. Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for those areas of concerns, the records may or may not substantiate his/her concerns. If the inspector substantiates a significant safety concern regarding a particular matter, it may be

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more appropriate to discuss this matter with DEP regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation the radiation safety program for that particular element of a focus area.

If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (e.g., licensee materials inventories), or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information.

The inspector should keep the licensee apprized of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

Whenever possible the inspector should keep DEP regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate DEP guidance under such circumstances.

03.01 Security and Control of Licensed Material

a. Adequate and Authorized Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition as submitted by the licensee in accordance with 10 CFR 35.13. Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

1. Additional Requirements for Licensees with Remote Afterloaders. Through direct observations made during tours of the licensee's facility and discussions with cognizant licensee representatives, the inspector should verify that unauthorized individuals are prevented from entering the use area, that the device and all associated sources are stored against unauthorized use or removal, and console keys are inaccessible to unauthorized persons. The inspector should note remote afterloaders placed in treatment rooms with other radiation-producing devices and ask authorized licensee personnel to demonstrate that only one device can be placed in operation at a time.

2. Additional Requirements for Licensees with High-, Medium-, and Pulsed-Dose- Rate Remote Afterloaders. Through discussions with cognizant licensee representatives and direct observations, the inspector should verify that the use of the afterloaders is limited to the areas approved by the license. From those discussions and observations, the inspector should determine whether each dedicated treatment room is equipped with a continuous viewing and intercom system to allow for patient observation and communication during treatment. In addition, the inspector should verify that these systems are checked for operation at the beginning of each day of

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use, and that either a backup system is available or the licensee suspends further treatments if the primary system requires repairs.

Through further discussions and observations, the inspector should verify that electrical interlock systems are installed and operational at each entry. The activation of the interlock will result in the source automatically being retracted. Also, the inspector should verify that, once activated, the automatic interlock must be reset before the afterloading device can be activated. In addition, the inspector should determine whether interlocks are tested at the required frequency.

During the conduct of the inspection, the inspector should ask an authorized licensee representative to demonstrate that interlock systems are operational and should inquire about what action is taken by the staff when the interlock systems are found to be non-operational. The inspector should also confirm that the backup system used to observe patients is operational and inquire about what action is taken by licensee staff when the backup system is non-operational.

3. Additional Requirements for Licensees with Low-Dose-Rate Remote Afterloaders. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the licensee has the capability to monitor the patient and device during treatment to ensure that the sources and catheter guide tubes are not disturbed during treatment/use.

b. Adequate Equipment and Instrumentation. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should independently check interlock systems and other systems for continuous observation of the patient. For unit operation, the inspector should check the control of console keys. These activities can best be reviewed by the inspector by having an appropriate licensee representative demonstrate how these systems operate while the inspector observes those actions to ensure that the systems operate as designed and that the individual conducting the activity is knowledge-able in those areas. If applicable, the inspector should check any self-contained dry-source-storage irradiators and/or survey instrument calibrators. If appropriate, the inspector should verify that these various systems and checks operate appropriately to ensure compliance to 10 CFR 35.61, 610, and 615.

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During the conduct of the inspection, the inspector should discuss with cognizant licensee representatives the routine maintenance and calibration performed on the units. If practicable, the inspector should ask appropriate licensee personnel to demonstrate some or all of the steps of the calibration procedure. If the inspector identifies concerns from those direct observations, a review of selected maintenance and calibration log may be necessary. If a review is necessary, the inspector should look for recurring problems/repairs and generic problems. If recurring problems are identified and of significance, the inspector should contact DEP regional management for further guidance. If applicable, the inspector should verify that the RSC was aware of the problem. The inspector should then review the matter with cognizant licensee representatives to determine if adequate action was taken by the licensee to address the problem. From those discussions and reviews, if necessary, the inspector should determine if any malfunctions should have been reported to the DEP, pursuant to 10 CFR 21.21.

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1. Remote Afterloader Unit Inspection, Servicing, Calibration and Spot Checks. Through direct observations made during the onsite inspection, the inspector should visually inspect the control console and unit for indications that alterations may have been performed by unauthorized persons. These indications may include off-the-shelf switches and timers, as well as wire jumpers and taped micro switches to bypass safety systems of the unit. If the inspector determines that alterations have been performed by unauthorized persons, the inspector should contact DEP regional management as soon as practicable for further guidance.

Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has properly calibrated the remote afterloader, the unit is calibrated at the required intervals (not to exceed one quarter or one year, whichever one is applicable), and before first patient use and after source exchange, relocation, and major repair or modification. The calibration of the unit should include all items listed in 10 CFR 35.633. In addition, the inspector should verify that spot checks are conducted on the unit at the required frequency, and as required by 10 CFR 35.643. Also, the inspector should verify that additional technical requirements are conducted on the unit at the required frequency as required by 10 CFR 35.647.

During the conduct of the inspection, if the inspector identifies equipment or instrumentation that has failed to perform as designed, the inspector should ensure that licensee operations are stopped immediately and that such equipment or instrumentation be appropriately repaired and tested prior to the next treatment. In some cases it may be appropriate to contact DEP regional management as soon as practicable to discuss the equipment or instrument failure and determine what appropriate steps should be taken to follow up on this matter.

2. Additional Requirements for all Licensees with Remote Afterloaders.

During the conduct of the inspection, the inspector should visually inspect the remote afterloading device and/or any source storage devices to verify that only authorized devices are in use and that they are properly labeled.

In addition, during the inspection, the inspector should ask an appropriate licensee staff personnel to demonstrate how the backup battery for the device and the source position indicators are checked for proper operation.

During tours of the licensee's facilities, the inspector should independently verify that emergency equipment is available near each treatment room to respond to a source dislodged from the patient or lodged within the patient following completion of the treatment. This equipment should include such items as shielded containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient, including scissors and cable cutters.

3. Additional Requirements for Licensees with Strontium-90 (Sr-90) Eye Applicators. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and a review of selected records, the inspector should verify that the licensee has in its possession, and uses, a certificate of calibration, or data from a manufacturer-supplied source identification plate, for each Sr-90 opthalmic

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applicator in its possession. Certificates of calibration must be supplied by either:

(a) The manufacturer/vendor of the Sr-90 applicator; or

(b) A calibration laboratory with established traceability to the National Institute of Standards and Technology (NIST) for performing Sr-90 opthalmic applicator calibrations.

From those discussions, observations, and reviews, the inspector should verify that each certificate of calibration, or source identification plate, must match, by source serial number, the source for which its data are being used.

Through further discussions, observations, and reviews, the inspector should verify that the source output (dose rate) is being properly corrected for source decay. The inspector should confirm this by independent calculation to ensure the adequacy of the licensee's corrections for the radioactive decay of Sr-90 sources.

4. Licensee Evaluation of Equipment Defects or Failures to Comply That Are Associated with Significant Safety Hazards. The inspector should verify a licensee developed procedures under 10 CFR 21.21 to identify and report safety component defects and, when needed, the procedures were implemented and DEP is also aware of the report.

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c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with DEP and applicable U.S. Department of Transportation (DOT) and Pennsylvania Dept. of Transportation (PA DOT) regulations and license conditions.

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Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

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If a records review is necessary, the inspector should verify that the licensee's procedures for receiving replacement sealed sources include how and when they will be picked up, radiation surveys and wipe tests of source containers to be done upon receipt, and procedures for opening source containers (such as the location in the facility where they are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are to be taken if surveys reveal source containers that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If replacement sources arrive during the course of an inspection,

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the inspector should observe, when practical, personnel perform the package receipt surveys as well as the area surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with DEP, PA DOT and DOT regulatory requirements for transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported.

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For further inspection guidance, the inspector should refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the DEP field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

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e. Material Security and Control. During tours of the licensee's facilities, the inspector should note areas where radioactive materials are used and stored. From those direct observations, the inspector should verify that the storage areas are locked and have limited and controlled access. The inspector should verify that radioactive materials, afterloaders, and storage devices are properly labeled. If from those observations, the inspector identifies concerns regarding access to storage areas, a review of the licensee's administrative controls may be necessary. For some licensee's the controls may include a utilization log to indicate when radioactive material is taken from and returned to storage areas.

The inspector should determine through direct observations that the treatment rooms containing remote afterloaders are under constant surveillance or physically secured when not in use. The inspector should discuss with appropriate licensee representatives the licensee's procedures for access controls in order to verify that adequate controls are in place and working effectively.

The inspector should determine that the safety and security of all sources are maintained according to 10 CFR 35.615 and 10 CFR 20.

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f. Written Directives. During the onsite inspection, the inspector should observe and interview individuals as they perform applicable duties to determine that individuals are knowledgeable about the need for written directives and if the licensee's written directives, as implemented, effectively ensure that radiation from byproduct material will be administered as directed by the authorized user in accordance with 10 CFR 35.40. The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with 10 CFR 35.41.

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g. Patient Release. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify the licensee's methods for establishing compliance with 10 CFR 35.75.

1. The inspector should note that the patient release criteria permits licensees to release individuals from control if the TEDE to any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with 10 CFR 35.75.

2. Through further discussions the inspector should verify that the licensee is familiar with the requirements in 10 CFR 35.75(b) to provide instructions to released individuals if the dose to any other individual is likely to exceed 0.1 rem. The inspector should note that, in general, the licensee is required to give instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable. The inspector may determine how the licensee is demonstrating compliance with this requirement by discussing the content of the instructions with appropriate licensee staff. If concerns are identified from those discussions, the inspector may find it necessary to review the sample instructions given to patients. If the licensee is required by the rule to provide instructions to breast-feeding women, the inspector should verify through further discussions and reviews, if necessary, that the instructions include guidance on the interruption or discontinuation of breast-feeding and information on the potential consequences of failure to follow the guidance.

3. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that if the TEDE to a breast-feeding child could exceed 0.5 rem if the breast-feeding were continued, the licensee has maintained documentation that instructions were provided in accordance with 10 CFR 35.75(d).

h. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by DEP regulatory requirements. If necessary, the inspector should conduct a review of selected records to independently verify those discussions with such individuals. If during the inspection, a previously unidentified medical event is identified by the inspector, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described 10 CFR 35.3045, "Report and notification of a medical event" or 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child", and 2) Upon identification of such an event, the inspector should notify DEP regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

i. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. The inspector should note that 10 CFR 20.1903 provides exceptions to posting caution signs. During those tours, the inspector should selectively examine signals and alarms to determine adequate operability. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

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During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, the licensee's controls may include tape, rope, or structural barriers to prevent access. The inspector should verify that high radiation areas have been strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high radiation area, warning lights, and audible alarms. The inspector should determine that areas occupied by radiation workers for long periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply in accordance with 10 CFR 19.11, 20.1902, and 21.6.

During tours of the licensee's facility, the inspector should verify that emergency procedures are appropriately posted at the control console in accordance with 10 CFR 35.610.

j. Waste Storage and Disposal. Through discussions with cognizant licensee representatives and direct observations made during tours of the licensee's facility, the inspector should verify that the licensee has appropriately disposed of brachytherapy sources. From those discussions and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that recipients of radioactive wastes are licensed to receive such waste (e.g., licensee obtains a copy of the waste recipient's current license before the transfer). Sealed sources, used in afterloaders, are exchanged on receipt of a new source. In addition, through further discussions, observations and reviews, if necessary, the inspector should verify that the licensee has appropriate methods to track the items in storage.

From those discussions and direct observations, the inspector should verify that radioactive wastes are disposed of in proper containers.

For further inspection guidance in this area, the inspector should refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61."

k. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources and brachytherapy sources in accordance with 10 CFR 35.67(g). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

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03.02 Shielding of Licensed Material

An inspector should determine that a licensee has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

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In an application for a license, an applicant must indicate the location and description of shielding along with calculations of estimated radiation levels. Through observations and interviews, an inspector should determine availability and placement of shielding, and inquire about unshielded activities and radiation exposure levels for the following areas.

a. Manual Brachytherapy. Determine use of manual brachytherapy source storage shields and body shields for applicator loading and unloading areas.

b. Patient Treatment Rooms. Facility shielding may have been installed for certain patient treatment rooms to reduce radiation levels in adjacent areas and areas above and below the room. If a viewing window is observed, check for leaded glass in the viewing window. Use of portable shielding in patient rooms may have been indicated. The inspector should visually confirm that the licensee has portable shields and should interview staff to confirm that the shields are set to the approved configuration for the room during procedures.

c. Sr-90 Eye Applicators. Determine the source is properly shielded or stored to prevent bremsstrahlung radiation or high ambient dose rates.

If shielding is not evident, then the inspector should assess the licensee's procedure to use shielding and the licensee's further evaluation of radiation doses to workers and members of the public respectively under 10 CFR 20.1201, 20.1301, and 20.1302. The inspector should verify that the licensee instructed workers under 10 CFR 19.12 about use of shielding. In certain cases, a licensee may have determined that shielding was not indicated under particular conditions to protect the patient or human research subject from a non-radiological hazard which has significant health and safety consequences to the patient or human research subject.

03.03 Comprehensive Safety Measures

During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration or the Pennsylvania Department of Labor and Industry.

During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.04 Radiation Dosimetry Program

The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

a. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.

b. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within DEP regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and discussions the

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inspector determines that a worker had exceeded an DEP regulatory limit, the inspector should immediately contact DEP regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

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10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor in accordance with 10 CFR 20.1501.

03.05 Radiation Instrumentation Surveys and Leak Tests

a. Equipment and Instrumentation

1. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with DEP regulatory requirements and the manufacturer's recommendations.

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The inspector should independently verify through direct observations that survey instruments have the appropriate range of use in accordance with 10 CFR 35.61. The inspector should also verify that the survey instruments are calibrated at the required frequency and checked for operability before use, in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff conduct the check for operability to ensure that these individuals are knowledgeable in how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee's that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee's calibration procedures.

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2. During the inspection, the inspector should independently verify that the licensee has access to a dosimetry system for performing the full calibration and spot-check measurements of remote afterloader unit output. The

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system must be calibrated in accordance with the requirements of 10 CFR 35.633. During the inspection, the inspector should review selected dosimetry worksheets from the previous full calibration measurements required by 10 CFR 35.633. If the licensee participates in intercomparison of dosimetry measurements, the inspector should review the licensee's performance results to determine that systemic measurement errors are identified and corrected.

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3. During the conduct of the inspection, the inspector should independently check the installed radiation monitors to ensure that they have been maintained in accordance with the applicable requirements. In addition, the inspector should independently verify the operability of permanent radiation monitors, availability of backup power supply for the source-retract systems, source position indicators, daily checks, service and maintenance of units. During the inspection, the inspector may have cognizant licensee staff demonstrate the operability of those devices to ensure that they perform as designed.

4. When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects.

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b. Area Radiation Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within DEP regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. If during the conduct of the inspection a brachytherapy procedure is currently in progress, the inspector should make independent measurements in adjacent unrestricted areas to confirm that the requirements of 10 CFR 20.1301 are met. However, the inspector must use DEP radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the DEP regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

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If practical and when appropriate, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured. The survey activities should be at a specified frequency, in accordance with the related licensee procedures. The inspector should also perform independent confirmatory measurements, as needed to verify licensee assumptions or measurements.

The inspector should verify by independent measurement that shielding surveys of the unit head and treatment room are in compliance with the requirements of 10 CFR 35.652. Indications of higher than expected dose levels by an inspector may indicate that the source is a higher activity than authorized or that the source is not fully shielded on retraction.

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c. Source Replacement Surveys. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has performed surveys following source changes, device repair, or device maintenance for remote after loader programs.

Through further discussions, direct observations of license activities, and reviews, if necessary, the inspector should verify the licensee's performance in conducting timely patient and area surveys for brachytherapies (both permanent and

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temporary implants), as well as source-removal, patient-release, and room-release surveys. For most brachytherapy procedures, a radiation survey of the patient must be performed immediately after source removal.

If from those discussions and direct observations the inspector determines that individuals do not understand, perform checks or conduct activities appropriately to ensure compliance to DEP regulatory requirements, the inspector should discuss this matter with appropriate licensee representatives as soon as practicable to ensure that previous activities have been conducted appropriately and retraining of the individuals is conducted prior to using such instruments for such surveys.

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d. Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed or contained sources are performed at the required frequency found in 10 CFR 35.67(b) or license conditions. Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.67(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels) or approved level included in a license condition, the inspector should verify that the licensee made the appropriate notifications per 10 CFR 35.67 (e) and removed the source from service.

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03.06 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). The inspector should note that it is the licensee's management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

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Of the training program elements, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users

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and supervised individuals understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

b. Operating and Emergency Procedures. Safety instructions will be developed, implemented and maintained by the licensee in accordance with 10 CFR 35.610 and may vary from step-by-step procedures to more generalized procedures. During the conduct of the inspection, the inspector should verify that these procedures are posted at the remote afterloader unit console in accordance with 10 CFR 35.610. During the inspection the inspector should interview operators of the unit to determine that actions required to be performed in the event of abnormal operation of the device are known by such individuals.

From those interviews, the inspector should determine if such individuals are aware of the location of the operating procedures and what procedures to follow in the event of an emergency. In particular the inspector should determine if cognizant licensee staff is aware of the requirement to carry a functional radiation detection devices into the room if the room monitor is non-functional. The inspector should determine if such staff is aware of the location of the alternative radiation detection devices since in an emergency the staff would not have time to look for the monitor. From further discussions, the inspector should determine if the individuals are aware that radiation surveys of the device and the patient are to be performed after a procedure is completed. In addition, from those interviews, the inspector should determine if cognizant staff is aware of the location of emergency source-recovery equipment. In addition, the inspector should attempt to interview nurses who have been involved in treatments using the device to determine their familiarity with the licensee's emergency procedures.

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. The inspector should discuss with cognizant licensee representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

c. Strontium-90 Eye Applicators

1. During the conduct of the inspection, the inspector should verify that the licensee is using the most recent calibration results. The inspector should note that a medical event has occurred if: 1) the licensee, in prescribing a dose and planning its delivery, does not use the most recent calibration results available to it at the time; and 2) the administered dose, calculated from the most recent calibration results available at the time of dose prescription, differs from the prescribed dose by greater than 20 percent. The inspector should not apply the dose rate results of a recent calibration to previous therapeutic administrations, for the purpose of identifying medical events, provided the previous calibration was considered valid at the time.

   At this time, two calibration laboratories are known to be capable of providing the required NIST-traceable calibrations of Sr-90 opthalmic applicators. They are NIST, itself, and the University of Wisconsin Accredited Dosimetry Calibration Laboratory.

2. The inspector should also refer to IN 96-66, "Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators," for additional inspection guidance. This IN discusses the need to ensure that

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the dose rate from the eye applicator is correct for assurance that the prescribed dose is the administered dose. The IN describes examples of misadministrations (medical events) and includes a decay table for the source.

3. The inspector should note that for convenience and because of physical characteristics of the device, eye applicator sterilization is usually accomplished by immersion/dwell in appropriate liquid, such as isopropyl alcohol, or by gentle sweeping contact with a liquid-saturated gauze pad. During discussions with cognizant licensee representatives, the inspector should verify that the licensee is not using liquids containing halogenated compounds. These liquids are to be avoided, as corrosion of typically-constructed applicators can occur.

4. Through direct observations made during the conduct of the inspection, the inspector should ensure that the licensee has properly shielded or stored the source to prevent bremsstrahlung radiation or high ambient dose rates.

5. The inspector should note that requirements for monitoring occupational exposure are specified in 10 CFR 20.1502. From direct observations made during the conduct of the inspection and discussions with cognizant licensee representatives, the inspector should ensure that proper ALARA techniques are used. Some techniques may include a method, such as the use of an opthalmic speculum, to hold the patient's eye open during treatment, to minimize occupational exposure to the user's fingers.

6. The inspector should note that in accordance with 10 CFR 71.9, the transportation of eye applicators between license-authorized offices or hospitals is to be conducted by a physician licensed by a State to dispense drugs in the practice of medicine, and licensed under 10 CFR part 35 or the equivalent Agreement State regulations.

03.07 Management Oversight

The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management, the RSO, and if applicable, the Chairperson of the RSC, and other members of the RSC. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to DEP. This information must be provided whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine if changes have occurred, or are anticipated, and ask personnel to confirm (to the

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inspector's satisfaction) that no changes have taken place. If there have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and DEP regional staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

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Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials Inspection Program," and regional policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with DEP regulatory requirements and the licensee's license. Also, the inspector should followup with this matter with appropriate DEP licensing staff to ensure that they apprized of this matter for proper licensing action.

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c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC, if applicable, to

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implement corrective actions, including termination of operations that pose a threat to health and safety.

2. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

3. RSC. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should note if the licensee is required to maintain an RSC in accordance with 10 CFR 35.24(f). If applicable, through discussions with cognizant Radiation Safety Committee (RSC) representatives, the inspector should independently verify that topics of discussion during RSC meetings included ALARA reviews, incidents, generic communications, authorized users and uses, safety evaluations, audits, and medical events, as defined in 10 CFR 35.2, etc. From those discussions, the inspector should verify that the committee is made up of representatives from each type of program area, the RSO, a representative of the nursing service, and a representative from management. If time permits, the inspector should review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness.

   From those discussions, the inspector should determine if the RSC has been aggressive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. The inspector should also determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also, the inspector should determine the effectiveness of the RSC to communicate the results of audits and trending analyses to appropriate personnel performing licensed activities.

d. Authorized Users. Authorized users (physicians and medical physicists) may either be named in the license application or appointed by the licensee dependent upon the scope of the licensed program. For those appointed by the licensee, the inspector should independently verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties.

   The inspector should noted that the regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. Also, these regulations do not specifically require that the authorized user be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.27(a), and is responsible for the supervision of operations involving the use of

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radioactive materials whether he/she is present or absent. Through discussions with cognizant licensee representatives, the inspector should verify that the appropriate individuals are present or available for assistance during treatments.

e. Authorized Uses. Through discussions with cognizant licensee staff and direct observations made during tours of the licensee's facilities, the inspector should independently verify that the licensee's use of byproduct material is limited to that which is authorized in the license. Uses of remote afterloader units for other than human use would require the licensee to comply with 10 CFR Part 36.

From direct observations of the use of licensed material, discussions with cognizant licensee personnel, and if necessary, a review of selected records, the inspector should determine that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license.

f. Financial Assurance and Decommissioning. The decommissioning recordkeeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100%), to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have received radiation exposures that exceeded DEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded DEP regulatory limits, the inspector should immediately contact DEP regional management for further guidance.

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Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify DEP. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be

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sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to DEP. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to DEP. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact regional management as soon as practicable from the licensee's site to discuss the situation.

Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

g. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply.

The inspector should note that the requirements of 10 CFR 30.36, 40.42 and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The Decommissioning Timeliness Rule became effective on September 15, 2001 through incorporation by reference of 10 CFR. If the license has expired or been revoked, or if the licensee has made a decision to permanently cease principal activities, and the licensee provided DEP notification before September 15, 2001, then September 15, 2001, is considered to be the date for initiating the decommissioning calendar (i.e., date of notification). If there has been a 24-month duration in which no principal activities have been conducted at the location before the effective date of the rule, but the licensee did not notify DEP, then the 24-month time period of inactivity is considered to be initiated on September 15, 2001, and the licensee must provide notification to DEP within either 30 or 60 days of September 15, 2003, (depending on whether the licensee requests a delay).

The inspector should note that the DEP has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failure to notify DEP, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

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Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should contact DEP Central Office management as soon as practicable for further guidance.

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For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG/BR-0241. "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees."

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these DEP communications, when a response is required.

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i. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Department. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embryo/fetus or a nursing child, etc.

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From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to DEP and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for followup and compliance to the appropriate DEP regulatory requirements.

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j. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of remote afterloader equipment for nonmedical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular DEP requirement.

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k. Research Involving Human Subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects", (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy, and 3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

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03.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new

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medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. The licensee may use byproduct material or a radiation source approved for medical use if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the DEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the DEP considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee's license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently verify that such use is authorized under the regulations. If further verification of such use is needed, the region should contact Central Office Licensing Section for further guidance.

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For further inspection guidance, refer to MC 2800.

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Appendices:

A."Decay Factors for Strontium-90 Sources"

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APPENDIX A

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	0.626
	0.623
	0.619
	0.615
	0.611
	0.608
	0.604
	0.6
	0.597
	0.593
	0.589
	0.586
	0.582
	0.579
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	0.562
	0.558
	0.555
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TABLE 1

FRACTION (EXPRESSED AS DECIMAL) OF ORIGINAL
SR-90 ACTIVITY REMAINING AFTER (t) YEARS

Years (t)	df	Years (t)	df	Years (t)	df	Years (t)	df
.25	0.994	6.5	0.854	12.75	0.734	19	0.63
.5	0.988	6.75	0.849	13	0.729	19.25	0.626
.75	0.982	7	0.844	13.25	0.725	19.5	0.623
1	0.976	7.25	0.838	13.5	0.72	19.75	0.619
1.25	0.97	7.5	0.833	13.75	0.716	20	0.615
1.5	0.964	7.75	0.828	14	0.712	20.25	0.611
1.75	0.958	8	0.823	14.25	0.707	20.5	0.608
2	0.953	8.25	0.818	14.5	0.703	20.75	0.604
2.25	0.947	8.5	0.813	14.75	0.699	21	0.6
2.5	0.941	8.75	0.808	15	0.695	21.25	0.597
2.75	0.935	9	0.804	15.25	0.69	21.5	0.593
3	0.93	9.25	0.799	15.5	0.686	21.75	0.589
3.25	0.924	9.5	0.794	15.75	0.682	22	0.586
3.5	0.918	9.75	0.789	16	0.678	22.25	0.582
3.75	0.913	10	0.784	16.25	0.674	22.5	0.579
4	0.907	10.25	0.78	16.5	0.67	22.75	0.575
4.25	0.902	10.5	0.775	16.75	0.666	23	0.572
4.5	0.896	10.75	0.77	17	0.662	23.25	0.568
4.75	0.891	11	0.765	17.25	0.658	23.5	0.565
5	0.886	11.25	0.761	17.5	0.654	23.75	0.562
5.25	0.88	11.5	0.756	17.75	0.65	24	0.558
5.5	0.875	11.75	0.752	18	0.646	24.25	0.555
5.75	0.87	12	0.747	18.25	0.642	24.5	0.551
6	0.864	12.25	0.743	18.5	0.638	24.75	0.548
6.25	0.859	12.5	0.738	18.75	0.634	25	0.545

DEP INSPECTION MANUAL

INSPECTION PROCEDURE 87133

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MEDICAL GAMMA STEREOTACTIC RADIOSURGERY
AND TELETHERAPY PROGRAMS

PROGRAM APPLICABILITY: 2800

87133-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with Pennsylvania Dept. of Environmental Protection (DEP) requirements.

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87133-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The DEP Inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation that could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted

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such that the inspector's presence does not interfere with patient care or a patient's privacy.

Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable, the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

Some of the following areas may not be applicable to all medical gamma stereotactic radiosurgery and teletherapy licensees.

02.01 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below DEP regulatory limits.

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02.02 Shielding of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records, that the licensee's performance has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's

performance has ensured that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, ALARA practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with DEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35, if the licensee has submitted the information required by 10 CFR 35.12(b) through (d), and the licensee has received written approval from the DEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the DEP considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used that have not been specifically amended to a licensee's license. If an inspector encounters such activity and uses, the inspector should contact DEP regional management as soon as practicable to independently verify that such use is authorized under DEP regulatory requirements. If further verification of such use is needed, the region should contact the Central Office Licensing Section for further guidance.

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87133-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with DEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by DEP, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

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Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected

observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records reviewed the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses. Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for those areas of concerns, the records may or may not substantiate his/her concerns. If the inspector substantiates a significant safety concern regarding a particular matter, it may be more appropriate to discuss this matter with DEP, regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation the radiation safety program for that particular element of a focus area.

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If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (e.g., licensee materials inventories), or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information.

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The inspector should keep the licensee apprized of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

Whenever possible the inspector should keep DEP, regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate DEP, guidance under such circumstances.

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Specific Guidance

03.01 Security and Control of Licensed Material

a. Adequate and Authorized Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition as submitted by the licensee in accordance with 10 CFR 35.13. Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

b. Adequate Equipment and Instrumentation. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate, operable, calibrated, adequately maintained, and conform to those described in the license. If appropriate, the inspector should verify that these various systems and checks operate appropriately to ensure compliance to 10 CFR 35.61, 35.615, 35.632, 35.635, 35.642 and 35.645. The inspector should verify that the gamma stereotactic radiosurgery and teletherapy units have been inspected and serviced at the required frequencies by persons specifically licensed to conduct such licensed activities by NRC or an Agreement State.

The inspector should verify that the dosimetry system used to perform full calibration measurements is in accordance with DEP regulatory requirements; and that safety systems are checked as required by DEP regulatory requirements. The inspector should independently check interlock systems, beam condition indicators, and other systems for continuous observation of the patient. For unit operation, the inspector should check the control of console keys. For teletherapy units, the inspector should check the operation of the source head in various orientations. These activities can best be reviewed by the inspector by having an appropriate licensee representative demonstrate how these systems operate while the inspector observes those actions to ensure that the systems operate as designed and that the individual conducting the activity is knowledgeable in those areas. If applicable, the inspector should check any self-contained dry-source-storage irradiators and/or survey instrument calibrators.

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During the conduct of the inspection, if the inspector identifies equipment or instrumentation that has failed to perform as designed, the inspector should ensure that licensee operations are stopped immediately and that such equipment or instrumentation be appropriately repaired and tested prior to the next treatment. In some cases it may be appropriate to contact NRC regional management as soon as practicable to discuss the equipment or instrument failure and determine what appropriate steps should be taken to follow up on this matter.

1. Gamma Stereotactic and Radiosurgery and Teletherapy Unit Inspection, Servicing, Calibration and Spot Checks. Through direct observations made during the onsite inspection, the inspector should visually inspect the control console and unit for indications that alterations may have been performed by unauthorized individuals. These indications may include off-the-shelf switches and timers, as well as wire jumpers and taped micro switches to bypass safety systems of the unit. If the inspector determines that alterations have been performed by unauthorized individuals, the inspector should contact DEP regional management as soon as practicable for further guidance.

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During the inspection, the inspector should ask cognizant licensee staff to demonstrate that stops and electronic controls used to limit the orientation of the head are operational.

During the inspection, the inspector should verify that proper calibration procedures are used for calibrating the gamma stereotactic radiosurgery and teletherapy unit, the unit is calibrated at the required intervals (not to exceed one year), and before first patient use and after source exchange, relocation,

and major repair or modification. The calibration should include all items listed in 10 CFR 35.632 and 635. The inspector should verify that spot checks are conducted at the required frequency, and as required by 10 CFR 35.642 and 645. Furthermore, the inspector should verify that the licensee has performed acceptance testing on the treatment planning system in accordance with 10 CFR 35.657.

2. Additional Requirements for Licensees with Teletherapy Units. If the teletherapy unit observed by the inspector is a Theratron-60 or Theratron-80 with a cast-iron arm, the licensee was required by NRC Bulletin 92-02, to commit to perform the special inspections per Theratronic's revised "Survey and Inspection I 1024 G091G10 REV C."

   If the teletherapy unit is a Picker model C-9 or an Advanced Medical System (AMS) model C-9, the inspector should be aware that a generic malfunction of the source retraction mechanism had been identified as described in Information Notice 99-27.

3. Licensee evaluation of equipment defects or failures to comply that are associated with significant safety hazards. The inspector should verify a licensee developed procedures to identify and report safety component defects and, when needed, the procedures were implemented and DEP is also aware of the report.

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c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with DEP and applicable U.S. Department of Transportation (DOT) and Pennsylvania Dept. of Transportation (PA DOT) regulations and license conditions.

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Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee's procedures for receiving replacement gamma stereotactic radiosurgery and teletherapy sealed sources include how and when they will be picked up, radiation surveys and wipe tests of source containers to be done upon receipt, and procedures for opening source containers (such as the location in the facility where they are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are to be taken if surveys reveal source containers that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If replacement sources arrive during the course of an inspection, the inspector should observe, when practical, personnel perform the package receipt surveys as well as the area surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that recipients of replaced sources are licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer). Generally, this is not a concern because sources are replaced by a service company authorized by DEP, NRC or an Agreement State.

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with DEP, PA DOT, and DOT regulatory requirements for transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported. However, this area is not a concern for most gamma stereotactic radiosurgery and teletherapy licensees because most of them are not authorized to perform these operations.

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For further inspection guidance, the inspector should refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the DEP field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

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e. Material Security and Control. The inspector should determine through direct observations that the treatment room is under constant surveillance or physically secured when not in use. The inspector should discuss with appropriate licensee representatives the licensee's procedures for access controls in order to verify that adequate controls are in place and working effectively.

The inspector should note that for some licensees the key to the unit console is often left in the console over the course of the day dependent on the licensee's patient work load. The inspector should interview appropriate licensee operators to determine their normal control of the console key during the periods that they are away from the console in accordance with 10 CFR 35.610.

f. Written Directives. During the onsite inspection, the inspector should observe and interview individuals as they perform applicable duties to determine that individuals are knowledgeable about the need for written directives and if the licensee's written directives, as implemented, effectively ensure that radiation from byproduct material will be administered as directed by the authorized user in accordance with 10 CFR 35.41. The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with 10 CFR 35.2040.

g. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by DEP regulatory requirements. If necessary, the inspector should conduct a review of selected records to independently verify those discussions with such individuals. If from those reviews a previously unidentified medical event is identified by the inspector, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045, "Report and Notification of a Medical Event;" and 10

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CFR 35.3047, "Report and Notification of an embryo/fetus or a nursing child;" and 2) Upon identification of such an event, the inspector should notify DEP regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

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h. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. The inspector should note that 10 CFR 20.1903 provides exceptions to posting caution signs. During those tours, the inspector should selectively examine signals and alarms to determine adequate operability. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. The inspector should verify that High radiation areas have been strictly controlled to prevent unauthorized or inadvertent access. Such controls for gamma stereotactic radiosurgery and teletherapy units may include, but are not limited to, direct surveillance, locking the high radiation area, warning lights, and audible alarms. Many licenses have received exemptions from the requirement to post the treatment room with the sign "GRAVE DANGER, VERY HIGH RADIATION AREA," required by 10 CFR 20.1902, because of its unsettling effect. This exemption will be noted in the license. The inspector should determine that areas occupied by radiation workers for long periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply in accordance with 10 CFR 19.11, 20.1902, and 21.6.

During tours of the licensee's facility, the inspector should verify that emergency procedures are appropriately posted at the control console in accordance with 10 CFR 35.610.

i. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of teletherapy sealed sources in accordance with 10 CFR 35.67(g). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

03.02 Shielding of Licensed Material. An inspector should determine that a licensee has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

Through observations and interviews, an inspector should determine shielding of the treatment room and radiation levels in the adjacent areas. In an application for a license, an applicant must describe the adjacent areas and the structural shielding of the treatment room and indicate the location of doors, windows, conduits, and other penetrations and voids and provide calculations of estimated radiation levels in the adjacent areas. Applicants also indicate the orientations of the primary beam and the plane of rotation for an isocentric mode of use. A licensee should have maintained the structural shielding so that if the surrounding areas were renovated then the structural shielding of the treatment room was unchanged. In cases where an outside wall of a treatment room was backfilled with earth, an inspector should determine that the height of earth against the outside wall of a treatment room remains unexcavated.

If facility shielding changes are evident, then the inspector should assess the licensee's procedure and process to alter the shielding and the licensee's further evaluation of radiation doses to workers and members of the public respectively under 10 CFR 20.1201, 20.1301, and 20.1302. The inspector should verify that the licensee instructed workers under 10 CFR 19.12 about facility shielding.

03.03 Comprehensive Safety Measures. During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration or the Pennsylvania Department of Labor and Industry.

During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.04 Radiation Dosimetry Program. The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

a. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.

b. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within DEP regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and discussions the inspector determines that a worker had exceeded a DEP regulatory limit, the inspector should immediately contact DEP regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

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10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor in accordance with 10 CFR 20.1501.

03.05 Radiation Instrumentation Surveys and Leak Tests

a. Equipment and Instrumentation

1. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with DEP regulatory requirements and the manufacturer's recommendations.

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The inspector should independently verify through direct observations that survey instruments have been calibrated at the required frequency in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee's that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee's calibration procedures.

2. During the inspection, the inspector should independently verify that the licensee has access to a dosimetry system for performing the full calibration and spot-check measurements of gamma stereotactic radiosurgery and teletherapy unit output. The system must be calibrated in accordance with the requirements of 10 CFR 35.632 and 635. During the inspection, the inspector should review selected dosimetry worksheets from the previous full

calibration measurements required by 10 CFR 35.632 and 635. Mistakes often made by licensees when performing these calibrations are misreading of barometric pressure and using the wrong value for the chamber composition and volume. If the licensee participates in intercomparison of dosimetry measurements, the inspector should review the licensee's performance results to determine that systemic measurement errors are identified and corrected.

3. During the inspection, the inspector should independently check the installed radiation monitors to ensure that they have been maintained in accordance with the applicable requirements. In addition, the inspector should independently verify the operability of permanent radiation monitors, availability of backup power supply, daily checks, service and maintenance of units. During the inspection, the inspector may have cognizant licensee staff demonstrate the operability of those devices to ensure that they perform as designed.

4. When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects.

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b. Area Radiation Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within NRC regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. However, the inspector must use DEP radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the DEP regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

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If practical and when appropriate, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured. When measuring dose rates near a gamma stereotactic radiosurgery and teletherapy unit head, the inspector should not use an open window Geiger-Muller tube, because the depleted uranium used in the trimmer bars, collimators, and shielding is a beta emitter that will cause the survey instrument to give a faulty measurement. The survey activities should be at a specified frequency, in accordance with the related licensee procedures. The inspector should also perform independent confirmatory measurements, as needed to verify licensee assumptions or measurements.

The inspector should verify by independent measurement that shielding surveys of the unit head and treatment room are in compliance with the requirements of 10 CFR 35.652. Indications of higher than expected dose levels by an inspector may indicate that the source is a higher activity than authorized or that the source is not fully shielded on retraction.

c. Source Replacement Surveys. During the conduct of the inspection, the inspector should verify by independent measurement that shielding surveys of the unit head and treatment room are in compliance with the requirements of 10 CFR 35.652. Indications of higher than expected dose levels by the inspector may indicate that

the source is a higher activity than authorized or that the source is not fully shielded on retraction.

If from those discussions and direct observations the inspector determines that individuals do not understand, perform checks or conduct activities appropriately to ensure compliance to DEP regulatory requirements, the inspector should discuss this matter with appropriate licensee representatives as soon as practicable to ensure that previous activities have been conducted appropriately and retraining of the individuals is conducted prior to using such instruments for such surveys.

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d. Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed sources are performed at the required frequency found in 10 CFR 35.67(b). Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.67(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 185 becquerel (0.005 microcurie), the inspector should verify that the licensee made the appropriate notifications per 10 CFR 35.67 (e) and removed the source from service.

03.06 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). The inspector should note that it is the licensee's management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

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Of the training program elements, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that

appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users and supervised individuals understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

b. Operating and Emergency Procedures. Emergency procedures will be developed, implemented and maintained by the licensee in accordance with 10 CFR 35.610 and may vary from step-by-step procedures to more generalized procedures. During the conduct of the inspection, the inspector should verify that these procedures are posted at the gamma stereotactic radiosurgery and teletherapy unit console in accordance with 10 CFR 35.610. During the inspection the inspector should interview operators of the unit to determine that actions required to be performed in the event of abnormal operation of the device are known by such individuals.

Discuss with cognizant licensee representatives, or if practicable, observe licensee personnel conduct periodic tests, especially for scenarios involving events that would require reporting to the DEP under 10 CFR 20.2202. Deleted: NRC

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. The inspector should discuss with cognizant licensee representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

03.07 Management Oversight. The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management, the RSO, and if applicable, the Chairperson of the RSC, and other members of the RSC. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to DEP. This information must be provided whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have taken place. If there have been no changes in the organization since the previous inspection, there is no need to Deleted: NRC

pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and DEP Central Office staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

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Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with DEP regulatory requirements and the licensee's license.

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c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC, if applicable, to implement corrective actions, including termination of operations that pose a threat to health and safety.

2. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees

are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

3. RSC. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should note if the licensee is required to maintain an RSC in accordance with 10 CFR 35.24(f). If applicable, through discussions with cognizant Radiation Safety Committee (RSC) representatives, the inspector should independently verify that topics of discussion during RSC meetings included ALARA reviews, incidents, generic communications, authorized users and uses, safety evaluations, audits, and medical events, as defined in 10 CFR 35.2, etc. From those discussions, the inspector should verify that the committee is made up of representatives from each type of program area, the RSO, a representative of the nursing service, and a representative from management. If time permits, the inspector should review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness.

   From those discussions, the inspector should determine if the RSC has been aggressive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. The inspector should also determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also, the inspector should determine the effectiveness of the RSC to communicate the results of audits and trending analyses to appropriate personnel performing licensed activities.

d. Authorized Users. Authorized users (physicians and medical physicists) may either be named in the license application or appointed by the licensee dependent upon the scope of the licensed program. For those appointed by the licensee, the inspector should independently verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties.

   The inspector should noted that the regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. Also, these regulations do not specifically require that the authorized user be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.27(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

e. Authorized Uses. Through discussions with cognizant licensee staff and direct observations made during tours of the licensee's facilities, the inspector should independently verify that the licensee's use of byproduct material is limited to that which is authorized in the license. Uses of gamma stereotactic radiosurgery or teletherapy units for other than human use would require the licensee to comply with 10 CFR Part 36.

From direct observations of the use of licensed material, discussions with cognizant licensee personnel, and if necessary, a review of selected records, the inspector should determine that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license. The inspector should independently verify that the:

1. Gamma stereotactic radiosurgery and teletherapy source activities do not exceed the maximum activity authorized either in the license or in the design specifications of the device's sealed source device registration certificate.

2. License authorizes depleted uranium shielding if used in the shielding of the gamma stereotactic radiosurgery or teletherapy unit.

f. Financial Assurance and Decommissioning. The decommissioning record keeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100%), to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have been received radiation exposures that exceeded DEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded DEP regulatory limits, the

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inspector should immediately contact DEP, regional management for further guidance.

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Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify DEP. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to DEP. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to DEP. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact Central Office management as soon as practicable from the licensee's site to discuss the situation.

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Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

g. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply.

The inspector should note that the requirements of 10 CFR 30.36, 40.42 and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The Decommissioning Timeliness Rule became effective on September 15, 2001 through incorporation by reference of 10 CFR. If the license has expired or been revoked, or if the licensee has made a decision to permanently cease principal activities, then September 15, 2001, is considered to be the date for initiating the decommissioning calendar (i.e., date of notification). If there has been a 24-month duration in which no principal activities have been conducted at the location before

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the effective date of the rule, but the licensee did not notify NRC, then the 24-month time period of inactivity is considered to be initiated on September 15, 2001, and the licensee must provide notification to NRC within either 30 or 60 days of September 15, 2003 (depending on whether the licensee requests a delay).

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The inspector should note that the DEP has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failure to notify either DEP or NRC, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

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Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should contact DEP Central Office management as soon as practicable for further guidance.

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For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG/BR-0241. "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees."

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these DEP communications, when a response is required.

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i. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Department. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embryo/fetus or a nursing child, etc.

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From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to DEP and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for follow up and compliance to the appropriate DEP regulatory requirements.

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j. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of teletherapy or gamma stereotactic radiosurgery equipment for non-medical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements,

and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular DEP requirement.

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k. Research Involving Human Subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and 3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. In accordance with the regulations in 10 CFR 35.1000, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the DEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the DEP considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee's license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently verify that such use is authorized under the regulations. If further verification of such use is needed, the region should contact the Central Office Licensing Section for further guidance. For further inspection guidance, refer to MC 2800.

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DEP INSPECTION MANUAL

INSPECTION PROCEDURE 87134

MEDICAL BROAD-SCOPE PROGRAMS

PROGRAM APPLICABILITY: 2800

87134-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with Pennsylvania Department of Environmental Protection (DEP) requirements.

87134-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The DEP Inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or a patient's privacy.

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Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable, the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

02.01 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below DEP regulatory limits.

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02.02 Shielding of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records, that the licensee's performance has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has ensured that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, ALARA practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with DEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used. If an inspector encounters such activity and uses, the inspector should contact DEP regional management as soon as practicable. If further verification of such use is needed, the region should contact the Central Office Licensing Section for further guidance.

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87134-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with DEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by DEP, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

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Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records reviewed the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses.

Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for those areas of concerns, the records may or may not substantiate his/her concerns. If the inspector substantiates a significant safety concern regarding a particular matter, it may be more appropriate to discuss this matter with DEP, regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation the radiation safety program for that particular element of a focus area.

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If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (e.g., licensee materials inventories), or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information.

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The inspector should keep the licensee apprised of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

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Whenever possible the inspector should keep DEP, regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate DEP guidance under such circumstances.

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Specific Guidance

03.01 Security and Control of Licensed Material

a. Adequate and Authorized Facilities. Changes to the licensee's facilities since the last onsite inspection should be discussed with licensee representatives since the licensee is allowed to make such changes to their facility without an amendment request in accordance with 10 CFR 35.15(c). Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

b. Adequate Equipment and Instrumentation. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee is appropriate to the scope of the licensed program. The inspector should independently verify through direct observations that survey instruments have been calibrated in accordance with 10 CFR 35.51. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional.

During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected.

1. Licensee evaluation of equipment defects or failures to comply that are associated with significant safety hazards. The inspector should verify a licensee developed procedures to identify and report safety component defects and, when needed, the procedures were implemented and DEP is also aware of the report.

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c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with DEP, and applicable U.S. Department of Transportation (DOT) and Pennsylvania Dept. of Transportation (PA DOT) regulations and license conditions.

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Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has methods for picking up, receiving, and opening packages that address how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are taken if surveys reveal that packages are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should observe, when practical, personnel performing the package receipt surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a small broad-scope facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large broad-scope facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with DEP, PA DOT, and DOT regulatory requirements for transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported.

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For further inspection guidance, the inspector should refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the DEP, field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

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e. Material Security and Control. Through direct observations made during tours of the licensee's facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee has maintained adequate security and control of licensed material. From those observations, the inspector should note areas where radioactive materials are used and stored. From further observations and discussions, the inspector should verify that licensed material in storage, in controlled or unrestricted areas, is secured from unauthorized removal or access. Also, the inspector should verify that the storage areas are locked and have limited and controlled access. For licensed material not in storage, in controlled or unrestricted areas, the inspector should verify that such material is controlled and under constant surveillance or physically secured. Controls may include a utilization log to indicate when, in what amount, and by whom, radioactive material is taken from and returned to storage areas. In addition, the inspector should verify that access to restricted areas is limited by the licensee.

f. Written Directives. During the onsite inspection, the inspector should observe and interview individuals as they perform applicable duties to determine that individuals are knowledgeable about the need for written directives and if the licensee's written directives, as implemented, effectively ensure that radiation from byproduct material will be administered as directed by the authorized user in accordance with 10 CFR 35.32. The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed.

g. Patient Release. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected records, the inspector should determine if a licensee is knowledgeable about patient release criteria and that a process exists to establish that a patient administered radiopharmaceuticals or permanent implants containing radioactive material is releasable from control in accordance with 10 CFR 35.75.

1. The inspector should note that the patient release criteria permits licensees to release individuals from control if the TEDE to any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with 10 CFR 35.75.

2. Through further discussions the inspector should verify that the licensee is familiar with the requirements in 10 CFR 35.75(b) to provide instructions to released individuals if the dose to any other individual is likely to exceed 0.1 rem. The inspector should note that, in general, the licensee is required to give instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable. The inspector may determine how the licensee is demonstrating compliance with this requirement by discussing the content of the instructions with appropriate licensee staff. If concerns are identified from those discussions, the inspector may find it necessary to review the sample instructions given to patients. If the licensee is required by the rule to provide instructions to breast-feeding women, the inspector should verify through further discussions and reviews, if necessary, that the instructions include guidance on the interruption or discontinuation of breast-feeding and information on the potential consequences of failure to follow the guidance.

3. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that if the TEDE to a breast-feeding child could exceed 0.5 rem if the breast-feeding were continued, the licensee has maintained documentation that instructions were provided in accordance with 10 CFR 35.75(d).

h. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by DEP regulatory requirements. If necessary, the inspector should conduct a review of selected records to independently verify those discussions with such individuals. If from those reviews a previously unidentified medical event is identified by the inspector, the inspector should remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.33, "Notifications, reports, and records of misadministrations", Upon identification of such an event, the inspector should notify regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

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i. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. The inspector should determine that areas occupied by radiation workers for long

periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply in accordance with 10 CFR 19.11, 20.1902, and 21.6.

j. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources in accordance with 10 CFR 35.59(g). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

NOTE: *Item k. below only applies to those licensees authorized to possess sufficient* quantities of source or special nuclear materials that the licensee is required to report the receipt, transfer or disposal of these materials to the NRC Nuclear Materials Management and Safeguards System (NMMSS). IMC 2800, Enclosure 7 contains specific guidance.

k. Through interviews with the RSO or other responsible licensee personnel, along with the review of relevant records, verify that the licensee has fulfilled the applicable reporting requirements relating to the NMMSS.

1. Discuss the location of all subject material possessed by the licensee. Compare the licensee's most recent record of physical inventory performed with the information documented in the licensee's NMMSS account on the DOE/NRC Form 742, "Material Balance Report."

2. Review the licensee's records documenting the receipt, transfer or disposal of NMMSS-reportable materials. Compare these records to the NMMSS TJ-45 report. Verify that each set of records properly documents and accounts for any receipt, transfer or disposal of NMMSS-reportable materials that may have occurred subsequently to the most recent filing of the DOE/NRC Form 742 by the licensee.

3. Verify the information listed on the licensee's inventory record by walking down the licensee's facility and (if practicable) visually identifying, at a minimum, a representative sample of the materials that the licensee reports possession of to NMMSS. If appropriate, verify the presence of the subject material with a radiation survey instrument.

NOTE: The inspector should not ask licensee personnel to open any container or otherwise change the container's shielding to facilitate this survey.

4. Review administrative information listed in the NMMSS-provided D-3 report with licensee personnel to ensure that the information is up to date. Verify that licensee personnel are cognizant of the need to make any required changes and the processes available for making any needed corrections.

l. Waste Storage and Disposal. The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less (300 days for sealed NARM sources) and can be decayed in storage until surveys are indistinguishable from background, then be disposed of as non-radioactive waste.

Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify the following areas, when appropriate:

1. Waste disposed in accordance with 10 CFR 35.92;

2. Waste compacted in accordance with license conditions;

3. Waste storage containers properly labeled and area properly posted in accordance with 10 CFR 20.1902 and 20.1904; and

4. Waste was returned from a landfill due to radioactive contamination.

For further inspection guidance, the inspector should refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61"; and Information Notice (IN) 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20."

m. Effluents. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that releases into a public sanitary sewerage system and septic tanks , if any, are consistent with the form and quantity restrictions of DEP regulatory requirements. If the inspector determines that a review of selected records is necessary, the inspector should pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water. If a review of selected records is necessary, the inspector should examine the waste release records generated since the last inspection, annual or semiannual reports, pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records.

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For liquid wastes, the inspector should determine through further discussions, observations and reviews, if necessary, if the licensee has identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complies with the regulatory requirements for disposal into sanitary sewerage.

Through further discussions, direct observations made during tours of the licensee's facility, and reviews, if necessary, the inspector should verify that waste-handling equipment, monitoring equipment, and/or administrative controls

are adequate to maintain radioactive effluents within DEP regulatory requirements and are ALARA (This should include xenon or other gas waste, also).

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For further inspection guidance, the inspector should refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA).".

03.02 Shielding of Licensed Material. Through observations and interviews, an inspector should determine that the licensee implemented appropriate shielding for various processes and types of use, especially for situations when large quantities are handled or when processes involve frequent handling of licensed materials.

a. Process, Engineering Controls, and Hot Cells. Processing equipment, ventilation, and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use. The inspector should evaluate whether the licensee is following license commitments for process and storage systems and equipment, such as glove boxes, hot cells, remote-handling devices, shields and shielding devices, ventilation systems, and retention tanks. For hot cells, the inspector should evaluate the control of entry and egress of personnel, and removal of material and decontamination procedures. For glove boxes, the inspector should evaluate procedures for routine maintenance (leak testing, filter loading, etc.), and removal of material and decontamination procedures. For temporary or portable shielding, the inspector should confirm that the licensee adequately controls movement of the shielding to prevent inadvertent or unauthorized removal.

   The inspector should review the adequacy of shielding during maximum loading of hot cells and gloveboxes. Verify, by surveying the areas near manufacturing processes to ensure the continued adequacy of shielding. If the licensee initiates new processes in existing hot cells or gloveboxes, verify that the licensee has evaluated the adequacy of shielding before beginning the new process.

b. Shielding for Large Quantities of Bulk Material. Verify that the licensee maintains adequate shielding for large quantities of stock or bulk radioactive materials. Verify that such shielding cannot be easily removed or opened. Verify that the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads. Ensure that licensee personnel are aware of lifting equipment load limitations and that the limitations are not exceeded.

c. Unit Shielding. Verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials (i.e., vials, syringes, individual sources, etc.) and that licensee personnel use the shields when handling the containers. Unshielded containers of hard-beta and gamma-emitting radionuclides should not be directly handled by personnel. ("hard-beta" means 500 keV average or greater, if the average beta energy is unknown use 1.0 MeV beta maximum or greater) Verify that unit shields are adequate for the quantities of radioactive materials typically contained therein.

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d. Shielding of Transferred Materials. Verify that the shielding included in packaging of materials that are transferred within the confines of the licensee's facility or to a carrier for transport/transfer to an off site location conforms to that described in the

SSD registry or license documents, as appropriate. The licensee may not make changes to the size, shape, or contents (i.e., lead versus stainless steel) of the shielding materials without prior approval of the NRC or the Agreement State that approved the registry, as applicable. Observe SSD that are ready for shipment and verify that the external radiation levels are consistent with the registry sheet/license document. Otherwise, determine that DOT requirements for shielding are met.

e. Shielding During Routine and Non-Routine Maintenance. By interviewing selected maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine that maintenance personnel verify, either through their own or health physics staff surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from equipment, entering rooms or areas (such as bunkers or hot cells) normally posted as high radiation or very high radiation areas, or entering tanks or vessels that normally contain or have contained radioactive materials. Verify that shielding removed for maintenance and opened access panels are properly replaced prior to lifting of maintenance holds when equipment is returned to service.

   For maintenance activities that include potentially significant radiological conditions, such as high dose rates (>100 millirem per hour general area or > 1 rem per hour contact) or contamination levels (>100,000 disintegrations per minute per 100 square centimeters), determine whether the licensee has established more stringent radiation work permit (RWP) requirements, such as more detailed pre-job briefing of personnel, appropriate protective clothing, and/or constant job coverage by a health physics technician.

03.03 Comprehensive Safety Measures. During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration or the Pennsylvania Department of Labor and Industry.

During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.04 Radiation Dosimetry Program. The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

a. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.

b. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within DEP regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and discussions the inspector determines that a worker had exceeded a DEP regulatory limit, the inspector should immediately contact DEP regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

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10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor.

Through discussions with cognizant licensee representatives and a review of selected records, the inspector should evaluate the adequacy of the licensee's methods used to assess the SDE to the portion of the skin of the extremity expected to have received the highest dose. The inspector should give particular attention to the distance between the location that is likely to have received the highest dose when sources are manipulated manually (even when shields are used) and where the extremity monitor is worn.

d. Internal Dosimetry. Through interviews with cognizant licensee representatives, and records review, if appropriate, verify that measurements for internal deposition of licensed materials are performed and evaluated in accordance with 10 CFR 20.1501.

03.05 Radiation Instrumentation Surveys and Leak Tests.

a. Equipment and Instrumentation

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are

appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with DEP regulatory requirements and the manufacturer's recommendations. The inspector should verify that:

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(a) The radiation survey instruments have been calibrated in accordance with10 CFR 35.51;

(b) The instruments used to measure the activity of unsealed byproduct material meet the requirements of 10 CFR 35.51; and

(c) Licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with 10 CFR 35.204, to ensure that humans are not administered a pharmaceutical containing more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m.

The inspector should independently verify through direct observations that survey instruments have been calibrated at the required frequency in accordance with 10 CFR 35.51. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee's that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee's calibration procedures.

2. When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects,

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b. Area Radiation Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within DEP regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. However, the inspector must use DEP radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the DEP regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

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If practical and when appropriate, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

c. Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed or contained sources are performed at the required frequency found in 10 CFR 35.59(b) or license conditions. Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review

of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.59(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels) or approved level included in a license condition, the inspector should verify that the licensee made the appropriate notifications per 10 CFR 35.59 (e) and removed the source from service.

03.06 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). The inspector should note that it is the licensee's management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of DEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of DEP requirements. Also, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

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Of the training program elements, training given to authorized users and nuclear pharmacists, and those individuals under the supervision of authorized users and nuclear pharmacists, is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users, authorized nuclear pharmacists and supervised individuals understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, "dry runs" for more complex or hazardous operations, and for authorized nuclear pharmacists instruction in the preparation of radioactive drugs.

b. Operating and Emergency Procedures. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if

necessary, a review of selected records, the inspector should verify that licensee staff are knowledgeable in conducting licensed activities in accordance with the licensee's operating procedures.

Discuss with cognizant licensee representatives, or if practicable, observe licensee personnel conduct periodic tests, especially for scenarios involving events that would require reporting to the DEP, under 10 CFR 20.2202.

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Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. The inspector should discuss with cognizant licensee representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

c. Safety Instruction for Personnel Caring for Non-Releasable Patients. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee provides radiation safety instruction for all personnel caring for patients who cannot be released under 10 CFR 35.75, in accordance with10 CFR 35.310. The inspector should note that radiation safety instruction must be conducted initially and at least annually an be commensurate with the duties of the personnel.

d. Specialized Training. The inspector should note that specialized instruction required in 10 CFR 35.25 was provided to supervised users using material for medical uses or preparing byproduct material for medical use. The inspector should note that authorized users and research laboratory personnel should receive periodic radiation safety training commensurate with their use of licensed materials. For example, these individuals should know how and when to use radiation survey instrumentation, fume hoods, and protective gear. They should know procedures concerning waste disposal, bioassays, surveys, inventories, etc. Also, if the licensee uses licensed material for therapeutic purposes, training specific to the types of therapy performed should be provided to the nursing staff and others caring for these patients. This training should include personnel who do not directly deal with patients, such as housekeeping, maintenance, security, etc. The training should also include such topics as contamination control, ALARA, emergency procedures, and sealed source identification. The inspector should determine that personnel are appropriately trained through interviews, demonstration, and direct observation of licensed activities.

e. Protective Clothing. Through direct observations of licensed activities and discussions with cognizant licensee representatives, the inspector should verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed. The observation of the protective clothing that research lab personnel or other applicable staff wear during their work activities should provide the inspector with an acceptable means of reviewing this requirement. If the inspector identifies a concern with this practice, the inspector should discuss this practice with appropriate licensee representatives to ensure that licensee staff are following licensee procedures for wearing adequate protective clothing.

03.07 Management Oversight. The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management, the RSO, and the Chairperson of the RSC, and other members of the RSC. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to DEP. This information must be provided whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have taken place. If there have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and DEP central office staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

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Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials Inspection Program," and regional policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector

determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with DEP regulatory requirements and the licensee's license. Deleted: NRC

In reviewing the scope of the licensee's program in this area, the inspector should discuss information that includes the numbers of laboratories, permit holders, lab personnel, and locations of use; human research and medical use activities; mobile nuclear medicine services; distribution of pharmaceuticals under 10 CFR Part 35 license; and principal types and quantities of licensed materials used.

c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC, if applicable, to implement corrective actions, including termination of operations that pose a threat to health and safety.

2. RSC. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should note if the licensee is required to maintain an RSC in accordance with 10 CFR 35.22. If applicable, through discussions with cognizant Radiation Safety Committee (RSC) representatives, the inspector should independently verify that topics of discussion during RSC meetings included ALARA reviews, incidents, generic communications, authorized users and uses, safety evaluations, audits, and medical events, as defined in 10 CFR 35.2, etc. From those discussions, the inspector should verify that the committee is made up of representatives from each type of program area, the RSO, a representative of the nursing service, and a representative from management. If time permits, the inspector should review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness.

   From those discussions, the inspector should determine if the RSC has been aggressive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. The inspector

should also determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also, the inspector should determine the effectiveness of the RSC to communicate the results of audits and trending analyses to appropriate personnel performing licensed activities.

Broad-scope medical programs may be authorized to conduct research involving the use of radioactive drugs or radiation-emitting devices in humans. Such research may require U.S. Food and Drug Administration (FDA) approval. In addition, approval to conduct research studies also requires input from an IRB, an RDRC, or other appropriate committee(s), including the RSC. The inspector should confirm that the licensee has received FDA approval, if required, and that studies involving the use of radioactivity in humans have been reviewed by the appropriate committee(s). The inspector should review the interaction between the RSC and the IRB and/or RDRC to assure compliance with the requirements in 10 CFR 35.6 as further discussed below in Section 3.10.K.

3. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Authorized Individuals. Authorized individuals (physicians, nuclear pharmacists, and medical physicists) are appointed by the licensee. The inspector should independently verify that the authorized individual meets the training and experience criteria in Part 35, are trained in accordance with the approved criteria, and have knowledge commensurate with operational duties.

The inspector should noted that the regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. Also, these regulations do not specifically require that the authorized user be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.25(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

Authorized users of licensed material for non-human use are generally designated by the RSC. The inspector should review the process of approving users through interviews with users, RSC members, and the RSO. The procedure for

designating users can be found in the license documents. Verify that the authorized user received training in accordance with approved criteria and/or Part 35, and has knowledge commensurate with operational duties.

e. Authorized Uses. Through discussions with cognizant licensee staff and direct observations made during tours of the licensee's facilities, the inspector should independently verify that the licensee's use of byproduct material (e.g., cell labeling, iodinations, animal research) is limited to that which is authorized in the license.

f. Financial Assurance and Decommissioning. The decommissioning recordkeeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100%), to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have been received radiation exposures that exceeded DEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded DEP regulatory limits, the inspector should immediately contact DEP regional management for further guidance.

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Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify DEP. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be

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sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to DEP. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to DEP. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact Central Office management as soon as practicable from the licensee's site to discuss the situation.

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Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

g. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply.

The inspector should note that the requirements of 10 CFR 30.36, 40.42 and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The inspector should note that the DEP has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failure to notify DEP, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

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Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should contact Central Office management as soon as practicable for further guidance.

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For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG/BR-0241. "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees."

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these DEP communications, when a response is required.

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i. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Department. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embryo/fetus or a nursing child, etc.

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From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to DEP and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for follow up and compliance to the appropriate DEP regulatory requirements.

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j. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of equipment for nonmedical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular DEP requirement.

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k. Research Involving Human Subjects. The inspector should verify through discussions with cognizant licensee representatives if research is conducted involving human research subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and 3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new

medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. The licensee may use byproduct material or a radiation source approved for medical use if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the DEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the DEP considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee's license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently verify that such use is authorized under the regulations. If further verification of such use is needed, the region should contact the Central Office Licensing Section for further guidance.

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For further inspection guidance, refer to MC 2800.

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INSPECTION PROCEDURE 92701

FOLLOW-UP

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PROGRAM APPLICABILITY: 2800

92701-01 INSPECTION OBJECTIVE

To ensure that follow-up inspection is performed for:

01.01 Unresolved items.

01.02 Open items.

01.03 Headquarters and regional requests.

01.04 Other follow-ups.

92701-02 INSPECTION REQUIREMENTS

02.01 Unresolved Item Follow-up. Evaluate the follow-up of unresolved items with respect to status of resolution, quality of resolution, and, if unresolved, the cause of delay, effort expended to resolve, and estimated resolution date.

02.02 Open Item Follow-up. Evaluate the follow-up of open items with respect to status of completion, expediency of completing the open item, and effectiveness of completion.

02.03 Headquarters or Regional Requests Follow-up. Take actions as appropriate to follow-up and complete headquarters or regional requests.

02.04 Other Follow-ups. Take actions as appropriate to perform other follow-ups.

92701-03 INSPECTION GUIDANCE

General Guidance. This procedure encompasses the follow-up of items applicable to all phases of the inspection program with the exception of those items already determined to be a violation or deviation, non-routine events, or those items whose performance is required by confirmatory action letters.

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For items resulting from previous inspection effort, follow-up performed using this procedure shall be reported under the number of the procedure in which the item was initially identified. Any other follow-up effort conducted utilizing this procedure shall be reported under procedure number 92701.

The periodicity for the performance of these follow-up items varies, depending upon the nature of the item. The follow-up periodicity shall be as follows:

a. Unresolved and open inspection items shall require follow-up soon after they are identified. Efforts are to be made to minimize the time needed to close out these items. It is recognized that follow-up time for these items is dependent upon the cooperation and effort expended by the licensee.

b. The follow-up of all other items included in this procedure shall be performed strictly on a when required basis, at the discretion of the inspector. [Documentation of any follow-up inspections shall be in accordance with the original procedures, except that for data entry into eFACTS, the type of inspection shall be entered as "follow-up" ("FLWUP" from list of values table).]

Specific Guidance

03.01 Unresolved Item Follow-up. An unresolved item is a matter about which more information is required in order to ascertain whether it is an acceptable item, a deviation, or a violation. Although a problem may not exist, the matter is to be resolved to the extent that the inspector can determine that the facility will not be operated in an unsafe manner before leaving the site.

03.02 Open Item Follow-up. An open item is a matter that requires further review and evaluation by an inspector. It is used to document, track, and ensure adequate follow-up on matters of concern to the inspector.

03.03 No inspection guidance.

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DEP INSPECTION MANUAL

MANUAL CHAPTER 0300

ANNOUNCED AND UNANNOUNCED INSPECTIONS

0300-01 PURPOSE

This chapter describes the policy to be followed in determining if inspections should be announced or unannounced to a licensee or vendor before the inspector arrives at the site of inspection.

0300-02 POLICY

The general policy for non-reactor inspections (fuel cycle and radioactive material inspections) is that inspections will be unannounced, unless this results in the DEP using its inspectors inefficiently.

The general policy for accelerator, X-ray, and MQSA inspections is that all routine inspections will be announced and scheduled, so as not to disrupt normal operations at these facilities. Non-routine inspections, e.g., follow-up inspections, at these facilities may be scheduled and announced.

The DEP will consider each policy exception individually after considering the affect on the facility, inspection objectives, and DEP inspectors.

These general policy statements may be modified by specific program policies in DEP Inspection Manual Chapters.

0300-03 DEFINITIONS

03.01 Announced Inspection. An inspection in which the Department notifies the licensee or vendor of the inspection before it is conducted. The advance notification may be made by a written communication, telephone call, or other communication made available to the appropriate level of management in the licensee's or vendor's organization and should include the approximate date, broad subject area, and type of inspection planned.

03.02 Unannounced Inspection. An inspection in which the Department does not notify the licensee or vendor of the inspection until the inspector arrives at the site where the inspection is to be conducted.

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Deleted: The general policy for the reactor inspection program is that each ¶ inspection (except those by resident inspectors) shall be announced ¶ except when announcing the inspection could reasonably compromise ¶ the objectives of the inspectors. ¶
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0300-04 APPLICABILITY

All regional and central office staff shall comply with the statements of policy in this manual chapter.

0300-05 DISCUSSION OF POLICY

05.01 General. Unannounced inspections allow inspectors to observe licensee or vendor personnel performing licensed activities under normal circumstances. The DEP would typically not announce inspections in which a significant portion of the inspection is devoted to evaluating licensee personnel perform specific licensed tasks such as security and health physics activities. However, the DEP would typically announce inspections that consist primarily of reviewing documents or verifying completed activities.

Announced inspections permit both the DEP and the licensee to plan for inspections, to avoid unnecessary impacts caused by multiple activities scheduled closely together. The inspector may not be able to complete the objectives of an inspection if the records or personnel of the licensee or vendor are not available when the inspector arrives at the inspection site.

05.02 Radioactive materials facility policy. The general policy for the radioactive materials inspection program is that inspections should be unannounced. This ensures that it is unlikely that advance notification of planned DEP inspections would enable the licensee to alter its activities significantly in such a manner that would prevent the DEP from achieving its inspection objectives. Decisions on whether to announce an upcoming inspection are the responsibility of the program manager, but may be delegated to the appropriate section chief.

05.03 Advanced Notifications. Advanced notification should include only the approximate date, the broad subject area, and the type of inspection planned. Examples of broad subject areas include electrical distribution system functional inspection (EDSFI), emergency preparedness exercise, startup testing, training, and operations. The types of inspection are routine, team, and reactive. Specific inspection areas are not identified in advance.

If a licensee requests the DEP to defer an announced inspection, the staff should consider the effect on the licensee against the effect on the ability of the inspectors to achieve their objective and the availability of DEP resources.

After providing advanced notification to the licensee, the DEP may need to obtain information to prepare adequately for the upcoming inspection. If requesting this information will indicate specific aspects of the inspection, the information should be requested close to the start of the inspection while providing sufficient time for the licensee to gather the information and for the inspector to prepare. The staff should usually request this information less than one month before the inspection.

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05.04 Unannounced Inspections. Inspectors should avoid following inspection patterns and practices in such a way that a licensee can predict when unannounced inspections will be performed. Inspection patterns may enable licensees to predict the time of inspections and prepare for the inspection of the working area, records, or other items.

a. Patterns of Visits. The staff should schedule unannounced inspections at irregular intervals (within the constraints of inspection schedule requirements) to avoid patterns that would enable the licensee to predict the date on which the inspection will be next performed.

b. Patterns of Travel. Employees of motels or hotels may be sources of information for licensees. The inspectors should occasionally vary travel plans and arrangements to the extent possible.

c. Patterns of Inspection Performance. To ensure that the licensee will not have the opportunity to prepare working areas, documents in use, and other items during the unannounced inspection, the inspection of the facility should start shortly after arriving on site. The inspector should vary the order of onsite activities so that the first several hours at the facility are not always spent meeting with management and reviewing records. The inspectors should conduct required walk-through inspections or inspections of working areas as soon as practicable after arriving at the site. The inspectors should also perform some of the inspection at times other than during the day shift.

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Reactor Policy. The NRC power reactor inspection program provides continuing observation and verification of the licensee's capability to safely design, build, and operate a nuclear power plant. The NRC verifies this assessment by assigning regional and headquarters inspectors to participate in various team and individual inspections. The NRC also relies on the resident inspectors who are present full-time to observe and evaluate

licensee's activities in a direct and unannounced manner. The resident inspector inspects all types of activities, including those conducted during the weekend, late evening, and early morning. This comprehensive method of conducting inspections ensures that it is unlikely that advance notification of planned inspections would enable the licensee to alter its activities significantly in such a manner that would prevent the NRC from achieving its inspection objectives.

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DEP INSPECTION MANUAL

MANUAL CHAPTER 0610

RADIOACTIVE MATERIAL SAFETY AND SAFEGUARDS INSPECTION REPORTS

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INSPECTION REPORTS

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0610-01 PURPOSE

To provide guidance on inspection report content, format, and style for radioactive material and safeguards inspection reports.

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0610-02 OBJECTIVES

To ensure that inspection reports:

02.01 Clearly communicate significant inspection results to licensees, DEP staff, and the public.

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02.02 Provide conclusions about the effectiveness of the programs or activities inspected. The depth and scope of the conclusions should be commensurate with the depth and scope of the inspection.

02.03 Provide a basis for enforcement action.

Note: see BRP Compliance and enforcement policy.

Deleted: NOTE: NUREG-1600 is the NRC Enforcement Policy. The NRC Enforcement Manual (NUREG/BR-0195) gives specific guidance on addressing noncompliance in inspection reports.

02.04 Assess licensee performance in a periodic, short-term context, and present information in a manner that will be useful to DEP management in developing longer-term, broad assessments of licensee performance.

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0610-03 DEFINITIONS

Apparent violation. A potential noncompliance with a regulatory requirement that has not yet been cited as a violation in a Notice of Violation or Order.

Certificate Holder. An entity responsible for meeting certain NRC requirements defined in an NRC-issued Certificate of Compliance (e.g., 10 CFR Part 71 or Part 72).

Conclusion. As used in this chapter, an assessment that relates one or more findings to the broader context of a licensee program.

Deviation. A licensee's failure to satisfy a regulatory commitment.

NOTE: For 10 CFR Part 21 and vendor inspections, the term "deviation" generally refers to the definition given in Part 21 (i.e., "a departure from the technical requirements included in a procurement document").

Draft Inspection Report. Any version of the inspection report before its official issuance.

Escalated Enforcement Action. A Notice of Violation for any Severity Level violation (or problem), or a civil penalty or order based on a violation.

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Finding. As used in this chapter, an observation that has been placed in context and assessed for significance.

Inspection. The examination and assessment of any licensee activity to determine its effectiveness, to ensure safety, and/or to determine compliance. A single inspection report may encompass resident inspection, in-office document review, and/or one or more visits by regional or central office inspectors; however, a single report is normally limited to a specific period of inspection.

Inspection Document. Any material obtained or developed during an inspection that is considered to be a DEP record (see below).

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Integrated Inspection Reports. A facility inspection report that combines inputs from all inspections (regional, central office, cross program etc.) conducted within a specific period.

Licensee. The applicant for or the holder of an DEP license or permit. The provisions listed as applicable to "licensees" in this chapter are also applicable to vendors and certificate holders.

Minor Violation. A violation that is not the subject of formal enforcement action, and not usually described in inspection reports or inspection records.

Non-Cited Violation (NCV). A violation which the staff has exercised discretion to refrain from issuing a Notice of Violation.

Noncompliance. A violation, non-cited violation, deviation, or nonconformance.

Nonconformance. A vendor's or certificate holder's failure to meet a contract requirement related to DEP activities, where the DEP has not placed the requirement directly on the vendor or certificate holder.

Notice of Violation (NOV). A formal written citation in accordance with the Act that sets forth one or more violations of a legally binding regulatory requirement.

DEP Record. Any written, electronic, or photographic record under legal DEP control that documents the policy or activities of the DEP or a DEP licensee).

Observation. A fact; any detail noted during an inspection.

Potentially Generic Issue. An inspection finding that may have implications for other licensees, certificate holders, and vendors whose facilities or activities are of the same or similar manufacture or style.

Regulatory Commitment. An explicit statement to take a specific action, agreed to or volunteered by a licensee, where the statement has been submitted in writing to the DEP. This may include a commitment in the licensee's application, a response to a Notice of Violation, etc.

Requirement. A legally binding obligation such as a statute, regulation, license condition, technical specification, or order.

Vendor. A supplier of products or services to be used in a licensed facility or activity. In some cases, the vendor may be an NRC, DEP or Agreement State licensee (e.g., nuclear fuel fabricator, radioactive waste broker) or the vendor's product may be required to have an NRC Certificate of Compliance (e.g., certain transport packages such as spent fuel casks or radiography devices).

Violation. The failure to comply with a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification.

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0610-04 RESPONSIBILITIES

All DEP inspectors are required to prepare inspection reports in accordance with the guidance provided in this Inspection Manual Chapter. General and specific responsibilities are listed below.

04.01 General Responsibilities: Each inspection of a licensee, vendor, and certificate holder shall be documented. A narrative inspection report consisting of a cover letter, a cover page, a summary, and inspection details as appropriate is required for escalated enforcement actions. Otherwise, refer to Appendixes A-D for normal Division-specific reporting requirements.

04.02 Report Writing

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a. Inspectors have the primary responsibility for ensuring that observations and findings are accurately reported, that referenced material is correctly characterized, and that the scope and depth of conclusions are adequately supported by documented observations and findings. Advice and recommendations are not to be included in inspection reports.

b. Inspectors are responsible for ensuring that the content and tone of the report, as issued, is consistent with the content and tone of the exit meeting presentation. When the report differs significantly from the exit meeting, the inspector (or the report reviewer) should discuss those differences with the licensee before the report is issued.

c. Report writers and reviewers should ensure that inspection reports follow the general format given in this chapter or the applicable appendix based on the type of inspection.

d. For inspections conducted by regional and resident inspectors, the report numbers should be issued per regional instructions and should be consistent with Departmental templates.

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Deleted: For inspections conducted by NMSS, the report number is in the following form: Docket No./Year (last two digits)-2 followed by the sequential number of the report in that year. For example, in February 2004 an inspector from the Spent Fuel Project Office completed an inspection of a licensee (Docket No. 07100115). The inspection was the first inspection in calendar year. The inspection report number is 07100115/04-201)

04.03 Report Review and Concurrence

a. Before issuance, each inspection report should, as a minimum, be reviewed by a member of DEP management familiar with the requirements in the area inspected.

b. The report reviewer (i.e., the member of management referred to above) should establish that conclusions are logically drawn and sufficiently supported by observations and findings, and that the observations, findings, and conclusions are consistent with DEP policies and requirements.

c. The report reviewer should ensure that assessments made in the inspection report represent the judgment of the issuing organization and established DEP policy rather than solely the personal views of an individual inspector or group of inspectors.

d. Regional Managers and Bureau Section Chiefs should establish internal procedures to provide a record of inspectors' and reviewers' concurrences. The procedures should address how to ensure continued inspector concurrence when substantive changes are made to the report as originally submitted, and how to treat disagreements that occur during the review process. As a minimum, substantial changes should be discussed with the inspector or inspectors involved to ensure continued concurrence, and disagreements that cannot be adequately resolved should be documented.

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04.04 Report Issuance

a. For regional inspection reports, the applicable regional program manager or designated section chief is responsible for the report content, tone, conclusions, and overall regulatory focus.

b. For central office inspection reports, the applicable division chief or designated section chief is responsible for the report content, tone, conclusions, and overall regulatory focus. Where applicable, central office report distribution should be consistent with that of the regions.

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04.05 Report Timeliness

a. General Timeliness Guidance. Inspection reports should be issued within time frames set by the Department. Typically, reports are issued no later than 30 calendar days after inspection completion or 45 calendar days for team inspections.

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NOTE: Inspection completion is normally defined as the day of the exit meeting. For integrated or resident inspection reports, inspection completion is normally defined as the last day covered by the inspection report.

b. Reports Preceding Escalated Enforcement Actions. Timeliness goals should be accelerated for inspection reports covering potential escalated enforcement actions. For specific enforcement timeliness goals, see the Radiation Protection Compliance and Enforcement Policy.

c. Expedited Reports for Significant Safety Issues. Whenever an inspector identifies an issue involving significant or immediate public health and safety concerns, the first priority is facility and public safety; issues of documentation or enforcement action are secondary. Based on the circumstances of the case, an expedited inspection report may be prepared that is limited in scope to the issue, or expedited enforcement action may be taken before the inspection report is issued. The Radiation Protection Compliance and Enforcement Policy provides additional guidance on matters of immediate public health and safety concern.

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0610-05 GUIDANCE FOR INSPECTION REPORT CONTENT

This section provides general guidance on the contents of an inspection report for radioactive materials and safeguards inspections. Appendices A - D contain specific guidance and examples for the preparation of inspection reports based on major materials programs. Appendix E provides Inspection writing style guidance.

The regions and divisions may prepare additional instructions or guidance on inspection reports based on the specific needs of the programs that they manage. Inspection reports that are prepared by the regions or divisions should take into consideration the additional specific guidance prepared by their respective organization.

The DEP Inspection Report is the document that states the official Agency position on what was inspected, what the inspectors observed, and what conclusions were reached relating to the inspection.

All enforcement, routine and escalated, and all other Agency actions which may derive out of an inspection (such as Orders) will be based upon the associated inspection report. Inspection reports must be clear, accurate, consistent and complete.

The package created to document a DEP inspection will usually consist of two or three separate documents, as appropriate. In essentially all cases, there will be a cover letter and the inspection report itself. When warranted by the inspection findings, there should also be a Notice of Violation.

The inspection report itself will normally contain a cover page, a summary and a set of report details. The report details will typically describe each specific area of inspection activity in three parts: the scope, the observations/findings, and the conclusions.

A cover letter is used to transmit the inspection report results. The cover letter must never contain any significant information, which is not also contained in the summary and supported in the report details.

The summary section of the inspection report highlights the most significant conclusions. These are usually organized into sections by inspection area, corresponding to the sections of the report. There may be conclusions in the body of the inspection report, which are of minor significance, so it is not necessary that every conclusion in the report details be repeated in the summary. There should never be any conclusions in the summary, however, which are not clearly and directly derived from the detailed discussion.

05.01 Cover Letter. The purpose of the cover letter is to transmit the inspection report results. Inspection reports are transmitted using a cover letter from the applicable DEP Regional Office to the designated licensee executive.

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a. Cover Letter Content. Cover letter content varies somewhat depending on whether the inspection identified findings. In general, however, every cover letter has the same basic structure, as follows:

Addresses, Date, and Salutation. Usual and appropriate DEP stationery and formatting apply.

For cover letters transmitting reports with findings assigned an enforcement action, its identification should be placed with the principal addressee's name and address. Additionally, the Nuclear Materials Events Database (NMED) number, if applicable, should also be included on the document after the enforcement identification. Reports associated with complaints, from DEP's Complaint Tracking System (CTS), the number assigned to the complaint should be placed in this letter.

The name and title of the principal addressee are placed in accordance with DEP format standards, followed by the licensee's name and address and license number(s). Note that the salutation is placed after the subject line.

b. Subject Line. The subject line of the letter should state the facility name (if it is not apparent from the Addressee line) and inspection subject. The words "NOTICE OF VIOLATION" (or "NOTICE OF DEVIATION," etc.) should be included if such a notice accompanies the inspection report.

c. Introductory Paragraphs. The first two paragraphs of the cover letter should give a brief introduction, including the type of inspection report.

d. Body. In keeping with the "Plain English Initiative," the body of the letter should discuss the most important topics first.

The cover letter is written to transmit the inspection report to the licensee's management, and to deliver the "big picture" message regarding the inspection. Because it is the highest-level document, it does not need to (and normally won't) detail all the items inspected and the inspection procedures used. It will note the areas covered by the inspection.

The tone of the cover letter must have a correct balance. The DEP focuses on performance issues. If a licensee performed some activity 100 times, and succeeded 99 times, we will be most interested in the single failure. But that does not mean that the cover letter will make it appear that the licensee rarely succeeded. The safety and regulatory significance of any licensee failure will be a primary consideration, above and beyond the numerical frequency of failure compared to success.

The cover letter must always be consistent with the inspection report. In addition, it must be consistent with the information, which the inspector conveyed to licensee managers at the exit meeting. If the inspector's understanding of the facts, or the perspective on the nature or significance of our findings changes after the exit meeting, the DEP shall call the licensee and re-exit. There should never be any surprises in a cover letter to anyone who was present at the exit meeting.

Lastly, the cover letter may contain recommendations. However, there shouldn't be any statements to the effect, "The licensee needs to...." or, "The licensee should...." If the licensee is not meeting safety or regulatory requirements, the statements should clearly show those facts. If the DEP believes that a licensee cannot ensure the safety of its activities, then an Order or some similar official action may be appropriate. Guiding licensee decision-making through the use a cover letter to an inspection report is not the appropriate method for accomplishing this type of action.

e. Closing. The final paragraph consists of standard legal language that varies depending on whether enforcement action is involved.

The signature of the appropriate DEP official is followed by the , , enclosures, and distribution list.

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05.02 Notice of Violation. Licensees are officially notified that they have failed to meet regulatory requirements when DEP issues a Notice of Violation (NOV). , NOVs may be sent to licensees as part of a package of documents which also includes a cover letter and associated inspection report. NOVs may be sent with a cover letter which refers to an inspection report that was distributed previously. An NOV should not be sent to the licensee in advance of the final inspection report.

Every NOV must be clear, so that there is little doubt that the licensee (or other interested reader) can understand the basis for the violation. The licensee may not agree with our basis, but they must understand our position.

Every NOV must clearly state what the requirement was that was not met. That may mean that the date and revision number of the applicable document will need to be provided. Then, a clear statement of what happened (including when, if the timing is important) will be provided. The intention is that any interested reader will be able to clearly see and understand what the requirement was and how it was not met. For additional guidance on documenting violations, refer to the Radiation Protection Compliance and Enforcement Policy. The NOV should be an enclosure to the cover letter. Additional guidance on enforcement actions is found below.

05.03 Cover Page. The report cover page gives a quick-glance summary of information about the inspection. It contains the license/certificate number, facility name, dates of inspection, names and titles of participating inspectors, and name and title of the approving Regional Manager.

05.04 Summary. The Summary will contain the important conclusions reached by DEP as a result of performing the inspection. The statements provided in this section may duplicate or condense the conclusions provided in the various separate sections of the report details. There should never be anything in the Summary which is new or different from the information provided in the detailed discussion. Not every conclusion contained in the inspection report needs to be repeated in the Summary, but the important conclusions, which would provide the bases for the results of the inspection stated in the cover letter should be included.

05.05 Table of Contents. For reports that are considered complicated or are of significant length (i.e., the Report Details section to the Exit Interview section is more than 20 pages long), the writer should include a table of contents as an aid to clarity.

05.06 Report Arrangement. The applicable example of report arrangements as shown in Appendices A-D should be used, as appropriate.

05.07 Report Details. The detailed discussion in the report provides the information which forms the bases upon which the other sections of an inspection report are developed. In most cases, the detailed discussion will be organized into one or more sections, each addressing an area of inspection. Each area will in turn be divided into three parts: scope, observations and findings, and conclusions. These are discussed in more detail below.

a. Inspection Scope. The "Scope" portion of each area inspected will describe what was inspected. In most cases, the approach that can be used in writing the scope should be consistent with the Inspection Procedure (IP) which was used in performing that portion. Much of the writeup can be extracted from the "Purpose" section(s) of the applicable IP. When describing the Scope, it is acceptable to state either what the inspector(s) did, or what the inspection accomplished. That is, a Scope section could be phrased, "This inspection included a review (or observation, or evaluation, etc.) of...."or it could be written as, "The inspectors reviewed (observed, evaluated) the...." The Scope statements might also describe why certain items were inspected. For example, "...to determine compliance with...."

The Scope section should not duplicate any portion of the Findings section. Therefore, when findings are identified, much of the required detail listed below

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should be stated only in the Findings section, resulting in a much shorter Scope section.

When no findings are identified, the Scope section should, when germane to the inspection, include (1) how the inspection was conducted (i.e., the methods of inspection), (2) what was inspected, (3) approximately when each activity was performed, (4) where the inspection took place (i.e., what room(s) or buildings), as well as, (5) the inspection objectives and/or criteria for determining whether the licensee is in compliance.

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b. Observations and Findings. The observations and findings are the foundation of every inspection report. They derive from performing inspections according to the applicable IP. There should always be a readily-identifiable connection between the stated Scope and the reported observations and findings. Thus, if the Scope was to review personnel dosimetry records, the observations and findings will not be about packaging and shipping problems.

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Observations and findings will be descriptive, and will be relatively detailed compared to the other parts of the report documentation package. The amount of detail will be as much as is needed to make clear what was found, and whether it was significant. The inspector should say what was observed or found in an unequivocal manner. If an inspector was looking to see if contamination was well controlled - and it was - the report should state: "Contamination was well controlled" not "Contamination appeared to be well controlled." If too small a sample was examined to reach an unequivocal conclusion, the qualifier state what specifically was inspected. For example, the report should state that, "Contamination was well controlled in the areas examined by the inspectors." If the inspector identifies no findings during an inspection (other than minor findings), the report should state "No findings of significance were identified."

Findings that are likely to have generic concerns should include details such as the manufacturer's name and model number for components, specifications, and other names and technical data that identify the item of concern.

In the case of a finding of a violation, it is critical that enough detailed information be given so that the interested reader can understand what the requirement was, and how it was not met. After the details of what occurred are provided, two specific concluding statements should be constructed. The first statement will define what the requirement was, including the regulation. For example, "10 CFR 20.1801, requires that licensees shall secure from unauthorized access or removal licensed materials that are stored in controlled or unrestricted areas." The second statement will describe (or refer to a preceding description) how the requirement was violated. For example, "Specifically, failure by the licensee to secure the radiographic exposure device (manufacturer model and serial nos.) that contained the sealed source of iridium-192 (manufacturer model and serial nos., activity, and date of activity) in storage, as described above, is considered a violation of 10 CFR 20.1801." Additional actions or responses by the licensee, if any, should be included to fully describe the violation.

If a finding is to be referred to the Bureau of Investigations (BOI), the inspection report should not lead a reader to conclude or infer that a BOI investigation is possible. For findings referred to BOI, the report should contain only relevant factual information collected during the inspection. The referral to BOI is made by correspondence separate from the inspection report and includes any additional information needed to support the referral. One available option is to document only the pertinent facts of the event and open an unresolved item or inspection follow-up item to track the issue until resolved. Any reports containing material that may be related to an ongoing investigation should be reviewed by BOI before being issued.

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3. Conclusions. The Conclusions are statements describing the quality of licensee performance in the area inspected. The report will discuss whether the licensee succeeded or failed, whether performance was good (or some other descriptor), and whether violations were identified. Every statement in a Conclusion section

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should have a basis (proof that it is correct) written in the observations and findings.

05.08 Exit Meeting(s) Summary. The final section of each inspection report briefly summarizes the exit meeting(s), which is also described in the first paragraph of the cover letter and identifies the most senior licensee manager who attended the meeting(s), and includes the following information:

a. Absence of Proprietary Information At the exit meeting, the inspectors should verify that information which the inspector reviews during the meeting and intends to include in the report is not proprietary. If the licensee does not identify any material as proprietary, the exit meeting summary should include a sentence to that effect.

NOTE: Inspectors should be aware of minimum requirements for handling classified and sensitive-unclassified information (i.e., safeguards information, official use only, and proprietary information). When an inspection is likely to involve proprietary information (i.e., given the technical area or other considerations of inspection scope), how to handle such information should be discussed at the entrance meeting.

b. Subsequent Contacts or Changes in DEP Position. The inspector should briefly discuss any contact with the licensee management after the exit meeting to discuss new information relevant to an inspection finding. In addition, if the DEP's position on an inspection finding changes after the exit meeting, that change should be discussed with the licensee before the report is issued.

The following information is normally not included in the exit meeting summary.

c. Characterization of Licensee Response. Licensee responses should not be included in the summary except in cases where the licensee disagrees with the inspection findings. In that case, the summary should state that the licensee took exception to the findings.

d. Oral Statements and Regulatory Commitments. If at the exit meeting or at any other time during the inspection, the licensee makes an oral statement that it will take a specific action in response to a non-compliance, the statement may be documented in the body of the report. Details of statements made at the exit meeting should not be included in the exit meeting summary. Such statements should only be characterized in the report if the statements represent licensee commitments in response to a non-compliance in order to eliminate the need for a subsequent licensee response. However, the report cover letter must include a provision for the licensee to respond if the commitment documented in the report does not accurately reflect the licensee's corrective actions or position. Otherwise, licensee commitments are documented by licensee correspondence, after which the inspector may reference the correspondence in the inspection report.

Because regulatory commitments are a sensitive area, the inspector should ensure that any reporting of licensee statements are paraphrased accurately, and contain appropriate reference to any applicable licensee document.

05.09 Report Attachments. The attachments discussed below may be included at the end of the inspection report if applicable to the inspection. The attachments may be combined into a single attachment entitled "Supplementary Information."

a. Key Points of Contact. The inspector lists, by name and title, those individuals who furnished relevant information or were key points of contact during the inspection (except in cases where there is a need to protect the identity of an individual). The list should not be exhaustive; a list of 5–10 individuals is sufficient. The alphabetized list includes the most senior licensee manager present at the exit meeting and DEP technical personnel who were involved in the inspection if they are not listed as inspectors on the cover page.

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b. List of Items Opened, Closed, and Discussed (Optional). The report should include a quick-reference list of items opened and closed. Open items that were discussed (but not closed) should also be included in this list, along with a reference to the sections in the report in which the items are discussed.

c. List of Documents Reviewed. A list of the appropriate key documents and records reviewed during an inspection that are significant to any finding, must be publicly available. Therefore, if a list is not otherwise made public, the report should include a listing of all the documents and records reviewed during the inspection that are not identified in the body of the report. "Reviewed" in this context means to examine critically or deliberately. The list does not include records that were only superficially reviewed. Lists consisting of more than six condition reports, documents reviewed or procedures, etc., should normally be removed from the body of the report and included as an attachment to facilitate reading.

d. List of Acronyms. Reports whose details section exceeds 20 pages should include a list of acronyms. For reports in which a relatively small number of acronyms have been used, the list is optional. In all cases, however, acronyms should be spelled out when first used in inspection report text.

05.10 Release and Disclosure of Inspection Reports

a. General Public Disclosure and Exemptions. Except for report enclosures containing exempt information, all final inspection reports will be available to the public. Sensitive-unclassified information (i.e., safeguards information, official use only, proprietary information) shall not be released.

b. Release of Investigation-Related Information. When an inspector accompanies an investigator on an investigation, the inspector must not release either the investigation report or his or her individual input to the investigation report. This information must not be circulated outside the DEP without specific approval of the BOI approving official.

0610-06 SIGNIFICANCE OF OBSERVATIONS

This section discusses the significance of observations including violations, non-compliances and enforcement actions. The guidance provided in this section is for informational purposes. Final agency actions shall be reviewed against the guidance contained in the BRP Compliance Enforcement Manual.

06.01 Thresholds of Significance. When conducting inspections, the NRC inspector only reviews a small number of selected procedures, events, and operations; he or she cannot hope to monitor all the activities in progress, nor to document every minor discrepancy that occurs. As part of maintaining a focus on safety, inspectors continually use NRC and DEP requirements, inspection procedures, industry standards, regional and headquarters guidance, and their own training and insight to make judgments about which issues are worth pursuing and which are not.

To communicate effectively, inspection reports must give evidence of that judgment and prioritization, discussing significant safety issues in appropriate detail, treating less significant issues succinctly, and avoiding excess verbiage. To maintain some consistency in how minor issues are treated, report writers must recognize certain "thresholds of significance": that is, they must use similar criteria in deciding whether an issue is important enough to document, important enough to track or follow up, etc.

a. Thresholds of Significance for Noncompliance Issues. Some violations of minor safety, environmental, and regulatory concern are a low the level of significance and severity. Because of their minor nature, these "minor" violations are not the subject of formal enforcement action and are not usually documented in inspection reports.

1. Minor Violations--Determining Whether to Document. In general, minor violations should not be documented; however, certain exceptions apply.

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Documentation may be necessary as part of the resolution of an allegation. In other cases, while the violation itself is minor, the associated technical information may relate directly to an issue of agency-wide concern. If, for these reasons or any other reason, the report writers and reviewers wish to document a minor violation, then it should be documented as a minor violation. For example, "This failure constitutes a violation of minor significance and is not subject to formal enforcement action."

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2. Violations Identified as Part of Licensee Self-Assessments. Under certain circumstances, even a violation that could be classified as "more-than-minor" need not be documented. This is generally justified when the violation has been identified and corrected as part of a licensee self-assessment effort. As a matter of policy, DEP enforcement seeks to encourage licensee self-assessment efforts, and seeks to avoid the negative impact that can result from a redundant DEP emphasis on problems which the licensee's responsible action has already identified and corrected.

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For example, suppose that while evaluating the licensee's quality assurance efforts in the fire protection area, an inspector reviews relevant audits and surveillances conducted over the previous year. The review reveals that the audits have been probing and thorough; the findings are well-developed and technically sound, and include six noncompliance issues, four of which might be classified minor.

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In such a case, the inspector should follow up on the non-compliances and other audit findings to ensure that root causes have been appropriately assessed, that appropriate and comprehensive corrective actions have been taken, and that no new examples of the violations exist. Provided, however, that no new problems are revealed by this follow-up, the inspector is normally not expected to cite the four violations individually, nor to report the details of those violations in the inspection report. Instead, the DEP report findings and conclusions should assess the adequacy of the licensee's quality assurance efforts, including a clear reference to the name, dates, and general subject matter of the audit or self-assessment.

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NOTE: This expectation only applies to minor violations. Even when identified through a licensee self-assessment, violations that could be categorized as significant must be documented in the inspection report and given appropriate follow-up.

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In some instances, reasons exist to document one or more of the violations found in a licensee audit or self-assessment. For example, if the report concludes that the licensee's self-assessment was especially negative, one or more examples should be given to support that conclusion.

In addition, the inspector may decide to document one or more of the violations found in a licensee self-assessment due to the technical significance or generic implications of the particular item. Technical details surrounding the violation may provide useful insight on equipment or system reliability, or on some aspect of human performance. In some cases, the inspector may decide to pursue additional follow-up of a particular licensee finding because of related licensee problems, previous DEP observations or violations involving the same or a related topic, or emerging agency or industry sensitivity in the given technical area.

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If, for any of these reasons, the inspector decides to discuss in the inspection report a particular licensee self-assessment finding or audit finding, and that finding involves a violation, then the violation must be clearly dispositioned in the report. The violation may be dispositioned as a non-cited violation (NCV) unless the circumstances results in an NOV requiring a formal written response from the licensee. If the issue represents a minor violation, it should be documented as follows: "This failure is considered a minor violation and should not be documented in the inspection report."

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Note, finally, that the discussion in this subsection applies to violations identified through licensee audits and self-assessments (i.e., cases in which the DEP's inspection is focused on the licensee's quality assurance efforts), and should not be applied to all licensee-identified violations. When the inspector pursues an issue as part of day-to-day licensee observation or other normal inspection activities, the decision on whether to document the issue should be based on its significance. Unless the inspection is specifically focused on licensee auditing and self-assessment capability, violations of more-than-minor significance should be documented and dispositioned, regardless of whether they are DEP- or licensee-identified.

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b. Thresholds of Significance for Non-Enforcement-Related Issues. Inspectors must also make judgments about the relative significance of non-enforcement-related findings. As with enforcement issues, the judgment of individual inspectors will differ; questions on the relative significance of an issue should be discussed with other inspectors and with DEP managers.

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1. Determining the Significance of Negative Findings. The following questions should be used to determine whether or not a finding should be documented in the inspection report:

   - Does this finding have any actual impact (or any significant potential for impact) on safety?
   - Is this finding illustrative of a programmatic licensee problem that could have a safety or regulatory impact?
   - Does this finding provide insights on an equipment, system, or human performance problem?
   - Could this finding be viewed as the possible precursor to a significant event?
   - If the licensee takes no action on this matter, will the condition worsen (i.e., will the safety significance increase)?
   - If this finding recurs, will its recurrence result in more significant or additional safety concerns?
   - Will this information be useful in assessing the long-term performance of this licensee program or functional area?
   - Does this finding have generic significance?

   If the answer to any one of these questions is "yes," the finding should be documented in the inspection report. If the answers to all questions are "no," the finding normally should not be documented.

2. Determining the Significance of Neutral or Positive Findings. For neutral or positive findings or for licensee improvements, similar thresholds of significance should apply. The inspector should ask questions similar to those below:

   - Does this licensee improvement have an actual positive impact (or a significant potential for positive impact) on safety?
   - Will the licensee's efforts to effect change in this area be likely to result in programmatic improvements to safety or regulatory performance?
   - Will this upgrade be likely to result in improved equipment or system reliability or improved human performance? Does this information provide useful equipment, system, or human performance insights?
   - Does this licensee action significantly reduce the probability of a particular event?
   - Will this information be useful in assessing the long-term performance of this licensee program or functional area?
   - Does this finding have generic significance?

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   If the answer to any one of these questions is "yes," the finding should be documented in the inspection report. If the answers to all questions are "no," the finding normally should not be documented.

NOTE: Inspectors should use care in giving credit or making strong positive statements for a proposed licensee action that has not yet been implemented, is in early stages of implementation, or has not been verified by the DEP.

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3. Findings Previously Covered in Licensee Self-Assessments. This decision should be treated similarly to the corresponding decision for enforcement issues. In general, little benefit exists in DEP's re-emphasis of issues already covered in licensee self-assessments, unless there is some problem with the licensee's actions.

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In some instances, however, the technical significance or generic implications of an issue merit ensuring that it is discussed on the docket and preserved as a matter of public record. If the licensee self-assessment that initially discussed the issue is already on the docket, the inspection report may simply refer to the discussion in the licensee self-assessment. If more detail is needed, or if the licensee self-assessment is not on record, the inspector may wish to discuss the issue in the inspection report narrative.

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06.02 Documenting Noncompliance. The primary guidance for all matters related to enforcement, including documentation, is given in the DEP Compliance and Enforcement Manual. The following discussion summarizes certain aspects of that guidance related to inspection reports.

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a. Types of Noncompliance. The manner of documenting a noncompliance in the inspection report depends on how that noncompliance will be dispositioned. A noncompliance may be addressed as a non-escalated enforcement action (i.e., a minor violation, a deviation, or a nonconformance); as an escalated enforcement action (i.e., an apparent significant violation); or as an NCV.

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Note that a noncompliance may not be documented simply as a "weakness," "licensee failure," or a similar informal characterization. If the report narrative describes a condition or event in a manner that suggests to the reader that a violation may have occurred, then the finding must be clearly dispositioned as a violation, an apparent violation, or an NCV. If a violation does not exist (e.g., no requirement exists in this area), it may be appropriate to clarify the finding by stating that "this condition [or event] does not constitute a violation of DEP requirements."

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1. Non-Escalated Enforcement Actions. Most violations of moderate significance (i.e., more than minor concerns) fall into the significant category. If at the time of issuing the inspection report a violation has been categorized as significant, then an NOV is generally sent out with the inspection report, as a "non-escalated" enforcement action. The cover letter for reports that include non-escalated enforcement actions should follow the appropriate DEP Compliance and Enforcement Manual guidance.

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NOTE: A violation's severity level should not be discussed in the report details. Whether an NOV accompanies the report or is issued later, the designation of severity level is made in the NOV itself.

Deviations and nonconformances are also considered non-escalated enforcement actions. When a licensee fails to meet a regulatory commitment or to conform to the provisions of an applicable code or industry standard, the failure may result in a Notice of Deviation. When a vendor or certificate holder fails to meet a contract requirement related to DEP activities, the failure may result in a Notice of Nonconformance. While less frequently issued than significant NOVs, these non-escalated enforcement actions follow a similar format and require a similar level of report detail.

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2. Potential Escalated Enforcement Actions. When an issue is being considered for escalated enforcement action, the inspection report narrative should refer to the potential noncompliance as an "apparent violation." The report details should not include any speculation on the severity level of such violations nor on expected DEP enforcement sanctions. Potential escalated

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actions, by their nature, require further agency deliberation (and, usually, additional licensee input) to determine the appropriate severity level and DEP action.

Similarly, report narratives that discuss apparent violations should be carefully constructed to avoid making explicit conclusions (i.e., final judgments) about the safety significance of the issue. The report should include any available details that demonstrate safety significance, or that would help in making such a decision and should also describe any corrective actions taken or planned by the licensee. However, since a potential escalated enforcement action automatically entails further evaluative steps, neither the inspection report details nor the accompanying cover letter should present a final judgment on the issue.

3. Non-Cited Violations. When enforcement discretion is applied, the report should briefly describe the circumstances of the violation, briefly describe the licensee's corrective actions, and conclude with the following boilerplate statement: "This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with DEP Compliance and Enforcement Policy."

   Willful violations may also be dispositioned as NCVs. In these cases, the inspection report should include additional discussion to address this before providing the standard conclusive language. For example: "Although this violation is willful, it was brought to the DEP's attention by the licensee, it involved isolated acts of a low-level individual without management involvement, and the violation was not caused by a lack of management oversight, and it was addressed by appropriate remedial action. Therefore, this non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section VI.A.8 of the DEP Compliance and Enforcement Policy."

4. Minor Violations. Minor violations should not normally be documented in inspection reports. However, to the extent that documentation is necessary, the standard language should be used: "This failure constitutes a violation of minor significance and is not subject to formal enforcement action."

5. Enforcement Discretion. Where discretion is exercised and formal citations are not issued, the approval of the Program Manager in consultation with Central Office management and counsel as warranted, is required. Where discretion is being reviewed for a violation the subject report should state: "Discretion is being exercised after consultation with Radiation Protection program management."

b. Supporting Details and Discussions of Safety Significance. The discussion of noncompliance issues must be sufficiently detailed to substantiate any DEP safety and regulatory concerns and to support any enforcement sanction the DEP may choose to issue. At a minimum, for a violation, the report should state:

- what requirement was violated;
- how the violation occurred;
- when the violation occurred, and how long it existed;
- who identified it, and when;
- any actual or potential safety consequence;
- the root cause (if identified);
- whether the violation appears isolated or programmatic; and
- what corrective actions have been taken or planned
- who was involved with the violation (i.e., management involvement or low-level individual).

The degree of detail necessary to support an enforcement action is a function of the significance and complexity of the noncompliance.

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Although supporting details clearly assist in determining the safety significance of the noncompliance, inspectors should be cautious in making direct statements regarding safety significance in the inspection report details. Violation severity levels are based on the degree of safety significance involved. In assessing the significance of a noncompliance, the DEP considers four specific issues: (1) actual safety consequences: (2) potential safety consequences, including the consideration of risk information; (3) potential for impacting the DEP's ability to perform its regulatory function: and (4) any willful aspects of the violation. As a result, if an inspection report refers to a noncompliance as being "of low safety significance" (meaning, in a general sense, that the noncompliance did not result in any actual adverse impact on equipment or personnel), the writer may have inadvertently made it difficult for the DEP to subsequently decide that the potential for an adverse impact or the regulatory significance of the noncompliance warrants classification as a significant violation. Therefore, before characterizing a violation as being of "low safety significance," the inspector should also address the potential consequences and regulatory consequences of the violation in addition to the absence of an actual adverse consequence.

c. Noncompliance Involving Willfulness. Inspection reports should neither speculate nor reach conclusions about the intent behind a violation, such as whether it was deliberate, willful, or due to careless disregard. As with any observation, the report discussion should include relevant details on the circumstances of the violation without making a conclusion about the intent of the violator:

EXAMPLE: "The radiographer failed to activate his alarming ratemeter, although he had informed the inspectors earlier that he had been properly trained on the use of the device;" not, "The radiographer deliberately failed to activate his alarming ratemeter."

Conclusions about the willfulness of a violation are agency decisions, and are normally not made until after the Bureau of Investigation has completed an investigation. A premature or inaccurate discussion of the willfulness of an apparent violation in the inspection report could result in later conflicts based on additional input and review. Inspection reports that include potentially willful violations must be coordinated with BOI where there is BOI involvement.

0610-07 RELEASE AND DISCLOSURE OF INSPECTION REPORTS AND ASSOCIATED DOCUMENTS

07.01 General Public Disclosure and Exemptions. Except for report enclosures containing exempt information, all final inspection reports will be available to the public.

07.02 Release of Investigation-Related Information

a. When an inspector accompanies an investigator on an investigation, the inspector shall not release either the investigation report nor his or her individual input on the investigation report unless authorized by BOI. BOI reports of investigations will not be circulated outside DEP without specific approval of the BOI approving official.

b. Generally, DEP technical and safety concerns can be communicated to a licensee without revealing that an investigation is contemplated or underway. However, when information cannot be released without risk of compromising an investigation, the Regional Director (RD) or Bureau Director (BD) will inform the BOI Director, in advance, that safety concerns require releasing to the licensee information related to an open investigation. BOI management will review the information to be released and advise the RD or BD of the anticipated effect on the course of the investigation. The RD or BD will release the information only after determining that the safety concerns are significant enough to justify the risk of compromising the pending investigation and any potential subsequent regulatory action.

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Deleted: and the Office of Enforcement (OE)
Deleted: routinely disclosed
Deleted: Information that should not appear in an inspection report is described in 10 CFR 2.790 and 9.17. Management Directive 8.8, Management of Allegations, addresses the manner in which an inspection report may be used to document allegation follow up activities. IMC 0620, "Inspection Documents and Records," provides guidance on acquisition and control of NRC records, including inspection-related documents.
Deleted: . This information is exempt from disclosure as provided by 10 CFR 9.17, subject to determination
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Conversely, when the RD or BD decides, after consultation with BOI management, to delay informing the licensee of an issue, the RD or BD should document this decision, including the basis of determining that the delay is consistent with public health and safety considerations. Any such decision should be reexamined every three months to assure validity of the delay to inform the licensee about the technical and safety concerns until the investigation is closed.

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c. When an emergency or significant safety or security issue appears to require immediate action, DEP employees, at their discretion, may discuss with, show to, or provide the licensee any pertinent material they believe the circumstances warrant. If time permits, regional management should be consulted first. An emergency situation meeting this criteria is one in which, in the opinion of the senior DEP management employee cognizant of the situation, a present danger to public health or safety or to the common defense and security requires the release of investigative information to a licensee without the delay necessary to consult with appropriate BOI personnel.

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d. If an issue disclosed during an inspection is to be referred to BOI for possible investigative action, the inspection report should not contain information that would lead a reader to conclude or infer that an investigation may be opened. In this case, the report should contain only relevant factual information collected during the inspection. The referral to BOI should be made by separate correspondence, with any additional information needed to support the referral.

END

Attachments:

Appendices A - E

APPENDIX A

Reserved

Deleted: GUIDANCE FOR INSPECTION REPORTS RELATED TO INDEPENDENT SPENT FUEL STORAGE AND TRANSPORTATION¶

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PURPOSE¶

¶

This appendix provides guidance for inspectors in the Spent Fuel Project Office (SFPO) and the regions on reporting inspection results to licensees or certificate holders (vendors). SFPO generally conducts two types of inspections; those related to radioactive material transport governed by 10 CFR Part 71, and those related to independent spent fuel storage installations (ISFSIs) governed by 10 CFR Part 72. The regions also perform inspections at ISFSI's.¶

¶

Inspection findings may be documented in one of two methods as controlled by Manual Chapter (MC) 2690. One method is to use the modified Form 591 (modified to reflect the range of groups inspected, i.e. certificate holders and licensees) and the other method is to generate a narrative written report. ¶

¶

With regard to inspections related to an ISFSI, the following Inspection procedures should be used as appropriate:¶

¶

IP 60851 . Design Control of ISFSI Components¶

IP 60852 . ISFSI Component Fabrication by Outside Fabricators¶

IP 60853 . On site Fabrication of Components and Construction of an ISFSI¶

IP 60854 . Pre-operational testing of an ISFSI¶

IP 60855 . Operation of an ISFSI¶

IP 60856 . Review of 10 CFR 72.212(b) Evaluations¶

IP 60857 . Review of 10 CFR 72.48 Evaluations¶

¶

With regard to inspection related to transportation packagings, IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings," should be used as appropriate. ¶

¶

¶

FORMAT AND STYLE¶

¶

When issuing a Form 591, MC 2690 is the governing document for this process. While MC 2690 provides guidance on when a narrative written report can or should be issued, Sections 05 and 06 of this MC (0610) shall be followed with respect to report format, content, and any required enforcement action.¶

¶

¶ ... [1]

APPENDIX B

Reserved

APPENDIX C

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¶
PURPOSE¶
¶
This appendix provides information regarding the preparation of materials inspection reports. IMC 2800, Materials Inspection Program, contains administrative procedures . Section 2800-08, Documentation of Inspection Results, addresses occasions for narrative inspection reports which should be prepared according to the instructions in IMC 0610. Most generally, an inspection record (NRC Form 591 M) will be completed instead of a narrative inspection report for a routine inspection, except as follows. ¶
¶
A narrative report is required for all team inspections (i.e., involving three or more inspectors or a member with special competence from Headquarters or another regional office or an agency outside NRC other than a State's agency) and actions involving an enforcement conference or escalated enforcement. For escalated cases, the narrative report need address only the areas in which safety concerns and violations are identified (all other areas may be documented using Enclosure 9 of IMC 2800). For medical events, the narrative report must follow the guidance in Management Directive 8.10. Narrative inspection reports may be used to document other types of inspections at the discretion of regional management. ¶
¶
¶
FORMAT, STYLE, AND EXAMPLES¶
¶
The ADAMS Package ML032681141 contains: (1) an annotated NRC Form 591M, (2) an annotated inspection report (IR), and (3) an index of sample IRs. ¶ ... [2]

Deleted: GUIDANCE FOR FUEL CYCLE INSPECTION REPORTS¶
¶
¶
GENERAL PURPOSE¶
¶
This appendix provides guidance for inspectors of fuel cycle facilities on reporting inspection results to the licensee or certificate holder. It recommends how to format and structure the inspection reports. Flexibility is provided in adapting the inspection report format to the needs of the particular inspection. Changes to the recommended format may be authorized by inspection manag ... [3]

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APPENDIX D

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¶
PURPOSE¶
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The purpose of this appendix is to provide guidance on the preparation of inspection reports for decommissioning inspections. There are two distinct types of Decommissioning Inspections that are performed. The first type is a materials site decommissioning inspection. The second type of decommissioning inspections is a permanently shutdown reactor inspection. The following provides guidance for each of these inspection types.¶
¶
¶
FORMAT AND STYLE FOR MATERIALS SITE DECOMMISSIONING INSPECTIONS¶
¶
For decommissioning in progress, inspectors should use NRC Form 591 (Safety Inspection Report and Compliance Inspection) with appropriate comments on Part 3. If surveys are done and data is transmitted to the licensee, a letter report is sent. The format of the letter report is:¶
¶
COVER LETTER¶
¶
COVER PAGE¶
¶
EXECUTIVE SUMMARY¶
¶
REPORT DETAILS¶
¶
PARTIAL LIST OF PERSONS CONTACTED¶
¶
INSPECTION PROCEDURES USED¶
¶
ITEMS OPEN, CLOSED, AND DISCUSSED¶ ... [4]

Deleted: **SUMMARY OF FACILITY STATUS AT PERMANENTLY SHUTDOWN REACTOR**

Deleted: Briefly describe the status of the facility and work completed since the previous inspection.¶
¶
1.0 Facilities Management and Control¶
¶
1.1 Safety Reviews, Design Changes, and Modifications¶
¶
The purpose of this portion of the report is to document whether design changes, test, experiments, and modifications were effectively reviewed, conducted, managed, and controlled during plant decommissioning and the program ... [5]

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APPENDIX E

INSPECTION REPORT WRITING STYLE GUIDANCE

The Inspection Report Writing Guide consists of "how to" instructions and information, arranged in alphabetical order for quick reference. These instructions are primarily derived from the NRC Editorial Style Guide and the Handbook of Technical Writing.

ABBREVIATIONS AND SYMBOLS

Chapter 9 of the *GPO Style Manual* is a good reference for standard letter symbols for units of measure. In addition, standard symbols apply for units of radiation.

EXAMPLE:

bp	boiling point	Ci	Curie(s)
kV	kilovolt	mCi	milliCurie
MW	megawatt	µCi	microCurie

In technical text, use abbreviations for units of measure only if they are used with figures.

EXAMPLE: 200 r/min (but--The text should tell us the number of revolutions per minute.)

ACRONYMS AND INITIALISMS

An acronym is an abbreviation that is formed by combining the first letter or letters of several words. Acronyms are pronounced as words and are written without periods.

EXAMPLE: Independent spent fuel storage installation (ISFSI); pronounced "is-fa-see"

An initialism is an abbreviation that is formed by combining the initial letter of each word in a multiword term. Initialisms are pronounced as separate letters.

EXAMPLE: Nuclear Regulatory Commission (NRC)

Limit the of acronyms and initialisms to those cases where not using them would lead to a distracting repetitiveness of phrasing. Sentence should not be begun with an acronym or initialism.

When you use an acronym always use capital letters without periods. Initialisms may be written in either upper case or lower case. Generally, do not use periods when they are upper case, but use periods when they are in lower case. Two exceptions are geographical names and academic degrees.

Treat the inspection report as three separate documents: the cover letter, the notice of violation, and the body of the report (this includes the executive summary). Avoid using acronyms or initialisms in the cover letter or the executive summary as much as possible. The first time an acronym or initialism appears in any document, write the complete term, followed by the abbreviated form in parentheses. An acronym or initialism should not be used in a title line within the report. When an acronym or initialism is first used in the text (*below the title line*), *define it at that time and then use the acronym.*

The plural for most acronyms and initialisms adds a lower case "s" without an apostrophe.

EXAMPLE: RSOs
GLs

To decide whether "a" or "an" should precede an acronym or initialism, pronounce the first letter or syllable of the abbreviation.

EXAMPLE: an NRC inspector (N is a vowel sound)

a GL (G is a consonant sound)

The acronym list at the end of the inspection report should be titled "Acronyms and Initialisms." No list is needed if the report is short and contained relatively few acronyms.

ACTIVE VOICE

Use the active voice for most of your inspection report writing.

EXAMPLE: Active Voice - The inspector surveyed the laboratory. The inspector interviewed and questioned the staff.

Passive Voice - The laboratory was surveyed by the inspector. It was evaluated by interviewing and questioning of the staff by the inspector.

Active voice provides information more simply and clearly. As a general rule, simple declarative sentences are best.

AFFECT/EFFECT

Affect is a verb that means "influence".

EXAMPLE: The NRC's decision concerning control rod placement affects all utilities.

Effect can function either as a verb that means "bring about" or "cause" or as a noun that means "result." It is best to avoid using *effect* as a verb. Use a less formal word, like *made*.

CHANGE: The inspector effected several report changes that had a good effect.

TO: The inspector made several report changes that had a good effect.

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APOSTROPHES

The apostrophe (') is used to show possession and to mark the omission of letters.

EXAMPLE: The inspectors' (possession) comments were very appropriate for that situation.

It's (omission of letters) my belief that the laboratory technician was performing his job correctly.

BRACKETS

The bracket symbol is used to insert comments or corrections in quoted material.

EXAMPLE: The *GPO [Government Printing Office] Style Manual* is an excellent reference tool.

CAPITALIZATION

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General rule: Use capitalization in report writing to emphasize a specific, important word. These words are important to the message of the report. Limit your capitalization to important words only.

Use the lower case for most terms (systems, components, etc), but capitalize anything that directly refers to a specific item (except page and paragraph).

EXAMPLES: Train A ..... disabled one train of ... disabled Train A of ...
Chapter 3 ..... reviewed the chapter on ... reviewed Chapter 3...
Appendix B
Plant 1

Capitalize specific titles of persons or organizations, but not general references to them. (However, do not capitalize the many common job titles at a large facility; for example, health physicist, reactor operator, plant superintendent.)

EXAMPLE:____Director, Office of Personnel (but--the office director)

Capitalize the following governmental organizations.

Federal
Federal Government
State (but--Do not capitalize local.)

Capitalize the first word and all important words in titles of publications and legislation.

EXAMPLE: The Paperwork Reduction Act of 1982.

Do not capitalize articles, prepositions (except for "To" as part of an infinitive), and conjunctions unless they are the first word of a title or important to its meaning.

Capitalize when referencing a violation, unresolved item, or inspector follow-up item that is used to reference a tracking number in the body of the inspection report.

EXAMPLE:____as a Violation of License Condition D.5 (PA-01978/A-021).

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Capitalize a trade name.

EXAMPLE:____Xerox
Halogen

COLONS

Use a colon (:) after a complete clause to introduce a list, whether or not the list is within a sentence.

EXAMPLE:____The test measures these three areas: management motives, management strengths, and styles of leadership.

Capitalize the first word of each item in a list that follows a colon or a dash (use a colon following a complete statement and a dash following a phrase). Use a semicolon after each item in a list and a conjunction after the next-to-last item in the list unless each item in the list is a complete sentence.

EXAMPLE:To renew your license you must complete the following:
(1) Complete and sign Form 61;
(2) Copy the original form; and
(3) Return the original to Personnel.

Everyone must –
(1) Complete and sign Form 61;
(2) Copy the original form; and
(3) Return the original to Personnel

COMMAS

Use a comma after each member of a series of three or more words, letters, figures, phrases, or clauses. Change the usual commas in a series to semi-colons if commas are prevalent within the elements of the series.

EXAMPLE: In addition, the DEP may, after assessing a situation, order a licensee to continue, curtail, or modify activities; ensure compliance with safety and emergency procedures; and maintain records of these mandatory actions.

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Use a comma after an introductory phrase of five or more words.

EXAMPLE: After reviewing the notes of the supporting specialist inspector, the team leader had a clearer understanding of the message.

Use a comma before and after an explanatory equivalent of another word or phrase.

EXAMPLE: Todd Brewer, President of FFUS, met with the Commissioner.

Use a comma before and after the State when citing the city and State in text.

EXAMPLE: The meeting is in Chicago, Illinois, on April 5 at 3:00 p.m.

Do not use a comma between the State and the ZIP Code in an address.

EXAMPLE: Bethesda, MD 20014

Use the following format when referring to a title or portion of a title of the *Code of Federal Regulations*.

EXAMPLE: 10 CFR Part 20, Appendix B, or
Appendix B to 10 CFR Part 20

Use a comma between independent clauses that are linked by a coordinating conjunction (*and,but, or, nor*, and sometimes *so, yet, and for*). The comma precedes the conjunction.

EXAMPLE: The inspectors were diligent about keeping their schedules consistent with demand, but this month travel constraints have been a problem.

Omit commas when the word or phrase does not interrupt the continuity of thought.

EXAMPLE: I therefore suggest that we begin the inspection.

Conjunctive adverbs (*however, nevertheless, consequently, for example, on the other hand*) joining independent clauses are preceded by a semicolon and followed by a comma.

EXAMPLE: Your idea is good; however, your format is poor.

A comma always goes inside quotation marks.

COMPOUND WORDS

Compound words are words formed when two or more words act together.

Write compounds as two words when the compounds appear with the words in their customary order and when the meaning is clear.

EXAMPLE: test case
sick leave

Most words with short prefixes are not true compounds. Such words are usually written without a space or a hyphen.

EXAMPLE: biweekly
Foretell
Semiannual

Hyphenate compounds that modify or describe other words.

EXAMPLE: rear-engine bracket

Compounds used as verbs require separate words.

EXAMPLE: to follow up
to shut down
to shut off
to stand by
to start up
to take off

DATES

When specifying dates in the body of the inspection report, avoid using the year when the date is clearly within the inspection period.

CHANGE: .....was noted on January 10, 2002.
TO: .....was noted on January 10.

Use a comma before and after the year in a three-element date written in the order of month, day, and year. Do not use a comma in a two-element date.

EXAMPLE: On February 26, 1992, the questions concerning nuclear waste were addressed in Pittsburgh.

On March 4 the inspector toured the facilities described as licensed locations of use.

USE of "e.g." and "i.e."

These abbreviations are from the Latin and they do not save enough space to justify possible misunderstanding. Avoid *e.g.* and *i.e.* in your writing.

FONT

The default font for an inspection reports is Arial 12. Do not use other fonts. If you are building a report from a source document which is in another font, change it to Arial 12.

HYPHENS

Avoid the use of double hyphenated words.

Chapters 6 and 7 of the *GPO Style Manual* present guidance for compounding words and a list of words indicating whether to use them open, solid, or hyphenated.
Compound terms that modify nouns are called unit modifiers. Those that precede nouns are typically hyphenated. Those that follow the nouns they modify are typically not hyphenated.

EXAMPLE: A DEP-sponsored study (but--a study sponsored by DEP)

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Use a hyphen between the modifier and present participle.

EXAMPLE: far-reaching effects
hard-working staff

Use a hyphen between the modifier and past participle.

EXAMPLE:____safety-related valves
well-defined goals

Do not hyphenate a modifier ending in *ly.*

EXAMPLE:____poorly managed facility

Put a hyphen after suspended modifiers.

EXAMPLE: industry- and agency-sponsored studies
long- and short-term goals

Hyphenate unit modifiers that include numbers.

EXAMPLE:____18-inch pipe
three-shift operation

Generally, do not hyphenate prefixes unless "Spell check" flags the word as misspelled.

EXAMPLE:____counterblow should be counter-blow
midpoint
nonperson
progovernment

INSURE / ENSURE / ASSURE

Insure, *ensure*, and *assure* all mean "make secure or certain." *Assure* refers to persons, and it alone has the connotation of setting a person's mind at rest (for instance, I assure you that the unit will be up and running by tomorrow.) *Ensure* and *insure* also mean "make secure from harm" (for instance, the environment needs to be clear of smoke to ensure that visibility is good.) Only *insure* is widely used in the sense of guaranteeing the value of life or property, (for instance, the licensee should insure the property.)

ITALICS

Italicize the titles of books, periodicals, newspapers, movies, and paintings.

Titles of chapters or articles within publications and titles of reports are placed in quotation marks, not italicized.

"Clarity, the Technical Writer's Tightrope" was an article in *Technical Communications.*

NOTICE OF VIOLATION GUIDANCE

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A considerable array of enforcement guidance material has been issued. This material should **[enter name of documents to be referenced for enforcement]** be used as a primary guide for enforcement documentation.

For each violation written there should be a "contrary to" statement. In the past, violations with numerous examples have had a "contrary to" statement to coincide with each example listed. There should only be one "contrary to" statement per violation, not one for every example, as follows.

1. License Condition No. x.x required.....
   a. Your letter to DEP dated xx-xx required.....
   b. The Radiation Protection Plan, Section x.x, required.....

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c. Procedure No. xx, "Radiological Surveys" required.....

Contrary to the above,

a.1. On December 1, 2001, ...

b.1. On December 1, 2001,.....

c.1. On December 3, 2001,.....

This is a Severity Level XX violation (Supplement X).

NUMBERS

Spell out numbers one through nine.

Use figures for a single number of 10 or more.

Spell out a number that begins a sentence.

When two or more related numbers appear in a sentence and one of them is 10 or more, use a figure for each number.

Use figures to express a unit of measurement, time or money. This usage does not affect other numerical expressions in a sentence.

EXAMPLE:____2 Curies
15 Roentgen
3:45 p.m.

An ordinal number expresses degree or sequence. Apply the general rules for numbers in this section to ordinal numbers.

EXAMPLE:____The third quarter earnings indicated an increase in sales.
The 22nd and 23rd years of plant operation were the most productive.
On the 27th of March (not March 27th)

When two numbers appear in sequence, use a figure for one and spell out the other.

EXAMPLE:____The inspector examined ten 12-inch pipes.

Spell out a fraction standing alone; a fraction followed by *of, a, or, an;* and a fraction approximation.

EXAMPLE:____The water on three-fourths of the site was contaminated.

Use figures for a fraction in a unit modifier.

EXAMPLE: ½-inch width

Use figures when combining whole numbers and fractions.

EXAMPLE:____2 ½ inches wide

Use figures for all decimals.

EXAMPLE:____1.2 gallons

For quantities of less than one, use a zero before the decimal point.

EXAMPLE:____0.04 mrem per hour

OBJECTIVITY

Avoid "preaching" in an inspection report. Preaching is personal. When writing an inspection report avoid wit, irony, sarcasm and personal comments.

PARENTHESES

Parentheses () are used to enclose words, phrases, or sentences. The material within parentheses can add clarity to a statement without altering its meaning.

EXAMPLE:Aluminum is extracted from its ore (called bauxite) in three stages.

PERCENT

The word "percent" is used instead of the symbol (%) except in tables.

PRONOUNS

Avoid the vague use of pronouns.

CHANGE: This is something to consider.
TO: This shortfall in payments is something to consider.

CHANGE: It was a good choice.
TO: Deciding to bring the unit offline was a good choice.

CHANGE: Those were issues.
TO: Housekeeping and maintenance items were issues.

CHANGE: These are difficult.
TO: The exercises are difficult.

QUOTATION MARKS

Commas and periods always go inside the quotation mark (." ,"). Semicolons and Colons always go outside the quotation mark ("; ":).

SEMICOLONS

Use a semicolon (;) to separate closely related or contrasting statements.

EXAMPLE:____He agrees; I do not.

UNITS OF MEASURE

The inspection report should follow the standard NRC policy which is SI units followed by the equivalent special units in parentheses.

EXAMPLE:____2 sieverts (200 rems)

VERB TENSE

Reports should be written in the past tense. You inspected before the report was written. You are describing what you did and what you found. It is permissible to use the present tense if it is clearly accurate to describe what not only was but still is, especially If the use of past tense diminishes the impact of any conclusion we had or have in the subject area.

VOCABULARY

Use plain language. The purpose of the inspection report is to report facts and the interpretation of those facts. Most of the time, simpler language is better.
For example, the word "about" is usually a better choice than "approximately."

Eliminate unnecessary words.

The following are examples of the many redundant words that are used in writing. The redundant expression appears in the left column; the right column provides simpler language.

absolutely essential	essential
assembled together	assembled
basic fundamentals	fundamentals
collect together	collect
continue on	continue

Avoid wordy phrases.

The following are a few examples of commonly used wordy phrases. The wordy phrase appears in the left column; the right column provides simpler language.

a large number of	many
a majority of	most
at that time	then
at the conclusion of	after
detailed information	details
in few cases	seldom
in the event of	if
prior to	before

WORD USAGE

To indicate a requirement in a rule, use *shall* with a person or organization and *must* with an inanimate subject. To indicate a prohibition, use *may not*.

EXAMPLE: The licensee shall record the data in a log.

The data must include the date and purpose of the visit and the visitor's name and affiliation.

The visitor may not enter any high-radiation area.

Always use the plural word *inspectors* unless only one inspector was responsible for the entire inspection period. This is a team effort.

When referring to an inspection report number in the body of a report use the complete title.

EXAMPLE:.... was referenced in Inspection Report 0300123/2002-002.

Appendix F

SAMPLE LIST OF ACRONYMS USED IN THIS INSPECTION MANUAL CHAPTER

BD	Bureau Director
CFR	Code of Federal Regulations
EA	Escalated Action
GPO	Government Printing Office
IMC	Inspection Manual Chapter
IPAP	Integrated Performance Assessment Process
MD	Management Directive
NCV	Non-Cited Violation
NOV	Notice of Violation
NRC	Nuclear Regulatory Commission
BOI	Bureau of Investigations
RD	Regional Director,
SI	International System of Units

Deleted: NMSS . Office of Nuclear Material Safety and Safeguards¶

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Deleted: TI . . Temporary Instruction

GUIDANCE FOR INSPECTION REPORTS RELATED TO INDEPENDENT SPENT FUEL STORAGE AND TRANSPORTATION

PURPOSE

This appendix provides guidance for inspectors in the Spent Fuel Project Office (SFPO) and the regions on reporting inspection results to licensees or certificate holders (vendors). SFPO generally conducts two types of inspections; those related to radioactive material transport governed by 10 CFR Part 71, and those related to independent spent fuel storage installations (ISFSIs) governed by 10 CFR Part 72. The regions also perform inspections at ISFSI's.

Inspection findings may be documented in one of two methods as controlled by Manual Chapter (MC) 2690. One method is to use the modified Form 591 (modified to reflect the range of groups inspected, i.e. certificate holders and licensees) and the other method is to generate a narrative written report.

With regard to inspections related to an ISFSI, the following Inspection procedures should be used as appropriate:

IP 60851 Design Control of ISFSI Components
IP 60852 ISFSI Component Fabrication by Outside Fabricators
IP 60853 On site Fabrication of Components and Construction of an ISFSI
IP 60854 Pre-operational testing of an ISFSI
IP 60855 Operation of an ISFSI
IP 60856 Review of 10 CFR 72.212(b) Evaluations
IP 60857 Review of 10 CFR 72.48 Evaluations

With regard to inspection related to transportation packagings, IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings," should be used as appropriate.

FORMAT AND STYLE

When issuing a Form 591, MC 2690 is the governing document for this process. While MC 2690 provides guidance on when a narrative written report can or should be issued, Sections 05 and 06 of this MC (0610) shall be followed with respect to report format, content, and any required enforcement action.

EXAMPLES

Specific examples of SFPO inspection reports can be found in NRC's ADAMs document control system in package ML032680534.

The examples in that ADAMS package include: a) Form 591 with attached inspector notes for a Part 72 vendor's fabricator inspection; b) a complex narrative inspection report (programmatic issues and enforcement action) for a Part 72 vendor; and c) a narrative report for inspection of a Part 71 QA program holder.

For the narrative reports, it should be noted that while the examples provided do not exactly conform to the revised 0610 guidance with respect to format, the cover letters and report details exemplify the typical writing style and level of detail acceptable to SFPO management for narrative reports.

GUIDANCE FOR MATERIALS INSPECTION REPORTS

PURPOSE

This appendix provides information regarding the preparation of materials inspection reports. IMC 2800, Materials Inspection Program, contains administrative procedures . Section 2800-08, Documentation of Inspection Results, addresses occasions for narrative inspection reports which should be prepared according to the instructions in IMC 0610. Most generally, an inspection record (NRC Form 591 M) will be completed instead of a narrative inspection report for a routine inspection, except as follows.

A narrative report is required for all team inspections (i.e., involving three or more inspectors or a member with special competence from Headquarters or another regional office or an agency outside NRC other than a State's agency) and actions involving an enforcement conference or escalated enforcement. For escalated cases, the narrative report need address only the areas in which safety concerns and violations are identified (all other areas may be documented using Enclosure 9 of IMC 2800). For medical events, the narrative report must follow the guidance in Management Directive 8.10. Narrative inspection reports may be used to document other types of inspections at the discretion of regional management.

FORMAT, STYLE, AND EXAMPLES

The ADAMS Package ML032681141 contains: (1) an annotated NRC Form 591M, (2) an annotated inspection report (IR), and (3) an index of sample IRs.

The annotated NRC Form 591 M consists of Part I, Part II, and Part III and instructions to complete the form. Electronic versions of the form are available from InForms or IMC 2800 (Enclosure 8) which is in the NRC Inspection Manual on the NRC external web site and the NRC internal web site. The external site provides a pdf.version of the form and the internal site provides a wpd.version of the form. Each region has a supply of the paper, multipart version of Parts I and II of the form. To replenish the supply, contact the Inspection Guidance Coordinator in NMSS/IMNS/RGB.

The Annotated Materials Inspection Report is a single file that describes the actual inspection of a gauge licensee but specific references to the licensee were removed. The file contains the letter of transmittal and enclosures 1 through 4 as follows: (1) Notice of Violation, (2) Inspection Report, (3) Factual Summary from the OI Report, and (4) Pre-Decisional Enforcement Conference Agenda. The ***bold or italicized*** comments explain the features of an IR and the <u>underlined</u> text indicates specific information to be provided by the inspector.

The Index of Sample Inspection Reports is a single file to assist inspectors in locating a particular type of IR. The index lists information about the IRs, i.e., Type of Use, Sample Type (e.g., Unsecured Gauge at Temporary Job Site), ADAMS ML No., Date, EA No. The samples demonstrate the IR format and style to be used by inspectors. The font face and size should be Ariel 11 for IRs. The samples illustrate how to use the standardized IR outline and how to adhere to the expected internal organization for each report section (as discussed in IMC 0610). Although the sample IRs do not include an example for each type of use of byproduct material, the sample IRs do include sufficient examples to illustrate the various ways that inspection findings would be normally documented in an IR. Inspectors who desire to provide an updated IR for the index should, through their supervisor, contact the Project Manager, NMSS Manual Chapters and Inspection Procedures, Rulemaking and Guidance Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

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GUIDANCE FOR FUEL CYCLE INSPECTION REPORTS

GENERAL PURPOSE

This appendix provides guidance for inspectors of fuel cycle facilities on reporting inspection results to the licensee or certificate holder. It recommends how to format and structure the inspection reports. Flexibility is provided in adapting the inspection report format to the needs of the particular inspection. Changes to the recommended format may

be authorized by inspection management through the issuance and use of approved branch procedures.

CONTENT

Flexibility is also provided in this area, because of the many disciplines covered by fuel cycle inspections. The level of detail desired in inspection reports is illustrated in report examples that are available in the ADAMS package referenced at the end of this appendix. Because fuel cycle inspections cover a variety of disciplines, the report writer is advised to follow the example of a report from the particular discipline or a similar discipline. Some inspection disciplines call for more detailed descriptions than others. In general, provide enough detail that the report will be understandable and also useful in the subsequent inspection. Violations of minor significance are generally not included in inspection reports that are subject to public disclosure.

FORMAT AND STYLE

01 Elements

Fuel cycle inspection reports include the following elements, arranged in the order listed:

Cover Letter
Notice of Violation (if applicable)
Cover Page
Executive Summary
Report Details
Exit Meeting Summary
Partial List of Key Licensee Personnel Contacted
List of Inspection Procedures Used
Summary of Items Opened, Closed and Discussed

02 Report Details

Report Details should be structured in terms of the programmatic area inspected. The outline form used is the standard NRC report format, namely, 1, 2 ,3, etc.; then a, b, c, etc.; then (1), (2), (3), etc.

Section 1 may be a programmatic area or a general statement, such as, **Summary of Plant Status**. If Section 1 is a general statement, it may include an overarching statement of the scope on the inspection. For team inspections and inspections by the resident inspector, Section 1 is generally an introductory paragraph covering topics such as background, an overview of the inspection, and/or a summary of inspection observations.

Section Break (Next Page)

For programmatic areas, the number of the applicable inspection procedure should be included; for example, **Transportation (IP 86740)** or **Physical Inventory (IP 85404)**. Each programmatic area section should cover one procedure (or possibly two overlapping procedures). Each section should be divided into two parts, namely **Scope and Observations** and **Conclusions**. Scope and Observations should consist of paragraphs that describe the scope of the inspection followed by observations and findings within the defined scope of that paragraph. The section ends with a stated conclusion based on the inspector's observations. The Executive Summary should repeat the conclusions in the Report Details or should include an equivalent statement. If a notice of violation is issued, the violation should be mentioned in the Conclusion and the Executive Summary.

Activities observed, documents reviewed, personnel interviews, and measurements (both independent measurements and confirmatory measurements) made by the inspector during the course of the inspection, which are significant, should be described in the applicable section of the Report Details.

The final section of the Report Details should cover the **Exit Meeting**.

The examples of fuel cycle inspection reports provided in ADAMS show the desired structure and recommended level of detail.

03 Style and Acronyms

Refer to guidance as shown in Appendix E of this document.

04 Enforcement Actions

When the inspection results in enforcement action, refer to the NRC Enforcement Manual on the NRC web-site at http://www.nrc.gov/what-we-do/regulatory/enforcement.html. Standard format for Cover Letters and Notices of Violation are provided on the web-site. A discussion of enforcement actions can be found in 0610-06.

RELEASE AND DISCLOSURE

In general, the entire inspection report is made available to the public. However, information in inspection reports concerning a licensee's physical protection, classified matter protection, or material control and accounting program, which is not otherwise designated as Safeguards Information or classified as National Security Information or Restricted Data, is withheld from public disclosure under 10 CFR 2.790(d). The cover letters are public, but the reports are not.

EXAMPLES

Examples of fuel cycle inspection reports can be found in the ADAMS package ML032681177. This ADAMS package provides report examples for disciplines such as plant operations, criticality safety, material control and accounting, and emergency preparedness, as well as a resident inspector report.

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GUIDANCE FOR DECOMMISSIONING INSPECTIONS

PURPOSE

The purpose of this appendix is to provide guidance on the preparation of inspection reports for decommissioning inspections. There are two distinct types of Decommissioning Inspections that are performed. The first type is a materials site decommissioning inspection. The second type of decommissioning inspections is a permanently shutdown reactor inspection. The following provides guidance for each of these inspection types.

FORMAT AND STYLE FOR MATERIALS SITE DECOMMISSIONING INSPECTIONS

For decommissioning in progress, inspectors should use NRC Form 591 (Safety Inspection Report and Compliance Inspection) with appropriate comments on Part 3. If surveys are done and data is transmitted to the licensee, a letter report is sent. The format of the letter report is:

COVER LETTER

COVER PAGE

EXECUTIVE SUMMARY

REPORT DETAILS

PARTIAL LIST OF PERSONS CONTACTED

INSPECTION PROCEDURES USED

ITEMS OPEN, CLOSED, AND DISCUSSED

LIST OF ACRONYMS USED

The Report Details section follows the format Inspection Scope, Observations and Findings, and Conclusions. Details on the content of these sections can be found in 0610-05.

FORMAT AND STYLE FOR PERMANENTLY SHUTDOWN REACTOR INSPECTIONS

The inspection report for a permanently shutdown reactor inspection should include the same items as the reports for Decommissioning inspections stated above.

The REPORT DETAILS section for an inspection report for a decommissioning inspection for a Permanently Shutdown Reactor should include the following: All of the reporting topics follow the format Inspection Scope, Observations and Findings, and Conclusions. Guidance on developing the other sections of the report can be found in 0610-05.

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Briefly describe the status of the facility and work completed since the previous inspection.

1.0 Facilities Management and Control

1.1 Safety Reviews, Design Changes, and Modifications

The purpose of this portion of the report is to document whether design changes, test, experiments, and modifications were effectively reviewed, conducted, managed, and controlled during plant decommissioning and the program is in conformance with 10 CFR 50.59 requirements.

1.2 Spent Fuel Safety

The results of the inspection should document the safe wet storage of spent fuel including pool siphon and drain protection; pool instrumentation, alarms, and leakage protection; pool chemistry and cleanliness control; pool support equipment operation; and power supplies. The permanently defueled technical specifications provide the safety limits, limiting conditions of operation, and surveillance requirements for the spent fuel pool.

1.3 Cold Weather Preparations

Report on licensee's actions to effectively protect safety-related systems against extreme cold weather.

1.4 Safeguards Program Implementation

Document the effectiveness of the security plans.

2.0 Decommissioning Performance and Status Review

Describe the status of decommissioning and report whether the licensee and its contracted workforce are conducting decommissioning activities in accordance with license and regulatory requirements.

2.1 Inspection of Final Surveys

Describe licensee activities associated with the final status survey to determine compliance with the Decommissioning Plan and License Termination Plan requirements. Discuss if confirmatory surveys were conducted to verify the adequacy and accuracy of the licensee's final status surveys.

3.0 Radioactive Waste Management

3.1 ISFSI Construction and Component Fabrication

This section of the report should document whether ISFSI dry cask storage system components were fabricated and installed in compliance with regulatory and technical requirements.

3.2 Effluent and Environmental Monitoring

Discuss the licensee's radioactive liquid and gaseous effluent programs to ensure that the licensee effectively controlled, monitored, and quantified releases of radioactive materials in liquid and gaseous forms to the environment.

Section Break (Next Page)

3.3 Transportation of Radioactive Materials

This section of the report should document whether transportation activities are being conducted in compliance with applicable NRC and U.S. Department of Transportation regulations.

4.0 Follow-up

Report on how the inspector conducted a review of Inspection Follow-up Items and Unresolved Items.

5.0 Exit Meeting Summary

Discuss how the inspection results were presented to members of licensee management at the exit meeting. The licensee should identify any proprietary information provided to, or reviewed by, the inspector.

EXAMPLES

Examples of specific inspection reports can be found in ADAMS package ML 032681179. This package contains examples of decommissioning inspections of permanently shutdown

DEP INSPECTION MANUAL

MANUAL CHAPTER 0620

INSPECTION DOCUMENTS AND RECORDS

0620-01 PURPOSE

01.01 To provide general guidance for requesting, controlling, and dispositioning DEP and legacy NRC inspection documents and records transferred under Agreement State during all phases of the inspection program. This is not intended to replace guidance in relevant agency manual chapters nor Commonwealth Management Directives identified in the reference section which serve as the final authority.

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0620-02 DEFINITIONS

02.01. NRC Documents Access and Management System (ADAMS). A document management and recordkeeping system that maintains the official records of the NRC and manages their disposition.

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02.02 Classified Information. Records that (1) are specifically authorized, under criteria established by a Presidential Executive Order or by statute, to be kept secret in the interest of national defense or foreign policy and (2) are, in fact, properly classified pursuant to such authority. These records normally include information in a document or correspondence that is designated National Security Information, Restricted Data, or Formerly Restricted Data. Such classifications may include, but are not limited to, Top Secret, Secret, and Confidential and are consistent with NRC Management Directive (MD) 12.2, "NRC Classified Information Security Plan."

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Comment [D1]: Will we have to follow this? If so, leave text as is; if not, then what? If there is a DEP equivalent, what is it?

a. Classified National Security Information. Information that has been determined pursuant to presidential Executive Order 12958 or any predecessor order to require protection against unauthorized disclosure and that is so designated.

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b. Restricted Data. All data concerning design, manufacture or utilization of atomic weapons, the production of special nuclear material, or the use of special nuclear material in the production of energy, but shall not include data declassified or removed from the Restricted Data category pursuant to Section 142 of the federal Atomic Energy Act.

02.03 Sensitive, Unclassified Information. Safeguards information (SGI), official use only information, proprietary information, and 10 CFR 2.390 publicly exempt information. It includes unclassified information from sources other than the NRC, its contractors, and licensees.

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a. Safeguards Information. Information not otherwise classified as National Security Information or Restricted Data that specifically identifies a licensee's or applicant's detailed, security measures for the physical protection of special nuclear material, or security measures for the physical protection and location of certain plant equipment vital to the safety of production or utilization facilities.

Comment [D2]: SNM protection is identified; but with the new security rules (post 09.11.2001), this now applies to other RAM.

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b. 10 CFR 2.390 Publicly Exempt Information. Information below the level of SGI that relates to the security measures for the physical protection of special nuclear material, or security measures for the physical protection of a facility, including inspection reports, findings, and potential vulnerabilities that can be identified to a specific site.

Comment [D3]: See comment above; how does this pertain to other RAM?

02.04 Document Types:

a. Controlled Document. Any document, correspondence, or information that is in the licensee's document control system. These documents are generally required to be retained for specific periods.

Also, any DEP or legacy NRC document that is classified, SGI, official use only, or any portion of a document that is determined to be exempt from public disclosure consistent with 10 CFR 2.390.

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b. Draft Document. A preliminary (written) document or a preliminary sketch or drawing. A document is considered to be a draft while it is being developed and reviewed. It ceases to be a draft only when it has been approved by responsible management and issued as a final document for implementation.

c. Inspection Document. Any material that is obtained or developed in preparation for, during, or resulting from the inspection of a licensee and that is considered to be an agency record.

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d. Uncontrolled Documents. Documents or information that is not in the licensee's or vendor's document control system.

02.05 Docket File. Files that contain those agency records or other information related to a specific agency docket number that provide a complete record of the transactions between the licensee and the agency whether the information has been made publicly available or not.

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Comment [D4]: Will we retain docket #s?

02.06 PA Right-to-Know Law (Law or RTKL). 65P.S. §§66.1-66.9; Cf. Pennsylvania Management Directive 205.36, as amended November 5, 2003. Describes the procedures for making DEP agency records available to the public for inspection and copying.

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02.07 Handwritten Note. An informal method of communicating information to individual members of the licensee or vendor staff during the performance of an inspection (while onsite). Examples include leaving a note on a licensee staff member's desk indicating the inspector had stopped by to see them, or writing down a procedure (drawing, record, etc.) number to give to a licensee document control clerk to retrieve.

02.08 Inspection. The examination, review, or assessment of any program or activity of a licensee to determine the effectiveness of the program or activity, to ensure that the health and safety of the public and plant personnel are adequately protected, to ensure that the facility is operated safely, and to determine compliance with any applicable rule, order, regulation, or license condition pursuant to the Radiation Protection Act or other statutory requirement.

02.09 Inspection Finding. A DEP-identified or self-revealing issue of concern that is related to a licensee performance deficiency. Findings may or may not be associated with a regulatory requirement and, therefore, may or may not result in a violation. Licensee-identified findings of very low safety significance, that are not violations of regulatory requirements are not documented in inspection reports.

02.10 Inspector's Notes. Notes made by individual inspectors for their own use in preparation for, during, or after an inspection, including notes relative to telephone conversations, are considered personal records. Inspector's notes may be stored electronically provided they are not shared with others and are located in a distinct subdirectory.

02.11 Licensee. The applicant for, or holder, of a DEP radioactive materials license or permit.

02.12 Official Issuance. The final publication, and distribution of a document that has been reviewed, concurred on, and signed by all appropriate levels of management.

02.13 Proprietary Information. Records that (1) contain trade secrets and commercial or financial information, obtained from a person or entity as privileged or confidential, the disclosure of which would result in substantial harm to the competitive position of the owner as supported by an accompanying affidavit signed and notarized by the owner of the information consistent with 10 CFR 2.390, (2) contain voluntarily provided information that the submitter would not normally release to the public, or (3) would harm the government's ability to obtain information in the future.

02.14 Records:

a. Documentary Material. A collective term for records, non-record documents, and personal papers that refers to all media containing recorded information regardless of the nature of the media or the methods or circumstances of recording.

b. Non-record Documentary Material. Documentary material such as unofficial copies of documents that are kept only for convenience or reference, or reference stocks of publications and processed documents, and library or museum material intended solely for reference or exhibition.

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c. DEP Record. Any record obtained or created by the DEP that is required for the conduct of government business. DEP records include any book, paper, map, photograph, brochure, punch card, magnetic tapes, sound recording, pamphlet, slide, motion picture or other video media, electronic data, or other documentary material, regardless of form or characteristics.

d. Official Records. All books, papers, maps, photographs, electronic or machine readable documentary materials regardless of form or physical characteristics created or received by any government agency in connection with the transaction of public business and that are preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data contained in these materials.

e. Personal Records. Records created by DEP personnel that are not required to be made, have not been circulated, are not commingled with agency records, and are not required to be retained by the DEP, or records of a personal nature that are not associated with government business regardless of the form or physical characteristics.

f. Privacy Act Records. Any item, collection, or grouping of information about an individual that is maintained by the DEP in a Privacy Act system of records, including but not limited to the individual's education, financial transactions, medical history, employment history, or criminal history, and that contains the individual's name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a fingerprint, a voice print, or a photograph and is retrieved by the individual identifier.

02.15 Regulatory Requirement. A legally binding obligation such as a statute, regulation, license condition, technical specification, or order.

02.16 Retained Records. Information taken into possession by the DEP as a DEP record to support an inspection finding. This information will be kept by the inspector after the inspection report has been issued.

0620-03 RESPONSIBILITIES

03.01 Program Managers and Regional Directors

a. Provide for the establishment of internal procedures in accordance with existing policies, guidance, and regulatory requirements for the acquisition, control, and disposition of documentation used in preparation for inspections, gained during the conduct of inspections, and resulting from inspections.

b. Take required corrective action when inspection documents are released contrary to DEP policies, procedures, regulations, and legal requirements.

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Deleted: 03.01 Executive Director for Operations (EDO). Approves the release of all inspection documents that have not been officially issued, or any information contained therein, except in cases where release authority for significant safety or safeguards issues has been granted to the office directors or regional administrators.
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Deleted: Obtain EDO approval before releasing a draft inspection document and before discussing the document in a way that is contrary to established NRC policies, procedures, and regulatory requirements for exit meetings, inspector discussions with licensees during inspection, etc. . ¶ ¶ c. . Notify the EDO immediately if substantive documents (i.e. allegations, documents containing OI findings or significant safety or safeguards issues) are inadvertently released or discussed.
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c. Ensure that management and staff are cognizant of, and adhere to, the policies and guidance in this inspection manual chapter (IMC).

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03.02 Inspector Supervisors

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a. Ensure that their staff is cognizant of, adheres to, and implements the policies and guidance contained in this IMC.

b. In accordance with this IMC and established policies, procedures, and regulatory requirements, provide for reviews, approvals, or denials of all inspection documentation before release to a licensee, or in response to a RTKL request.

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c. As appropriate, immediately inform the respective division, staff, or project management when draft inspection documents are inadvertently released to a licensee, or the public, contrary to DEP policies, procedures and regulatory requirements, and report the facts concerning the release.

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d. Review and approve extensive list of documents requested from licensees.

03.03 Inspectors

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a. Maintain a working knowledge of, and adhere to, the regulatory requirements, policies, and guidance for the acquisition, control, and disposition of inspection documentation.

b. May release on own authority, if time is critical, draft inspection documents to prevent or mitigate an emergency or significant safety or safeguards event.

c. Where approved by division or regional management, may provide the licensee with a written list of significant issues identified during the inspection before the issuance of the inspection report, if necessary to communicate inspection findings that require prompt corrective action.

d. If documents or information are inadvertently left unattended for a brief period of time in an area accessible by the licensee or the public, determine whether the subject matter was reviewed in detail by third parties or if a substantive release of information was evident. If release of information is evident, notify supervisor or program manager for further discussion.

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03.04 Division of Radiation Control

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a. Develops and interprets the information contained in this IMC.

b. Provides guidance on situations not covered in this IMC.

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04.01 Requesting Documents

a. Requesting Documents for Inspection Preparation.

1. Requests for documents or information needed either to prepare for an inspection or during an inspection are to be reasonable and should not put an excessive burden on the licensee.

2. Documents that are already available within the DEP records system or NRC records within ADAMS shall not normally be requested.

3. Inspectors should not normally request draft licensee documents or analyses that do not exist in the licensee's document control system.

4. Inspectors shall not request that a licensee generate documents such as analyses, position papers, or calculations, that are not needed to meet a regulatory requirement. Inspectors can request from the licensee listings of specific records in the licensee's document control system such as listings of modifications or corrective action program documents sorted by date, subject, status, or other attribute.

5. The lead inspector or team leader should prepare a list of documents that are needed for the inspection or that the inspector would like to have available upon arrival at the site. If the list is lengthy, or if requested by the licensee, or if directed by DEP management, the list should be sent in a letter which includes the docket or radioactive material license number, to the licensee. The purpose of this is to avoid placing an excessive burden on the licensee.

6. Lengthy requests for documents should be communicated, either orally or in writing, to the licensee at least 30 days before the documents are needed.

7. For team inspections, corresponding with the licensee via e-mail is appropriate to request additional documents after the initial request has been formally made. Documents that contain classified information (i.e. National Security Information, and Restricted Data) may not be transmitted via e-mail. SGI may be sent via e-mail if the files are encrypted.

Additionally, e-mail may be used for exchanges of general information on administrative activities such as schedules, meeting preparations, travel plans, etc.

8. Some inspections or site visits may require requests for the same information from each licensee within a selected group. If the same information will be requested from ten or more licensees in a region during a one-year period, DEP management review and approval is required before such requests are submitted to the licensee.

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b. Obtaining Documents.

Acceptable practices for obtaining licensee documents include:

1. Requesting the licensee to send the documents to the DEP regional office addressed to the individual inspector.

2. Requesting that the documents be sent electronically to the team leader or lead inspector. Documents that contain Classified Information (i.e. National Security Information, and Restricted Data) cannot be transmitted via e-mail. SGI may be transmitted electronically if properly encrypted.

3. Sending a designated inspector to the site to obtain the needed documents from the licensee.

4. Sending the regional inspectors' office staff to retrieve the needed documents from the licensee or vendor.

5. Using the licensee's computer with approved DEP agreement.

6. Using the licensee's copy machine to make copies of materials relevant to the inspection.

NOTE: If a licensee asserts that any of the documents or document excerpts to be retained by an inspector as a DEP record contain proprietary or company classified information, an application for withholding consistent with 10 CFR 2.390(b)(1) along with an explanatory affidavit shall be requested from the licensee before any of the documents are removed from the site. The affidavit must be provided to the lead inspector or team leader by the licensee at the exit meeting or within 10 working days after the exit meeting.

04.02 Controlling Documents and Records

a. Use of Cameras on Licensee Premises.

1. Inspectors are required to obtain licensee permission to take photographs or videos during the inspection of licensee facilities. It is suggested that the inspector obtain blanket approval from the licensee before the start of the inspection to prevent burdening either the licensee or the inspector. Follow guidance on the use of recorded images during the inspection process in Exhibit A.

b. Handwritten Notes to the Licensee

1. The inspector should use caution when providing handwritten notes to a member of the licensee's staff. It is acceptable for an inspector to provide handwritten notes to licensee's document control staff listing a reasonable number of specific licensee documents.

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2. It is also acceptable for an inspector to leave a brief handwritten note on the desk or at the work station of a licensee employee indicating that the inspector had stopped by while the employee was out of the office. This handwritten note should be limited to the inspector's name, the date and time of the visit, a brief description of the topic to be discussed, and information related to how or when the inspector would like to be contacted in the future.

3. Handwritten notes shall not request the licensee employee to provide a response to a specific question.

4. Handwritten notes shall not take the place of a request for information from a licensee to support preparation for an inspection.

c. Inspector Notes

1. Inspector's notes are retained or discarded at the inspector's sole discretion because the DEP has exercised no control or dominion over them as long as they have not been shared with anyone.

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2. The team leader normally makes an integrated list of the significant inspection findings identified at team meetings; the findings are considered inspector's notes. As a courtesy, the team leader or lead inspector discusses them daily with licensee management so that there will be no surprises at the exit meeting. However, the written list of preliminary inspection findings is not to be shown to licensee management. If it is, it may be requested under a RTKL request.

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d. Storage and Disposal of Inspector Notes and Materials

1. Personal records and DEP records may be stored in the same file cabinet or in an inspector's desk. However, personal records must not be kept in the same file folder or same drawer or on the same computer disk as agency records. If stored in separate folders in the same drawer or on the same computer disk as DEP records, such personal records may be considered to be commingled or mixed with DEP records and, as such become part of DEP records.

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2. While onsite, inspectors should take care to ensure draft material or notes developed at licensee facilities are appropriately disposed of when no longer necessary. This precaution is to ensure pre-decisional or draft information is not inadvertently reviewed by the licensee.

3. Before using licensee facilities for disposal of documents or notes prepared by the inspector, the inspector should evaluate whether the information, if made available to the licensee, would interfere with the Department's ability to effectively regulate the licensee or would be an embarrassment to the DEP or the inspector.

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e. Licensee Controlled Information and Space

1. Inspectors should inform licensee management before the inspection that they may be requesting documents from the licensee's document control staff.

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2. When the licensee uses a form to request controlled documents from its storage facility or document control clerks, the inspector may fill out this form following the licensee's procedures.

3. Controlled copies of licensee records and documents may be reviewed at any time during the inspection on licensee-owned property. This documentation is not to be removed from the licensee's property or disposed of without the licensee's permission. With the licensee's permission, controlled copies of their records and documents may be reviewed offsite. Disposition of the licensee controlled information not retained by the inspector will be as directed by the licensee.

4. Any office space provided onsite for the use of inspectors is not considered DEP office space. This space and any licensee documents under review or used by inspectors in this office space, are the property of the licensee, and not the DEP. However, the licensee or vendor is not permitted to go through documents or materials used by DEP inspectors in this space nor share in any conversations held between DEP inspectors in this space.

f. Licensee Forms and Written Documentation

1. Some licensees supply inspectors with forms, during team inspections, to ask written questions or to request information and documents that are needed to continue the inspection. Similar written forms are also generated by licensees to give inspectors written interim and final answers to inspectors' questions.

2. Written answers by licensee personnel in response to oral questions by an inspector on a licensee form that are retained by the inspector, after leaving the site, as the basis of an inspection finding are also DEP records subject to public disclosure. The inspector shall notify the licensee that the retained form will be considered a DEP record subject to public disclosure and provide them the opportunity to request withholding the information consistent with 10 CFR 2.390(b)(1) and the RTKL law.

3. Written answers in response to oral questions by an inspector on licensee forms that provide background information or do not provide the basis for an inspection finding, and are not retained by the inspector after leaving the site are not DEP records and, therefore, are not subject to public disclosure. Disposition of the licensee forms not retained by the inspector will be as directed by the licensee.

4. Written interim answers given by licensee personnel to an inspector on a prepared form or any type of paper, including computer printouts, that may give the appearance that the inspector has helped the licensee to answer the question(s), or may reflect the opinion of an individual staff member rather than the official position of the licensee, or may give the appearance of the licensee doing the inspector's job, are not an acceptable substitute for obtaining information first-hand.

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g. Release of Information Before Inspection Report Issuance

1. Discussions with licensees related to information contained in the inspection report should be limited to the observations made by the inspector during the inspection and the inspector's preliminary assessment of the observation.

2. Under rare circumstances, a written list of significant issues identified during the course of inspection may be provided to the licensee by the lead inspector to facilitate the communication of inspection findings that require prompt corrective action. This list must be approved by the inspector's supervisor before it is released and it must be attached to the inspection report.

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3. Consistent with DEP policies, procedures and regulatory requirements, no portion of any inspection report shall be shown to or given to licensees, or any other group or person external to the DEP before formal issuance of the inspection report, without the explicit written permission of the Department.

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4. If inspection documentation is inadvertently or improperly released by the DEP, its contractors, or other agencies, the Program Manager or Regional Director shall be immediately notified of the release and the facts about the release. Following such notification, the involved individual shall document the release of information to his Program Manager. Corrective action shall be taken by the responsible division or region to retrieve the documentation and prevent recurrence of such a release.

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Comment [D6]: "informed in writing" too restrictive, and also is not "immediate." "Notified" is better (since we have telephone or electronic mail capabilities). Is there a requirement (by NRC) that it be written? Suggest follow-up documentation of the release, however.

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5. Significant safety or security-related information shall be promptly and clearly communicated to responsible licensee management to obtain prompt evaluation and corrective action. There are few circumstances where this information cannot be relayed orally. Therefore, no draft inspection documents shall be given to the licensee unless the issue is so critical that verbal communication will not suffice to expeditiously correct the situation.

6. If the release of draft inspection information is necessary, prior approval shall be obtained from the inspector's management, when possible. If time is critical to the release of draft inspection documents to prevent or mitigate an emergency or significant safety or security event, the inspector shall release the documentation on his or her own authority and inform the responsible DEP management of the release and the circumstances surrounding the release as soon as practical. Such draft inspection documents shall be attached to the inspection report.

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04.03 Dispositioning Documents and Records

a. FOIA and RTKL Requirements.

1. Documents that are in the possession and control of the NRC or DEP may be subject to a FOIA / RTKL request.

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2. Documents that may be captured by a FOIA / RTKL request include, but are not limited to:

(a) Memoranda, facsimile transmissions (faxes), and electronic files, such as e-mail, word processing files, and databases.

(b) Licensee documents, including photographs, diagrams, and video-tapes, in the possession of and under the control of an inspector. These include, but are not limited to, controlled, uncontrolled, and draft copies of licensee documents.

(c) Agency-originated photographs, video-tapes, or sound recordings that are in the possession of agency staff.

(d) Documented conversations that have been shared with others or commingled with NRC or DEP records.

(e) Inspector notes, including annotated licensee documents, that have been shared with others or commingled with NRC or DEP records.

(f) Background material in the possession and control of NRC or DEP staff.

(g) Preliminary inspection findings that have been shown to licensee management.

3. Documents may be withheld in part or withheld in their entirety if they fall within one or more of the FOIA or RTKL exemptions. FOIA exemptions are defined in 10 CFR Part 9 (see NRC MD 3.1 for more detailed explanations of FOIA exemptions; see PA Management Directive 205.36 for RTKL exemptions).

Note: A copy of all records that are within the scope of the FOIA / RTKL request must be provided. Any record to be withheld in part or in its entirety must be bracketed with the appropriate FOIA / RTKL exemption noted.

04.04 Records Disposition

a. Retaining Records

1. The inspector shall only retain as a DEP record the information necessary to support the inspection finding. Most of the time it is acceptable to just identify the source of the information (procedure number, revision, title, etc.) in the inspection report, which becomes the agency's official record.

Note: It should be a rare occurrence that inspection documents are retained.

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Deleted: (a) Documents or portions of documents that fall within one or more of the nine FOIA / RTKL exemptions defined in 10 CFR Part 9. (See also MD 3.1 for more detailed explanations of FOIA exemptions; see PA Management Directive 205.36 for RTKL exemptions)¶

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2. The question that should be asked when determining what information should be retained is: Can the DEP retrieve the document or information from the licensee in the foreseeable future? With this in mind, the inspector should evaluate what level of detail related to the licensee controlled information should be provided in the inspection report.

3. If a document is the sole basis for an inspection finding and is not retrievable from the licensee, it should be listed as an attachment to the inspection.

0620.05 REFERENCES

42 U.S.C. 2011 et. Seq., "Atomic Energy Act of 1954."

5 U.S.C. 552, "Freedom of Information Act."

10 CFR 2.390 "Public Inspection Exemptions, Requests for Withholding".

10 CFR Part 9 "Public Records" (FOIA's, Privacy Act Information).

Pennsylvania Right-to-Know Law, 65 P.S. §§66.1-66.9

Pennsylvania Management Directive 205.36, as amended November 5, 2003

Pennsylvania Management Directive 210.5, Records Management

10 CFR 70.55 "Inspections (Special Nuclear Material)

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Comment [D8]: Perhaps DEP will move toward electronic documentation; in that event, 1) we won't use ADAMS and 2) we'll have our own pertinent acronym.

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¶
The documents listed below are required to be placed in ADAMS:¶
¶
1. Written correspondence, including e-mails, to the licensee requesting documents for inspection preparation.¶
¶
2. Inspection reports.¶
3. Photographs, video-tapes, or recordings that do not contain personal privacy, classified, proprietary, or safeguards information, that were relied on (solely) to substantiate inspection findings.¶
¶
4. Documents or excerpts of documents retained by an inspector that were used to substantiate an inspection finding.¶ ... [1]

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10 CFR 50.70 "Inspections" (Power Reactors).

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EXHIBIT A

USE OF RECORDED IMAGES DURING THE INSPECTION PROCESS		
QUESTION	ANSWER	SOURCE
1. Do I need the licensee's permission to take photographs or videos?	Yes, if a photograph or video is requested to be made by the DEP during an inspection, it should be pre-announced and all participants informed. If someone objects, the objection should always be honored. On occasions where it is not possible to get the licensee's permission in advance, be sure to notify the licensee as soon as possible. Use common sense in recording images as part of your routine inspection activities. Avoid taking images of personnel or plant features related to security. Follow the licensee's policy on the use of photographic equipment, including the prohibition of flash photography in areas of sensitive plant equipment.	IMC-0620 Inspection Documents and Records
2. What if the licensee does not grant permission?	Discuss the licensee's concerns with your supervisor.	
3. Can I forward video or photographs to my management electronically without the licensee's review?	No. If images are recorded during an inspection, it should be reviewed by the licensee to determine if it contains any personal privacy, classified, proprietary, or safeguards information.	IMC-0620 Inspection Documents and Records

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4. Do I need something in writing from the *licensee that says they* have reviewed the images for safeguards, personal privacy and propriety information?	No.	

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5. Is there agency guidance on how to forward images that contain classified or sensitive unclassified information?	Yes. Images that contain proprietary information or are for Official Use Only can be forwarded electronically (via email or fax) . Images that contain classified or safeguards information cannot be forwarded via email. However, if it is necessary to provide these images to management or to DEP experts to assist in making an inspection determination, you must print the images and forward them via a secure fax machine utilizing appropriate controls established in agency guidance. If secure fax capability is not available, the images must be mailed in accordance with DEP requirements and the approved DEP classified mailing address must be used if classified information is involved. Also, all images believed to contain classified or sensitive unclassified information must be marked in accordance with DEP requirements. The camera used to take the classified images must be protected as classified and secured when unattended.	
6. How do I know when images must be retained? When are images required to be destroyed?	If the images **are used** to substantiate an inspection finding and they do not contain classified or safeguards information, they are considered official agency records. **Examples** of images used to substantiate an inspection finding include images that are relied on to support regulatory decision-making. In some cases, the photograph may be the sole basis for the inspection finding. If the images **are not** used to substantiate an inspection finding and they contain personal privacy, classified, proprietary or safeguards information they must be destroyed in accordance with DEP requirements. **Examples** of images not used to support an inspection finding include: (1) those images that are used as memory	

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If images are not used to support inspection findings can they be retained for training purposes?	joggers to assist the inspector in finalizing the inspection report and (2) images forwarded electronically to regional management to clarify or to discuss findings. images of this nature are not relied on for regulatory decision-making. If the images do not contain personal privacy, classified, proprietary, or safeguards information, they may be retained for informal training purposes. If the images contain personal privacy, classified, proprietary, or safeguards information, then they must be destroyed in accordance with IMC 0620.	
7. What if the licensee requests that a images be withheld from public disclosure because it contains personal privacy or proprietary information.	If it is necessary to keep a images containing personal privacy or proprietary information, the licensee must request that it be withheld from public disclosure consistent with 10 CFR 2.390 (b) (1). If the information is proprietary the request must be accompanied by an affidavit. If the image is the basis for a finding, it should be edited by the licensee to delete the sensitive information unless that information is necessary to support the finding. REMINDER–Under IMC-0620 if the images contains personal privacy, classified, proprietary, or safeguards information it must be destroyed if it is not the basis for an inspection finding.	

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USING RECORDED IMAGES FOR INFORMAL TRAINING		
QUESTION	**ANSWER**	**SOURCE**
8. If recorded images are not used to support inspection findings can they be retained for training purposes?	If the recorded images do not contain personal privacy, classified, proprietary, or safeguards information, they may be retained for informal training purposes. If the recorded images contain personal privacy, classified, proprietary, or safeguards information, then they must be destroyed in accordance with IMC 0620.	IMC-0620 "NRC Documents, Records, or Information"
9. Do I need the licensee's permission to keep recorded images?	You do not need the licensee's permission to retain these recorded images for training purposes if you believe the recorded images would be helpful in carrying out DEP's regulatory responsibilities. However, follow the guidance that relates to requesting the licensee's permission and review to determine if the recorded images contain proprietary, personal privacy, classified, or safeguards information.	DEP's authority under the Radiation Protection Act
10. Are images recorded for training subject to FOIA / RTKL?	Yes.	NRC MD 3.1 "Freedom of Information Act"; Pennsylvania Right-to-Know Law, 65 P.S. §§66.1-66.9
11. How should the recorded images be identified?	Recorded images that contain proprietary information must be labeled as such consistent with 10 CFR 2.390(b) and should include the date and name of the facility or facility owner.	10 CFR 2.390

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	There are no agency requirements that non-sensitive photographs be labeled and dated. However, for ease of FOIA/ RTKL searches, recorded images be dated and labeled.	
12. If the recorded images contain classified and safeguards information can they still be used for training purposes?	Yes, but only if absolutely necessary and only if the photographs support an inspection finding (REMINDER- staff reviewing such photographs must possess the appropriate clearance levels and have a "need to know"). If this is the case, such recorded images and or digital media that contain classified and safeguards information must be secured and agency guidance followed. Follow guidance in IMC-0620 regarding licensee review of such recorded images.	IMC-0620 Inspection Documents Records
13. How long should photographs used for informal training (OJT and learning opportunities) be retained?	Recorded images be destroyed when they are no longer needed.	

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: ADAMS is a recordkeeping system that maintains the official records of the agency and manages their disposition. Official agency records include all books, papers, maps, photographs, and machine readable documentary materials regardless of form or physical characteristics created or received by any agency of the United States Government under Federal law or in connection with the transaction of public business and that are preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data contained in these materials.

The documents listed below are required to be placed in ADAMS:

1. Written correspondence, including e-mails, to the licensee requesting documents for inspection preparation.

2. Inspection reports.

3. Photographs, video-tapes, or recordings that do not contain personal privacy, classified, proprietary, or safeguards information, that were relied on (solely) to substantiate inspection findings.

4. Documents or excerpts of documents retained by an inspector that were used to substantiate an inspection finding.

5. Where approved by regional management, written lists of significant issues identified during the course of the inspection that require prompt corrective actions provided to the licensee at the exit meeting. This list must be attached to the inspection report. This should be a rare occurrence.

6. Any documentary information, relative to inspection activities, distributed by an NRC inspector at a management meeting with the licensee. Such written material must be attached to the inspection report.

7. Any information or document sent to the NRC by mail or overnight express, with the exception of those sent directly to an NRC inspector as personal mail. (See NRC MDs 3.50, "Document Management" and 3.23 "Mail Management.")Note: Documents or portions of documents that meet the requirements above and fall within the exempt categories of 10 CFR 2.390 and 10 CFR 9.13, are not to be made publicly available.

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NRC Management Directive 3.1, "Freedom of Information Act."

NRC Management Directive 3.50, " Document Management."

NRC Management Directive 3.53, "NRC Records Management Program."

NRC Management Directive 12.1, "NRC Facility Security Program."

NRC Management Directive 12.2, "NRC Classified Information Security Plan."

NRC Management Directive 12.4, "NRC Telecommunication Systems Security Program."

NRC Management Directive 12.6, "NRC Security Manual Sensitive Unclassified Information Security Plan."

NRC Management Directive 3.2, "Privacy Act."

NRC Inspection Manual Chapter 0330, "Guidance for NRC Review of Licensee Draft Documents."

NRC Inspection Manual Chapter 0612, "Power Reactor Inspection Reports."

NRR Office Instruction COM-203, Rev 1 dated 04/04/05, "Informal Interfaces and Exchange of Information with Licensees and Applicant." (ML050800544)

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MD 12.2 "NRC Classified Information Security Program"

MD 12.4 "NRC Telecommunication Systems Security Program"

MD 12.6 "NRC Sensitive Unclassified Information Security Program"

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NRC's authority under the Atomic Energy Act, § 161©)

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MD 12.1 "NRC Facility Security Plan"

MD 12.2 "NRC Classified Information Security Plan"

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NO, if the photographs are used for informal training (OJT and learning opportunities). **Yes,** if the photographs are used for formal training (e.g. Technical Training Center).

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MD 3.53 "NRC Records Management Program"

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13. Are photographs used for training purposes required to go in ADAMS?

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14. How long should photographs used for informal training (OJT and learning opportunities) be retained?

How long should photographs used for formal training be retained.

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Recommend that the photographs be destroyed when they are no longer needed.

Currently, only formal training is thru HR/TTD, and retention schedules exist for them. Regional offices typically provide only informal training.

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DEP INSPECTION MANUAL

MANUAL CHAPTER 1120
PRELIMINARY NOTIFICATIONS

1120-01 PURPOSE

To provide instructions regarding the prompt dissemination of information about significant events occurring at facilities or relating to activities licensed by the Department, Nuclear Regulatory Commission or an Agreement State.

1120-02 POLICY

02.01 Implementation. Oral, electronic and/or written preliminary notifications (PNs) will be made for all matters that meet the criteria specified in this manual chapter (see Sections 1120-07 and -08 below). PNs should normally address the more significant events that warrant immediate attention of upper management.

02.02 Issuing office. A PN will be generated by the DEP regional or headquarters office that received information about an event. Central office will be responsible for the dissemination of the PN.

1120-03 OBJECTIVES

The objectives of the PN system are as follows:

a. To provide promptly to the Department and other NRC and Agreement State management new and current information on matters that are of significant safety or safeguards concern or have, or potentially could have, high public interest.

b. To provide to others in the DEP, NRC and the Agreement States on a less urgent basis, information on matters that are the subject of PNs.

1120-04 DEFINITIONS

Preliminary Notification (PN). An early notice of an event of possible safety or safeguards significance or of high public interest; information presented is as initially received without complete verification or evaluation and is essentially all that is known at the time notification is made.

1120-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Program Managers and Division Chiefs or Designees

a. Evaluate data received to determine if the criteria for PNs have been met.

b. Assure that during normal duty hours adequate consultation is made between the affected regional office and the appropriate central office division regarding the need for a telephonic notification before issuing the written PN.

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c. Assure, when practical and appropriate, that the accuracy of technical information included in the written PN has been confirmed with licensee management before the PN is issued. Also assure, when practical and appropriate, that all PNs containing information relevant to radiation exposure of licensee employees or of the public are reviewed for technical accuracy by management staff having responsibility for the radiation protection inspection program.

d. Review and approve PNs prior to issuance by central office.

e. Maintain awareness of significant matters described in PNs

05.02 Lead Central Office Division Chief, or Designee

a. For urgent matters of radiological significance, the lead DEP central office program manager will promptly inform by telephone call the NRC Office of State and Tribal Programs (STP) liaison officer and the Radiation Protection Program Office in each affected State outside Pennsylvania.

b. Prepare, approve, and promptly distribute PNs electronically that are to be issued by central office within its programmatic areas (See Section 1120-11).

f. Evaluate the performance of regional offices in the implementation of this inspection manual chapter.

g. Promptly re-distribute PNs of interest issued by the NRC once PNs are received (See Section 1120-11).

05.04 Central office NMED Coordinator

a. Post publicly available non-sensitive PNs to the public web site.

b. Maintain PN distribution list.

1120-06 NUMBERING OF WRITTEN PRELIMINARY NOTIFICATIONS

Each written preliminary notification is designated by an alphanumeric code specifying the originating organization (SW, SC, SE, CO for DEP; and I, II, III, IV, H or IIT for NRC), the year of issuance, and the sequential number of the PN in that year. Thus, PNO-SW-93-03 is the third written preliminary notification of an event or unusual occurrence reported by DEP Southwest Regional Office in 1993. Note: The designation H is for Headquarters, CO is for central office, and IIT is for Incident Investigation Team (NUREG-1303).

If subsequent written PNs are to be issued to update or correct a previously issued PN, the original written PN number is retained and a letter added to the end of the number to indicate the supplement. For example, PNO-SW-93-02C is the third supplement of PNO-SW-93-02.

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¶

f. Promptly inform by telephone call the appropriate HQ office(s), such as Nuclear Reactor Regulation (NRR), Nuclear Materials Safety and Safeguards (NMSS), Nuclear Security and Incident Response (NSIR), Public Affairs (OPA), State and Tribal Programs (STP), etc., of the most significant matters that are the subject of PNs issued by the Regional Office. When the matter has radiological significance, contact the Radiation ... [6]

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1120-07 CRITERIA FOR ISSUING A WRITTEN PRELIMINARY NOTIFICATION

Written PNs shall be issued for (but shall not necessarily be limited to) the types of incidents, events and occurrences described below:

a. Events which prompt a licensee to declare an alert, site area emergency or general emergency; and unusual events which may be of significant interest to the news media, government or the public.

b. Any situation that results in significant personnel contamination, or significant contamination event requiring a special inspection.

c. Occupational dose or probable occupational dose in excess of the limits in 10 CFR 20.1201, 20.1206, 20.1207 and 20.1208.

d. A public dose or probable public dose in excess of the limits in 10 CFR 20.1301.

e. Significant transportation incidents such as those involving significantly damaged, leaking or lost Type B or fissile packages or those involving high public interest (i.e., major highway closed, etc.)

f. Serious natural occurrences and their effects, such as flooding, hurricane, or icing; assessment of the effects of earthquakes or tornadoes at or near licensed facilities, even when no major damage was done; major damage to licensed facilities resulting from natural occurrences.

g. Significant environmental events such as releases immediately reportable under 10 CFR 20.2202 or events which violate NRC or DEP regulatory requirements.

h. Fires or explosions that (1) affect safety-related equipment, or (2) cause significant damage to licensed facilities.

i. Significant operational events or equipment problems. This includes events such as significant safety equipment failures during operations, damage to portable gauges resulting in unshielded sources, ruptured well logging sources, etc.

j. Any significant loss of criticality safety controls.

k. Events of security significance directed toward or occurring within licensed facilities or information concerning threats to licensees such as: actual or apparent breaches of security systems, actual or threatened sabotage, malicious mischief or vandalism, bomb threats, or arson.

l. Lost or stolen licensed material immediately reportable under 10 CFR 20.2201 when the material poses a significant safety hazard, generates high public interest, or involves radioisotopes and activities of concern for a radiological dispersal device (RDD). A PN is not mandatory for lost or stolen gauges, or other devices posing a low safety hazard. In such cases, however, the theft of such a device may warrant action on the part of local law enforcement, and media interest in regaining custody and control of the lost radioactive materials.

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m. Other significant events related to licensed activities in which national, state, or local news media interest already exists, or as deemed appropriate when media interest is expected but not certain, as well as updated information on events related to licensed activities that have previously attracted media attention.

n. Significant medical events reported under Subpart M of Part 35.

It should be noted that allegations are not appropriate subjects for PNs.

1120-08 CRITERIA FOR TELEPHONE CONFERENCE CALL NOTIFICATION

08.01 During normal duty hours only the most noteworthy events of the types listed in Section 1120-07 warrant a conference call notification. The decision to do so will usually depend on the speed with which the event is breaking compared to the time it could take to prepare and dispatch a written PN. During other than normal duty hours, the threshold for oral notifications may be somewhat lower simply because the information received concerns a matter that must be promptly brought to the attention of DEP upper management before a written PN can be prepared and dispatched upon resumption of normal duty hours.

08.02 The decision concerning oral notifications for events will usually be made by the responsible regional program manager or central office division chief (or designees).

08.03 The conference call should include the following or their designees and may include others, as appropriate*.

Director, Bureau of Radiation Protection
Regional Director (Optional)
Director of Emergency Response (Optional)
Chief, Emergency Response Section (Optional)
Community Relations Coordinator or PIO (Optional)
Regional Radiation Protection Program Manager
Lead Central Office Division Chief

*other program management support or individuals with direct knowledge of events

1120-09 FORMAT OF WRITTEN PRELIMINARY NOTIFICATION

09.01 General. The format and content of a written PN are shown in Exhibit 1. To facilitate the preparation of a PN and to have a consistent format for electronic transmission and ultimate processing by recipients, documents will be generated with common software such as Microsoft Word and posted in portable document format (Adobe PDF).

09.02 Specific Parts of Preliminary Notification. The following is a description of each part of the PN:

a. The heading "PRELIMINARY NOTIFICATION" must be included at the top of the page.

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¶
q. An event at an NRC or Agreement State licensed facility (including facilities issued a construction permit) that results in a serious injury to a contaminated person or a fatality. A PN is not appropriate for serious injuries involving uncontaminated persons. ¶
¶
r

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t. Significant fitness-for-duty events reportable under 10 CFR 26.73.¶
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Emergency Officer (NRR or NMSS)¶
Director, Office of Nuclear Reactor Regulation ¶
Director, Office of Nuclear Security and Incident Response ¶
Section Break (Continuous)
Director, Nuclear Material Safety and Safeguards¶
Commissioners' Assistants¶
Executive Director for Operations¶
Director, Office of Public Affairs¶
Director, Office of Congressional Affairs¶ ... [21]

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b. Date of issuance.

c. PN number (see Section 1120.06)

d. An introductory, boilerplate statement must be included in all PNs as follows:

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region staff on this date.

e. Facility - Identify the facility, its location (city/state) and the licensee.

f. Subject - Enter a brief, one-line description of the matter.

g. Report Content - The body of the PN contains a brief factual description of the problem or event including the time and date of occurrence, and plant, buildings, areas or systems affected by the occurrence. The PN also should describe any controls, protective measures and/or plan of action employed or immediately initiated to minimize the magnitude of the event or its effects. The accuracy of technical information should be confirmed with the licensee's plant management when practical, particularly when the information was not initially obtained from the licensee plant management. PNs should avoid speculation, or should specifically identify speculative statements when their use is considered necessary. Recognizing the balance that must be made between promptness of issuance and depth of detail, attempt to include the following when applicable:

1. Radionuclides of concern

2. Actual or estimated quantity of release

3. Dose estimate, dose rate estimate, percentage of Technical Specifications (TS) or 10 CFR 20 limit, or some other means of interpreting the significance of the release or exposure

4. Areas involved (restricted, unrestricted, or owner controlled).

If the licensee or the DEP plans to issue or has issued a press release, so state. The PN should not contain negative statements such as "no media interest is expected."

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If media inquiries have been made, the PN should so state.

When reference is made to a regional office, that office should be identified by location as well as by number the first time it is used in each PN.

PNs should not include the names of licensee employees; rather, the title of individuals should be used when it is necessary to specify an individual. An exception to this is when individual names are important to the notification and the names have previously been provided to the public.

PNs must not contain any information exempt from disclosure,

If State Program Offices or other affected organizations have been notified, identify the states or organizations and the method of notification.

If the PN contains all the pertinent information expected to be received regarding the matter being reported and no further action is believed necessary, then the PN should contain a statement similar to the following:

> This preliminary notification is issued for information only and no further action by the staff is anticipated.

The closing paragraph of the body of the PN must contain information regarding the time and manner of receipt of information. A standard sentence similar to the following should be included in each PN:

> DEP _____ Region received initial notification of this occurrence by _____ (the means of notification, that is, letter, telegram, or telephone call) from _____ (source of information) at (time and date). The information presented herein has been discussed with the licensee, and is current as of _____ (time and date).

h. Contact - The PN should include the names, email addresses, and telephone numbers of individuals who can supply additional information if needed. Two contacts are normally listed.

1120-10 ACTIONS FOLLOWING RECEIPT OF INFORMATION

10.01 Normal Duty Hours. After information about an event of the type described in 1120-07 (or of like significance) is received, prompt consideration is given to the necessity for a Conference Call (see Section 1120-08). If Conference Call Notification is likely, the regional program manager (or designee) consults with the appropriate central office division chief (or designee) that such notifications be made. The lead central office division chief ensures that required Conference Call is made promptly (normally within 1-2 hours after receipt of the initial report).

Following the above decision (and action if required) concerning telephonic notification, a PN is prepared and electronically dispatched, normally within 2 hours after receipt of the initial information.

10.02 Other than Normal Duty Hours. Information about a significant event received during other than normal duty hours will most likely be reported initially through PEMA to the Emergency Response Coordinator, who in turn reports the event to the Bureau Director or cognizant central office program manager, as appropriate. The event is evaluated and a decision regarding telephone notification is made by the Bureau Director in accordance with 1120-08.

The appropriate regional and HQ program managers (or their designees), ensures that information received during other than normal duty hours concerning events which meet

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the PN criteria is later disseminated by PN. These PNs should be dispatched electronically within about 2 hours after resumption of normal duty hours, or sooner if conditions warrant.

10.03 The appropriate central office division chief (or designee) notifies the NRC Office of State and Tribal Programs liaison by telephone when a PN is being issued that has direct or indirect connection with Agreement States and that involves radioactive materials primarily exposures, transportation accidents, theft of sources, etc.).

1120-11 DISPATCH OF PRELIMINARY NOTIFICATIONS

11.01 The issuing program shall dispatch PNs electronically. The distribution consists of 3 parts; a basic distribution required for all PNs, a supplementing distribution required by the issuing organization, and the PN specific requirements.

11.02 If there is a failure of the E-Mail system that prevents the transmission of a PN, the issuing program should transmit the PN by facsimile and follow-up electronically.

11.03 An example of the basic distribution list that shall be utilized by the issuing program for all PNs is provided in Exhibit 2. Each region should supplement this distribution by making direct distribution to others to satisfy regional or PN specific needs.

1120-12 SUPPLEMENTAL PRELIMINARY NOTIFICATION

Supplemental PNs normally are issued only when it is necessary to notify DEP or NRC management promptly of additional or corrected information relating to a significant matter previously described in a PN. This may occur, for example, if the situation previously described in a PN worsens significantly or if the information in a PN is determined to be incorrect.

1120-13 DISPOSITION OF MATTER PRESENTED IN PRELIMINARY NOTIFICATIONS

PNs need not contain sufficient information to close a matter. Also, it is not necessary that the resolution of a matter be reported through the issuance of subsequent PNs. The tracking of matters described in PNs to ensure appropriate resolution is accomplished through handling of licensee reporting and follow-up inspections.

1120-14 REVIEW OF ALL PNs FOR ABNORMAL OCCURRENCE REPORTING

DEP may review the events described in each PN against the criteria contained in NRC Management Directive 8.1, "Abnormal Occurrence Reporting Procedure," and take follow-up actions on the basis of the reported PN.

END

Exhibits:
1. Example of a Preliminary Notification
2. Example of Standard Distribution List

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Deleted: Note that there is a 48 hour (2 business days) delay for agreement state ENs and PNs. Information pertaining to this requirement can be located in STP-02-047 (available in ADAMS ML021650172), dated June 13, 2002.
Deleted: 10.04 . If the NRC enters the Standby, Initial Activation or Expanded Activation Modes of the NRC Incident Response Plan, only an initial PN is issued. Status Summary reports are issued in lieu of PNs until a return to the Normal Mode occurs. Status Summary reports are distributed to the NRC offices via the E-Mail system. A final PN is issued to note the disposition of the NRC response.¶
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Exhibit 1

EXAMPLE

January 7, 1994

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE
PNO-SW-93-076C

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Southwest Regional staff on this date.

Facility	**Licensee Emergency Classification**
Duquesne University	____Notification of Unusual Event
	____Alert
	____Site Area Emergency
	____General Emergency
	__x__Not Applicable

Subject: UPDATE - LOSS of Neutron Howizter

The Duquesne Department of Physical Sciences reported the loss of 5 Ci of PuBe on December 13, 1993 resulting in an order to temporarily suspend licensed activities (ref Corrective Actions Letter and Order of December 15, 1993). An Augmented Inspection Team was dispatched on December 26, 1993.

The AIT leader held an exit meeting with the licensee on January 2, 1994, in Pittsburgh, PA, and issued a press release on January 6, 1994.

The licensee's corrective actions were sufficiently comprehensive to resolve the problems identified by the Augmented Inspection Team. A meeting was held among the licensee, DEP SWRO and DEP CO in Harrisburg, PA on January 5, 1994, to satisfy the requirements of the CAL.

Based on the AIT findings, verification of the completion of the licensee's corrective actions by the Regional Staff, reviews made by DEP CO and discussions during the meeting, suspension of the license was lifted on January 6, 1994.

The information presented herein has been discussed with the licensee, and is current as of 8:00 a.m., January 7, 1994.

This preliminary notification is issued for information only and no further action by the staff is anticipated.

Contact: J. Yusko
(412) 555-1166
jyg@PA.gov

Exhibit 2

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Deleted: McGuire Unit 2 declared an unusual event on December 27, 1993, due to a loss of offsite power and subsequent safety injection. An Augmented Inspection Team (AIT) was dispatched to the site on December 29, and a Confirmation of Action Letter (CAL) was issued to Duke Power Company on December 29, 1993.
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EXAMPLE

PRELIMINARY NOTIFICATION (PN) STANDARD DISTRIBUTION LIST

PN RECIPIENT LIST

CO	Director, BRP
	Chief, Rad Control Div
	Chief, Rad Mat Lic Sec
	Chief, Nuc Safety Div
	Chief, Emerg Resp Sec
	Chief, Decom & Surv Div
	Director, Emergency Response
	PIO
SWRO	RPPM
	RD (opt)
	CRC (opt)
SCRO	RPPM
	RD (opt)
	CRC
SERO	RPPM
	RD (opt)
	CRC (opt)
NRC	OSTP Liaison (opt)
Affected States	RCPD (opt)

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chmnpn . . TLA . . Terry Agneu¶
¶
diazpn . . RKD . . Roger Davis¶
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edopn . . CEJ . . Cathy Jaegers¶
¶
merripn . . LPP . . Lorna Pini Kipfer¶
¶
mcgafpn . . JAL . . Judy Ledbetter¶
¶
nmsspn . . CJP2 . . Cathy Poland¶
¶
nrrpn . . PN1 . . Kathy Gray¶
¶
nsirpn . . MFW . . Mike Weber¶
¶
ocapn . . NDB2 . Nancy Belmore¶
¶
oepn . . SLF . . Sandra Figueroa¶
¶
ogcpn . . TMM . Terry Mayberry¶
¶
oigpn . . AXP . . Alicia Penaherrera¶
¶
oippn . . AVL . . Vicki Lewis¶
JMW1 . Jeannette Whitaker¶
¶
rds pn distribution . DTK . . Dan Kube [contractor]¶
¶
respn . . MEM2 . Mike Mayfield¶
¶
ripn . . CMY . . Connie Yusko¶
¶
riipn . . MLH . . Melba Hawkes¶
¶
riiipn . . BAB1 . Bruce Berson¶
¶
rivpn . . JAC1 . Jo Carson¶
¶
¶
Section Break (Continuous)
secypn . . RIDSSECYMAILCENTER¶
¶
OPA¶
STPMAIL¶
WEBWORK email publicly available nonsensitive PN **ML#** [from PARS availability] with PNO document date, licensee/facility, subject/title of PN [do not email WP file]

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and should supplement existing event reports. When an Event Notification (EN) has been issued to document a report to the Headquarters Operations Center, another report (i.e., PN or Morning Report) will not be issued to report the same information. Morning Reports are intended to address those events or situations considered routine or of lesser significance where immediate attention of upper management is not required

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Regional offices usually will have jurisdiction over the issuance of PNs for events occurring in the regions, including events that are first reported to the Headquarters Operations Officer. The text of the PN will be created using WordPerfect or other available software (see ADAMS Desk Reference Manual for acceptable software). The issuing office will add the PN to ADAMS in a pre-determined subdirectory. They will also provide the document information to the Document Processing Center in the Office of the Chief Information Officer (OCIO) via electronic distribution, for secondary processing. The issuing office

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using the distribution list provided by OCIO

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Oral notification during a conference call is also known as a Commissioners' Assistants Briefing, and is always followed up with a written PN.

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e. Assure that written PNs are promptly distributed electronically to designated offices (See Section 1120-11).

f. Promptly inform by telephone call the appropriate HQ office(s), such as Nuclear Reactor Regulation (NRR), Nuclear Materials Safety and Safeguards (NMSS), Nuclear Security and Incident Response (NSIR), Public Affairs (OPA), State and Tribal Programs (STP), etc., of the most significant matters that are the subject of PNs issued by the Regional Office. When the matter has radiological significance, contact the Radiation Protection Program Office in each affected State.

g. ~~Make oral notification of significant matters or assure that a conference call is~~ established with the Headquarters Operations Officer. (See Section 1120-08)

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Office (NMSS or NRR) Directors

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Promptly inform the appropriate regional and HQ offices orally of significant matters that are the subject of PNs, for those cases in which a HQ office is the issuing office. When the matter has radiological significance, contact the Radiation Protection Program Office in each affected State. As appropriate and when practical, assure that the accuracy of technical information included in the written PN has been confirmed with licensee management before the PN is issued.

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c. When the HQ office is most knowledgeable on a subject, provide special guidance to the regional offices upon issuing the PNs.

d. Make oral notifications of significant matters or assure that a conference call is established with the Headquarters Operations Officer (See Section 1120-08).

e. Maintain awareness of significant matters described in PNs.

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05.03 Headquarters Operations Officer (HOO)

a. Sets up and conducts Commissioners' Assistants briefing, if requested.

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Office of the Chief Information Officer (OCIO)

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b. Setup and maintain a link (via the sites Electronic Reading Room) for each publicly available nonsensitive PN to the actual publicly available PN in the ADAMS public library (PARS).

c

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At nuclear power plants, this includes events such as activation of the ECCS, abnormal depressurization, pipe breaks or leaks, malfunction of relief valves resulting in pressure transients, or failure of diesel generators, which would cause or are expected to cause plant shutdown in excess of 3 days or which would be expected to cause such shutdown if the plant were operating. [Extensions of plant outages to perform testing and maintenance activities unrelated to the event that prompted the shutdown, or outages caused by balance-of-plant equipment problem with no direct regulatory (or operational safety) implications, do not require the issuance of a PN.] Additional guidance pertaining to significant operational events may be found in Inspection Procedure 71153, "Event Follow-up," and Management Directive 8.3, "NRC Incident Investigation Program," and IMC 0309, "Reactive Inspection Decision Basis For Reactors."

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j. Initial criticality at a nuclear plant.

k

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Any operational problem concerning reactivity, such as inadvertent criticality or significant abnormal flux distribution. For fuel cycle facilities, this includes a

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A little before this, statements related to safety concerns. In this post-9/11/2001 era, do we *really* want to publicize security breaches or threats? Recognizing that this was prepared in 2003, there are classes of

information that should not be readily disseminated.

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, theft, discovery or discharge of firearms, demonstrations resulting in arrests or violence

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m. Reported inventory differences (ID), as follows:

1. for licensees subject to 10 CFR 70.51(e), ID that exceed both 300 grams of U-235 and 1.5 times the prescribed limit of error of inventory differences (LEID);

2. for licensees subject to 10 CFR 74.31, ID that exceed the licensee's detectable threshold value;

3. for licensees subject to 10 CFR 74.51, ID that exceed both 300 grams of U-235 and 3 times the standard error of inventory differences (SEID).

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gas chromatographs, static eliminators, explosive/chemical agent detectors, and

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o. Strikes of employees at any major licensed facility; strikes of security guards or honoring of picket lines by these employees; or strikes of craft employees at plants under construction which result in violence, damage, or a construction delay of more than 1 month.

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Regional Duty officer
Emergency Officer (NRR or NMSS)
Director, Office of Nuclear Reactor Regulation
Director, Office of Nuclear Security and Incident Response
Director, Nuclear Material Safety and Safeguards (continuous)
Commissioners' Assistants
Executive Director for Operations
Director, Office of Public Affairs
Director, Office of Congressional Affairs
Director, Office of State and Tribal Programs
Director, Office of International Programs

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the issuing office will use WordPerfect or other available software (see ADAMS Desk Reference Manual for acceptable software) and the ADAMS template NRC-004 (available in ADAMS ML031150184) "NRC Preliminary Notifications (PNOs)." Each issuing office shall track and maintained their perspective numbering systems (see Section 1120.06)

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Anyone on the distribution list who believes that a PN has been issued, but has not received it, should call the appropriate coordinator to determine if the contact has received a copy and, if necessary, arrange to get a copy. Each Office is responsible for notifying OCIO of any changes to the basic list. The above is to provide a minimum required distribution; further distribution by any of the above recipients is anticipated.

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to the Operating Experience Section (OES) in NRR and NSIR (Operations Center)

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After completing the facsimile transmission, a phone call should be made by the issuing organization to the contacts listed for the Operations Center, NRR, and NMSS (when the PN is for a materials licensee). The time these calls were completed should be recorded on the retained hard copy. These phone calls will alert the Headquarters staff that a PN was sent and verify that the PN was received. The contacts will assist by dispatching PNs to the Headquarters Offices identified on the basic distribution list until equipment problems have been corrected. Copies will be hand carried by the Operations Center to the EDO's office and to the mailroom of the Office of the Secretary for distribution to the Commission. The Operations Center should provide a copy to the Director, NSIR .

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As changes occur in coordinators, please contact OCIO . OCIO will update the distribution list and make copies available to the regions and Headquarters (available in ADAMS ML003736389).

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A Morning Report should be used to supplement a PN when the new information alone does not warrant issuing a PN supplement.

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Headquarters and regional staffs responsible for issuing PNs shall

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the prescribed actions for those events meeting the criteria

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The unit is currently at 50% power. Region II received initial notification of this occurrence by a telephone call from the licensee at 22:22 (EST) on December 27, 1993.

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DEP INSPECTION MANUAL

MANUAL CHAPTER 1220

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PROCESSING OF DEP FORM 241, "RECIPROCITY - REPORT OF PROPOSED ACTIVITIES IN PENNSYLVANIA, IN AREAS OF DEPARTMENT JURISDICTION," AND INSPECTION OF RECIPROCITY LICENSEES OPERATING UNDER 25 PA CODE CHAPTER 217 SUBCHAPTER J

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1220-01 PURPOSE

To establish procedures for processing Department of Environmental Protection (DEP) Form 241 and changes to DEP Form 241; provide information to licensees for filing DEP Form 241; and institute the frequencies and requirements for inspection of licensees operating under reciprocity in areas of DEP jurisdiction.

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1220-02 OBJECTIVES

02.01 To ensure that licensed material is used in accordance with regulatory requirements and that licensed operations are conducted in a manner to ensure protection of the public health and safety.

02.02 To ensure compliance with 25 Pa. Code Chapter 217 subchapter J, "RECIPROCITY."

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02.03 To provide information to appropriate regional offices and to DEP's Central Office regarding licensees operating under reciprocity.

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1220-03 DEFINITIONS

03.01 Agreement State. Any State with which the Commission (or the Atomic Energy Commission) has entered into an effective agreement under SubSection 274b, "Cooperation with States," of the Atomic Energy Act of 1954, as amended.

03.02 Non-Agreement State. Any State that is not an Agreement State.

03.03 Exclusive Department Jurisdiction. An area over which the Department exercises legal control without interference from the jurisdiction and administration of Federal law.

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03.04 Reciprocity. Department recognition of certain Agreement State, Non-Agreement State and NRC licenses for work performed in areas of Department jurisdiction.

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03.05 Reciprocity Activities. Activities conducted by Agreement State, Non-Agreement State and NRC licensees in areas of exclusive Department jurisdiction, under the general license provisions of 25 Pa. Code 217.203.

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03.06 Filing. Filing will be deemed to be complete as of the time of Department receipt, either by mail, facsimile or other electronic means as the Department may provide for.

03.07 Initial Filing. Department receives DEP Form 241 filed by licensees requesting reciprocity for activities conducted in Pennsylvania. Filing by facsimile is considered acceptable if the facsimile includes 4 copies of the DEP Form 241 and evidence that the appropriate fee requirements will be met within 3 days. This evidence can be a copy of the check or money order, that will be mailed to the Department. The licensee should receive confirmation (by telephone, e-mail, or facsimile) that DEP has received the facsimile.

1220-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Radioactive Materials Licensing Section. Maintain the computer-based Reciprocity Tracking System (RTS) to track reciprocity activities, in order to assist in the planning of inspections of those activities, and to provide summaries of reciprocity activities and inspections on a Department-wide basis; and to establish the following procedures and guidelines for use in processing DEP Form 241.

a. Each year, at least 60 days prior to the anniversary of a general license for reciprocity, provide: a Procedures Letter (Appendix II) to the reciprocity licensee, from the previous year with the procedures and information required for filing DEP Form 241 for reciprocity and for withholding reciprocity information from public disclosure; the applicable regulations and Information Notices; copies of DEP Form 241; and other pertinent information.

b. Review DEP Form 241 when received to ensure that the proposed activities are in accordance with 25 Pa. Code 217.203 and are authorized under their State or NRC license in accordance with the procedures described in Appendix I. If not, contact the licensee regarding the lack of conformance with the DEP general license in 25 Pa. Code 217.203.

c. Enter the licensee information into the RTS, and distribute copies of the signed DEP Form 241 (include a copy of the licensee's State or NRC specific license with the initial forms) to the DEP Regional Office(s) having jurisdiction in the area(s) in which the licensee intends to operate. Signature authority for the reviewing official of the reciprocity activities, as requested by DEP Form 241, may be designated according to Central Office Licensing Section policy.

d. Maintain records of reciprocity activities in the RTS.

e. Maintain Form 241 requests for at least 5 years following the year for which the Form 241 was effective.

04.02 Regional Offices

a. Schedule, conduct, and track inspections to achieve the overall objectives of the inspection program, including the objectives of this chapter.

b. Inspect licensees operating in areas of exclusive Department jurisdiction under reciprocity using the same provisions used for equivalent DEP-licensed activities. Carry out enforcement actions against those licensees when violations are found during a DEP inspection. (See Appendix III for specific procedures and frequency.)

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I. "Procedures and Guidelines for Processing DEP Form 241"
(Appendix I provides the procedures to be followed, by the reviewers, in processing reciprocity requests from the receipt of DEP Form 241 to the input of data into the RTS to the final distribution of completed actions.)

II. "Procedures Letter"
(Appendix II contains a sample Procedures Letter to be sent, by the Central Office Licensing Section, to licensees each year, providing information concerning filing for reciprocity (including Forms 241 and procedures for filing, applicable guidelines, and regulations).)

III. "Inspection of Reciprocity Licensees"
(Appendix III provides information for use by regional inspectors concerning inspection frequencies and the tracking of inspections through the RTS.)

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APPENDIX I

PROCEDURES AND GUIDELINES FOR PROCESSING DEP FORM 241

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A. PURPOSE

To establish the procedures and guidelines for implementing the requirements of this chapter.

B. FILING OF INITIAL DEPARTMENT OF ENVIRONMENTAL PROTECTION FORM 241

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The following points address requirements for filing the initial DEP Form 241.

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1. Agreement State, Non-Agreement State and NRC licensees requesting reciprocity for activities conducted in Pennsylvania in areas of exclusive Department jurisdiction, are subject to 25 Pa. Code 217.203. Prior to the first time within a 12 consecutive month period that an Agreement State, Non-Agreement State or NRC licensee conducts activities in areas of Department jurisdiction, it must file a copy of a completed DEP Form 241, four copies of its license, and the appropriate fee as specified in fee category 16 of 25 Pa. Code Chapter 218, Appendix A.

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Note: A licensee operating under reciprocity pursuant to 25 Pa. Code 217.203 does not have to obtain affirmative authorization from DEP before performing activities requested on DEP Form 241 providing the pre-notification requirement of 25 Pa. Code 217.203(a)(2) is met. Licensees that do not qualify for the general license will be informed of this determination, within 3 days of receipt of DEP Form 241 (See Item 4., "Deficient DEP Forms 241).

Note: Verify that those licensees engaging in radiography activities are registered as a user for each approved package issued a Certificate of Compliance number(s), in accordance with the requirements of 10 CFR 71.12, Item 8.

Note: If a company has more than one license, a separate DEP Form 241 must be submitted for work conducted under each license used during the calendar year.

Note: All fee payments and questions concerning fees should be referred to the Central Office.

2. In completing DEP Form 241, the licensee must provide sufficient information to enable DEP to conduct inspections.

Note: The licensee should only identify work to be conducted during a single 12 consecutive month period.

3. In general, the preferred method of filing is through the facsimile transmission of DEP Form 241, a copy of the Agreement State, Non-Agreement State or NRC license, and evidence that the appropriate fee requirements will be met within 3 days. This evidence can be a copy of the check or money order that will be mailed to the Department. The licensee should receive confirmation (by telephone, e-mail, or facsimile) that DEP has received the facsimile. Alternatively, the licensee may file the required information through the mail or other means as long as DEP receives the information at least 3 days before the licensee engages in the activity.

4. If the facsimile or other acceptable method for filing all of the required information is not available to the licensee because of an emergency or for other reasons, the Chief, Radioactive Material Licensing Section or his designee can waive the time requirements specified in Code 217.203(a)(2) for the filing of DEP Form 241, provided the licensee:

   a. informs the Central Office by telephone, facsimile, DEP Form 241, or letter of initial activities ; and

   b. receives oral or written authorization for the activity(ies) from Central Office; and

   c. files DEP Form 241, 4 copies of the Agreement State, Non-Agreement State or NRC license, evidence (as described in paragraph B.3 above) that the appropriate fee requirements will be met within 3 days.

C. PROCESSING OF DEP FORM 241

Reciprocity licensees are required to report their proposed activities in Pennsylvania to the Central Office. The Central Office shall take the following actions in processing DEP Form 241.

1. RECEIPT

   Verify that the filing is timely. Stamp or otherwise note the date of receipt on all copies of DEP Form 241. The form must normally be received by DEP Central Office at least 3 calendar days before the licensee's beginning work.

   Note: The Chief, Radioactive Material Licensing Section or his designee may waive the 3-day time requirement, as discussed in B.4. above.

2. INITIAL DEP FORM 241

   a. Immediately upon receipt of DEP Form 241, verify that the required information has been provided and that the certification block has been signed and dated by the Radiation Safety Officer or management representative.

   b. Verify that the fee for the appropriate amount and 4 complete copies of a valid, active Agreement State, Non-Agreement State or NRC license are included with the initial DEP Form 241.

      Note: For DEP Forms 241 received without evidence of the fee payment, notify the licensee, by telephone, that the required fee must be provided before conducting activities under reciprocity.

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In cases where the licensee seeks a waiver of the time requirements, the reviewing personnel may authorize reciprocity activities before receipt of the fee only after contacting Central Office technical management for approval.

c. Review the license that was submitted with DEP Form 241 to verify that the proposed activities are authorized by the license and that the license will be in effect during the time of the proposed activities.

Note: The Agreement State, Non-Agreement State or NRC licensee cannot qualify for a general license under 25 Pa. Code 217.203, if the specific license limits the activity authorized by the license to specified installations or locations; only if the license authorizes temporary job site locations will the general license of 25 Pa. Code 217.203 apply.

d. For initial DEP Forms 241, enter the licensee and fee information into the Reciprocity Tracking System (RTS).

e. Enter work location information into the RTS.

Note: The Location Reference Number (LRN) is used by the RTS and is necessary for the tracking of DEP Form 241 and any changes to DEP Form 241 and is described in the RTS Users Manual. This number should be entered on DEP Form 241 for use by the licensee on subsequent changes.

f. If DEP Form 241 is deficient (i.e., does not contain the required information, or the information provided indicates that the applicant does not qualify), see Item 4. , "Deficient DEP Forms 241." When it is determined that the required information has been submitted and the fee payment has been provided, sign and date DEP Form 241 as the reviewing official and forward a copy to the licensee. This copy may be transmitted via facsimile.

Note: For cases where DEP Form 241 is received and the filing indicates that the licensee does not qualify for a general license under 25 Pa. Code 217.203, notify the licensee of this fact within 3 days of receipt of DEP Form 241 and return the fee to the applicant.

Note: Signature authority for the reviewing official of the reciprocity activities as requested by DEP Form 241 should be designated according to licensing section policy.

j. Promptly notify and distribute a copy of DEP Form 241 and supporting documentation to the Region(s) where the work is to be performed.

3. CHANGES TO DEP FORM 241

a. Verify that DEP Form 241 indicates a request for a change for additional work locations, or changes to the radioactive material, or work activities different from the information previously identified by the licensee on the initial Form 241. The preceding may include updates to or deletions of specific locations or work sites, work site contacts, or dates of work previously identified by the licensee.

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h. . In the lower right hand corner, mark the NRC's signed Form 241 (or letter in lieu of Form 241) with the assigned ADAMS code and write "copy to Region __" indicating the appropriate region for distribution. Forward the completed Form 241 or letter, a copy of the Agreement State license, and evidence of the fee payment to LFARB for fee processing. After determining that the appropriate fee has been paid, LFARB will enter the fee payment information on NRC Form 241 and forward the completed ... [8]

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b. Confirm that the information on file in the RTS for the initial DEP Form 241 is current and correct before revising the licensee's reciprocity record in the RTS.

c. Obtain the number of total usage days to date from the RTS (number of days activities are conducted and/or licensed material is stored in Department Jurisdiction and record on DEP Form 241.

d. For new locations of work, additional dates, or different activities, enter the information into the RTS. Assign an LRN for each new location of work listed on DEP Form 241.

e. If DEP Form 241 is deficient, see Item 4. , "Deficient DEP Forms 241." When it is determined that the required information has been submitted, sign and date DEP Form 241 as the reviewing official or send a letter indicating that the revisions to the reciprocity activities submitted on the initial DEP Form 241 have been reviewed and found sufficient, and forward a copy of the authorized DEP Form 241 to the licensee. Signed DEP Forms 241 may be transmitted via facsimile.

Note: For cases where changes to DEP Form 241 are received and the filing indicates modifications in activities that would no longer allow the licensee to qualify for a general license under 25 Pa. Code 217.203, notify the licensee of this fact within 3 days of receipt of DEP Form 241.

Note: It is not necessary for the licensee to resubmit the Agreement State license unless the license has been amended since the filing of the initial NRC Form 241.

h. Promptly notify and distribute a copy of DEP Form 241 and supporting materials to the Regions(s) where the work is to be performed.

4. DEFICIENT DEP FORMS 241

a. If DEP Form 241 contains omissions or errors, try to first resolve them by telephone contact with the licensee within 3 days of receipt of the DEP Form 241 request. If the discrepancies can be resolved by telephone contact, mark the form with the corrections and emphasize to the licensee the need to comply with the requirements of 25 Pa. Code 217.203 and that the Agreement State licensee must confirm, in writing or by facsimile, the information provided by telephone.

b. If the deficiencies cannot be resolved by telephone, send a letter requesting the necessary additional information, identifying to the licensee the errors, omissions or deficiencies. Emphasize to the licensee the need to comply with the requirements of 25 Pa. Code 217.203 before conducting activities under reciprocity and notify the licensee that further review will continue on receipt of the requested information.

c. If the discrepancies cannot be resolved with the licensee, notify the licensee by telephone and send a follow-up letter, within 3 days of receipt of the DEP Form 241 request, explaining that the licensee has not submitted the required information and thus does not qualify for a general license under 25

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Deleted: f. In the lower right hand corner, mark the NRC's signed copy of NRC Form 241 (or letter in lieu of Form 241) with the assigned ADAMS Distribution code for reciprocity documents, and write "copy to Region "indicating the appropriate region for distribution. After processing, the form will be returned to the regional office for the official files.
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g. . Promptly notify, by e-mail, the NRC regional office(s) responsible for the area in which the activity will be conducted, of completed action
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Pa. Code 217.203. Indicate to the licensee that work is not to be performed in Department jurisdiction, until DEP, receives the required information. Return the fee payment to the applicant.

Note: It is the responsibility of the licensee to file for reciprocity if work is to be performed in an area of Department jurisdiction. However, in situations where the licensee requests assistance in making a determination about such an area, the reviewing official should refer the licensee to the procedures for determining exclusive Department jurisdiction, contained in Appendix II, "Procedures Letter."

d. For licensees whose proposed reciprocity activities are approaching or would exceed the 180-day limit, the licensee should be notified by telephone or mail that a specific DEP license must be applied for and obtained if activities in Department jurisdiction in excess of 180 days are to be conducted within the calendar year.

5. APPARENT NON-COMPLIANCE WITH 25 PA CODE 217.203.

If DEP Form 241 describes activities that appear to be in noncompliance with the applicant's specific license or other regulatory requirements, the following actions shall be taken:

a. Where the license limits use to a specific address or location, advise the licensee, by telephone or in writing (with a copy to the appropriate State or NRC) within 3 days of receipt of the DEP Form 241 request, to apply to the licensing authority for a license amendment permitting temporary job site locations, or apply for a specific DEP license. The reviewer should note the resolution or proposed action on DEP Form 241.

b. Cases where activities were started before the initial DEP Form 241 was submitted; where the applicant's license is expired, limits locations, or otherwise is ineligible for reciprocity; or where the 180-day limit is exceeded are violations of 25 Pa. Code 217.203 and should be treated in accordance with the DEP Enforcement Policy.

c. Cases where activities, because of their nature or necessity (e.g., emergencies, weekends), were started before changes were phoned in or submitted (but the initial DEP Form 241 was submitted) should be reviewed on a case-by-case basis when determining compliance with 25 Pa. Code 217.203.

Note: Staff should consider other instances of failure to change DEP Form 241 as noncompliance with the general license provisions of 25 Pa. Code 217.203.

6. DEP FORMS 241 - EQUIVALENCE OR MISDIRECTION

a. Equivalence - There may be cases where the licensee submits a letter in lieu of DEP Form 241. This is acceptable, provided that the submittal contains all of the information required by DEP Form 241, including 4 complete copies of a valid Agreement State, Non-Agreement State or NRC license, if applicable, and the required fee.

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b. Misdirection of DEP Form 241 - If an applicant inadvertently submits DEP Form 241 to a regional office, the receiving office shall promptly notify the Central Office office, by telephone and send the DEP Form 241 to Central Office, by facsimile. The original DEP Form 241 and the backup documentation may be sent by mail.

D. WITHHOLDING RECIPROCITY INFORMATION FROM PUBLIC DISCLOSURE

Applicants that seek to withhold information contained in DEP Form 241 from public disclosure, must submit an application and affidavit for withholding, when the initial DEP Form 241 is filed. The Central Office shall take the following actions in processing requests for withholding of information on DEP Form 241 from public disclosure.

1. RECEIPT

a. Verify that the licensee has submitted an application for withholding information and an affidavit with the initial DEP Form 241. Confirm that two versions of the Form 241 have been submitted with brackets ([ ]) placed around the information sought to be withheld. One version should have the information in brackets intact for the Department's use in processing the request for reciprocity. The other version should be "sanitized" for public disclosure with the information sought to be withheld deleted or erased. Confirm that the additional information outlined in Attachment 1, Appendix I, has also been supplied in the application.

Note: If the licensee has already submitted a DEP Form 241, it must submit an application and affidavit within a week of DEP's receipt of DEP, Form 241.

Note: Only the information contained in Items 8 to 12 of DEP, Form 241 can be requested for consideration for withholding from public disclosure as proprietary information.

b. If the application or affidavit are deficient (i.e., do not contain the required information) or request that information other than that found in Items 8 to 12 be withheld, notify the licensee by telephone within 3 days of receipt of the request that additional information is needed and that the review will continue on receipt of the required information. Inform the licensee that for DEP, to consider withholding the information contained in DEP, Form 241 from public disclosure, it must review the information to ensure its status, with respect to being withheld, and that the review of its request for reciprocity will continue on receipt of this information.

c. Review the application or affidavit to determine whether the information contained in the application and affidavit for withholding is complete and sufficient. Notify the licensee by letter, signed by the Radiation Control Division Chief with the concurrence of Department Counsel, acknowledging agreement or disagreement in whole or in part with its claim for proprietary treatment and the appropriateness of its affidavit. Attachment 2 of this appendix contains samples of the letters to be sent to licensees when acknowledging agreement or disagreement with requests for withholding specific information contained in Form 241 from Public Disclosure.

Note: Once the application and affidavit request for withholding information have been determined to be sufficient, the request will be maintained by the DEP Central Office for as long as the

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licensee continues to perform reciprocity activities and submit DEP Form 241s. If the licensee skips a year between filing reciprocity requests, the application and affidavit for withholding must be resubmitted for review.

d. Information originated by licensees that has been determined to be proprietary must be marked to ensure proper handling and that the information is only released on a need-to-know basis. The words "Proprietary Information" should be placed at the top and bottom of the page on the front of each document containing proprietary information.

E. RETENTION AND DISPOSAL OF RECIPROCITY LICENSING DOCUMENTS

1. All reciprocity licensing documents, the initial DEP Form 241s, changes, and requests to withhold information must be retained for 5 years after the licensee is no longer regulated by the Department. Withheld information must be destroyed upon disposition of the associated records.

2. In-active license records may be archived according to Department policy.

END

Attachments:

1. Information Needed For Withholding Information From Public Disclosure
2. Sample Letter #1 - Acknowledging Agreement With Request to Withhold Form 241 Information from Public Disclosure
3. Sample Letter #2 - Acknowledging Disagreement With Request to Withhold Form 241 Information from Public Disclosure
4. Sample Letter #3 - Acknowledging Partial Agreement With Request to Withhold Form 241 Information from Public Disclosure

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Deleted: Documents containing Proprietary Information must be covered by a Proprietary Information cover sheet, NRC Form 190. Documents containing Proprietary Information must be transmitted between NRC facilities and outside NRC facilities in a single opaque envelope or wrapper. The single opaque envelope or wrapper must not bear any markings or indications that the document contains Proprietary Information.

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Deleted: and/or destroyed in accordance with the approved records disposition schedules contained in NUREG-0910, "NRC Comprehensive Records Disposition Schedule." NRC Schedule 2-24.4.d, as rewritten, requires that NRC Form 241 license files be retained for 20 years after license termination

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Deleted: retired to off-site storage through the Records and Archives Services Section (RASS), Information and Records Management Branch, Office of Information Resources Management (IRM). They will remain in storage for the remainder of their 20-year retention period following the year for which the Form 241 was effective. Procedures for retiring records are contained in NRC Management Directive 3.53, "NRC's Records Management Program."

Deleted: 3. . Retired records are available for recall from the RASS, IRM, through each respective region's Records Liaison Officer. Requested records (complete box or individual file folders) can be received by the requester via express mail or the internal mail system within 1 to 4 days after RASS receives a request.

Comment [COMMENT3]: The following references to attachments were missing from the previous revision of this document.

ATTACHMENT 1

INFORMATION NEEDED FOR WITHHOLDING INFORMATION
FROM PUBLIC DISCLOSURE

Licensees wishing the Department of Environmental Protection (DEP) to withhold, as proprietary or confidential, the information contained in Items 8 to 12 of DEP Form 241 from public disclosure should submit an application for withholding accompanied by an affidavit. Note: Only the information requested to be withheld as proprietary needs to be accompanied by an affidavit. For the Department to determine whether the information should be withheld from public disclosure, the following information should be provided in sufficient explanatory detail:

1. Clear identification of the document(s), or parts thereof, to be withheld as proprietary or confidential.

2. Statement that this information is held in confidence by the owner of the information.

3. A rational basis for requesting withholding of the information, clearly stating the reasons why the company believes the information contained therein is proprietary or confidential.

4. Confirmation, with details provided, that the information transmitted to, and received by, DEP is held in confidence.

5. Statement as to whether the information is currently available in public sources.

6. Confirmation whether the company customarily treats this information, or this type of information, as confidential, with an explanation.

7. Determination whether the public disclosure of the information would be likely to cause substantial harm to the competitive position of the company, with an explanation in detail as to why. Affidavit should also include the value of the information to the company, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

8. Clear identification of the position of the person executing the affidavit (an officer or upper-level management official delegated to review the information sought to be withheld and authorized to apply for withholding on behalf of the company.)

9. Statement that the company submitting the affidavit is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary and that the affiant is an employee of the company.

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ATTACHMENT 2

SAMPLE LETTER #1 - ACKNOWLEDGING AGREEMENT WITH REQUEST TO WITHHOLD FORM 241 INFORMATION FROM PUBLIC DISCLOSURE

(Licensee's Name)
(ATTN: Contact Name)
City, State Zip Code

Dear _____:

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON DEP FORM 241

By DEP Form 241, "Reciprocity - Report of Proposed Activities in Pennsylvania in Areas of Exclusive Department Jurisdiction," letter from (Licensee's Name) dated ____, and affidavit dated ___, you submitted proprietary material consisting of client information and requested it be withheld from public disclosure. This is the response to that request.

You stated that the submitted information should be considered exempt from public disclosure for the following reasons:

1.

2.

We have reviewed your application and the material and, on the basis of your statements, have determined that the submitted information sought to be withheld does contain proprietary information. Therefore, the client information contained in Items 8 to 12 of DEP Form 241, marked as proprietary, will be withheld from public disclosure. Your request for withholding will be maintained by the Division of Radiation Control, indefinitely for as long as you continue to perform reciprocity activities and submit DEP Form 241s. If you skip a year between filing reciprocity requests, you must resubmit for review an application and affidavit for withholding information contained in DEP Form 241 from public disclosure.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the Department. You should understand that DEP may have cause to review this determination in the future. In all review situations, if DEP makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at (XXX) XXX-XXXX.

Sincerely,
(Chief, Division of Radiation Control)

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SAMPLE LETTER #2 - ACKNOWLEDGING DISAGREEMENT WITH REQUEST TO WITHHOLD FORM 241 INFORMATION FROM PUBLIC DISCLOSURE

(Licensee's Name)
(ATTN: Contact Name)
City, State Zip Code

Dear _____:

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON DEP FORM 241

By DEP, Form 241, " Reciprocity - Report of Proposed Activities in Pennsylvania in Areas of Exclusive Department Jurisdiction," letter from (Licensee's Name) dated ____, and affidavit dated ___, you submitted proprietary material consisting of client information and requested it be withheld from public disclosure. This is the response to that request.

We have reviewed your application and the material and, for the following reasons, have determined that the submitted information, in whole or in part, sought to be withheld does not contain proprietary information:

1.

2.

Therefore, we have determined that the material, specifically Items 8 to 12, DEP Form 241, should be free for release. This information is being forwarded to you as notice that the information will be available to the public thirty (30) days from the date of this letter. If within thirty (30) days of this letter, you request withdrawal of these documents, or provide additional reasons for the withholding of information, your request will be considered in light of applicable statutes and regulations and a determination made as to whether the documents should be withheld from public disclosure or returned to you.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public disclosure should change in the future such that the information could then be made available for public inspection, you should promptly notify DEP. You should understand that DEP may have cause to review this determination in the future. In all review situations, if DEP makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at (XXX) XXX-XXXX.

Sincerely,
(Chief Division of Radiation Control)

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SAMPLE LETTER #3 - ACKNOWLEDGING PARTIAL AGREEMENT WITH REQUEST TO WITHHOLD FORM 241 INFORMATION FROM PUBLIC DISCLOSURE

(Licensee's Name)
(ATTN: Contact Name)
City, State Zip Code

Dear _____:

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION CONTAINED ON DEP FORM 241

By DEP Form 241, " Reciprocity - Report of Proposed Activities in Pennsylvania in Areas of Exclusive Department Jurisdiction," letter from (Licensee's Name) dated ____, and affidavit dated ___, you submitted proprietary material consisting of client information and requested it be withheld from public disclosure. This is the response to that request.

We have reviewed your application and the material and, on the basis of your statements, have determined only certain information contained in Items 8 to 12 of DEP Form 241 to be proprietary.

The client information contained in Item(s) ___ of DEP Form 241, marked as proprietary, does contain proprietary information and will; therefore, be withheld from public disclosure. Your request for withholding will be maintained by the Division of Radiation Control indefinitely or for as long as you continue to perform reciprocity activities and submit DEP Form 241s. If you skip a year between filing reciprocity requests, you must resubmit for review an application and affidavit for withholding information contained in DEP Form 241 from public disclosure.

We have also determined that, for the following reason(s), the information contained in Item(s) of DEP Form 241 does not contain proprietary information:

1.

2.

Therefore, the client information contained in Items ___ of DEP Form 241, should be released for public disclosure. This information is being forwarded to you as notice that the information will be available for public disclosure thirty (30) days from the date of this letter. If within thirty (30) days of this letter, you request withdrawal of these documents, or provide additional reasons for the withholding of information, your request will be considered in light of applicable statutes and regulations and a determination made as to whether the documents should be withheld from public disclosure or returned to you.

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SAMPLE LETTER #3 - ACKNOWLEDGING PARTIAL AGREEMENT WITH REQUEST TO WITHHOLD FORM 241 INFORMATION FROM PUBLIC DISCLOSURE

(Licensee Name) -2-

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public disclosure should change in the future such that the information could then be made available for public inspection, you should promptly notify DEP. You should understand that DEP may have cause to review this determination in the future. In all review situations, if DEP makes a determination adverse to the above, you will be notified in advance of any public disclosure.

If you have any questions concerning this action, please feel free to contact me at (XXX) XXX-XXXX.

Sincerely,
(Chief Division of Radiation Control)

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APPENDIX II

PROCEDURES LETTER TO BE SENT TO LICENSEES
WITH PROCEDURES AND INFORMATION FOR FILING DEP FORM 241

A. PURPOSE

To provide licensees with procedures and applicable guidelines, regulations and information for filing Department of Environmental Protection Form 241.

B. SAMPLE PROCEDURES LETTER

(Licensee's Name)
ATTN: (Contact Person)
(Title)
(Licensee's Address)
(City), (State) (Zip)

Dear (Contact Person):

Agreement State, Non-Agreement State and NRC licensees (licensees) seeking to conduct activities under reciprocity in Pennsylvania in areas of exclusive Department jurisdiction, for the first time in a consecutive 12 month period, must submit DEP Form 241, " Reciprocity - Report of Proposed Activities in Pennsylvania in Areas of Exclusive Department Jurisdiction; 4 copies of the Agreement State, Non-Agreement State or NRC specific license; and the fee specified in fee Category 16, Appendix A, 25 Pa. Code Chapter 218. DEP must receive this filing at least 3 days before the licensee engages in activities permitted under the General License established by 25 Pa. Code 217.203 (Enclosure 1). This general license authorizes persons holding a specific license from a State or the NRC to conduct the same activity, if the specific license does not limit the authorized activity to specified locations or facilities.

A licensee operating under reciprocity pursuant to 25 Pa. Code 217.203 does not have to obtain affirmative authorization from DEP before performing activities requested on DEP Form 241. If, however, in processing DEP Form 241, DEP determines that the DEP Form 241 contains omissions or errors, the staff will contact the licensee in an attempt to obtain the correct information. If the discrepancies cannot be resolved and the applicant does not qualify for the general license, staff will inform the applicant of this determination and indicate that the applicant has not complied with the requirements of 25 Pa. Code 217.203, and work is not to be performed in Pennsylvania in areas of exclusive Department, until DEP receives the required information.

Licensees cannot perform work in Pennsylvania in areas of exclusive Department jurisdiction without either (a) filing DEP Form 241 for reciprocity in accordance with 25 Pa. Code 217.203 or (b) applying for a specific DEP license. An area of exclusive Department jurisdiction is an area over which the state government exercises legal control without interference from the jurisdiction and administration of

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Federal law. For example: Federal facilities such as Veterans Administration Hospitals are not under the exclusive jurisdiction of the Department and reciprocity from the Department is not required to work there. If the work is to be performed on Federal property in an Agreement State, the licensee must first determine the jurisdictional status of the area where it plans to work. If the licensee is unsure about the jurisdictional status of the work location on Federal land, it should contact the Federal agency that controls the facility where the work is to be performed. Enclosure 2, "All Agreement States Letter SP-96-022," contains procedures developed by NRC's Office of State Programs for determining exclusive Federal jurisdiction. A written statement concerning the jurisdictional status is not required, to file for reciprocity. However, it is recommended that the licensee obtain such a statement for the file for future reference.

Under the general license, licensees conducting reciprocity activities, including storage (usage), are limited to a total of 180 days in any calendar year. DEP tracks reciprocity usage on the basis of approved usage days. DEP will not approve any activity, under the general license, that causes the total usage days to exceed 180 days. DEP may note, and notify the licensee, that a filing proposes reciprocity activities which approach or would exceed the 180-day limit. It is important that licensees track the days of use and submit changes to dates of work when applicable.

Licensees who perform activities using separate licenses must submit separate reciprocity requests. For example, if a licensee has separate radiography and service licenses, and performs reciprocity work under both, the licensee must submit a separate DEP Form 241 with evidence of the appropriate fee for the initial filing for each license. The activities under reciprocity for each license will be limited to 180 days.

Enclosure 3 contains guidelines to follow in filing DEP Form 241. It is expected that licensees will review this information, as well as the regulations cited in 25 Pa. Code 217.203, to ensure that the radiation safety program is in compliance with DEP regulations before conducting activities under reciprocity.

DEP will perform inspections of activities performed in Pennsylvania by A licensees operating under a general license pursuant to DEP. These inspections will occur at the listed work site location(s).

Licensees operating under reciprocity, must conduct activities involving radioactive materials in accordance with the conditions specified in the licensee's Agreement State, Non-Agreement State or NRC license, representations made in DEP Form 241, and other rules, regulations, and orders of DEP, now or hereafter in effect. Failure to comply with these regulations or to conduct your radiation safety program in compliance with DEP regulations before operating under reciprocity may result in DEP enforcement action(s) against the licensee. Such actions could include the issuance of a notice of violation, the proposed imposition of a civil penalty, or an order suspending, modifying, or revoking the license.

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During the review of enforcement actions taken against licensees operating under reciprocity, it was noted that some licensees have not always made the effort to become aware of DEP regulations. This is the licensee's obligation. The lack of awareness of DEP requirements, and applicable provisions is not an acceptable justification to preclude DEP enforcement actions.

For your information and use in filing for reciprocity, I have enclosed Pennsylvania Regulations for Radiological Health (Enclosure 1), Guidelines for Filling DEP Form 241 (Enclosure 2), DEP Form 241 (Enclosure 3), DEP Form 2900-FM-RP0003, "Notice to Employees" (Enclosure 4), 10 CFR Parts 19, 20, 71 (as applicable, 10 CFR Parts 30, 34, 35, 39, 40, 61, and 70) (Enclosure 5).

If you have any questions about the regulations or the application process, please feel free to contact me at (XXX) XXX-XXXX.

Sincerely,

(Reviewing Official)

Enclosures:

1 Regulations For Radiological Health 25 PA Code Article V
2. Guidelines for Filing DEP Form 241
3. DEP Form 241, "Reciprocity – Report of Proposed Activities in Pennsylvania in Areas of Exclusive Department Jurisdiction"
4. DEP Form 2900-FM-RP0003, "Notice to Employees"
5. 10 CFR Parts 19, 20, 71 (as applicable, 10 CFR Parts 30, 34, 35, 39, 40, 61, and 70) incorporated by reference

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ENCLOSURE 1

GUIDELINES FOR FILING DEPARTMENT OF ENVIRONMENTAL PROTECTION FORM 241

Initial Filing

Agreement State, Non-Agreement State and NRC licensees (licensees) seeking to conduct activities under reciprocity in Pennsylvania in areas of exclusive Department jurisdiction, for the first time in a 12 consecutive month period, must submit: DEP Form 241, "Reciprocity - Report of Proposed Activities in Pennsylvania in Areas of Exclusive Department Jurisdiction,"; 4 copies of the Agreement State, Non-Agreement State or NRC specific license; and evidence of the fee specified in fee Category 16, Appendix A, 25 Pa. Code Chapter 218, with the Central Office Radioactive Materials Licensing Section. DEP must receive this filing at least 3 days before the licensee engages in activities permitted under the General License established by 25 Pa. Code 217.203. Failure to file DEP Form 241 may result in civil or criminal penalties.

To facilitate DEP 's inspection of licensees working under reciprocity, it is important that the information submitted on DEP Form 241 be specific regarding the location(s) and date(s) of use as well as the activity requested. If it is not possible to provide complete addresses for the locations of work, the licensee should provide as much information as possible, concerning the work site(s) or client(s) location such as the town, county, or area (e.g., the Bisco pipeline in Somewhere County, Any State). Please note that reciprocity activities will not be approved for locations such as "temporary jobsites in the county" or "in the city of ___." The licensee is responsible for providing new or additional information concerning addresses or locations of work as soon as such information becomes available. A Location Reference Number will be generated by DEP for use in tracking reciprocity activities and is specific for each work location. Location Reference Numbers will be provided to licensees on the signed Form 241 copies and should be referenced for any changes to work location information provided on the initial filing of DEP Form 241.

For the dates of work, it is acceptable to indicate that the licensee will operate under reciprocity for 180 days in the 12 month period commencing..., provided the licensee narrows down or deletes dates as they become known. For example: the initial DEP Form 241 may list March 1 - March 31 for the site at the Bisco pipeline; however, because of rain, work was not performed on March 2 - March 10. The need to delete work dates becomes important when a licensee approaches the 180-day limit; therefore, the licensee should delete the dates when work was not performed. (See Changes, below.)

In general, the preferred method of filing is through the facsimile transmission of DEP Form 241, 4 copies of the applicant's license, and evidence that the appropriate fee requirements will be met within 3 days. This evidence can be a copy of the check or money order that will be mailed to the NRC. The licensee should receive confirmation (by telephone, e-mail, or facsimile) that DEP has received the facsimile. Alternatively, the licensee may file the required information through the mail or other means as long as DEP receives the information at least 3 days before the licensee engages in the activity.

In addition, the licensee must also submit, by mail, 4 copies of DEP Form 241, 4 copies of the applicant's license, and the fee or evidence that the fee has been paid, within 3 days of the facsimile transmission. Alternatively, the required information may be transmitted through the mail or other means as long as DEP receives the information at least 3 days before the initiation of licensed activities.

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Changes

Additional work locations or clients, changes to the radioactive material, or work activities that are different from the information submitted on the initial DEP Form 241 must be filed with the DEP. When submitting revision requests, file by DEP Form 241 or letter, so that DEP receives the filing at least 3 days before the licensee engages in such activity. It is not necessary to resubmit the applicant's license unless the license has been amended since the filing of the initial Form 241. Filing by facsimile is acceptable provided: (1) the licensee confirms that DEP has received the facsimile; and (2) DEP receives, within 3 days, DEP Form 241 or letter in lieu of Form 241.

Emergency Filing

If you are unable to file all the required information by facsimile or other acceptable method for filing, because of an emergency or for other reasons, the Department may waive the time requirements specified in 25 Pa. Code 217.203 for the filing of NRC Form 241 if you:

a. Inform the Central Office by telephone, facsimile, a DEP Form 241, or a letter of initial activities or changes to the information submitted on the initial DEP Form 241; and

b. Receive oral or written authorization for the activity(ies) from the Central Office; and

c. Submit a copy of DEP Form 241, and 4 copies of your Agreement State, Non-Agreement State or NRC license (for initial filings).

DEP Receipt

When it has been determined that the required information has been submitted and the fee payment has been provided, DEP will sign and date the DEP Form 241 and will forward a copy to the applicant. A licensee operating under reciprocity pursuant to 25 Pa. Code 217.203 does not have to obtain affirmative authorization from DEP before performing activities requested on DEP Form 241 provided the Form 241 was filed at least 3 days before the licensee engaged in reciprocity activities. If, however, in processing DEP Form 241, DEP determines that the DEP Form 241 contains omissions or errors, the DEP staff will contact the licensee in an attempt to obtain the correct information. If the discrepancies cannot be resolved and the applicant does not qualify for the general license, DEP staff will inform the DEP of this determination and indicate that work is not to be performed in Pennsylvania in areas of exclusive Department jurisdiction until DEP receives the required information.

Fees

Under the current fee regulations in 25 Pa. Code Chapter 28, initial filings of DEP Form 241 require payment of a fee.

Withholding Information

Licensees wishing DEP to withhold, as proprietary or confidential, the information contained in Items 8 to 12 of DEP Form 241 from public disclosure must submit an application for withholding accompanied by an affidavit. An applicant may submit an affidavit to withhold information from public disclosure after filing DEP Form 241, however, the Department is not responsible for any material that may be disclosed prior to processing the withholding request.

Only the information requested in Items 8 to 12 of DEP Form 241 can be considered for withholding from public disclosure as proprietary information. Therefore, if your company wishes DEP to withhold the information contained in DEP Form 241, Items 8 to 12, from public disclosure, you or the company, as owner of the information, must submit an application and affidavit for withholding.

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Only the information requested to be withheld as proprietary needs to be accompanied by an affidavit. For the Department to determine whether the information should be withheld from public disclosure, you should address the following items in sufficient explanatory detail:

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1. Clearly identify the document(s), or parts thereof, to be withheld as proprietary or confidential.

2. State whether this information is held in confidence by the owner of the information.

3. Provide a rational basis for requesting withholding of the information. Clearly state the reasons why your company believes the information contained therein is proprietary or confidential.

4. Confirm that the information transmitted to, and received by, NRC is held in confidence. Please give details.

5. To the best of your knowledge, state whether the information is currently available in public sources.

6. Confirm whether your company customarily treats this information, or this type of information, as confidential. Please explain why.

7. Determine whether the public disclosure of the information would be likely to cause substantial harm to the competitive position of your company. If so, explain why in detail. Your affidavit should also include the value of the information to your company, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

8. Clearly identify the position of the person executing the affidavit (an officer or upper-level management official delegated to review the information sought to be withheld and authorized to apply for withholding on behalf of the company.)

9. State that the company submitting the affidavit is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary and that the affiant is an employee of the company.

Two versions of the Form 241 should be submitted with brackets ([ ]) placed around the information sought to be withheld. One version should keep the information in brackets intact for DEP's use in processing the request for reciprocity. The other version should be "sanitized" for public disclosure by deleting the information sought to be withheld. If the information is determined to be proprietary, the "sanitized" version will be the version available for public disclosure.

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On reviewing your application and affidavit, the Department will notify you by letter acknowledging agreement or disagreement with your request for information to be maintained as proprietary information. For deficient affidavits, you will be requested to provide additional information.

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Once approved, a request for withholding proprietary or confidential information will be maintained by the Department indefinitely or for as long as you, as the licensee, perform reciprocity activities and submit DEP Form 241s. If you should skip a year between filing reciprocity requests, you must resubmit your request and affidavit for withholding proprietary information.

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Additional Requirements

Additional pertinent regulations are cited in 10 CFR 150.20(b) incorporated by reference in 25 Pa Code 217.201. In particular, radiographers and radiographers' assistants must, at all times during radiographic operations, wear direct reading pocket dosimeters, alarm ratemeters, AND either film badges or thermoluminescent dosimeters (TLDs) as required by 10 CFR 34.47. Secondly, radiographic exposure devices, sources, and associated equipment must comply with the requirements described in 10 CFR 34.20. Licensees need to be aware that when exposure devices are transported, PA Department of Transportation and US DOT regulations must be followed. These regulations can be found in 49 CFR and are incorporated by reference in 25 Pa. Code Chapter 230 and 10 CFR 71.5. Also, to transport certain devices, licensees must be registered as users for all approved packages issued Certificate of Compliance numbers. Package users also need to have a quality assurance program as specified in 10 CFR 71.17(c) and outlined in NRC Bulletin 95-01, "Quality Assurance Program for Transportation of Radioactive Material." Industrial radiography licensees in the Agreement States should be aware that 10 CFR 34.31(b)(2) requires each licensee to have written procedures for inspection and maintenance of Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the Certificate of Compliance or other approvals.

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APPENDIX III

INSPECTION OF RECIPROCITY LICENSEES

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Comment [COMMENT7]: The entire content of this appendix has been replaced by the corresponding section in TI-1220-001

A. PURPOSE

Policy and guidelines for performing inspections of licensees working under reciprocity.

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B. INSPECTION

The regional office(s) that have jurisdiction in the area(s) in which the reciprocity licensees will operate shall take the following action:

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1. Frequency

   Inspections of licensees operating under general licenses under 25 Pa. Code 217.203 should be conducted using the same provisions used for equivalent DEP-licensed activities, except as specifically defined in this chapter. These provisions include, but are not limited to, inspection processes and inspection records as defined in DEP Manual Chapter 2800 (MC 2800). However, the inspection frequencies for reciprocity licensees are not subject to the provisions in MC 2800 and are not to be extended for good licensee performance.

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   To determine if a reciprocity licensee should be a candidate for inspection, should do the following:

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   a. Determine if the reciprocity licensee has had DEP enforcement in the past 2 years.

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   b. Review the Nuclear Materials Event Database (NMED) to determine if the reciprocity licensee has had a significant NMED event (e.g., source disconnects, lost sources, overexposures) in the past 2 years.

   If DEP has inspected the reciprocity licensee (in the field), in the last calendar year, and the licensee has not had escalated enforcement or a significant NMED event in the past 2 years, then the reciprocity licensee is NOT to be considered a candidate for inspection. All other reciprocity licensees are to be considered candidates for inspection.

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   The percentages of inspections of reciprocity licensees to be inspected each year are based on the number of candidates for inspection per region. The percentages of inspections are determined by NRC equivalent program code and priority should be as follows, priorities 1, 2, and 3 program codes - 20 percent of the candidate licensees from the candidate pool are to be inspected each year.

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   ¶
   P

   All other program codes - Are to be inspected each year, as resource and inspection schedules permit.

   NOTE: Central Office will distribute the DEP Form 241 information and any changes to Form 241 schedules to the affected regional offices.

   Deleted: If the work to be performed by the reciprocity licensee (who is a candidate for inspection) is within a Region other than the Region that received the Form 241, the Region receiving the Form 241 should promptly notify the Region where the work is to be done of the Accession Number of the Form 241 and supporting documentation

NOTE: In cases where a licensee performs reciprocity activities in several regions, the Region with the first opportunity to inspect the licensee at a work site should do so. The completed inspection should be recorded as a completion for the inspecting Region. The inspecting Region shall notify the Central Office and enter the information in the Department inspection tracking system.

2. Location

Inspections of licensees operating under reciprocity pose many difficulties, such as short lead time and logistics. Nevertheless, reciprocity inspections are to be conducted during actual field work. Such inspections should be unannounced, but may be announced, when necessary, in the interest of effectiveness and efficiency.

END

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¶
Inspection records (unless escalated enforcement action is anticipated) shall be prepared for all inspections of Agreement State licensee activities. The inspecting Region should enter any pertinent information [as described in the Reciprocity Tracking System (RTS) Users Manual] about inspections and escalated enforcement actions into the RTS. The inspection report number should be recorded in the comment field in the RTS.¶
¶
Note: For assist inspections, follow the procedures in MC 2800. ¶
¶
"General Policy and Procedure for NRC Enforcement Actions," NUREG-1600, shall be used as the policy and criteria for taking enforcement actions against the licensee. Copies of the enforcement correspondence shall be sent to:¶
¶
The Agreement State authority issuing the license under which the Agreement State licensee is operating;¶
¶
The NRC regional office in which the Agreement State is located; and ¶
¶
Other distribution, in accordance with existing procedures.

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Division of Industrial and Medical Nuclear Safety, Nuclear Material Safety and Safeguards

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04.02 Regional Offices

a. Schedule, conduct, and track inspections to achieve the overall objectives of the inspection program, including the objectives of this chapter.

b

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of Agreement State licensees

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appropriate authorities (as described in Appendix I), including

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e. Inspect Agreement State licensees operating in non-Agreement States, areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under reciprocity using the same provisions used for equivalent

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DEP-licensed activities. Carry out enforcement actions against those licensees when violations are found during an

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DEP inspection. (See Appendix III for specific procedures and frequency.)

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g. Promptly notify, by e-mail, the reviewing official for reciprocity activities in the NRC regional office responsible for the area in which the activity will be conducted, of the completed action.

Section Break (Next Page)

h. In the lower right hand corner, mark the NRC's signed Form 241 (or letter in lieu of Form 241) with the assigned ADAMS code and write "copy to Region __" indicating the appropriate region for distribution. Forward the completed Form 241 or letter, a copy of the Agreement State license, and evidence of the fee payment to LFARB for fee processing. After determining that the appropriate fee has been paid, LFARB will enter the fee payment information on NRC Form 241 and forward the completed package to the NRC Document Control Desk for ADAMS processing . After processing, the form will be returned to the regional office for the official files.

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Note: The Office of Enforcement is prepared to forgo enforcement action in cases where an Agreement State licensee has relied in good faith on an inaccurate determination made by the official of the Federal installation where the work is to be conducted.

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to the appropriate NRC regional office,

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and forward the evidence of any required fee payment with the signed original copy of NRC Form 241 to LFARB for fee review and ADAMS processing

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NRC Regional Administrator

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, non-Agreement States, or in offshore waters

Page 2: [14] Comment [COMMENT6] COMMENT

There is no attachment containing information pertaining to 10 CFR 170 or 171.

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According to 10 CFR 171.11(a), fees will not be assessed for a license applied for, by, or issued to, a nonprofit educational institution for the possession and use of byproduct material, source material, or special nuclear material.

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The application and affidavit must be submitted in accordance with 10 CFR 2.790(b)(1) and should be submitted with the initial submittal of the Form 241 for the calendar year.

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This means that an application and affidavit for withholding information must be submitted, either the first time an Agreement State licensee submits NRC Form 241 for a calendar year, or if the licensee has already submitted an NRC Form 241 for the year, it must submit an application and affidavit for withholding information within a week of NRC's receipt of the Form 241.

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NRC's Office of the General Counsel has determined that o

in accordance with 10 CFR 2.790(b)(1

MC1232
Collection Preparation and Shipment of Independent Measurement Samples

Decommissioning and Surveillance Division/Environmental Surveillance Section

SECTION 1.0
INTRODUCTION

The purpose of this Procedures Manual is to provide a standardized set of procedures that document activities of the program. Procedures presented in this section are limited to those associated with non routine independent sample collection activities; routine operations of the Environmental Surveillance Section (ESS) are presented in the Technical Procedures Manual (TPM).

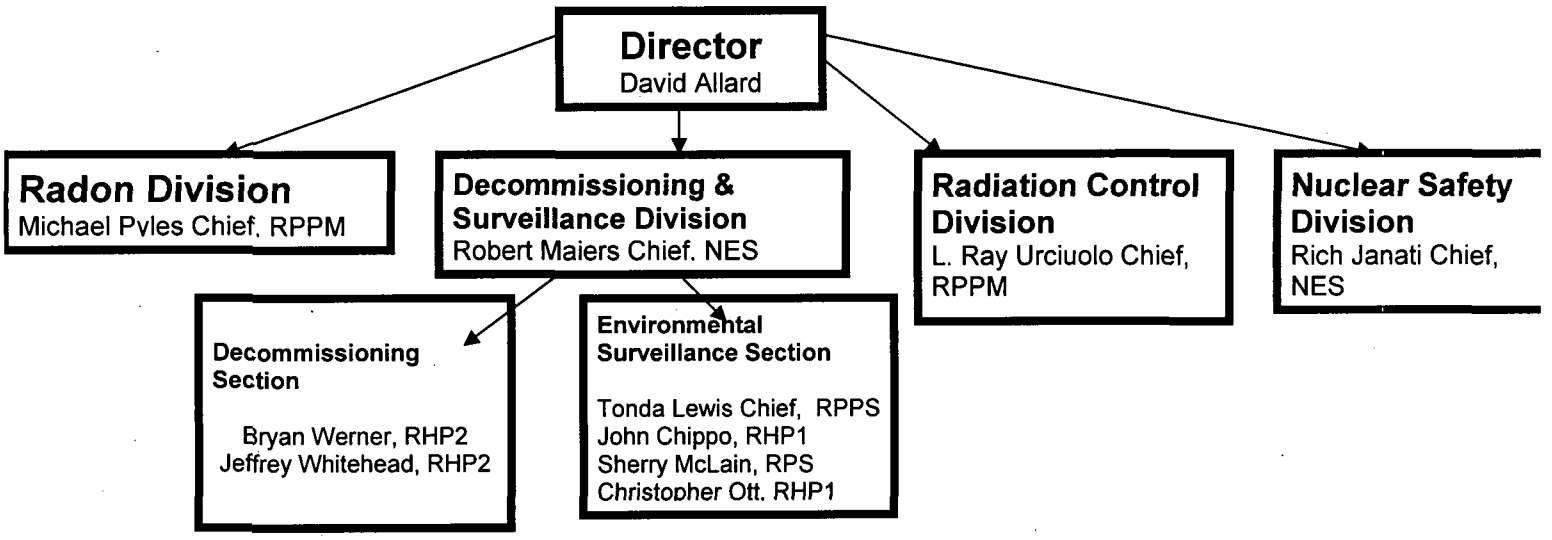
It is important to note that the information presented within this document is intended to serve as the standard operating procedures (SOPs) for the Environmental Surveillance Section's survey activities not covered in the routine sampling instructions in the TPM. However, due to site- and project-specific requirements that may occur or be requested, the SOPs may be modified or revised procedures adapted to meet project requirements.

SECTION 2.0
ORGANIZATION AND RESPONSIBILITIES

Following is the current organizational chart showing the Bureau of Radiation Protection/Decommissioning & Surveillance Division/Environmental Surveillance Section position. Detailed responsibilities for various staff positions are documented in position description questionnaires, which have been developed for all employees. Additional information is included in the ESS Technical Procedures Manual.

With respect to the field sampling activities, it is the general responsibility of the ESS's Radiation Protection Program Supervisor (RPPS) to assure that all personnel performing environmental monitoring duties follow these procedures and to continually evaluate results for accuracy and precision. Site coordinator is a generic title, which applies to any individual designated as the Bureau's representative and on-site supervisor. It is the responsibility of each individual collecting, preparing and shipping environmental samples to abide by all aspects and details presented in this manual and to report deviations or abnormal results to the responsible supervisor.

The RPPS is responsible for development and ensuring periodic revision of procedures related to field sampling activities are made. Procedures may be developed, reviewed, and/or revised at any time as may be determined to be necessary by the RPPS. Field sampling procedures require approval of the Radiation Protection Program Manager (RPPM) of the Decommissioning & Surveillance Division (DSD).



SECTION 3.0
SUMMARY OF ACTIVITIES

Within its operations, the ESS conducts two major categories of sample collections for environmental monitoring:

1. Routine, predetermined sample collections monitoring the environment around facilities that are using, or have used radioactive materials. This includes but is not limited to Pennsylvania's nuclear power facilities and sites undergoing decommissioning activities.
2. Non routine sample collections to characterize a site where there are indications there may be radiological contamination that could pose health risks to the public and determine whether there is a need to establish a routine environmental monitoring program.

Assignments are received from the D&S RPPM. A scoping visit is usually performed by RPPM or their designee to gather additional details concerning the site. Such details include a site-specific health and safety analysis, area and building descriptions, site accessibility for gridding and surveying, special equipment requirements, security arrangements, site contacts, recommended local accommodations, area maps and photographs. Other pertinent information is obtained through reviews of records and reports of the regulatory agencies. A proposed survey plan is prepared for submission to appropriate parties. Due to differences in sites, each plan is site-specific. Factors considered in the plan include the type of survey, site size and complexity, operational history, potential radionuclides present, and available manpower and equipment resources. The sample collection plan may require modification based on findings as collections are made and screened. The plan is written to allow for such field changes. It is the responsibility of the site coordinator to make appropriate changes in the plan at the field location. All such changes must be documented in the site logbook or on the appropriate field survey forms. Subcontracts and purchase requisitions for specialized services and equipment are initiated.

When the sampling plan has been approved and the schedule finalized, the Radiation Protection Program Supervisor will select personnel for the collections and the site coordinator prepares a listing of supplies and instruments required. Travel arrangements are also initiated. All samples collected at the site are returned to the Bureau of Laboratories/Radiation Measurements Laboratory for analysis, unless arrangements have been made with an alternative lab and approved by the Radiation Protection Program Manager. Bureau of Radiation Protection personnel interpret results unless other arrangements have been made with prior approval. A report will be provided to appropriate parties.

SECTION 4.0
GENERAL INFORMATION

The Environmental Surveillance Section (ESS) collects, prepares and ships samples in a manner that assures the quality and accuracy of developed data from analysis and provides auditable documentation of activities.

The ESS conducts routine environmental monitoring programs around PA nuclear power plants. The procedures for these sample collections and submittal of both routine and non-routine samples to the Bureau of Laboratories Radiation Measurements Lab are documented in detail in the ESS Technical Procedures Manual (ESS-TPM). This document and the ESS-TPM are intended to support one another in the complete operations of the ESS.

SECTION 4.1
RECORDS AND REPORTS

A site-specific environmental sampling plan is developed prior to the start of on-site activities. Changes in the sampling plan are often necessary due to unanticipated findings as the survey progresses. The designated site coordinator has the authority to make appropriate changes to the plan. Modifications not directly requested by the funding agency must have a defendable technical basis and a change of any kind must be documented in the site logbook. The site coordinator is responsible for reviewing data for accuracy and completeness before on-site activities are concluded. Electronic records may be substituted, provided appropriate access authorization procedures are in place and quality assurance requirements are met. All data, notes, measurements, calibrations, and other information pertinent to a survey site must be recorded and maintained. Records must conform with the following basic requirements:

1. Marked with date of entry.
2. Signed (or initialed) by the author of the entry.
3. Written or printed, in pen, in a legible manner.
4. Contain all pertinent information in a concise, accurate entry.

-Records may be in several forms. These include: maps, standard record forms for specific survey measurements, and the field data logbook; which is the daily diary and notebook of the site coordinator.

-Electronic records may be substituted, provided appropriate access authorization procedures are in place..

-If data corrections are necessary a single line will be drawn across the entry. New data, initials of the collector and date of correction will be recorded. Data will not be obliterated by erasing or use of white-out.

-Original drawings and maps may first be drawn in pencil but must be made permanent by tracing in ink or producing a photocopy prior to the addition of data to the page.

In some instances imaging equipment such as still cameras or video cameras may be used to document site orientation, site conditions, equipment, etc. Such equipment should be operated in accordance with manufacturer's instruction manuals. Images shall be considered critical records if used for documentation of measurement or sampling locations. Critical record images will be archived with site file information. GPS coordinates should be recorded for every sample location.

The results of sampling are documented in reports. The complexity and style of the report and its distribution are determined based on the type of study and the requirements established by management.

SECTION 4.2
SCREENING SAMPLES

All samples must be surveyed at the time of collection to ensure they are within appropriate levels for transport and submission to the RML.

Calibrations of field instrumentation shall be scheduled with services that will use standards traceable to the National Institute of Standards and Technology (NIST) using procedures in accordance with recommendations of *International Standard. ISO 7503-1, Evaluation of Surface Contamination - Part 1: Beta-emitters (maximum beta energy greater than 0.15 MeV) and alpha-emitters. August 1, 1988* and *NUREG-1507. Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions. U.S. Nuclear Regulatory Commission. Washington, DC; June 1998.*

SECTION 4.2 (Cont.)

All equipment and instrumentation used in potentially contaminated areas are to be scanned, and cleaned if necessary, prior to leaving the site to assure that contamination is not inadvertently moved out of controlled areas and does not interfere with accuracy of subsequent measurements. The results of these scans must be documented in the site logbook.

When there is a potential for contamination of containers or vehicles during sample transport, suspect surfaces will be surveyed. Should decontamination be necessary, a follow-up survey will be performed to assure that all surfaces maintain activities that are as low as reasonably achievable. Surveys of equipment or other items should be documented in the site logbook.

SECTION 5.0
SAMPLE HANDLING

Purpose

To describe the approach for the maintenance of sample accountability, field control of cross contamination, and sample screening for laboratory contamination control.

Responsibilities

- The site coordinator is responsible for assuring that this procedure is implemented.
- Sampling team personnel are responsible for following this procedure.
- Other specific responsibilities are described under the appropriate subsection.

Procedure; **The following applies to all sampling situations not covered in the routine procedures described in the ESS Technical Procedures Manual.**

Sample Chain-of Custody

Sample accountability and integrity is maintained by use of the chain-of-custody Procedures .

Sample custody documentation is initiated upon collection or receipt of the samples by the program and continues until the samples are consumed in analysis, transferred to another organization, or disposed of properly. An acceptable chain-of-custody is maintained when the sample is under direct surveillance, kept in a tamper-free container, or is within a controlled access facility.

Samples collected by other organizations that are provided to field personnel will have chain-of-custody initiated for them by the individual receiving the samples. When the organization has an established chain-of-custody in place, a copy of the form will be attached to the BRP form.

SAMPLE CHAIN-OF-CUSTODY

Chain of Custody

Sample Matrix:

Relinquished By	Received By	Date	Time	Reason for Change of Custody

Remarks:

SECTION 5 (Cont.)
If Samples are to be delivered to BOL by collector, see ESS Technical Procedures Manual

Equipment
- Samples in appropriate containers
- Indelible pen
- Chain-of-Custody forms

A sample collector assumes responsibility as custodian and initiates a chain-of-custody form in duplicate.
- The sample(s) must be under direct surveillance of the sample custodian, secured in a locked vehicle or building, or in a tamper-proof container at all times.
- Each sample may be listed on the chain-of-custody form separately or a group of samples having common characteristics from a single site may be recorded as a single entry using a sample identification number range. If an item is not applicable "NA" is entered.
- Samples collected by other organizations that are provided to field personnel will have chain-of-custody initiated for them by the individual receiving the samples. When the organization has an established chain-of-custody in place, a copy of the form will be attached to the ESS form.

Transfer of custody
- Samples are inspected prior to custody transfer to determine any evidence of tampering. Evidence of tampering and/or any deviations must be explained in the "remarks" section of the form. If sample integrity is questionable for any reason, a nonconformance report will be initiated, including, as part of the corrective action plan, determination of the effect on the usefulness of the analytical data.
- Sample custody is transferred by the custodian signing the "relinquished by" block and the receiver signing the "received in good condition by" block.

Security & transport
- Sample security seals may be placed on the container of samples to ensure container is tamper-proof. The number of the seal must be entered on the chain-of-custody form. Numbered seals may be replaced by tape with the samplers or custodians initials.

NOTE: Containers with security seals do not have to remain in a secured area but precautions should be taken to restrict access to the samples to authorized individuals.
- The original of the chain-of-custody form must contain all signatures and other pertinent records regarding custody. Therefore, the original is retained in the possession of the individual who has custody at any specific time.
- As long as samples remain with the custodian, both copies of the Chain-of-Custody Form are to accompany the samples.

When shipping samples ahead of the custodian, the copy of the chainof-custody record must be signed and mailed to the DEP/BOL/Radiation Measurements Laboratory Supervisor or designee.

SECTION 5 (Cont.)

Field Control of Cross Contamination

Equipment and supplies used for collection and storage of samples must be handled in such a manner as to prevent accidental contamination. The degree of concern and precautions followed will be determined by the specific site conditions and activity levels involved. Equipment used for sample collection should be surveyed, and cleaned as necessary, following each use.

Equipment
- tap water
- deionized water
- non-phosphate detergent
- alcohol (isopropyl)
- spray bottles
- stiff bristle brush
- paper towels

Cleaning Procedure for Contaminated Sampling Equipment
- Wipe equipment surfaces free of loose material using paper towels
- Rinse with tap water
- Wash with detergent solution and brush
- Rinse with deionized water
- Rinse thoroughly with isopropyl alcohol
- Allow to air dry

Monitoring routinely performed at the sampling location will provide an indication as to the need for special attention following sampling. Any necessary decontamination should be performed such that potentially contaminated waste, generated in the process, can be collected and assessed to determine the appropriate disposal method. All samples known or suspected of containing levels of radioactivity which could present a contamination or exposure problem in the field or laboratory are to be placed in clean outer containers and identified with a radiation warning label or other explanatory information, as appropriate in accordance with the ESS sample screening requirements.

Sample Screening Process

The following three categories of samples have been established for the purpose of controlling contamination in the laboratory during sample analysis:

• **Low Activity (LA)**—Samples containing less than 1000 pCi/g (soil/sediment) or 1000 pCi/l (liquid). Samples of small size, e.g., smears, are limited to 1000 pCi total activity, when the activity is dispersable (i.e., in other than a solid matrix) or the analysis entails other than strictly physical operations (weighing
or direct counting).

• **Moderate Activity (MA)**—Samples with activity levels between 1 and 100 times the upper limits for the Low Activity category.

• **High Activity (HA)**—Samples containing greater than the Moderate Activity category limits.

On the basis of empirical data, responses of typical field survey instruments to samples, containing Moderate Activity and High Activity levels of some commonly encountered contaminants, have been determined; these response data are summarized in Table 1 of this Section. When potential sample contaminants would be expected to provide instrument responses comparable to those in this Table, action levels from this Table may be used. Action levels for other contaminants or mixtures of contaminants, for which a comparable material is not provided in this Table, may be chosen on the basis of conservative assumptions and expected instrument response characteristics. Certain contaminants (for example, very low energy pure beta emitters, and pure alpha emitters in soil and water) will not be detectable at the Moderate Activity and/or High Activity levels using direct

SECTION 5 (Cont.)

monitoring methods. Site history and other analytical data (if available) may be used as a basis for initially identifying samples as potentially containing levels requiring special laboratory handling. The conservatively estimated activity level should beassumed. Any such samples would, in addition to the activity category, be further identified as "Suspect."

Prior to collection of samples (or receipt of samples that are submitted directly to the laboratory by other organizations), the cognizant project supervisor will evaluate the potential that samples may contain activity levels in excess of the Low Activity category limits. If it is determined that such a potential does not exist, that evaluation is documented by a note to the project file, a notation in the project logbook, a statement in the project Safety Plan, or other documentation in the permanent record.

If it is determined that there is a potential for receiving samples containing Moderate Activity and/or High Activity levels, a plan for screening will be developed by the project supervisor. The plan will identify:

- potential radionuclide contaminants which may exceed Low Activity levels
- areas of the survey site from which samples may contain such levels
- screening techniques (instruments, site history) to be used
- instrument response action levels (if appropriate) to be used for designating categories

This information becomes part of the project file; project personnel will receive instruction in its implementation.

- At the time of collection by ESS personnel, those samples containing other than Low Activity levels (by virtue of field measurements, site history, or sample characteristics) will be identified. Identification tape will be affixed to the containers and a notation will be added to the sampling record form. HA samples will be labeled with red tape, MA samples with yellow tape. Samples for which screening by direct monitoring is not applicable, which are suspect for other reasons, will also include the wording "Suspect."
- When samples are to be received from another collecting organization, the ESS project supervisor will request the providing organization to include information as to the anticipated activity levels and to identify those specific samples suspected of containing Moderate Activity and High Activity.
- During log-in, samples received from other organizations will be monitored by direct measurement to confirm (where possible) the activity category. Again, the information in Table 1 will provide guidance as to the category levels. Those samples not previously identified as requiring special handling, will be labeled. Categories and screening level data will be noted on the containers and in the sample database.

<u>Guidance for performing sample screening</u>

- Select the instrument which will provide the greatest sensitivity for the potential contaminant.
- Scan the sample to locate the point of maximum direct radiation.

Determine the maximum direct contact radiation level and compare with the appropriate action levels for sample category. Note the screening category on the sample label and in the sampling record form or sample database, as appropriate. The scan and measurement should be performed in a manner that provides an optimum condition for identifying activity, but prevents the possibility of contaminating instruments, personnel, and other samples. For example, soil samples may be monitored through the plastic collection bag and smears may be monitored directly, while avoiding contact between the detector face and the smear.

- Where direct screening methods are not sufficiently sensitive to identify activity levels of the Moderate and High categories, but the sample is suspected for other reasons of containing such levels, enter the notation "Suspect" on the sample label and in the sample database.

-In certain cases, other routine measurements may be sufficient to categorize a sample, without additional screening.

SECTION 5 (Cont.)

Examples are:

(1) where surface activity measurements indicate a total activity level below the upper limit for Low Activity Samples, screening of smears will not be necessary, and

(2) when in-situ soil contact gamma measurement indicates that a sampling location does not potentially contain elevated concentrations of gamma emitters, gamma screening of the sample will not be required.

- The supervisor will prepare or direct preparation of the Lab Sample Submission Sheet, such that analyses of samples of Low, Moderate, and High activity are requested separately and that Sample Submission Sheet include notation as to the sample activity category. Moderate to High activity samples may be archived at the discretion

EXAMPLES OF TYPICAL INSTRUMENT RESPONSE FOR SAMPLE SCREENING PURPOSES

Sample Media	Contaminant	Contact Radiation Level (c/m)								
		Low Activity (<1000 pCi/l)			Moderate Activity (1000 to 10,000 pCi/l)			High Activity (>100,000 pCi/l)		
		α scintillation[a]	GM[b]	γ scintillation	α scintillation	GM	γ scintillation	α scintillation	GM	γ scintillation
Liquid	Sr-90	---	---	---	---	---	---	---	>430	---
	Cs-137	---	---	---	---	---	---	---	>110	>5000
	Co-60	---	---	---	---	---	---	---	>1000	>20,000
	Thorium (natural)	---	---	---	---	---	---	---	>230	>8000
	Uranium (processed-natural)	---	---	---	---	---	---	---	>170	---
	Ra-226	---	---	---	---	---	---	---	>350	---
	pure alpha emitters	---	---	---	---	---	---	---	---	---
	pure beta emitters E-max <150 keV	---	---	---	---	---	---	---	---	---

[a]Eberline AC3-7 or equivalent.

[b]Pancake detector-Eberline HP-260 or equivalent.

[c]NaI-Victoreen 489-55 or equivalent.

[d]Dash indicates instrument not adequately sensitive to radiation.

Section 6
Sampling Site Preparation
CLEARING TO PROVIDE ACCESS

To establish a policy regarding requirements for clearing materials from facilities and open land areas in preparation for gridding and survey measurements and sampling.

- Removal or relocation of equipment and materials which may entail special precautions to prevent damage or maintain inventory accountability should be performed by the property owner whenever possible.
- Clearing open land of brush and weeds will usually be performed by a professional land clearing organization under subcontract arrangements. However, survey personnel may perform limited minor land clearing activities as required.
- The site coordinator is responsible for determining the degree of clearing needed and for supervising onsite clearing activities to assure compliance with conditions of survey plans and subcontract agreements.
- The Survey Projects Manager will prepare or approve the necessary plans, subcontracts, and other documents describing and implementing the clearing operations.

Procedures

- The extent of site clearing required in specific areas will be primarily dependent upon the potential for radioactive contamination existing in those areas. - Where the radiological history and/or results of previous surveys do not indicate potential contamination of an area, it may be sufficient to perform only minimum clearing to establish a reference grid system.
- Areas where contamination is known to exist or that have a high potential forcontamination must be completely cleared to provide access to all surfaces.
- Findings as the survey progresses may require that additional clearing be performed.
- Clearing includes providing access to potentially contaminated interior surfaces, e.g., drains, ductwork, tanks, pits, and equipment by removal of covers, disassembly, or other means of producing adequate openings.
- Open land areas may be cleared by heavy machinery, e.g., bulldozers, bushhogs, and hydroaxes; however, care must be exercised to prevent relocation of surface contamination or damage to site features such as drainage ditches, utilities, fences, and buildings.
- Minor land clearing may be performed using manually operated equipment such as brushhooks, power saws, knives, and power trimmers.
- Brush and weeds should be cut to the minimum practical height, not to exceed 30 cm. Care should be exercised to prevent unnecessary damage to or removal of mature trees.

Section 7
SAMPLE COLLECTION
7.1 SURFACE SOIL SAMPLING
Procedures for collecting samples of surface soil for routine radiochemical/radiophysical analysis.

Equipment

- Vegetation cutters if needed: hand clippers/trimmer
- Digging implement: garden trowel, shovel, spoons, post-hole digger, etc.
- Bucket
- Plastic zipper bags, approximately 25 cm x 35 cm
- Twist-ties.
- Masking tape.
- Record forms and/or logbook.
- Labels and security seals.
- Indelible pen.
- Plastic sheeting
- Equipment cleaning supplies, as appropriate
- GPS Unit

Sample Collection

NOTE: Because standard surface soil contamination criteria for radionuclides are usually applicable to the average concentration in the upper 15 cm of soil, the usual sampling protocol described here is based on obtaining a sample of this upper 15 cm. Special situations, such as to evaluate trends or airborne deposition, determining near surface contamination profiles, and measuring non-radiological contaminants, necessitate special sampling procedures. These special situations are evaluated and incorporated into site-specific survey plans as the need arises.

Direct surface and 1 meter gamma radiation measurements may be performed at each location before initiating sampling. This will identify the presence of gross radionuclide contamination which will require special handling and equipment cleanup procedures. Contact the site coordinator if the exposure rate measurement exceeds the capability of the instrumentation available on site before proceeding with sample collection. If contamination is suspected a beta-gamma "open" and "closed" measurement may also be desired before sampling begins.

- Loosen the soil at the selected sampling location to a depth of 15 cm, using a trowel or other digging implement.
- Remove large rocks, vegetation, and foreign objects (These items may also be collected as separate samples, if appropriate.)
- Place approximately 1 kg of this soil into a container sufficient to ensure moisture leakage and/or cross-contamination does not occur. If it is not possible to reach a depth of 15 cm using a hand tool (i.e. trowel or shovel) 1 kg of soil should be collected from the accessible depth. The actual depth should be recorded on the sample container and the data form.
- Seal the sample container.
- Label and secure the sample container in accordance with Section 8.15 and the chain-of-custody procedures in Section 8.16. Record pertinent information on the Chain-of-Custody Form (Figure B-16, or equivalent).
- Record sample identification, location, and other pertinent data on appropriate record forms (Figures B-13, B-14, B-15, or equivalent), maps, drawings, and/or site logbook.

7.1 SURFACE SOIL SAMPLING (cont.)

-If the location has been identified as having elevated activity a measurement should be obtained after the sample is collected to determine the possibility of contamination at a depth greater than 15 cm. If a subsurface sample is deemed necessary, refer to Section 8.2.
- Clean sampling tools, as necessary, before proceeding to the next sampling location, in accordance with instructions.

Field Compositing of Samples

NOTE: The application of composite sampling is determined on a site-specific basis as directed by the site coordinator. Data quality objectives for the project, analytical cost considerations, and special case site conditions are used to identify situations where sample compositing may be employed. Generally, five samples may be included in a composite with a maximum number of ten. The area represented by a composite sample will vary and should not exceed 100 m2 unless directed by the site coordinator. Refer to the note under Step 3.2 for applicable information related to sampling depths and measurements.
- Collect equal aliquots of soil over 15 cm depth intervals from each location that will be included in the composite and place in bowl, on plastic sheeting or other type of containment.
- Thoroughly mix sample and break up aggregates.
- Divide soil into equal quadrants.
- Place an equal aliquot (approximately 50 to 100 grams) from each quadrant into the sample container.
- Repeat previous steps a total of 3 times. Total sample amount collected should approximate 1 kg.

7.2 SUBSURFACE SOIL SAMPLING

To describe the procedure for collecting samples of subsurface soil.
• The site coordinator is responsible for assuring that this procedure is implemented.
• Survey team personnel are responsible for following this procedure.

Procedure

Equipment
- Manual auger.
- Plastic bags, approximately 10 cm diameter x 30 cm long.
- Trowel or spatula.
- Plastic containers (1 quart size) or geology sample bags.
- Twist-ties.
- Masking tape.
- Large rubber bands.
- Sample Submission sheets, and logbook.
- Labels and security seals.
- Indelible pen.
- Equipment cleaning supplies, as appropriate
- GPS unit

Sample Collection
- When direct radiation measurements are required (surface and borehole logging) they are to be performed prior to sample collection in order to identify the presence of gross radionuclide contamination requiring special handling or cleanup.
- When a borehole fills with water and a water sample is desired refer to the subsurface water sampling procedure.

7.2 SUBSURFACE SOIL SAMPLING (Cont.)

NOTE: Special considerations, such as those described for surface sampling, may require deviations from this procedure. These will be described in the site-specific survey plan as the need arises.

- Systematic Subsurface Sampling (Option 1)

Procedures applicable to shallow boreholes, generally no greater than 2 to 3 m maximum depth.

- Assemble suitable auger (i.e. standard bucket auger or mud, sand, etc. augers) to extentions with "T" handle. Ensure depth demarcation are noted on the auger and extension handles.
- Advance auger to each desired depth. Extract the auger to remove soil as the borehole is advanced. Direct monitoring should be performed and if contamination is suspected, decontaminate the auger between each sampling interval.
- At the desired depth, remove the sample from the auger and transfer the sample to a container (plastic bag, plastic jar, etc.) and seal the container in a manner sufficient to ensure moisture leakage and/or cross-contamination does not occur.
- Label and secure the sample container in accordance with Section 8.15 and the chain-of-custody procedures in Section 8.16. Record pertinent information on the Chain-of-Custody Form, (Figure B-16, or equivalent).
- Record sample identification, location, depth, and other pertinent data on the appropriate record forms, map, drawing, and/or site logbook.
-Clean sampling tools, as necessary, before proceeding with further sample collection, in accordance with instructions in Section 4.5.

Systematic Subsurface Sampling (Option 2)

Procedure applicable to depths of approximately 3 m when boreholes or trenches have been dug and remain uncollapsed or do not contain water.

NOTE: If borehole logging is to be done it should be completed before sampling begins (see Section 7.2). If multiple samples are collected from a borehole, sampling is to be initiated at the deepest location and proceeds at subsequent depths toward the surface. Prior to collecting samples, dress the borehole wall at each sampling location in order to remove any soil that was potentially transferred from other depths.

- Place a plastic bag liner into the downhole sampler and secure with a large rubber band.
- Lower the sampling tool to the desired depth in the borehole or trench.
- Scrape the inside borehole or trench wall with the toothed edge of the tool until approximately 1 kg of sample is collected.
- Transfer the plastic bag and sample into container sufficient to ensure moisture leakage and/or cross-contamination does not occur.
- Repeat previous steps of this section.

Systematic Subsurface Sampling (Option 3)

Procedures applicable to depths exceeding 3 m and in boreholes where walls do not remain intact or that fill with water.

- Drill the borehole to the desired sampling depth using an auger.
- Drive a split-spoon or shelby tube collector beyond the augered depth. The driving distance should be 30 to 60 cm.
- Withdraw the collecting device and remove the collected core. Remove and appropriately discard the top 1 to 2 inches of the core as this material may represent soil that had collapsed into the borehole from other depths.
- Place the core, or a portion of the core, into a container sufficient to ensure moisture leakage and/or cross-contamination does not occur. (The core may be split into multiple segments, representing different sampling depths.)

-Repeat previous steps

7.2 SUBSURFACE SOIL SAMPLING (Cont.)

Biased Subsurface Sampling

Procedures applicable when a surface sample has been collected and radiation levels are still elevated sufficiently above background as to require further investigation at the location.

- Using a shovel, post hole diggers, manual auger, drill rig, etc. collect 1 kg of the next 15 cm of soil and place into a container sufficient to ensure moisture leakage and/or cross-contamination does not occur. Care must be taken and sampling methods selected to ensure that soil that may have collapsed into hole from the surface is removed and not included in the subsurface sample.
- Repeat previous steps.
- Monitor the sample hole to determine activity level. If the activity level is still elevated, repeat previous steps. If the activity level has dropped to background, record the measurement and monitor the area, including personnel and equipment, to determine the extent of decontamination that may be necessary.

NOTE: Contact the site coordinator if the exposure rate measurement exceeds the capacity of the instrumentation available on site.

7.3 SEDIMENT SAMPLING

To describe the procedures for collecting samples of sediment.

- The site coordinator is responsible for assuring that this procedure is implemented.
- Survey team personnel are responsible for following this procedure.

Procedure

Equipment

U Digging implement: garden trowel, post-hole digger, etc.
U Thin walled metal or plastic tube (shelby tube).
U Ponar "clam-shell" dredge (with rope).
U Wide-mouth plastic bottle (approximately 1 liter size).
U Labels and security seals.
U Record forms and/or logbook.
U Indelible pen.
U Cleaning supplies, as appropriate (see Section 4.5)
U GPS Unit.

Sample Collection

NOTE: This procedure applies to the usual requirements for sediment samples for radiological contamination measurement. Special requirements other than those described below will necessitate other sampling procedures and considerations; these will be evaluated and described in detail in site-specific survey plans as the need arises.

- Shallow Sediment Sampling
- For shallow streams, wade into stream and facing upstream, use a collecting tool to obtain approximately 1 kg of sediment by scraping the material in an upstream direction. Include all material collected
- rocks and foreign objects can be discarded during sample preparation, as appropriate. Alternatively, a shelby tube with an "egg shell" insert may be advanced into the sediment to obtain the sample. The sample may be collected remotely from the stream bank if water levels are too deep or the current is too strong for wading—by attaching extension handles to the collecting tool.

- Deep Water Sediment Sampling
- Deep water sediment samples are collected using a Ponar dredge sampler or similar device.
- Attach adequate length of rope to dredge.
- Open dredge and insert locking bar into cut out on hinge.
- Lower dredge at a rate of descent adequate to ensure penetration of the dredge into the sediment but without displacing lighter sediments.
- Release tension on the rope to allow closure of dredge.
- Retrieve dredge, decant excess liquids, open dredge and collect contents.
- Place the sediment into a plastic bottle and tighten the screw cap.
- Label and secure the sample container in accordance with Section 8.15 and the chain-of-custody procedures in previous Section Record pertinent information on the Chain-of-Custody Form (Figure B-16 or equivalent).
- Record sample identification, location, lat./long., depth, and other pertinent information on the Miscellaneous Sample Record Forms (Figure B-17 or equivalent) and/or logbook.
- Clean collecting equipment, as necessary, before proceeding with further sample collection, in accordance with instruction in previous section.

7.4 WATER SAMPLING

Purpose

To describe the procedure for collecting samples of water from surface and subsurface sources.

Responsibilities

- The site coordinator is responsible for assuring that this procedure is implemented.
- Survey team personnel are responsible for following this procedure.

Equipment

- Bailing implement: Borehole bailer - ORISE design, cup, can, pail, or other appropriate device.
- Submersible vacuum, or peristaltic pump with power source.
- Four liter plastic container, storage boxes and tags, or other container type as applicable.
- Funnel.
- Large Erlenmeyer Flask with two-hole stopper.
- Tygon tubing.
- Labels and security seals.
- Indelible pen.
- Record forms and/or logbook.
- Cleaning supplies, as appropriate (see Section 4.5).
- Sample preservatives as appropriate.
- Field filtering apparatus as appropriate.
-GPS Unit

Surface Sample Collection

- Dip water carefully from the selected location or if using pump, insert collection tube into surface water being careful to avoid collection of bottom sediment or vegetation.
- Using a funnel, transfer the water into a container or when using a pump discharge directly into sample container.
- Collect a total of 3.8 liters of sample. Lesser amounts may be adequate, dependent upon analytical parameters.
- Cap the container tightly.
- Label and secure the sample in accordance with Section 8.15 and the chain-of-custody procedure in Section 8.16. Record pertinent information on the Chain-of-Custody Form (Figure B-16 or equivalent).
- The container should be placed in a cardboard box (also properly labeled) for better storage.

7.4 WATER SAMPLING (Cont.)

- Record pertinent data on the Sample Submission Form and/or site logbook.
- Clean collecting equipment, as necessary before proceeding with further sample collection, in accordance with instructions in Section 4.5. Note: When using a pump and tubing for sample collection, rinse tubing and pump (as applicable) with three volumes of deionized water.

Groundwater (well or borehole) Sample (Option 1)

NOTE: If sampling from an established monitoring well, calculate the volume of the well and purge the well of three well volumes (V= Br2h). Collect purged water for appropriate handling. Monitoring of water quality parameters (i.e. dissolved oxygen, pH, eH, conductivity, temperature, etc.) may be required until parameters have stabilized ± 10% to ensure adequate purging. The necessary equipment for parameter monitoring is procured on a site-specific basis and operated in accordance with the manufacturers instructions.

- Lower the bailer apparatus into the borehole or other sub-surface source of water.
-Allow water to flow into the bailer (use care to avoid buildup of sediments on the bailer diaphragm, which could prevent the diaphragm from sealing).
- Retrieve the bailer and transfer contents into a container. If sampling for volatile organics, care must be taken to avoid aerating the sample.
- Repeat procedure until 3.8 liters or other specified volume of sample has been collected.
- Repeat previous steps
- Groundwater Sample (Option 2)
- Lower the inlet end of tubing until it contacts the water surface in a well or borehole or is located at the desired depth interval in a body of water.
- Start pump and collect water directly into a flask or sample container, avoiding sample aeration.
- Empty flask into container as necessary.
- Repeat until 3.8 liters of sample or other appropriate volume has been
-Repeat previous steps

7.5 VEGETATION SAMPLING

Purpose

To describe the method for collecting samples of vegetation.

Responsibilities

- The site coordinator is responsible for assuring that this procedure is implemented.
- Survey team personnel are responsible for following this procedure.

Equipment

- Knife, shears, or similar cutting tool.
- Plastic bags, medium size.
- Burlap bags.
- Masking tape.
- Baggage tags.
- Labels and security seals.
- Indelible pen.
- Record forms and/or logbook.
- Cleaning supplies, as appropriate (see Section 10).
- GPS Unit

Sample Collection

- Cut vegetation of desired type from selected location as close as possible to the surface. Alternatively, specific plant structures may be collected, dependent upon the survey scope. If the root system is collected, remove adhered soil by gently shaking. Any remaining soil will be removed in the laboratory.
- Collect a total of approximately 1 kg of vegetation.
- Place the sample in a plastic bag (if water is to be retained in the vegetation)or burlap bag (if vegetation is acceptable dry).
- Secure the top of the bag with masking tape.
- Attach a baggage tag.
- Label and secure in accordance with Section 8.15 and the chain-of-custody procedures. Record pertinent information on the Chain-of-Custody Form.
- Record all pertinent information on the Miscellaneous Sample Record Forms and/or the site logbook.
- Clean sampling equipment, as necessary, before proceeding with further sample collection in accordance with instructions in Section 4.5.

7.6 AIR SAMPLING

Procedures for continuous air sampling of volumes >/= 3.5 cubic ft./minute collections on filters and/or charcoal filters, refer to the ESS Technical Procedures Manual for air sampling procedures.

DEP INSPECTION MANUAL

MANUAL CHAPTER 1301

RESPONSE TO RADIATION SOURCE INCIDENTS

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1301-01 PURPOSE

To establish a method for regional and central office staffs to respond to radiation source incidents. Incidents that require activation of the Department's Nuclear Power Station Response Plan and emergencies are outside the scope of this manual chapter (MC). This MC is applicable to events where there is a loss of control of a radiation source (e.g., discovery of radioactive material at a sanitary landfill, recycling facility, or private residence, etc.).

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1301-02 OBJECTIVE

To ensure that appropriate and necessary action is taken, as warranted by the nature and hazard associated with the incident and that the follow-up actions taken are documented.

1301-03 DEFINITIONS

03.01 Radiation Source Incident. Any event, reported to the Department that involves or may involve the loss of control of a radiation source. It may not be known whether the source is subject to NRC or Agreement State jurisdiction when the incident is reported.

03.02 Radiation Source. Is radioactive material including source material, by-product material, special nuclear material (SNM), naturally-occurring radioactive materials (NORM), accelerator-produced radioactive material (ARM), technologically-enhanced NORM (TENORM), etc. It may also involve an apparatus or device that emits or is capable of emitting ionizing radiation this also includes X-ray machines and accelerators.

1301-04 APPLICABILITY

This chapter and its appendices apply to the Department and its regional offices.

1301-05 RESPONSIBILITIES

The Regional Program Manager shall have the lead responsibility for follow-up actions for radiation source incidents. The central office Chief, Division of Radiation Control shall have the lead responsibility if the incident involves several regional offices, coordination with out-of-state entities, or when DEP management decides the incident would be better handled through central office, to ensure a coordinated response among the various regulatory agencies and licensees involved.

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1301-06 GENERAL RESPONSE PROCEDURE

The guidance in this section is for DEP staff use in responding to any radiation source incident that does not require activation of an incident response program. If the Department determines that the incident is an emergency, this guidance will not apply.

First and foremost is that the Department is notified of an actual or potential incident involving a radiation source in the public domain. The public has many ways of communicating this to the DEP including, but not limited to, contact with DEP's Emergency Response Coordinators, complaints, through the Pennsylvania State Police (PSP), through the Pennsylvania Emergency Management Agency (PEMA), through county EMA (e.g., 9-1-1 calls), or directly with the Radiation Protection program.

NOTE: State and local governments have primary responsibility for determining and implementing emergency measures to protect life, property, and the environment in areas not under the control of a Federal agency. In these areas, Federal agencies typically respond only at the request of State or local governments, unless their regulatory responsibilities require responses. Any request for a Federal response shall be referred to the Lead Federal Agency (LFA). See Appendix A for a list of LFA's extracted from the Federal Radiological Emergency Response Plan. Phone numbers for referring reports to Federal agencies are provided in Appendix B.

06.01 Confirm Incident

Obtain a description of the incident from the individual reporting it. Verify the call. Obtain information as to location of the radiation source, name of facility involved (if applicable), caller name and telephone number(s), radiation sources involved (if known), exposure rates (if known), whether radioactive contamination is present (if known), whether the incident is a transportation event, names / telephone numbers of other individuals (responders or others) involved.

If there are no "First Responders" on the scene, advise the caller to take the following actions as applicable:

i. Do not handle any objects at the scene.
ii. Provide first aid if qualified.
iii. As a precaution, please move and ask others to move away from a hazard area a reasonable distance (say 50 m); this does not include first aid or/and casualty rescue personnel.
iv. Confine the area if possible.
v. Do not eat, drink or smoke near the accident area.
vi. Ask people present to remain on location, away from the hazard, until the arrival of emergency response services.
vii. Wait for emergency response services and brief the on-scene controller.

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06.02 Response

1. Obtain the details surrounding the incident (see Section 1301-07), so as to be able to decide on what action to take. Consult with the regional Emergency Response Coordinator (or his assistant), and with the Regional Director or Assistant Regional Director if additional resources may be necessary. Refer to MC 1302, "Follow-up Actions and Action Levels for Radiation Exposures Associated With Incidents Involving Members of the Public" and MC 1330, "Response to Transportation Accidents Involving Radioactive Materials," for further details.

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2. Report the incident to central office, other regional offices, and other State agencies, as appropriate. The BRP central office will notify any appropriate Federal agencies, in accordance with interagency agreements, of any event involving: (1) declaration of an emergency at a facility; (2) release of radioactive material; (3) potential or actual exposure of a member of the public; or (4) considerable public, media, or legislative interest.

3. Evaluate the need for a medical consultant if any individual(s) received a large dose of radiation.

4. In cases involving intakes of radioactive materials that are reportable under 10 CFR 20.2202:

   (a) Assess the assumptions made in obtaining the initial assessments, to make sure they are reasonable under the circumstances. The initial assessment is important because it will determine the type of actions to be taken, to mitigate the consequences of the intake. Request immediate additional measurements if the initial assessment appears inadequate.

   (b) A medical consultant should be retained in cases where the estimated committed dose equivalent exceeds 2.5 Sv (250 rem) to any individual organ or tissue other than the lens of the eye. Sources of information and assistance in these areas include; Oak Ridge Institute for Science and Education; Radiation Emergency Assistance Center/Training Site (REAC/TS); and publications such as National Council on Radiation Protection and Measurements Publication No. 65, "Management of Persons Accidentally Contaminated with Radionuclides." Phone numbers for contacting REAC/TS are provided in Appendix B.

5. Evaluate the need for a hazardous chemical consultant (do this through the regional Emergency Response Coordinator(s)).

6. Evaluate the need to dispatch one or more regional staff.

7. Request assistance from other regional offices, as necessary.

NOTE: If the event involves the discovery of radioactive material in an unrestricted area, and it is urgent that someone take possession of the material, immediately contact the regional emergency response coordinator and provide as much of the information outlined in MC 1303 as possible. Try to have the material secured at the incident site until help can arrive. If the material must be moved immediately, work with local agencies and nearby licensees to store the material. DEP personnel should confiscate material **only as a last resort**. If the material can be temporarily secured at the incident site, work with the party possessing the material to find an appropriate disposition (i.e., return material to its original owner, ship material to disposal site, etc.). Only when all appropriate disposal options are exhausted, the Department may request that DOE take emergency possession (see MC 1303).

1301-07 ADDITIONAL GUIDANCE ON EVENTS

07.01 Establish Degree of Health Hazard

Establish the degree of health hazard, considering the following factors:

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Determine how far and where the radioactive material has spread, considering the following factors:¶
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a. . Possible need for assistance from other State or Federal agencies. ¶
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b. . Possible need to request DOE to conduct an aerial survey [i.e., Aerial Measurements System (AMS) flights] over selected areas, to identify unknown areas of contamination. The Department may request DOE AMS support through DOE Headquarters.

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a. Possible scenarios and / or re-enactments of incident, to provide a best estimate of radiation dose.

b. Pathways for ingestion or inhalation by persons and possible doses from intake of radioactive material.

c. Calculate possible doses to persons from exposure to ionizing radiation (internal and external).

d. Nature of population at risk: groups of individuals, number of individuals.

e. Calculate total population doses (collective dose), considering the extent of radioactive material and radiation levels in public places.

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07.02 Determine How Far the Radioactive Material Has Spread

Determine how far and where the radioactive material has spread, considering the following factors:

a. Possible need for assistance from other State or Federal agencies.

b. Possible need to request DOE to conduct an aerial survey [i.e., Aerial Measurements System (AMS) flights] over selected areas, to identify unknown areas of contamination. The Department may request DOE AMS support through DOE Headquarters.

07.03 Stop Spread of Radioactive Material

Ensure that no radioactive material is further disseminated to other areas, considering the following factors:

a. The reliability of the licensee that controls the locations or the articles where radioactive material has been detected.

b. Steps necessary to prevent further dissemination of the radioactive material.

07.04 Control, Recovery, and Disposal of Radioactive Articles

Ensure control, recovery, and safe disposal of radioactive articles, considering the following factors:

a. Exposure potential.

b. Cost/benefit impacts in barring use of radioactive materials.

c. Degree of radiation hazard.

d. Keeping public exposure as low as is reasonably achievable.

e. Alternative methods of decontaminating property and disposing of radioactive and contaminated materials and waste.

When it is not possible to locate the responsible licensee, or the responsible licensee is unable to take possession of any radioactive material in question, radioactive material discovered in unrestricted areas may need to be immediately disposed of (see MC 1303, "Requesting Emergency Acceptance of NRC-Licensed Material by DOE").

07.05 Control, Recovery and Disposal of Radiation-Producing Equipment

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Ensure control, recovery, and safe disposition of radiation-producing machines and equipment. Determine who the responsible party (registrant) is, contact that party to notify it of the loss of control (assuming that they haven't notified the Department already of that loss of control), and ensure that they make arrangements to recover the machine and bring it back to their facility. Follow up as necessary. Note: There is the remote possibility of the presence of hazardous material in pre 1979 x-ray equipment (PCBs in transformer oil or x-ray tubes and lead around tubes.)

1301- 08 Keep Public Informed

Inform the public about the incident, through the regional Community Relations Coordinator(s). The Community Relations Coordinator(s) are the principal media contacts for any dissemination of information to the public, not RP staff. Press releases should be coordinated with other local authorities, whenever possible. Consider the following factors:

a. Extent of public risk and public perception of the risk.

b. Extent of media interest.

c. Confidence in validity of information reported to DEP.

d. Reassessing the measures that have been taken (e.g., health physics and medical services that have been made available to the public).

e. Coordination of information among the offices and other State and local agencies. Ensure that other agencies are informed of any information to be released to the media or the public.

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f. Assurance of correctness of information provided to the news media and the public.

1301-09 Follow-up Actions

Regional offices are responsible for the screening, evaluation, follow-up, and closeout of reports of all types of incidents reported by licensees under their cognizance. The regional offices should:

a. Use the Nuclear Medical Event Database (NMED) system to track, review, and follow up written reports of incidents. Initial input of entries is handled by central office.

b. Document all types of reports of incidents in an inspection report or other type of record. Corrective actions should be tracked to completion.

Documentation Guidance

Any follow-up actions that the regional staff takes on a reported incident should be summarized in writing and maintained in an official regional file.

1301-10 Examine Regulatory Significance of Incident

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Examine regulatory significance of the incident and close out the DEP response, considering the following factors:

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a. Possibility of generic implications.

b. Value of documented case study

c. Need to prevent recurrence.

d. Possible need for new rulemaking.

END

APPENDICES

A. Identification of Lead Federal Agency for Radiological Emergencies according to FRERP

B. Telephone Numbers for the U.S. Environmental Protection Agency, Radiation Emergency Assistance Center/Training Site, Federal Bureau of Investigation, Department of Energy 24-Hour Emergency Operations Center, Department of Energy/Radiological Assistance Program (RAP), and Department of Energy Regional Offices"

C. Lead and Alternate Contacts in the Office of Nuclear Material Safety and Safeguards (NMSS) and NRC Operations Center"

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APPENDIX A

IDENTIFICATION OF LEAD FEDERAL AGENCY FOR RADIOLOGICAL EMERGENCIES ACCORDING TO FRERP[i]

The agency responsible for leading and coordinating all aspects of the Federal response is referred to as the lead Federal agency (LFA) and is determined by the type of emergency. In situations where a Federal agency owns, authorizes, regulates, or is otherwise deemed responsible for the facility or radiological activity causing the emergency and has authority to conduct and manage Federal actions onsite, that agency normally will be the LFA.

Type of emergency	LFA
1. Nuclear Facility:	
A. Licensed by NRC or an Agreement State	NRC
B. Owned or operated by DOD or DOE	DOD or DOE
C. Not licensed, owned, nor operated by a Federal agency or an Agreement State	EPA
2. Transportation of radioactive materials:	
A. Shipment of materials licensed by NRC or an Agreement State	NRC
B. Materials shipped by or for DOD or DOE	DOD or DOE
C. Shipment of materials not licensed nor owned by a Federal agency or an Agreement State	EPA
3. Domestic satellites containing radioactive materials:	NASA or DOD
4. Impact from foreign or unknown source:	EPA, DOD, or NASA
5. Criminal activity or terrorism involving radioactive material:	DHS or DOJ
6. Other types of emergencies:	LFA's confer

Note: Acronyms:

NRC = U.S. Nuclear Regulatory Commission
DHS = U.S. Department of Homeland Security
DOD = U.S. Department of Defense
DOE = U.S. Department of Energy
EPA = U.S. Environmental Protection Agency
DOJ = U.S. Department of Justice
NASA = National Aeronautic and Space Administration

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APPENDIX B

[i] 61 FR 20944, May 8, 1996.

TELEPHONE NUMBERS FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE, FEDERAL BUREAU OF INVESTIGATION, DEPARTMENT OF ENERGY 24 HOUR EMERGENCY OPERATIONS CENTER, DEPARTMENT OF ENERGY/RADIOLOGICAL ASSISTANCE PROGRAM (RAP), AND DEPARTMENT OF ENERGY REGIONAL OFFICES

The regional 24-hour emergency contact numbers for reporting incidents to the U.S. Environmental Protection Agency are:

Region III (DC, DE, MD, PA, VA, WV)	215-814-9016
National Response Center	800-424-8802
Radiation Emergency Assistance Center/Training Site (REAC/TS)*:	
8:00 am to 4:30 pm	865-576-3131
After hours (Oak Ridge Operations Center)	865-576-1005

* REAC/TS is a Department of Energy resource headquartered in Oak Ridge, Tennessee. It is available 24 hours a day to provide medical and radiological assistance either from the REAC/TS facility or the accident site. Additionally, REAC/TS maintains a listing of other professionals throughout the country who are recognized as having highly specialized expertise and equipment to manage a particular area of concern.

FBI contact number	202-324-6928
DOE 24-hour Emergency Operations Center	202-586-8100

DOE Radiological Assistance Program (RAP) regional contact numbers:

RAP Region 1 (Brookhaven Operations Office) (DC, MD, DE, PA, NJ, CT, NY, RI, VT, MA, NH, ME)	516-344-7309 (2200) Steve Centore centore@bnl.gov
Philadelphia Regional Office (DE, MD, PA, NJ, VA, WV, DC)	215-656-6950 215-656-6955 Fax 215-656-6981

Note:

Acronyms:

DOE = U.S. Department of Energy
FBI = Federal Bureau of Investigation
RAP = Radiological Assistance Program

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¶
LEAD AND ALTERNATE CONTACTS IN THE¶ OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS (NMSS)¶ AND NRC OPERATION CENTER¶
¶
The U.S. Nuclear Regulatory Commission (NRC) Operations Center should receive and coordinate all initial notifications of an incident of radioactive material 24 hours a day, 7 days a week. The Operations Center will notify other Federal agencies of any event involving: (1) declaration of an emergency at a facility; (2) release of radioactive material; (3) potential or actual exposure of a member of the public; or (4) considerable public, media, or Congressional interest. The following lead contacts in the Office of Nuclear Material Safety and Safeguards (NMSS) should determine the path for all later information, except for those follow-up notifications noted in this inspection manual chapter. ¶
¶
NRC Operations Center¶
¶
(301) 816-5100 (collect calls are accepted)¶
(301) 415-0550; (301) 951-0550¶
Fax: (301) 816-5151¶
¶
NMSS Day Emergency Officers¶
¶
¶
Lead Contact ... [1]

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APPENDIX C

LEAD AND ALTERNATE CONTACTS IN THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS (NMSS) AND NRC OPERATION CENTER

The U.S. Nuclear Regulatory Commission (NRC) Operations Center should receive and coordinate all initial notifications of an incident of radioactive material 24 hours a day, 7 days a week. The Operations Center will notify other Federal agencies of any event involving: (1) declaration of an emergency at a facility; (2) release of radioactive material; (3) potential or actual exposure of a member of the public; or (4) considerable public, media, or Congressional interest. The following lead contacts in the Office of Nuclear Material Safety and Safeguards (NMSS) should determine the path for all later information, except for those follow-up notifications noted in this inspection manual chapter.

NRC Operations Center

(301) 816-5100 (collect calls are accepted)
(301) 415-0550; (301) 951-0550
Fax: (301) 816-5151

NMSS Day Emergency Officers

Lead Contact	Director, Division of Industrial and Medical Nuclear Safety	(301) 415-7197
Alternate Contact	Deputy Director, Division of Industrial and Medical Nuclear Safety	(301) 415-7196
Incident Response Coordination Contact	Chief, Materials Safety and Inspection Branch	(301) 415-7231
Alternate Contact	Section A Leader, Materials Safety and Inspection Branch	(301) 415-7213
Alternate Contact	Section B Leader, Materials Safety and Inspection Branch	(301) 415-7875
Alternate Contact	Regional Coordinator	(301) 415-5723
Alternate Contact	Chief, Rulemaking and Guidance Branch	(301) 415-8125
Alternate Contact	Section A Leader, Rulemaking and Guidance Branch	(301) 415-6825

The functions of the NMSS Day Emergency Officers are described in "NMSS Emergency Officer (EO) Procedure," which is a document published by the Incident Response Operations.

NMSS Off-Hours Emergency Officers

NMSS Off-Hours Emergency Officers can be contacted by calling the NRC Operations Center.

DEP INSPECTION MANUAL

MANUAL CHAPTER 1302

FOLLOW-UP ACTIONS AND ACTION LEVELS FOR RADIATION EXPOSURES ASSOCIATED WITH INCIDENTS INVOLVING MEMBERS OF THE PUBLIC

1302-01 PURPOSE

To provide advice and guidance on a course of action to follow in case of incidents involving radiation exposure to members of the public. The guidance provided in this document is for Bureau of Radiation Protection (BRP) staff to use in responding to incidents that do not require activation of the Department's Nuclear Power Station Emergency Response Plan. It is specifically for use after actions have been taken to prevent the source of exposure from further affecting the public, and it is intended for use as initial guidance, when situations arise. This Manual Chapter (MC) should be used in conjunction with MC 1301, "Response to Radiation Source Incidents."

1302-02 OBJECTIVES

To ensure that correct follow-up action is taken when there is an incident involving radiation exposure to members of the public.

1302-03 DEFINITIONS

03.01 Agreement State. A state that has signed an agreement with the NRC under which the State regulates the use of by-product, source and small quantities of special nuclear material and NARM within that state.

03.02 Member of the Public. Any individual except when that individual is receiving an occupational dose

03.03 Radioactive Material in the Public Domain. Any radioactive material, subject to NRC or Agreement State jurisdiction, for which control in accordance with NRC or Agreement State regulations or with applicable license conditions is not being implemented, and which may, or have already resulted in, radiation exposures to members of the public.

1302-04 APPLICABILITY

This MC applies to BRP staff in central office and in the regional offices.

1302-05 RESPONSIBILITY

The responsible Region shall have the lead responsibility for follow-up actions for incidents involving radiation exposure to members of the public, with the following exception. Central Office may have the lead responsibility when the incident involves several regional offices, international entities, or when BRP management decides the incident would be better

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handled by Central Office to ensure a coordinated approach among the various agencies and licensees involved.

1302-06 GENERAL GUIDANCE

Incidents involving radiation sources are, by nature, event-specific. Because the conditions surrounding each incident are unique, follow-up action must be developed on a case-by-case basis. The information provided in this MC is meant to be a guide, and should not be used in isolation of other guidance for incidents and basic radiation safety principles.

Staff should use the guidance in MC 1301, "Response to Radiation Source Incidents" in conjunction with the guidance provided in this MC when responding to incidents involving radiation exposures to members of the public. Manual Chapter 1301 provides detailed guidance for responding to radioactive source incidents, including incident assessment; dose assessment if individuals are exposed to radiation; need for medical consultants; interaction with other Federal, State and local government agencies; types of inspections, etc.

As part of the guidance in MC 1301, procedures direct staff to: (1) evaluate the potential or actual exposure of a member of the public, (2) keep public exposures as low as possible, and (3) evaluate the potential radiological consequences and personnel exposures. Staff should follow the guidelines in MC 1301 for incident assessment and documentation. With any incident, staff will be working closely with any known licensees involved with the incident. If a responsible licensee is not immediately known, general response procedures are outlined in MC 1301, which include descriptions of which Federal, State or local entity would be in charge under various circumstances. The purpose of MC 1302 is to provide additional information and dose ranges/guidance if members of the public are exposed to radiation. Also, there are additional references in Attachment 1 regarding dose limits and radiation exposures.

Some incidents may be considered abnormal occurrences. NRC submits an abnormal occurrence report to Congress annually. The report, NUREG-0090, "Report to Congress on Abnormal Occurrences," includes the criteria for abnormal occurrences. As part of an incident assessment involving radiation exposure to members of the public, Central Office should also provide appropriate information to the NRC State Liaison in accordance with current procedures for submitting incidents considered possible Abnormal Occurrences.

06.01 Specific Guidance

The guidance in this MC is intended for incidents involving radiation sources and not for routine, non-accident operations. The regulations have specific limits for exposures to members of the public. The dose limit for members of the public is given in Section 20.1301, "Dose limits for individual members of the public." Licensees are to conduct operations so that the limits in Section 20.1301 are not exceeded for members of the public. Currently, the public dose limit is 1 mSv (100 mrem). Section 20.1301(c) allows a licensee to permit visitors to an individual who is undergoing medical treatment and cannot be released under Section 35.75 to receive a dose not to exceed 5 mSv (500 mrem). Note that any accidental exposures to members of the public may be investigated, depending on the nature of the exposure, regardless of the dose. However, exposures from routine operations, for example, when material is disposed or released via effluents in accordance with the regulations, would not be part of the scope of this MC.

If a licensee is required to report to the Department, under 10 CFR Section 20.2202, "Notification of incidents," and Section 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," the licensee is responsible, in accordance with Section 19.13(d), for notifying and providing an exposure

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Develops policy and guidance for the Headquarters and regional staff who respond to incidents involving radiation exposures from licensed material to members of the public. Develops and administers the program for NRC follow-up actions and coordinates incident follow-up activities. ¶
¶
05.02 . Director, Office of Nuclear Security and Incident Response¶
¶
Maintains and staffs the NRC Operations Center at NRC Headquarters. Receives and documents incident reports from NRC regional offices, licensees, or other parties. Makes initial and follow-up notifications within NRC, and to other Federal agencies and State agencies, coordinating with NMSS.¶
¶
05.03 . Regional Administrator¶
¶
Completes incident response activities according to the policy and guidance established by NMSS and refers questions on policy matters to NMSS for resolution.¶
¶
05.04 . Director, Office of International Programs¶
¶
Coordinates international aspects of incident follow-up activities with the Department of State, International Atomic Energy Agency (IAEA), foreign governments, and other international groups.¶
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05.05 . Director, Office of State and Tribal Programs¶
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Coordinates applicable incident follow-up activities with State, local, and Native American tribal governments.¶
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05.06 . Director, Office of Public ... [1]

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report to any individuals that were exposed. Depending on the circumstances of the incident, BRP may also notify the affected individuals. For example, BRP might notify individual(s) if the staff believes that the licensee response is not adequate, a responsible licensee is not known at the time, or the staff wants to make sure the individual(s) is(are) getting complete information. A list of the type of information that should be included in any notification to a member of the public is provided in Attachment 2.

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The actual doses to members of the public are likely to be uncertain, especially during the initial follow-up after an incident. Doses will usually be estimated in a dose range or a maximum dose based on the circumstances of the incident. For this reason, it is important to talk with exposed individuals because this can help the staff in assessing the incident and in estimating the dose.

Depending on the nature of the incident, further analysis of the estimated dose may be necessary, using techniques such as bioassays, whole body counting, and cytogenetic analysis, and should be considered as the estimated doses approach 10-20 rem and up. In evaluating the need for these types of analyses, staff should keep in mind that performing the study can help reassure an individual who was exposed to radiation, but it can also increase the anxiety about the exposure. Therefore, staff should be sensitive to this and use their best judgement in deciding when to recommend cytogenetic analysis.

Deleted: All cytogenetic analyses should be coordinated with NMSS. NMSS is the lead for coordinating testing through the testing laboratory and for obtaining laboratory samples. Also note that other dose evaluations may need to be coordinated with NMSS as well. Staff should follow current procedures and guidelines.

Because people are often more anxious about radiation exposure than with other hazards and risks, staff should be especially sensitive when providing information about the incident and the estimated doses. Staff must be as factual as possible about characterizing the dose based on available information, without causing undue stress. Staff should not discuss medical issues or provide medical advice to exposed individuals. Instead, staff should refer individuals to their personal physicians.

06.02 Dose Ranges and Guidance

1. Dose Range from 0 to 1 mSv (100 mrem)

Exposures with estimated doses in this range are within the public dose limit in 10 CFR Part 20. There are no regulatory requirements requiring reporting and notifications. Typically, no further action is needed, but the need for additional action must be evaluated based on the specific incident.

2. Dose Range from 1 mSv (100 mrem) to 50 mSv (5 rem)

In cases when the estimated dose is between 1 and 50 mSv (100 mrem and 5 rem), staff will need to determine if a medical consultant is necessary. If a medical consultant is necessary, the medical consultant will determine whether or not a medical evaluation of exposed individuals is necessary. Staff should not discuss medical issues with an individual who was exposed, or provide medical advice. Instead, if an individual expresses concern or wishes additional information on possible medical affects, staff should refer the individual to his/her personal physician or to the department's medical consultant, if DEP has consulted with one to analyze the incident. If additional assistance is needed, BRP staff can call the Radiation Emergency Assistance Center/Training Site (REAC/TS). Information on REAC/TS is provided below in Attachment 3, "Medical Assistance in Radiation Exposure Emergencies."

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3. Dose Range Greater than 50 mSv (5 rem)

For estimated doses that appear to be over 50 mSv (5 rem), assess the incident following the guidance in 2. above. If the calculated effective dose equivalent is more

than 100 mSv (10 rem), further medical evaluation should be considered. Depending on the circumstances of the incident, a medical consultant may be brought in, the exposed individual will be referred to his/her personal physician, and/or REAC/TS may be consulted for additional guidance. At dose estimates in this range, and approaching 200 mSv (20 rem), the need for further analysis of the dose, as discussed above, should be evaluated.

4. Members of the Public Who Are Pregnant

Information regarding the disclosure of pregnancy must be on a voluntary basis because of issues involving individual privacy. If, in the course of evaluating an incident involving exposures to members of the public, staff is informed by a female member of the public that she is pregnant, the follow-up action is essentially the same as in 1. through 3. above, extending the evaluation to look at the impact on the embryo/fetus. A medical consultant will probably be asked to evaluate the incident and the likely dose to the embryo/fetus. As stated previously, staff should not discuss medical issues or provide medical advice to the woman, but should refer her to her personal physician. Additional information on exposures to the embryo/fetus can be found in: 1) NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure," and 2) National Council on Radiation Protection and Measurements Report No. 128, "Radionuclide Exposure of the Embryo/Fetus." Additionally, staff may get additional guidance if needed from REAC/TS.

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REFERENCES FOR DEVELOPING GUIDANCE ON RADIATION EXPOSURE ASSOCIATED WITH INCIDENT FOLLOW-UP

The following references may assist staff with incident follow-up. These references provide additional information on recommended dose limits and radiation exposures.

I. U.S. Nuclear Regulatory Commission

1. NRC's current 10 CFR Part 20 establishes an explicit dose limit of 1 mSv (100 mrem) per calendar year, resulting from any licensed activity, to any individual in an unrestricted area, with 5 mSv (500 mrem) per year allowed in certain temporary NRC pre-approved situations. Part 20 also establishes a dose limit of 5 mSv (500 mrem) to the embryo-fetus during the entire pregnancy for the occupational exposure of a declared pregnant woman. If the fetal dose has exceeded that level before the pregnancy is declared, other limits apply.

2. NRC's Regulatory Guide 8.13, Revision 3, "Instruction Concerning Prenatal Radiation Exposure," Revision 3, June 1999, provides occupationally exposed women with guidance on the biological effects of radiation on the embryo-fetus and whether or not to declare pregnancy.

3. Regulatory Guide 8.29, "Instruction concerning Risks from Occupational Radiation Exposure," Revision 1, February 1996, describes the information that licensees should provide to workers about health risks from occupational exposure.

II. NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS

National Council on Radiation Protection and Measurements Report No. 128, "Radionuclide Exposure of the Embryo/Fetus" provides information about radiation doses to the embryo/fetus and the effects of radionuclide exposure during pregnancy. The report includes information on approaches for estimating radiation doses to the embryo/fetus that result from radionuclide burdens or intakes by a pregnant woman that relate to medical, occupational and environmental sources of radioactive material. The dosimetry of external sources is beyond the scope of this report.

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ATTACHMENT 2

OUTLINE OF INFORMATION TO PROVIDE TO MEMBER OF PUBLIC

NOTE: THIS LETTER SHOULD NOT BE THE FIRST CONTACT TO AN INDIVIDUAL THAT HE/SHE WAS EXPOSED TO RADIATION.

If the licensee is required to report to the Department under 10 CFR Sections 20.2202 or 20.2203 incorporated by reference, the licensee is responsible, under Section 19.13(d), for notifying and providing an exposure report to any individuals that were exposed. Depending on the circumstances of the incident, DEP may also notify the affected individuals, as discussed earlier in this MC. Also, if DEP is on-site evaluating an incident, staff may have already had interactions with members of the public who were, or were possibly, exposed to radiation.

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1. State why the letter is being provided

   a. Explain that DEP is conducting or has conducted an investigation of the incident.
   b. Explain that the individual is being notified because they received an exposure to radiation.
   c. Cite the regulations that require that they be notified.
   d. Provide details of the incident, such as location; any information about the incident; an estimate of the dose, along with an example for a comparison dose, i.e. chest x-ray is about 10 mrem; etc.

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2. Refer individuals to their personal physician for any medical questions or concerns. Depending on the nature of the incident, DEP may request a medical consultant, who may evaluate individuals who were exposed. Refer to MC 1301.

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3. Include information that the radiation dose information contained in this letter is exempt from disclosure under the Right to Know Law.

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4. Include contact information for the primary NRC staff contact in case the individual or the individual's personal physician has questions or needs additional information.

5. Signature: typically, a Program Manager or Division Chief signs the letter.

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ATTACHMENT 3

MEDICAL ASSISTANCE IN RADIATION EXPOSURE EMERGENCIES

In the early stages of a response, BRP staff may have to determine whether medical evaluations are warranted for members of the public who are, or who were potentially, exposed to radioactive materials. It should be noted; however, that staff should not discuss medical issues with members of the public or provide medical advice in cases dealing with an exposure to radioactive material. Always refer any medical questions or concerns about biological effects of radiation exposure to a physician. For some incidents, a medical consultant may be used (see MC 1301) to evaluate exposures to members of the public. Also, the Radiation Emergency Assistance Center/Training Site (REAC/TS) is a source of information on radiological effects.

If medical advice is needed, or if the exposed person's physician is not trained in the effects of radiation exposure and the treatment of such effects, and wants additional information or guidance, call or refer the physician to the Radiation Emergency Assistance Center/Training Site (REAC/TS). REAC/TS is a U.S. Department of Energy (DOE) response asset that maintains a radiological emergency response team consisting of physicians, nurses, health physicists, coordinators, and necessary support personnel. It is on 24-hour call to provide first-line responders with consultative or direct medical and radiological assistance at the REAC/TS facility or at the accident site. They have expertise in, and are equipped to conduct: (1) medical and radiological triage; (2) decontamination procedures and therapies for external contamination and internally deposited radionuclides, including diethylene triamine pentaacetic acid (DPTA) chelation therapy; (3) diagnostic and prognostic assessment of radiation-induced injuries; and (4) radiation dose estimates by methods that include cytogenetic analysis, bioassay, and in-vivo counting.[1]

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[1]REAC/TS website: www.orau.gov/reacts/resources.htm

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Deleted: The REAC/TS emergency telephone number is 1-865-576-1005 (ask for REAC/TS). If the telephone numbers have changed, the NRC Headquarters Operations Center should be called for the new number at (301) 816-5100.

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05.01 Director, Office of Nuclear Material Safety and Safeguards

Develops policy and guidance for the Headquarters and regional staff who respond to incidents involving radiation exposures from licensed material to members of the public. Develops and administers the program for NRC follow-up actions and coordinates incident follow-up activities.

05.02 Director, Office of Nuclear Security and Incident Response

Maintains and staffs the NRC Operations Center at NRC Headquarters. Receives and documents incident reports from NRC regional offices, licensees, or other parties. Makes initial and follow-up notifications within NRC, and to other Federal agencies and State agencies, coordinating with NMSS.

05.03 Regional Administrator

Completes incident response activities according to the policy and guidance established by NMSS and refers questions on policy matters to NMSS for resolution.

05.04 Director, Office of International Programs

Coordinates international aspects of incident follow-up activities with the Department of State, International Atomic Energy Agency (IAEA), foreign governments, and other international groups.

05.05 Director, Office of State and Tribal Programs

Coordinates applicable incident follow-up activities with State, local, and Native American tribal governments.

05.06 Director, Office of Public Affairs

Prepares, coordinates, and disseminates information about incidents involving radioactive material to the public and news media.

05.07 Other Federal Agencies

Roles of other Federal agencies in responding to incidents involving radioactive material are summarized in MC 1301, "Response to Radioactive Materials Incidents That Do Not Require Activation of the NRC Incident Response Plan."

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MANUAL CHAPTER 1303

REQUESTING EMERGENCY ACCEPTANCE OF RADIOACTIVE MATERIAL BY THE U.S. DEPARTMENT OF ENERGY (DOE)

1303-01 PURPOSE

To establish procedures for requesting emergency assistance from the U.S. Department of Energy (DOE) in retrieving and storing inadequately-controlled, radioactive material licensed by NRC or an Agreement State.

1303-02 OBJECTIVE

To ensure adequate protection of the public health and safety from radiation hazards arising from situations in which (1) radioactive material licensed by NRC or an Agreement State is discovered to be inadequately controlled; and (2) appropriate governmental actions are needed because of the lack of a capable licensee.

1303-03 APPLICABILITY

This chapter applies to the DEP's Bureau of Radiation Protection.

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1303-04 DEFINITIONS

04.01 Inadequately-Controlled Radioactive Material. Byproduct, source or special nuclear material, licensed by NRC or an Agreement State, that is (1) in the possession of an unlicensed party, (2) in the possession of a licensee not authorized to possess the material, or (3) in the possession of a licensee authorized to possess the material, but for which there is little confidence that the licensee will be able to continue to maintain appropriate security of the material. Examples of such situations are abandoned sources or devices containing sources that are traceable to a licensee that cannot take control of the material; unauthorized transfer of licensed material by or to licensees; and licensed material in the possession of licensees or former licensees who are unable to adequately control the material.

04.02 Emergency Situation. For the purpose of requesting emergency acceptance by DOE, an emergency situation is a situation that is causing, or has

high potential to cause, a significant health and safety risk to members of the general public.

1303-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Director, Office of State Programs (OSP)

a. Receive and evaluate requests from Agreement States for emergency acceptance by DOE of material licensed by the Agreement State.

b. Coordinate Agreement State requests with the Source Containment and Devices Branch (SCDB/NMSS).

05.02 Chief, Division of Radiation Control

a. Determines when a situation involves licensed material lacking a capable licensee to control it, and requests DOE emergency acceptance in accordance with this manual chapter.

b. Assign a regional point-of-contact to coordinate DOE retrieval of licensed material (normally, this would be the Regional Manager or the Section Chief for Radioactive Materials).

1303-06 BASIC REQUIREMENTS

06.01 General Guidance

a. Guidance for immediate response actions is contained in DEP IMC 1301, Response to Radioactive Material Incidents. This manual chapter contains the procedure to be followed after any immediate actions to secure inadequately-controlled material have been taken, and it has been determined that emergency acceptance by DOE is required to eliminate a significant threat to public health and safety because all other available options for disposing of the material have been exhausted.

b. In general, this procedure is intended for situations involving discrete sources at a single location, or locations that are closely related geographically or functionally. Other situations shall be evaluated on a case-by-case basis.

c. DOE will retrieve inadequately-controlled radioactive material that has been traced to a DOE facility or prime contractor. For material licensed by NRC or an Agreement State, DOE has agreed to accept the material only when it is clear that the material is causing, or has high potential to cause, a significant threat to public health and safety; and the responsible licensee is not available, or not capable of adequately controlling it.

Deleted: An emergency situation under this manual chapter differs from an emergency incident as defined in Inspection Manual Chapter (IMC) 1301 in that an emergency situation may not require activation of the NRC Incident Response Plan in Management Directive (MD) 8.2

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Deleted: 05.03 Director, Division of Industrial and Medical Nuclear Safety (IMNS), NMSS Review and approve all NRC and Agreement State requests for DOE emergency acceptance of licensed material. ¶
¶
05.04 Chief, Source Containment and Devices Branch (SCDB), IMNS, NMSS ¶
¶
a. Receive and coordinate requests for DOE emergency acceptance of licensed material in accordance with this manual chapter. ¶
¶
b. Determine whether requests are sufficient to request DOE assistance. ¶
¶
c. Prepare letters to DOE requesting emergency acceptance of material licensed by NRC or an Agreement State. ¶
¶
05.05 Chief, Storage and Transport Systems Branch (STSB), IMNS, NMSS. Provide assistance with issues involving the transportation of radioactive materials. ¶
<#>¶
05.06 Chief, Low-Level Waste and Decommissioning Projects Branch (LLDP), Division of Waste Management, NMSS. Maintain a listing of licensed material accepted by DOE and its location within DOE. ¶

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d. NRC shall always make the initial request to DOE for emergency acceptance of material licensed by NRC or an Agreement State. Agreement States should not contact DOE directly.

06.02 Requesting Emergency Acceptance by DOE

a. Agreement States requesting emergency acceptance of State-licensed material shall contact OSP and OSP shall coordinate the request with SCDB/NMSS. The Agreement State should recount and document a chronology of events, discuss results of actions taken to identify a responsible licensee and dispose of the material, provide a description of the material, and designate a point-of-contact (POC). The information required to request emergency acceptance by DOE is outlined in Exhibit 1.

Deleted: Regions requesting emergency acceptance of NRC-licensed material shall contact the Chief, SCDB/NMSS

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b. If all the above information is received by SCDB and determined to be sufficient to request DOE assistance, SCDB personnel shall prepare a letter to the Deputy Assistant Secretary for Waste Management, DOE, Washington DC 20545, requesting that DOE accept management of the material, and forwarding a summary of the information listed above.

c. All requests for DOE emergency acceptance of radioactive material shall be signed by the Director, IMNS/NMSS, or an alternate designated official.

d. In addition, SCDB personnel shall inform the following individuals of emergency assistance requests:

• Director, Office of Technical Support, DOE for Greater-Than-Class-C (GTCC) radioactive material, or

• Director, Office of Site Operation, DOE for all other radioactive material, and

• Chief, LLDP/NMSS.

e. DOE Headquarters will contact the appropriate DOE regional office or facility to arrange for the management of the material. The DOE regional office or facility will work directly with the designated Region/State point-of-contact to make detailed arrangements for the pick-up.

f. After acceptance by DOE, the Region/State point-of-contact shall document the chronology of events including dates and times, ultimate disposition of the material, names of individuals involved (including any individuals associated with the pick-up by DOE), and any other pertinent information. This chronology is to be sent to the Chief, SCDB/NMSS, and a copy is to be sent to the Chief, LLDP/NMSS. Agreement States should submit a copy to OSP also. LLDP

maintains a listing of the material accepted by DOE and its location within DOE.

Exhibits:
1. Information to be Provided to SCDB/NMSS for DOE Requests

Exhibit 1

INFORMATION TO BE PROVIDED TO SCDB/NMSS FOR DOE REQUESTS

General:

Region/State Point-of-Contact: Phone:
( ) -
Possessor's Name:
Contact Name: Phone: ( ) -
Street Address: Fax: ( ) -

City: State: Zip:

Exact location of material (address, if different than above, and location within facility):

Describe the current security of the material (e.g., in a locked room, file cabinet, etc.):

Description: Include as much information as possible for each discrete source or device. Attach additional sheets as necessary.

1) Form of material: Nuclide:
(ceramic matrix, pellets, etc.)
Activity Level: Assay Date: /
/ (mCi or Ci) (if applicable)

2) Form of material:
Nuclide: (ceramic matrix,
pellets, etc.)

Activity Level: Assay Date: /
/ (mCi or Ci) (if applicable)

Verify that the waste classification of the material is in accordance with 10 CFR 61.55 and the Branch Technical Position (BTP) on Waste Concentration Averaging, if possible (contact LLDP/NMSS for a copy of the BTP).

Waste Classification:

Reviewer: Date:

IMPORTANT: IF THE MATERIAL IS POSSESSED BY A LICENSEE NO LONGER ABLE TO CONTROL IT ADEQUATELY, YOU MUST ATTACH A COPY OF THE LICENSE LISTING THE MATERIAL.

Region/State POC: Possessor:

For devices, provide the weight in pounds of any depleted uranium used as shielding: lbs.

For Neutron Sources, provide Target Element [e.g., Beryllium (Be)]:

If the material is possessed by a licensee that will transport it to DOE, provide a description of the approved transportation package and any special handling tools necessary to remove the material from the transport package.

A. Device Containing a Sealed Source: Information must be provided for each device. Attach engineering drawings, specifications, descriptions, etc., as available. Complete Section B for the sealed source. Attach additional sheets as necessary.

Device Model Number:
Device Serial Number:
Date of manufacture or age of device (if known):
Weight of device (including any DU shielding):
Physical dimensions of device:
Device condition: Damaged: Intact: Contaminated:

B. Sealed Source: Information must be provided for each source. Attach engineering drawings, specifications, descriptions, etc., as available. Attach additional sheets as necessary.

Is this sealed source associated with the device above? ___ Yes ___ No

Sealed Source Manufacturer:
Sealed Source Model Number:
Sealed Source Serial Number:
Physical Dimensions of source/source holder:
Date of manufacture or age of source (if known):
Source condition: Leaking: Damaged: Intact:

Attach most recent leak test results (within last 6 months), if available.

The owner of the material should make the following certification (including the warning statement) in a letter.

I, the undersigned, certify the transfer of ownership to the U.S. Department of Energy (DOE) of [clearly identify material], and assert that the radioactive material has not been acquired solely to make it eligible for acceptance by the DOE.
I certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts [list applicable parts, i.e., 30, 31, 32, 33, 34, 35,

36, 39, 40, and 70] and that all information, contained herein, is true and correct to the best of my knowledge and belief.

SIGNATURE OF CERTIFYING OFFICER DATE
NAME TYPED/PRINTED TITLE

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat.749 makes it a criminal offense to make a willfully false statement or representation to any Department or Agency of the United States as to any matter within its jurisdiction.

COMMONWEALTH INSPECTION MANUAL

MANUAL CHAPTER _1330

RESPONSE TO TRANSPORTATION ACCIDENTS
INVOLVING RADIOACTIVE MATERIALS

1330-01 PURPOSE

This Chapter serves as a means of documenting the Commonwealth's policy concerning the Department's response to transportation accidents involving radioactive materials. In addition, it provides supplemental information and instruction regarding the carrying out of that policy.

1330-02 OBJECTIVES

The Commonwealth's policy pertains only to radioactive materials in transit. It does not deal with packaged materials that have not yet been delivered to a carrier nor to packaged materials that have already been delivered to the receiver.

1330-03 DEFINITIONS

BRP – PA Department of Environmental Protection Bureau of Radiation Protection
Department – PA Department of Environmental Protection (DEP)
PEMA – Pennsylvania Emergency Management Agency
PSP – Pennsylvania State Police

1330-04 RESPONSIBILITIES AND AUTHORITIES

04.01 The Department of Transportation and the Commonwealth. Under 49 CFR of the Transportation Regulations, Sections 171.15 and 171.16, reporting of accidents to USDOT and USDOT's response is limited to, "fire, breakage, spillage or suspected radioactive contamination." While reporting accidents involving the above to USDOT is required by the carrier, responding to the scene by USDOT is rarely done.

Police departments usually are the first to respond to transportation accidents and know by the shipping papers and/or the vehicle placarding that radioactive material is involved. If fire is involved, the police will notify fire departments. The Commonwealth will then be notified in accordance with the Pennsylvania Emergency Incident Reporting System. Commonwealth representatives in almost all cases respond; in most cases the consignor of the shipment also responds. The Commonwealth is responsible for assuring control of the accident scene to protect the health and safety of the public.

04.02 Role of the Department. Because carriers are exempt from DEP radiological health regulations in most cases, there is no obligation for the DEP regional offices to respond and assist in the aspects of radioactive materials control following transportation accidents that occur in transit, except as provided below. However, if it is known that an accident may be a serious health hazard to members of the general

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Deleted: Transportation accidents for which the Department of Transportation (DOT) and states have responsibility are those that take place after delivery of radioactive materials to a carrier for transport and before delivery of radioactive materials to a consignee, that is, if the accident occurs in transit. This is spelled out in the Memorandum of Understanding (MOU) between DOT and the Nuclear Regulatory Commission (NRC) dated June 8, 1979.¶
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public, it is expected that the Department will respond and work with local representatives of other government agencies, the consignee and consignor.

1330-05 GENERAL REQUIREMENTS

05-01 Emergency Preparedness Procedures The Department's emergency preparedness procedures shall include special instructions for transportation accidents involving radioactive material shipments.

1330-06 SPECIAL INSTRUCTIONS

In any accident or incident occurring in connection with the transportation of radioactive material in which a report is required to be sent to the National Response Center by DOT regulations in 49 CFR 171.15, the Department's radiation safety assessment actions will consist of the following.

- Call PEMA to report or update the incident log for transportation accidents involving radioactive materials as soon as practicable to ensure that the appropriate state agencies have been informed of the incident and it's status.
- Offer BRP technical assistance in the form of information, advice, and evaluations to the appropriate State agencies.
- Assure awareness of the incident by other affected agencies such as DOE, including any agencies specifically designated by the Federal Emergency Management Agency.
- Maintain awareness of the situation until normal conditions are restored at the scene of the accident.
- Provide information on packaging characteristics in response to any query regarding NRC approved packages.
- Respond to requests for information on BRP activities in connection with the event. Requests for specific information on an accident normally will be referred to the appropriate State agency, or to the DOE if the situation relates to DOE activities.
- If the shipper is a BRP licensee, ensure that the shipper provides complete and accurate information concerning the radioactive material and details of the shipment to emergency response personnel.
- Any BRP personnel at the scene of a transportation accident will notify the on-scene coordinator of his or her presence and make clear that, unless BRP assistance is requested by the on-scene coordinator, BRP activities will be primarily limited to information collection.
- Provide recommendations to emergency response personnel on radiological issues if BRP assistance should be requested by the on-scene coordinator or if a need is recognized by BRP personnel.

The policy here set forth relates solely to radiological concerns. Responding to any attempt to steal or sabotage a shipment of nuclear material is a responsibility of the Federal Bureau of Investigation (FBI) as delineated in the NRC/FBI Memorandum of Understanding dated April 27, 1979, and published December 20, 1979, at 44 FR 75535.

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a. . Call the PEMA to respond to transportation accidents involving radioactive materials as soon as practicable.¶
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b. . Offer BRP technical assistance in the form of information, advice, and evaluations to the local responders at the time the initial notification is made to the PEMA.¶
¶
c. . Assure awareness of the incident by Department of Energy (DOE) and other affected agencies specifically designated by Department of Homeland Security (DHS).¶
¶
d. . Maintain awareness of the situation until normal conditions are restored at the scene of the accident.¶
¶
e. . Provide information on packaging characteristics in response to any query regarding NRC-approved packages.¶
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f. . Respond to requests for information on activities in connection with the event. Request for specific information on an accident normally ... [1]

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The Commonwealth will:

a. Call the PEMA to respond to transportation accidents involving *radioactive materials as soon as practicable.*

b. Offer BRP technical assistance in the form of information, advice, and evaluations to the local responders at the time the initial notification is made to the PEMA.

c. Assure awareness of the incident by Department of Energy (DOE) and other affected agencies specifically designated by Department of Homeland Security (DHS).

d. Maintain awareness of the situation until normal conditions are restored at the scene of the accident.

e. Provide information on packaging characteristics in response to any query regarding NRC-approved packages.

f. Respond to requests for information on activities in connection with the event. Request for specific information on an accident normally will be referred to the PEMA, or to the DOE if the situation relates to DOE activities.

g. *If the shipper is an NRC licensee, ensure that the shipper provides* complete and accurate information concerning the radioactive materials and details of the shipment to emergency response personnel.

h. In accordance with the Agreement State requirements (or should we delete this), PSP will act as the lead agency for investigating all accidents, incidents, and instances of actual or suspected leakage involving packages of radioactive materials regulated by the NRC. Any Department personnel at the scene of a transportation accident will notify the on-scene coordinator of his or her presence and make clear that, unless Department's assistance is requested by the on-scene coordinator, the Department's activities will be primarily limited to information collection.

i. Provide recommendations to emergency response personnel on radiological issues, if NRC assistance should be requested by the on-scene coordinator and/or if a need is recognized by NRC personnel.

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In accordance with established practice and procedure, the Department will conduct a special inspection of the incident when this is judged necessary in order to obtain the facts concerning (1) a possible significant violation of NRC requirements. Such a special inspection is equivalent to the word "investigation" in the DOT-NRC MOU.

GENERAL STATEMENT OF POLICY

RESPONSE TO ACCIDENTS OCCURRING DURING
TRANSPORTATION OF RADIOACTIVE MATERIAL
(Should this be included?)

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(The State government is responsible for assuming control of the accident scene to protect the health and safety of the public.)

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DECOMMISSIONING OVERSIGHT AND INSPECTION PROGRAM FOR MATERIALS LICENSEES

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2602-01 PURPOSE

To establish policies and guidance for the decommissioning oversight and inspection program for DEP licensed materials facilities and non-licensed materials facilities.[1]

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2602-02 OBJECTIVES

02.01 To provide general guidance for the coordination and regulatory oversight of DEP licensed materials facilities undergoing decommissioning.

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02.02 To provide general guidance for planning and conducting inspections of DEP licensed materials facilities undergoing decommissioning.

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02.03 To obtain information through direct observation and verification of licensee activities to determine whether the facility or site is being decommissioned safely, that radioactive material is safely stored onsite prior to removal from the site, and that decommissioning activities are in conformance with applicable regulatory requirements, licensee and non-licensee commitments, and management controls.

02.04 To ensure that the programs and techniques for license termination activities are adequate and in accordance with regulatory requirements. These programs include in part and as necessary, management and organization effectiveness; self-assessment, auditing and corrective actions; maintenance and surveillance; radiation protection; radioactivity measurements; and effluent controls.

02.05 To identify declining trends in licensee performance and perform inspections to verify that the licensee has resolved the issue(s) before performance declines below an acceptable level.

02.06 To provide for effective allocation of resources for the inspection of DEP licensed materials facilities undergoing decommissioning

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To meet these objectives, and assist individuals involved in decommissioning nuclear facilities, DEP staff utilizes NUREG-1757, Consolidated NMSS Decommissioning Guidance, Volumes 1-3, which summarize the regulations, policies, and procedures that NRC staff use during the decommissioning of NRC licensed fuel cycle and materials facilities. This manual chapter summarizes the basic framework for the inspection of these decommissioning facilities, while NUREG-1757 provides the framework for the overall regulatory oversight process used to ensure an adequate and consistent decommissioning of the decommissioning facilities. Any significant deviations from this guidance shall be approved by regional management prior to performing an inspection.

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[1]Throughout this manual chapter, unless stated otherwise, any reference to a licensee or licensed facility also applies to all non-licensed (and/or formerly licensed) materials facilities at which the decommissioning is being conducted under DEP oversight.

2602-03 APPLICABILITY

This manual chapter applies to all DEP licensees under 10 CFR Parts 30, 40, and 72 undergoing decommissioning. The principal regulations and policy governing such decommissioning are: (1) General Requirements for Decommissioning Nuclear Facilities, Final Rule, 53 FR 24018, June 27, 1988, which incorporated changes into 10 CFR Sections 30.4, 30.35, 30.36, 40.4, 40.36, 40.42, 70.4, 70.25, 70.38, 72.3, 72.18, and 72.38; (2) Timeliness in Decommissioning of Materials Facilities, Final Rule, 59 FR 36026, July 15, 1994, which incorporated changes into 10 CFR Sections 30.4, 30.36, 40.4, 40.42, 70.4, 70.38, 72.3, and 72.54; and (3) License Termination Rule, Final Rule, 62 FR 39058, July 21, 1997, which incorporated the final rule on "Radiological Criteria for License Termination" as Subpart E to 10 CFR Part 20. Various guidance documents are referenced in this inspection program and should be utilized by DEP inspection staff for applicability to each site undergoing decommissioning.

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2602-04 DEFINITIONS

04.01 ALARA. Acronym for "as low as is reasonably achievable," which means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, consistent with the purpose for which the licensed activity is undertaken, and taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to the benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest (see 10 CFR 20.1003).

04.02 Complex Materials Site. A site or facility where the complexity of the decommissioning will require more than minimal technical and administrative support from BRP headquarters. It is expected that these sites will take more than a year to complete the decommissioning process. Examples of complex materials sites include: sites with ground water contamination; sites containing significant soil contamination; sites in which the owners are in bankruptcy; any site where a decommissioning plan is required and sites where there is significant public and/or legislative interest.

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04.03 Confirmatory Survey. A survey conducted by DEP or its contractor, to verify the results of the licensee's final status survey. Typically, confirmatory surveys consist of measurements at a small percentage of the locations previously surveyed by the licensee, to determine whether the licensee's results are valid and reproducible.

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04.04 Decommissioning. The process of removing a facility or site safely from service and reducing residual radioactivity to a level that permits (1) the release of the property for unrestricted use or (2) release of the property under restricted conditions. For licensed facilities or sites, decommissioning includes termination of the license or amending the license to remove the facility or site as a location of use from the license. For non-licensed sites, decommissioning includes documenting in correspondence to the site owner that the facility or site is released for unrestricted use.

04.045 Decommissioning Plan (DP). A detailed description of the activities that the licensee intends to use to assess the radiological status of its facility, to remove radioactivity attributable to licensed operations at its facility to levels that permit release of the site in accordance with DEP's regulations and termination of the license, and to demonstrate that the facility meets DEP's requirements for release.

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04.06 Final Status Survey (FSS). Measurements and sampling to determine the radiological conditions of a site or facility, following completion of decontamination activities (if any) and in preparation for release of the site or facility.

04.07 Master Inspection Plan. A site-specific plan of inspection activities that ensures the inspection program is properly focused and facilitates the efficient allocation of inspection resources.

04.08 Significant Decommissioning Activity. Any decommissioning activity that the DEP feels compelled to observe and evaluate to ensure the protection of workers, ensure the protection of public health and safety or the safety of the environment, ensure the secure use and management of radioactive materials, or ensure openness in the regulatory process.

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2602-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Director, Bureau of Radiation Protection. Provides overall direction for the materials decommissioning inspection program.

Deleted: Director, Office of Nuclear Materials Safety and Safeguards

05.02 Manager, Decommissioning and Surveillance Division. Coordinates, develops, and implements materials decommissioning inspection requirements and policies.

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05.03 Regional Program Manager. In concert with headquarters, directs the implementation of the inspection program for decommissioning materials facilities and sites. Ensures, within budget limitations, that the regional office staff includes adequate numbers of inspectors in various disciplines to carry out the inspection program as assigned and described in this chapter. Applies inspection resources, as necessary, to deal with issues and problems that arise at specific facilities undergoing decommissioning.

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05.04 All DEP personnel implementing the decommissioning oversight and inspection program for materials facilities undergoing decommissioning shall use the guidance identified in this manual chapter and NUREG-1757. This includes formerly licensed sites where the license was terminated, and sites involving source, special nuclear, or byproduct material subject to DEP regulation for which a license was never issued. Significant deviations from this guidance shall be employed only after review and approval by the appropriate DEP management.

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05.05 The responsibility for managing inspection activities and conducting inspections resides with the regional office in which the decommissioning facility or site is located. Regional management is responsible for developing the inspection program for each decommissioning facility or site under it's jurisdiction. The Central Office Decommissioning and Surveillance Division will provide overall program direction to the regional offices for decommissioning facilities and oversight of the regions to ensure that decommissioning activities are being conducted in a consistent and adequate manner.

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2602-06 DECOMMISSIONING PROGRAM OVERSIGHT

06.01 Timing of Decommissioning. NRC regulations incorporated by reference from 10 CFR 30.36(d), 40.42(d), and 70.38(d) describe the conditions under which a licensed facility would be required to commence decommissioning operations. Collectively, these are known as the Timeliness Rule. In short, any separate building or area that has not been used for two years must be promptly remediated if the remediation activities are allowed by the existing license. If the remediation activities are not currently allowed under an existing license, the licensee must develop a Decommissioning Plan (DP) and submit a request for

a license amendment within one year. The decommissioning process is to be completed within two years, unless an alternative schedule is approved. Section 5 of the NUREG-1757 Vol. 1 provides guidance on how to determine if decommissioning is needed and the actions necessary to achieve it.

06.02 Radiological Criteria for Decommissioning. On July 21, 1997, NRC published the final rule on "Radiological Criteria for License Termination" (the License Termination Rule) as Subpart E to 10 CFR Part 20 (62 FR 39058). The License Termination Rule (LTR) establishes criteria for license termination. The criterion for termination with unrestricted release is residual radioactivity, which is distinguishable from background, results in a total effective dose equivalent (TEDE) to an average member of a critical group that does not exceed 0.25 millisievert per year (mSv/y) (25 mrem/y). In addition, the residual radioactivity has been reduced to levels that are as low as is reasonably achievable (ALARA). For license termination with restrictions on future land use, the LTR establishes criteria of 1.0 mSv/y (100 mrem/y) or 5.0 mSv/y (500 mrem/y) under certain conditions.

06.03 Decommissioning Records Management. DEP regulations prescribe recordkeeping responsibilities for DEP licensees. During licensed operations DEP requires licensees to maintain records important to safe and effective decommissioning. For licensees who must submit a DP, these records should subsequently be used to develop the site description specific portion of the DP. Following decommissioning and before license termination, additional DEP regulations prescribe the disposition of these records, in most cases to DEP. Finally, DEP staff are responsible for maintaining decommissioning records following license termination. DEP staff should refer to Section 3 of NUREG-1757 Vol. 3 for information on recordkeeping requirements for decommissioning facilities.

06.04 Reserved

06.05 Decommissioning Groups. Activities to decommission a site depend on the type of operations conducted by the licensee and the residual radioactivity present. Generally, the staff will evaluate the decommissioning of nuclear facilities using one of seven review processes (referred to as "Groups"). Typically, Groups 1 and 2 will not require a DP and will be able to demonstrate compliance with 10 CFR Part 20.1402. Group 3 sites will require an abbreviated DP, without a site-specific dose modeling analysis. Group 4 through 7 sites are required to submit a DP with site-specific dose modeling in accordance with NRC regulations incorporated by reference 10 CFR 30.36(g)(1), 40.42(g)(1), or 70.38(g)(1). Although it is anticipated that most licensees will fall under the decommissioning types as outlined, it should be expected that the actions may not always be appropriate for each licensee. The intent is to present the generally appropriate actions to be taken by DEP staff, recognizing that the unique nature of some facilities may require site- specific modifications to the procedures. The staff shall ensure that any departure from these established procedures is reviewed and approved by DEP management and documented in writing prior to their implementation. NUREG 1757 Vol. 1, Sections 7 through 14, contain guidance for the determination of the appropriate decommissioning review process and the actions and oversight required by group.

06.06 Decommissioning Plans. The objective of the DP is to describe the activities and procedures that a licensee intends to undertake to remove residual radioactive material attributable to licensed activities at the facility to levels that meet DEP criteria in sufficient detail to allow DEP staff to determine whether decontamination of the facility can be accomplished safely. To the extent that licensed material is mingled with elevated (i.e., above background levels) naturally occurring radioactive material (NORM) the elevated NORM is also remediated in decommissioning. NRC regulations, 10 CFR Parts 30, 40 and 70, incorporated by reference require that certain information be provided by licensees in the DP. NUREG 1757 Vol. 1, Sections 16 through 18 provide a description of the contents of specific DP modules, as well as evaluation and acceptance criteria for use in

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Deleted: The National Environmental Policy Act of 1969. The National Environmental Policy Act (NEPA) of 1969 requires Federal Agencies, as part of their decision-making process, to consider the environmental impacts of actions under their jurisdiction. Both the Council on Environmental Quality (CEQ) and NRC have promulgated regulations to implement NEPA requirements. The CEQ regulations are contained in 40 CFR Parts 1500 to 1508, and NRC requirements are provided in 10 CFR Part 51. The NEPA review (also referred to as the environmental review) process for decommissioning is initiated by a licensee's request for a license amendment to decommission. NRC staff should refer to Section 15.7 of NUREG-1757 Vol. 1 and NUREG-1748, Environmental Review Guidance for Licensing Actions Associated with NMSS Programs, for information on the appropriate procedures to follow to comply with NEPA.

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reviewing DPs and other information submitted by licensees to demonstrate that the facility is suitable for release in accordance with DEP requirements.

a. Site Characterization. DEP requirements for decommissioning under 10 CFR 30.36(f)(4), 40.42(f)(4), and 70.38(f)(4), incorporated by reference require that proposed DPs include "...a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan." Licensees can develop this information using institutional knowledge about radioactive material use at their facility, by performing a site characterization survey, or by a combination of these methods. Some licensees may require heightened attention by DEP staff during characterization planning. For these licensees it may be appropriate for DEP staff to meet with the licensee prior to, or during, site characterization. DEP staff should refer to NUREG-1757 Vol. 2 for additional discussion of site characterization.

b. Financial Assurance for Decommissioning. NRC regulations at 10 CFR 30.35, 40.36, and 70.25, incorporated by reference specify the requirements for certain licensees to provide financial assurance for decommissioning. The requirement to provide financial assurance is based on the authorized possession limits specified in the DEP license. In general, above a threshold quantity of radioactive material, the licensee must provide increasing amounts of financial assurance as its authorized possession limit increases. Financial assurance may be provided in certain proscribed amounts where the authorized possession limit falls within specified bounds. DEP staff should refer to Section 4 of NUREG-1757 Vol. 3 for additional discussion of financial assurance.

c. Final Status Survey Plans. Licensees wishing to terminate their licenses must demonstrate to DEP that residual radioactive material at their facility attributable to past licensed operations does not exceed DEP criteria for release of the facility. NRC regulations at 10 CFR 30.36(f)(4), 40.42(f)(4), and 70.38(f)(4), incorporated by reference require that all DPs contain a description of the planned final radiation survey to demonstrate that the facility meets DEP's criteria for release and termination of the license. In addition, NRC regulations at 10 CFR 30.36(l), 40.42(l), and 70.38(l), incorporated by reference describe the information that must be submitted to DEP to support a demonstration that a licensed facility is suitable for release from regulatory control.

d. License Termination. The final action required by the licensee after it has completed remediation and adequately demonstrated that the facility is suitable for release in accordance with DEP's requirements is the submission of DEP Form 2900-PM-RP0314. If the licensee has satisfied all of the conditions for remediating its site, DEP staff terminates the license for the site. For sites with non-radiological contamination, DEP should inform other State programs that may have jurisdiction over any hazardous chemical contamination and the U.S. Environmental Protection Agency about the intent to terminate the license. In addition, the termination is intended as final agency action and should include appropriate language in the termination letter to reflect this intent.

e. Restricted Use and Alternate Criteria. DEP staff will review the information supplied by the licensee to determine if the description of the activities undertaken by the licensee is adequate to allow the staff to conclude that the licensee has complied with the applicable requirements of 25 Pa. Code 219.7 for those licensees who intend to request termination of their radioactive materials licenses using either the restricted use or alternate criteria provisions of 10 CFR Part 20 Subpart E incorporated by reference. The basic requirement for license termination under restricted conditions is that the licensee provide institutional controls that limit the

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calculated dose to 0.25 mSv/y (25 mrem/y). Further, the licensee must reduce residual radioactivity so that if these controls fail, the calculated dose would not exceed 1 mSv/y (100 mrem/y). In rare instances, the calculated dose may exceed 1 mSv/y (100 mrem/y), but it may not exceed 5 mSv/y (500 mrem/y). Additional institutional controls would be established to meet regulatory requirements. In the unlikely event that a licensee is not able to reduce residual radioactivity to a level that limits the calculated dose such that it is not in excess of 0.25 mSv/y (25 mrem/y) with restrictions in place, the licensee may request permission from the Commission to use alternate criteria. DEP staff should refer to NUREG-1757 Section 17.7 for guidance on restricted use and alternate criteria.

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f. Partial Site Decommissioning. A licensee who has submitted a DP that has not yet been approved or a licensee who has an approved DP may opt to release a portion of its site early. For the case of partial site release, the licensee must submit a request for a license amendment to the extent that the actions are not described in the DP. A site enters into partial site decommissioning in one of two ways: the licensee requests a portion of its facility be removed from the license, or; a licensed facility is required per 10 CFR 30.36(d)(1-4), 40.42(d)(1-4), and 70.38(d)(1-4), to begin decommissioning at a portion of its facility.

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2602-07 DECOMMISSIONING INSPECTION PROGRAM

07.01 Program Discussion. The decommissioning fuel cycle and material inspection program covers a diverse range of decommissioning activities. The level of complexity varies from complex sites requiring remediation of ground water contamination to the less complex sites only requiring verification a radiological laboratory meets the unrestricted release criteria prior to license termination. It is anticipated that fuel cycle facilities will require a defined, substantial decommissioning effort, requiring the submittal of a decommissioning plan. In contrast, most of the non-fuel cycle materials licensees have facilities which, for the most part, will not require submittal of a formal decommissioning plan for DEP review and approval and will not be a major effort. Because of this wide range of decommissioning activities and safety considerations, this manual chapter promulgates inspection program requirements and guidance necessary to provide reasonable assurance that DEP regulatory oversight contributes to public health and safety for a broad array of decommissioning activities. This inspection program focuses on ensuring that:

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1. Licensee documents are adequately implemented, maintained, and reflect the status of decommissioning.

2. Licensee activities, organization, and controls are effective to provide reasonable assurance that decommissioning can be conducted safely and in accordance with regulatory requirements.

3. DEP staff project oversight and inspection resources are effective, consistent, and appropriately focused.

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4. Licensee radiation and radioactivity measurement programs provide accurate quantification and classification of radioactivity.

The management of decommissioning sites will be shared between the regions and the headquarters program office. Normally, headquarters will project manage the complex materials decommissioning sites, and non-complex materials decommissioning sites will be managed in the regional offices.

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07.02 Timing and Frequency of Inspections. The decommissioning inspection program is formally initiated when the licensee is required to begin decommissioning under DEP regulations. The inspection program continues until the site, including all buildings and other structures and outdoor areas, are remediated in accordance with DEP requirements and the appropriate licensing action is completed, which could be license termination or amendment, or documentation the site is being released for unrestricted use if it is a non-licensed entity.

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The frequency of inspections will vary depending on the decommissioning activities taking place. In determining the inspection frequency, the region should factor in the radiological history of the licensee, the licensee's past performance, the licensee's planned schedule of activities, the potential for the decommissioning activities to affect the health and safety of workers and the public, and the level of public interest. Inspections should be scheduled to allow the inspector to observe, at a minimum, all significant decommissioning activities. Inspection of significant activities can include activities such as: observing the removal or dismantlement of equipment that possess a high source term; conducting confirmatory measurements that coincide with the licensee's surveying activities, particularly for situations where no other reasonable opportunity will exist; verifying licensee compliance with license commitments, decommissioning plans, regulatory requirements, or procedures; following up on previously identified violations or other identified weaknesses; evaluating performance following a significant change in the licensee or contractor work force; a routine inspection prior to an upcoming public meeting or; a special inspection to address public concerns. It is expected that once a region has developed an acceptable level of confidence in a licensee's performance, the frequency of inspections would be reduced. Periodically verifying continued good performance and compliance with regulatory requirements and commitments is acceptable and expected. However, the inspector should not repeatedly review the same area when no procedural or program changes have occurred, or no performance problems have been noted.

Some sites have separate buildings and outdoor areas where licensed activities have ceased and are being decommissioned, while licensed activities continue to be conducted at other site locations. In these cases, inspections of the locations being decommissioned can be coordinated with inspections of routine operations or be performed independent of operations at the discretion of the inspection staff.

Although inspections are expected to be conducted at sites that are being actively remediated, there are times when inspections or site visits are warranted even though there is little to no site remediation taking place. For example, when a significant amount of public, State and/or Congressional interest exists, inspections and visits may be warranted to ensure that regional staff and management have first hand knowledge of the condition of a site as well as familiarization with licensee personnel. In other cases, no inspection activities may be needed. For example, a formal inspection is normally not necessary for a license termination for a medical practitioner licensed to use a sealed source, where the decommissioning effort is essentially the removal of the source from the licensee's facility. In addition, if no decommissioning activities are being conducted at the site, such as if the site owner is developing a decommissioning plan, an inspection is not warranted. The minimum inspection frequency for a site in a standby or possession-only status with no ongoing remediation activities will be determined by Central Office on a case-by-case basis and in conjunction with Regional office management prior to the Regional staff performing the inspections. For sites where major decommissioning activities are occurring such as the active remediation of structures, soils, or groundwater, inspections shall be scheduled to conform to significant decommissioning activities. Because of the nature and variance of decommissioning activities it is not efficient or effective to establish minimum inspection frequencies applicable to every situation. For major decommissioning efforts that involve large quantities of contaminated soil, groundwater contamination, onsite disposal, extensive surface contamination,

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dismantlement of major buildings and structures, or the potential for significant worker or public exposures, at least one inspection should be conducted while the site is being characterized. For such major efforts, the inspection schedule should also include an inspection during remediation of key buildings, equipment, and outdoor areas, and during and after the licensee's final survey. In general, inspections may be conducted more frequently if necessary to verify that work and public exposures are maintained ALARA.

07.03 Master Inspection Plan. At the onset of the decommissioning of a complex materials site, a Master Inspection Plan (MIP) should be developed. The purpose of the MIP is to ensure that the inspection program is properly focused and that sufficient resources are available to conduct the inspections when necessary. The MIP should be based on the expected schedule of licensee activities, and should include inspections of all significant decommissioning activities. The regional lead inspector is responsible for developing the MIP, and he or she shall obtain the agreement of the cognizant Central Office Project Manager (PM) for those complex sites being project managed by Headquarters before conducting the inspection. The inspection schedule provided in the MIP should be reviewed every 6-12 months and modified as needed to reflect changes in licensee schedules.

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The MIP should provide the inspections that are planned, the activity or program area being inspected, the procedure(s) that will be used to conduct the inspections, and the approximate time frame for when the inspection is expected to occur.

Some factors that should be considered while developing and implementing a master inspection plan include: unique or challenging decommissioning approaches and procedures or hydrological conditions (such as diversion of the radiological effluent stream, excavation of contaminated soils from below a water table, or dredging of soils from outfalls or intakes); licensee performance; staffing plans; public interest; transportation of radioactive waste; effectiveness of management oversight and contractor control; decommissioning funding, and; the timing and scheduling of significant decommissioning activities.

07.04 Periodic Management Visits to Meet with Licensee Representatives

For significant decommissioning projects, DEP headquarters and regional management should consider visiting the facility to understand the licensee's plans to decommission their facility. Licensee programs for the control and handling of radioactive materials, licensee staffing, public interest, experience and expertise, and the master inspection plan, are possible topics of discussion.

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As decommissioning progresses, additional site visits may be held periodically or prior to major changes in the status of decommissioning to gain licensee management insights and perspectives. The intent of these visits is to understand licensee plans and schedules, and the controls implemented to provide quality, cost management, and safety. Performance elements involving radiation dose, curie removal and transportation, scheduler accuracy, and nuclear and radiological safety could be discussed to ascertain the licensee's assessment of their own performance. Discussions could include the dissemination of press and public information; status of site radiological surveys, results and problems; problems associated with staffing and contractors; and, storage and transportation of radioactive material.

The DEP maintains an "open door" policy with regard to access by the public or state or local officials to the DEP staff or to publicly available electronic documentation concerning a licensee's performance. Some local officials or community groups may desire increased interaction with the DEP's staff and inspectors. The degree of interaction that is considered necessary to ensure openness in the DEP's decommissioning program is

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expected to vary widely depending on the situation at each decommissioning site. In each case where inspectors are utilized for this purpose, regional management must carefully balance the use of inspection resources to complete inspections with the need to enhance public confidence.

07.05 Extent of Licensee Decommissioning Activities. When a licensee is able to use existing approved procedures to perform decommissioning activities, the inspector should be able to perform inspections using the same routine inspection procedures that were used during operational inspections. In these cases, a closeout inspection using Inspection Procedure (IP) 83890 can be used when license termination is requested. A few facilities, however, such as manufacturers of radiochemicals and certain research and development institutions, will typically require significant decommissioning efforts by the licensees and significant inspection activities by DEP inspection staffs. For these decommissionings, activities should be inspected using IP 87104, and supplemented with other procedures as necessary. Section 07.14 lists specific existing inspection procedures applicable to decommissioning.

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07.06 Security and Control of Contaminated Material. Inspections conducted throughout decommissioning shall continue to assess licensee security and control of contaminated material. Inspections shall verify that contaminated material at licensed and unlicensed sites undergoing decommissioning is secured and controlled in accordance with 10 CFR 20.1801, and posted in accordance with 10 CFR 20.1902. Containers of contaminated materials shall be labeled in accordance with 10 CFR 20.1904 and 20.1905. Contaminated materials in buildings shall be secured and controlled by locking buildings, rooms, or areas. Contaminated materials in outside areas shall be secured and controlled by fencing or soil covers. Eight foot cyclone-type fencing is generally acceptable. Other fencing types, such as barbed wire fences, may be sufficient in low population, rural areas. Three to four foot thick soil covers over contaminated soil, slag, or tailing piles are also generally acceptable. Access to buildings, rooms, or indoor and outdoor areas having contaminated materials shall be limited only to individuals having the licensee's or responsible party's permission for access.

Normally, decommissioning activities will not involve materials subject to safeguards requirements. On decommissioning sites that do involve materials subject to safeguards requirements, safeguards inspections should be coordinated with decommissioning inspections on an as needed basis.

07.07 Inspection Coordination. Prior to performing inspections at a site undergoing decommissioning, the regional inspector should coordinate inspection activities, as appropriate, with the following personnel and organizations:

- For sites that are project managed by Headquarters, inform the cognizant Central Office Project Manager (PM) who has responsibility for the site of the inspection. Offer the PM an opportunity to accompany the inspector during inspection.

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- For sites that are project managed by the regional office, coordinate with the regional lead inspector (or PM) who has responsibility for the site. If the inspector conducting the inspection is also the lead inspector (or PM), coordinate the inspection with regional management for overall content and scheduling considerations.

- Contact the licensee and discuss inspection plans (unless the inspection is unannounced).

- For sites with an DEP-approved decommissioning plan, where the decommissioning plan identifies Federal, State and other organizations interested in or affected by site activities, contacts should be made in accordance with established procedures at each site.

- Coordinate with the U.S. Environmental Protection Agency or the appropriate State program if the decommissioning involves hazardous wastes.

- Coordinate requests for technical assistance for survey work to be performed by a DEP contractor through Central Office. It is recommended that the need for contractor support be determined early in the decommissioning process to assist in resource planning.

07.08 Scope of Inspections - General. It is recommended that all significant activities of a particular site undergoing decommissioning, including prior to, during, and after remediation, be identified and inspected. Major efforts in the inspection program should be focused on those activities where either data or experience indicate that potential problems may exist. In most cases, field sampling and independent measurements performed by inspection staff should be consistent with that performed during routine surveys associated with the use of licensed materials during operations at the site.

Inspectors should review environmental data related to airborne and liquid effluent releases and groundwater sampling for compliance with DEP standards and requirements. Airborne and liquid effluents should meet 10 CFR Part 20 requirements. Groundwater monitoring should be performed at sites with substantial volumes of contaminated soils, known groundwater impacts, or onsite disposal areas. If groundwater concentrations exceed US EPA interim maximum contamination levels for radionuclides in public drinking water systems (40 CFR Part 141), DEP hydrological staff should be consulted to evaluate the significance of the groundwater contamination and the need for further groundwater monitoring programs.

07.09 Scope of Inspections Prior to Dismantlement. During the typical decommissioning effort, there are planning and preparation activities that occur prior to dismantlement and demolition that may require inspection. Inspections may be conducted to: ensure proper implementation of DEP-approved site characterization plans; audit the Special Nuclear Material (SNM) inventory cleanout (for SNM licensees); and ensure adequate management and security controls for the duration of the decommissioning effort. In addition, the inspector should review the license for any new conditions that may have been added for decommissioning.

07.10 Scope of Inspections During Remediation and Dismantlement. The remediation of structures, soil, sediment, surface waters and groundwater, the dismantlement of buildings and other structures, and the disposal of waste constitute the majority of a typical decommissioning effort for sites with widespread contamination. Inspections shall be conducted against DEP regulations, approved decommissioning plans, and license conditions for key decommissioning activities that are important for health and safety. These activities may include: physical security; criticality safety; essential systems and services; radiation protection for workers; material control and accountability, if applicable; environmental programs related to possible offsite releases of radioactive materials; fire protection; onsite waste management prior to offsite disposition; transportation of radioactive wastes for disposal; and implementation of a licensee quality assurance program carried on throughout the decommissioning process.

07.11 Scope of Inspections After Remediation. Decommissioning activities after remediation of the site include a licensee-conducted final status survey and in some cases, a DEP confirmatory survey.

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a. Licensee Final Survey. As part of the decommissioning plan, the licensee will prepare a final survey plan. The purpose of the final survey will be to demonstrate compliance with the DEP decommissioning criteria. The final survey should include the licensed premises and offsite areas that were or may have been contaminated by the licensee's operations. Although the formal DEP review and acceptance of a licensee's final survey plan and report is performed by the DEP Project Manager (or other equivalent staff), it is recommended that inspectors have adequate familiarity with licensee documents to facilitate planning and executing inspections. As necessary to ensure confidence in the licensee's survey results, the inspection may include independent DEP analysis of the licensee's samples.

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A final survey and report may not be required if a licensee can demonstrate the absence of radioactive contamination in some other manner, such as documentation that the licensee used only sealed sources that never showed evidence of leakage.

In most cases where a licensee is only decommissioning a few rooms or laboratories, the final status survey consists of conducting 100 percent scans of the floors, walls, tabletops, and equipment, and the collection of wipe samples. Typically, a confirmatory survey is not required in these cases. However, depending on the adequacy of the surveys conducted, the quality of the final status survey report, the licensee's history of use, the isotopes used, the form of the isotopes, whether there were documented past spills, the potential for contamination in drains, or any other issue, the inspector must determine whether a DEP confirmatory inspection would be appropriate. If an inspection can be conducted during the licensee's final status survey (during which side-by-side surveys can be conducted) the need for a confirmatory inspection would in most cases be eliminated. However, many licensees have completed the final status survey prior to informing the DEP of the desire to release the areas for unrestricted use, so this is not possible.

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b. Confirmatory Surveys. The purpose of the DEP confirmatory survey is to perform an audit of the licensee's final survey results to independently confirm that the licensee's final survey report is accurate and representative of site conditions. In most cases a comprehensive confirmatory survey will be performed following the decommissioning of a complex material site. However, based on the frequency, types, and results of in-process inspections, Regional management may decide that a confirmatory inspection is not necessary. Examples where a confirmatory survey would almost always be conducted would be: (1) an in-process inspection of the licensee's final survey program identifies multiple weaknesses; (2) repetitive violations are identified during the decommissioning process; (3) significant public or Congressional interest exists; or (4) in-process inspections were not conducted.

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DEP confirmatory surveys should not be used to demonstrate, for the licensee, compliance with DEP residual contamination standards. The licensee always retains responsibility for compliance. The licensee's final survey plan and report should be adequate to demonstrate the condition of the site before any confirmatory survey is conducted by DEP or its contractor. Licensee surveys and DEP confirmatory surveys may be conducted in phases as decommissioning proceeds.

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Prior to arranging a confirmatory survey, the inspector should review the documentation of decommissioning activities and the results of the licensee's final radiological survey. Any questions or concerns that the inspector might have concerning the survey should be communicated to the licensee for substantiation or clarification. When such issues are resolved to the inspection staff's satisfaction, a written confirmatory survey plan should be prepared, and the survey conducted at the earliest possible date. Unresolved issues related to the adequacy of the licensee's final survey report should be communicated to management staff before conducting a confirmatory survey.

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Confirmatory surveys may be performed by regional staff or by technical assistance contract support. In most cases, contractor support will not be necessary. The use of a contractor may be justified if one of the following conditions exist: (1) the licensee's final survey involves unique or complex technical issues, (2) the confirmatory survey is expected to require significant resources to complete field surveys and sampling, or (3) the confirmatory survey is a very high priority that cannot be completed by DEP staff in a timely manner. In addition to the three conditions listed above, there may be other site-specific considerations that justify the use of a contractor. Contractual support should be coordinated through Central Office. Inspectors should be onsite for at least part of the confirmatory surveys performed by contractors. . Coordination with contractors should be initiated at the earliest time to develop high quality plans for the confirmatory surveys. Regional staff shall contact the HQ staff manager responsible for the contract to arrange the confirmatory survey

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c. Multi-Agency Radiation Survey and Site Investigation Manual. For most sites that are undergoing significant decommissioning activities, particularly at those sites where a decommissioning plan has been approved, the final status survey is performed using the guidance provided in NUREG-1575, (Rev 1) Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM). MARSSIM provides a standardized approach for planning, conducting, evaluating, and documenting radiological surveys to demonstrate compliance with regulatory requirements. Because MARSSIM uses a statistically derived decision making process to assess and interpret the adequacy of the survey and sample results, under certain conditions, a confirmatory survey may not be necessary. However, this increases the need for the inspector to verify the adequacy of the licensee's survey and sampling program. This is done by evaluating the licensees survey, sampling and counting procedures, as well as the adequacy of the analytical laboratory counting the samples. Inspections should also be conducted when the licensee is conducting surveys and collecting samples so that side-by-side surveys can be performed, split samples can be collected, and the licensee's survey and sampling technique's can be observed and evaluated. The goal is verify that the final status survey demonstrates compliance with the License Termination Rule.

07.12 Basic Inspection Process In addition to the information given below, additional guidance regarding the basic inspection process can be found in Inspection Manual Chapter 2800. All inspections should be conducted in a similar manner in accordance with headquarters staff instructions and regional administrative processes.

The inspection starts with the planning of inspections in the master inspection plan, as described in Section 07.03. Implementation of the MIP also includes the coordination of

site visits and inspections to promote regulatory efficiency and effectiveness and to reduce regulatory burden on the licensee. Then, inspections are conducted, inspection reports are written, license performance is assessed, feedback on the decommissioning inspection program should occur, and this process should repeat until the site is decommissioned. A basic inspection process should entail:

- Preparation for the inspection by reviewing appropriate background material (e.g., license, license file, decommissioning plan, past inspection reports, allegations, and other pertinent information).

- Preparation of an inspection plan describing the scope and major areas of emphasis that will be reviewed, evaluated, or assessed. This plan should be reviewed by a supervisor.

- Inspectors shall utilize appropriate and calibrated radiation detection instrumentation or any other equipment to verify licensee activities, if applicable for the inspection. *In-situ* measurements with licensee personnel can be beneficial in future determinations as to the scope of confirmatory surveys required for the facility.

- Inspectors shall conduct an entrance meeting with the licensee. Inspectors should discuss the inspection scope with licensee management and articulate whether open items will be reviewed. The inspector should state that the inspection may involve the observation of facility operations, interviews with staff, document reviews, and/or radiation surveys to obtain independent and confirmatory data. Any change or potential change to the onsite inspection plan should be communicated with appropriate NRC management.

  Although unique plant conditions may exist following the permanent cessation of operations, DEP inspectors should not face situations in which license conditions, regulatory requirements, or licensee commitments do not apply. In cases where unique situations or unclear configurations may be identified and considered potentially adverse to the conduct of safe decommissioning or public health and safety, the inspector(s) should discern whether the licensee is aware of the situation and taking appropriate action, if necessary, to correct and preclude recurrence. Such cases or problems involving NRC requirements and licensee commitments should be raised to the responsible DEP manager. Equally important, the inspector should determine if the situation is beyond the scope of the inspector's expertise. If it is beyond the inspector's expertise, the inspector should promptly inform his or her supervision and make recommendations, so that management can determine the urgency of the request for assistance, what type of expertise is required, and what extent of effort is required.

- An exit meeting shall be conducted with licensee management at the conclusion of the inspection. The inspection scope and applicable findings shall be presented emphasizing their impact on safety.

- Upon return to the regional office, the appropriate supervisory personnel should be briefed on the inspection findings and conclusions.

- Inspection findings, open items, follow-up items, and conclusions shall be documented. Inspections resulting from allegations will also be documented.

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Because decommissioning involves the reduction of residual radioactivity to a level that permits release of the property and license termination, inspections at decommissioning facilities should act as a historical record of the licensee's ability to effectively and accurately conduct radiological surveys and characterizations, manage occupational dose, maintain the facility licensing and design basis, and control radiological effluents. This record should help focus inspections in areas of licensee performance directly related to site release and license termination activities.

07.13 Documentation of Inspections The inspection staff shall fully document, in the form of either a written report, all visits to and inspections of each site undergoing decommissioning. Inspectors should be certain to document the results of the inspection activities related to the security and control of radioactive materials and reviews of environmental data (airborne and liquid effluent releases and groundwater sampling data).

07.14 IMCs and IPs for the Decommissioning Program The DEP Inspection Manual Chapters (IMCs) and procedures (IPs) listed below are applicable and are recommended for inspections at sites undergoing decommissioning. These documents should be used as guidelines for inspectors in determining the inspection requirements for decommissioning and radiological safety aspects of various types of licensee activities. The core decommissioning IPs are annotated with an (*). The other listed procedures are used on an "as needed" basis.

Document Number	Title
IMC 2800	"Materials Inspection Program".
IP 83822	"Radiation Protection".
IP 83890*	"Closeout Inspection and Survey".
IP 84900	"Low-Level Radioactive Waste Storage".
IP 86740	"Inspection of Transportation Activities".
IP 87103	"Inspection of Materials Licensees Involved in an Accident Incident or Bankruptcy Filing".
IP 87104*	"Decommissioning Inspection Procedure for Materials Licensees".
IP 88035*	"Radioactive Waste Management" * To be developed. Interim use of NRC Inspection Procedure.

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IP 88055 . . "Fire Protection".

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IP 93001 . . "OSHA Interface Activities".

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DEP INSPECTION MANUAL

MANUAL CHAPTER 2800

MATERIALS INSPECTION PROGRAM

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2800-01 PURPOSE

To establish the inspection program for licensees authorized to possess, use, transfer, and dispose of radioactive material associated with various types of use, i.e., industrial, academic, research and development, manufacturing, distribution, irradiators, well logging, industrial radiography, medical programs, various types of service (i.e., leak testing of sealed sources, calibration of instruments, servicing of devices, collection and repackaging of radioactive waste for final disposal), and transportation related thereto.

2800-02 OBJECTIVES

02.01 To establish the general policy for the materials inspection programs.

02.02 To describe a performance-based inspection approach and to identify specific conditions of poor performance which require the licensee to be inspected more frequently.

02.03 To place the major emphasis of the materials inspection program on timely and thorough follow-up of incidents and events.

02.04 To continue and enhance risk-informed, relative priorities for routine inspections of all licensees.

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02.05 To aid in the achievement of a consistent process of inspection for materials licensees.

2800-03 DEFINITIONS

03.01 Initial Inspection. The first inspection after a license is issued to a licensee.

03.02 Inspection. The act of assessing licensee performance to determine whether the licensee is using radioactive material safely and whether an individual or organization is in compliance with established standards, such as regulations, license conditions, and the licensee commitments submitted in support of a license (and incorporated by "tie-down" conditions). Inspections involve a visit to a licensee's facility and/or temporary jobsite by Department of Environmental Protection (DEP) inspector(s), observations of licensed activities, interaction with licensee personnel, and transmission of the inspection findings. Pre-licensing visits and telephone contacts are not considered inspections.

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03.03 Inspection Plan. An inspection plan is a written outline listing the licensee's activities and programs that will be covered during an inspection.

03.04 Inspection Priorities. An inspection priority code is assigned to a particular type of use which is authorized by a radioactive material license. The same priority code is assigned to all licenses which authorize that particular type of use. The priority code (i.e., 1, 2, 3, or 5) is the interval between routine inspections, expressed in years. Enclosure 1 lists the program codes (types of use) along with the assigned priority codes. The priority represents the relative risk of radiation hazard for the type of use. Priority Code 1 presents the greatest risk to the health and safety of workers, members of the public, and the environment. Priority Code 5 presents less potential risk to health and safety. Because a license may authorize multiple types of use, the priority codes are designated as primary and secondary codes, with the shortest routine inspection interval as the primary code.

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03.05 Reactive Inspection. A reactive inspection is a special inspection in response to an incident, allegation, or special information obtained by DEP (i.e., report of a medical event, other agency interests). Reactive inspections may focus on one or several issues, and need not examine the rest of a licensee's program. If the reactive inspection does not cover the activities normally reviewed on a routine inspection, then it does not satisfy the requirement to inspect the licensee at the routine, established interval.

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03.06 Routine Inspection. Periodic, comprehensive inspections performed at a specified interval, as defined in Enclosure 1 of this Inspection Manual Chapter (MC).

03.07 Special Inspection Activities. Those inspection activities specified in Section 2800-0 7 of this MC where special guidance is needed. Those activities cover: 1) inspections of expired licenses, terminated licenses, and licensees undergoing decommissioning; 2) inspections of significantly expanded licensee programs; 3) reciprocity inspections; 4) temporary job-site or field site inspections; 5) team inspections; 6) inspections of abandoned licenses; and 7) general licensee inspections.

03.08 Team Inspections. For the purposes of this MC only, team inspections are defined as those inspections conducted by three or more inspectors, or any materials inspection that includes an inspector from outside DEP (other than members from NRC). Often, at least one of the inspectors is included on the team because of specialty in a particular field, or at least one of the team members comes from a different region or Headquarters. Team inspections can be routine inspections of a major licensee, or reactive inspections in response to a particular incident or event. Team inspections do not include those where a supervisor or program office staff member accompanies an inspector to evaluate the inspector's performance.

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Deleted: In this context, team inspections are not meant to cover Augmented Inspection Teams (AITs) or Incident Investigation Teams(IITs), described in Management Directive 8.3, "NRC Incident Investigation Program."¶

03.09 Telephonic Contacts. These are contacts, made by telephone and documented in the docket file, to determine the status of licensees' activities, to assess compliance of priority T licensees [see Section 05.05], or to exchange information with the licensee. Examples such as reminding a licensee that its license is near expiration, calling to determine whether there are sufficient licensee operations to conduct an inspection, or calling to determine whether the licensee actively possesses licensed material are types of telephonic contacts. Telephonic contacts are not inspections.

2800-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Central Office Director, Bureau of Radiation Protection. Provides overall program direction for the DEP materials inspection program.

Deleted: Director, Office of Nuclear Materials Safety and Safeguards (NMSS)

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04.02 Regional Radiation Protection Supervisor. Oversees implementation of the materials inspection program within their respective region.

04.03 Central Office Chief, Division of Radiation Control

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a. Develops and directs the implementation of policies, programs, and procedures for inspecting applicants, licensees, and other entities subject to DEP jurisdiction.

b. Assesses the effectiveness, uniformity, and completeness of implementation of the materials inspection program.

c. Approves changes to the materials inspection program.

d. Ensures that operating plans are consistent among the Regions responsible for materials inspections.

04.04 Regional Radiation Protection Program Manager,

Deleted: Director, Regional Division of Nuclear Materials Safety (DNMS)

a. Manages the implementation of the inspection program elements performed in a Regional Office.

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b. Ensures, within budget limitations, that the Regional Office staff includes adequate numbers of inspectors to carry out the inspection program described in this chapter, including that which may be needed for reactive inspections.

c. Applies inspection resources, as necessary, to deal with significant issues and problems at specific facilities.

d. Coordinates, with Central Office, to obtain technical assistance, as necessary.

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e. Recommends changes to the materials inspection program to the Central Office Chief, Division of Radiation Control.

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Deleted: Director, IMNS

04.05 Regional Radiation Protection Supervisor(s)

Deleted: Chief(s), Regional Inspection Branch(es)

a. Proposes changes to the materials inspection program.

b. Implements the Regional materials inspection program.

c. Reviews and approves inspection schedules.

d. Ensures that Regional inspectors achieve and maintain qualifications.

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e. Appraises the performance of each inspector during actual inspections at least once during each fiscal year.

2800-05 BASIC REQUIREMENTS

The Materials Inspection Program designates reactive inspections [see Section 05.02] as the highest priority, followed by initial inspections [see Section 05.03] and routine inspections [see Section 05.04] for the Priority Codes (in ascending numeric order) listed in Enclosure 1. Telephonic contacts [see Section 05.05] are not inspections and are performed as resources permit.

All routine materials inspections should be performed on an unannounced basis, with the following exceptions.

Since considerable travel is required, inspectors may telephone licensees located in remote locations to verify that a routine inspection can be performed before undertaking such travel.

The license reviewer shall assign a primary program code which sets the inspection priority for each new license. Some licenses authorize activities that can be classified under more than one program code. If a license involves more than one type of use, each part of the program shall be inspected in accordance with its assigned priority. For example, a license for a medical institution (Program Code 02121, Priority Code 5) may be amended to authorize use of a high dose rate (HDR) remote afterloader unit (Program Code 02230, Priority Code 2). The licensee's primary program code would be Program Code 02230. The HDR-related activities would be inspected during every routine inspection while the other portions of the licensee's program would be inspected during every other routine inspection.

Inspection plans should be developed for complex, non-routine inspections. Inspection plans may also be developed for any other inspections, as decided by the region. After the inspection, the inspection plan may be discarded. It need not be filed or kept by the region.

05.01 General Inspection Process. The purpose of this MC is to describe the types of materials inspections and the general inspection program. For each inspection, the inspector should implement the process described below for pre-inspection activities, onsite inspection activities, and post-inspection activities. The IPs listed in Enclosure 4 provide more specific guidance for onsite inspection activities. Section 2800-08 provides guidance for documentation of inspection results.

a. Pre-inspection activities. The goal of inspection preparation is to ensure that the inspector is sufficiently familiar with the types of uses and the generic requirements applicable to the licensed program. The effort expended on inspection preparation should be based upon the complexity and scope of licensed activities and on the experience level of the individual inspector. The extent to which an inspector prepares for routine inspections should be based on discussions with the supervisor.

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Deleted: For inspection of Master Materials Licensees (MML), the lead region shall notify the MML of the dates of the inspection and the documentation that the MML should have available for the inspectors to review. [See IMC 2810] The lead region should also request assist inspections (i.e., accompaniment inspections and independent inspections) to be completed by the regional offices. The accompaniment inspections will be completed according to the MML's audit schedule with NRC inspectors accompanying the MML's staff during the radiation safety audits of the MML permittees. [See IP 87129] NRC inspectors will complete the independent inspections according to the request from the lead region by using the program-specific inspection procedures in Enclosure 4. The independent inspections will be unannounced just as routine inspections of other NRC licensees are unannounced. [See Section 07.08]

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Deleted: To provide a reliable, uniformly implemented budgetary basis, the inspector shall charge inspection hours in the Human Resources Management System (HRMS, formerly the Resource Information Tracking System [RITS]). For routine inspections, the inspector shall designate the hours for the license docket number only to the program-specific inspection procedure (i.e., Inspection Procedures 87121, 87122, 87123, 87124, 87125, 87126, 87127, 87129, 87130, 87131, 87132, 87133, and 87134 [See paragraph 10.01.c.3 for OSHA Interface activities]) within the Task Codes for preparation and documentation, direct inspection onsite activities, enforcement activities, and time spent in travel status. There are separate Task Codes for reactive inspections, routine inspections, allegation follow up. Telephonic contacts are not inspections. As such the inspector shall charge time for activities described in Enclosures 2, 3, 4, and 5 to HRMS as direct inspection effort under Program Code PA No. 203232E, (generic TAC No. A10159).

To adequately prepare, an inspector shall review:

1. the license to determine if it has any unusual license conditions that would affect the approach to the inspection, i.e., authorization for an incinerator, authorization for use of material at temporary job sites,

2. the licensee's recent inspection and enforcement history, i.e., results of the last inspection and any outstanding open items and determining whether any events have been reported by the licensee during the current inspection cycle,

3. any commitments made by the licensee or restrictions imposed by DEP as a result of a Confirmatory Action Letter or an Order issued since the last inspection,

4. any notes in the file regarding special inspection emphasis, i.e., license reviewer's note to request a near term inspection regarding a significant licensing action. For example, an amendment for a new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of the amendment [see Section 07.02.b].

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It is not necessary for the inspector to review all the current licensing documents and procedures on file. For problems identified during the course of the routine inspection, the inspector should ask the licensee for pertinent procedures and backup licensing documents maintained onsite by the licensee. If the documents are not available from the licensee, the inspector should contact the region for assistance. This practice would apply to routine inspections only.

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To prepare for a reactive inspection, the inspector will review specific information for reactive inspections as determined by the inspector and his or her supervisor on a case-by-case basis [see Section 05.02].

While reviewing the license, the inspector should determine if the licensee is authorized to possess sufficient quantities of source or special nuclear material to be required to report the possession of these materials to the NRC Nuclear Materials Management and Safeguards System (NMMSS). If the licensee is authorized to possess reportable quantities of NMMSS materials, the inspector will contact the NMMSS contractor via telephone at (678) 328-1116 and request a "Task 8 Inspection Package." A minimum of seven calendar days should be allowed prior to the start of the inspection trip to allow sufficient time for the package to be mailed to the inspector. The inspector should contact the NMMSS Project Manager, Division of Nuclear Security, Office of Nuclear Security and Incident Response if unable to contact the NMMSS contractor.

Additional information regarding inspection of licensees holding NMMSS accounts including a complete description of the Task 8 Inspection package can be found in Enclosure 6.

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Inspectors should anticipate whether or not they will encounter protected information during inspection of a licensee. Inspectors should be aware of minimum handling requirements for sensitive–unclassified information, i.e., Safeguards Information, Official Use Only, and Proprietary Information. For current instructions, contact the Central Office for direction.

The inspector should identify the location of the licensee, make travel arrangements, discuss special aspects of the inspection with his or her supervisor (i.e., inspection of temporary job sites), and obtain the supervisor's approval for the travel itinerary.

Finally, the inspector selects appropriate and calibrated radiation detection instrumentation for the inspection and obtains the necessary inspection forms.

b. Onsite Inspection Activities. Based on the pre-inspection activities, the inspector should be prepared to evaluate a licensee's performance of the licensee's radiation safety program. Inspection activities described below include: focus areas, performance-based approach, necessary review and retention of copies of a licensee's records, communication of findings during an inspection, awareness of a licensee's safety culture, and common elements to every inspection.

1. The inspector should conduct the inspection in a manner that will develop conclusions about licensee performance relative to the following focus areas:
   (a) security and control of licensed material;
   (b) shielding of licensed material;
   (c) comprehensive safety measures;
   (d) radiation dosimetry program;
   (e) radiation instrumentation and surveys;
   (f) radiation safety training and practices; and
   (g) management oversight.

   These focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss, or unauthorized use of radioactive material. The focus areas are described in Section 3 of each program-specific IP.

   If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a focus area, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are appropriate, and a review of selected records maintained by the licensee documenting activities and outcomes.

2. The inspector should use a performance-based approach to evaluate the focus areas. A determination regarding safety and compliance with DEP

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requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by DEP, independent measurements of radiological conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should provide an inspector with reasonable assurance of a licensee's ability to safely use byproduct material and is preferable to a review of selected records alone.

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In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments). Observations of licensee operations, interviews with staff, review of licensee documents to complement and support inspector observations, and radiation surveys to obtain independent and confirmatory measurements should then be conducted. Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program, and integration of safety.

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The inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to occur or continue in his or her presence in order to provide a basis for enforcement action.

Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with licensed activities. For example, an inspector should not insist on interviews when:

(a) a worker is delayed in performing scheduled work activities (i.e., delayed departure to a temporary job site)
(b) a worker is preparing or administering dosages or doses,
(c) a worker is providing patient care, or
(d) a licensee is dealing with customers or members of the public.

3. Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of "historical" records should only occur if the current records are out of compliance and the inspector believes it necessary to determine the presence of a prevalent or persistent problem. If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies, while onsite, of all records that are needed to support the apparent violation. The inspector should be aware whether or not the

information reviewed or gathered has been declared as proprietary information by the licensee.

In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete.

Inspectors shall ensure that the licensee understands that the retained record will become publicly available, and shall give the licensee the opportunity to provide redacted copies or to request withholding the information pursuant

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4. The inspector should advise the licensee of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management. The inspector should allow ample time during the inspection for a licensee to correlate information about root cause, consequence, and corrective action for an apparent violation. The inspector shall clearly present apparent violations and confirm the licensees understanding and agreement that a violation occurred, preferably before leaving the site.

Whenever possible the inspector should keep DEP regional management informed of significant findings (i.e., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate DEP guidance under such circumstances.

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5. To have a positive impact on maintaining safety and effectiveness, the inspector should develop a general sense of the licensee's safety culture for licensed activities (i.e. , workers have a "questioning attitude" and generally adhere to procedures, workers are duly cautious when engaged in licensed activities, worker relationships with supervisors are conducive to raising safety concerns). The inspector's conclusions about safety culture may only be useful when violations are identified and linked to significant risk (i.e. , there are an unacceptable number of occurrences with unacceptable health and safety consequences).

6. Common elements to every inspection are discussed below.

   (a) Entrance Meeting. After arriving on site, the inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This notification should be made as soon as practical after arriving on site. However, in certain instances, the inspector may choose to inform the licensee of his or her presence on site after initial observations of licensed activities currently in progress.

   The purpose of the entrance briefing is to inform licensee management

that an inspection is being conducted and to indicate the tentative schedule for discussing or reviewing selected inspection items with various licensee staff personnel. However, in some instances, the inspector may only need to inform management of DEP's presence on site, and apprize management that an exit meeting will be conducted at the end of the inspection to detail the inspection findings.

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This is often an opportune time for the inspector to identify personnel to be interviewed. Scheduling interviews will enhance inspector efficiency and give the licensee the opportunity to have the most knowledgeable individuals present to respond in the areas being inspected.

The licensee representative should be asked to identify any recent problems related to the licensed program, such as equipment failures and unusual radiological problems (i.e., excessive personnel exposures, unexpected releases to the environment, QA problems, etc.). The representative's responses may help the inspector assess licensee management's awareness of the radiation protection program.

When an inspection is likely to involve proprietary information, given the technical area or other considerations of inspection scope, the inspector should discuss with licensee management during the entrance meeting how the information will be handled during the inspection.

(b) Follow up on Previous Items. Determine whether the licensee followed up on cited violations identified during the previous inspection. Determine whether the licensee took the corrective actions as described in its response to the NOV and followed-up on safety concerns and unresolved issues identified during the previous inspection.

(c) General Overview. The inspector should understand the current organization for radiation safety at the facility and the size of the current and anticipated radiation use program.

(1) Organization. Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management, the Radiation Safety Officer (RSO), and, if applicable, the Chairperson and other members of the Radiation Safety Committee (RSC).

(2) Scope of Program. Interview cognizant personnel to determine the types, quantities, and use of byproduct

material, frequency of use, staff size, etc., and anticipated changes in the range of the radiation use program. Determine if the licensee possesses material in accordance with a general license.

(d) *Observation of Actual Facilities and Licensed Activities.* Ideally, the inspector should observe work in progress that involves NRC-regulated activities. If there is no opportunity, then the inspector should ask the workers to demonstrate and explain selected licensed activities. It is of utmost importance to inspect licensed activities at temporary job sites [see Section 07.04].

(1) Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed.

(2) Conduct inspections of licensed operations that are a potentially significant contributor to dose, regardless of shift.

(3) Perform routine inspections, when applicable, during first run operations.

(4) Make direct observations of radiation safety systems and practices in use.

(5) The walk-through may be performed at any time during the inspection. The inspector may need to return to some portions of the facility at a later time to observe specific activities.

(e) Independent and Confirmatory Measurements. Independent measurements are those performed by the inspector without comparison to the licensee's measurements. Confirmatory measurements are those whereby the inspector compares his or her measurements with those of the licensee's.

(1) The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility. Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (i.e. , inspector's detection equipment malfunctions during an inspection trip). Measurements of dose rates at the boundaries of restricted areas should be performed at the surfaces of the most accessible planes.

(2) Examples of measurements that may be performed include

area radiation surveys, wipe samples, soil samples, leak tests, air flow measurements, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, etc.

(3) The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation, if the licensee possesses survey instrumentation. However, the inspector must use DEP's instruments for independent verification of the licensee's measurements. The inspector's instruments must be in current calibration and source checked before they leave the office.

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(f) *Special License Conditions.* If applicable, verify the licensee's compliance with any special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions.

(g) Exit Meeting. At the conclusion of the inspection the inspector should conduct an exit meeting with the most senior licensee representative present at the facility.

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Deleted: As appropriate, the inspector should prepare NRC Form 591M before the exit meeting so that the form can be properly executed during the exit meeting. [See Section 08.04]

If a senior management representative is unavailable for the exit meeting, the inspector should hold a preliminary exit meeting with appropriate staff onsite. As soon as practical after the inspection, the inspector shall hold an exit meeting directly with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting). This meeting involving the licensee's management and RSO will usually be held by telephone conference call.

(1) For initial and routine inspections, the inspector should request the meeting and control the meeting for purposes of the inspection. During the meeting, the inspector shall explain any cited violation of DEP requirements and the inspector's understanding of the licensee's corrective action plan for each violation [See Section 05.01.b.4 about keeping the licensee informed of apparent violations during the inspection].

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To avoid the formal disputed violation process [See DEP Enforcement Manual], the inspector should confirm the licensee's agreement and mutual understanding of cited violations and associated corrective action plans. If the licensee disagrees with a violation, the inspector should contact his or her supervisor before leaving the site to obtain further instructions. It may be necessary to continue the inspection or modify the cited violation.

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Together, the inspector and supervisor should make decisions about the enforcement strategy. Before leaving the site, the inspector should inform the licensee about the next steps in the enforcement process.

The inspector should explain safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations.

Prompt corrective action must be initiated by the licensee for safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated. If the inspector and the licensee disagree on the magnitude of the concern regarding safe operation of the facility, regional management should be notified immediately.

Although deficiencies identified in some areas (i.e., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report or Notice of Violation (NOV).

At the exit meeting, the inspector should verify whether the licensee considers any materials provided to or reviewed by the inspector to be proprietary in nature. If so, the inspector should assure proper handling of the information.

(2) For a reactive inspection, the inspector should refer to IP 87103 for specific instructions about the exit meeting. It is particularly important that the inspector keep regional management informed of the inspection details and explain the exit meeting strategy with his or her supervisor before beginning the meeting. During the exit meeting, the inspector should explain the preliminary inspection findings including any apparent violations of regulatory requirements. The inspector should ask the licensee to confirm the licensee's understanding of the findings. If the licensee does not provide additional information and disagrees with the preliminary findings and apparent violation(s), the inspector should assure the licensee that the inspector will convey the licensee's disagreement to regional management. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to regional management. The licensee's next opportunity to discuss the findings will be after the regional management has reviewed these matters.

c. Post-inspection activities. After returning from an inspection trip, the inspector shall discuss the results of the inspection trip with his or her supervisor. This discussion should be sufficient to alert management to significant enforcement, safety, or regulatory issues. This meeting need not be documented, but it should be held in all cases. To complete the inspection, the inspector documents the inspection results.

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05.02 Reactive Inspections. Inspections performed to follow up on incidents (i.e., medical event, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. Regional management shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary. Regional management, in consultation with Central Office, shall also determine if the event warrants the recommendation for an AIT or IIT, rather than a reactive inspection. The emphasis during the reactive inspection will be on the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes, and to the formulation of corrective actions to prevent recurrence. Generally, issues of compliance will be addressed after all safety issues and program weaknesses are identified and clearly understood.

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Reactive inspections will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy."

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A narrative inspection report will be written for all reactive inspections. The narrative report will include a discussion of the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident. The inspector shall annotate inspection reports with the NMED Event No. if the reactive inspection was initiated by an NMED reportable event. Enclosure 3 provides instructions to properly "complete" the record for NMED. Enclosure 5 may be completed to document inspection findings that were unrelated to the event [see Section 08.03.b].

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Reactive inspections involving a medical event will be performed using the guidance in Management Directive 8.10, "NRC Medical Event Assessment Program." All other r

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05.03 Initial Inspections: Initial inspections of a new licensee or an existing licensee which obtained an amendment for Program Code 02240 (Medical Therapy–Other Emerging Technology) shall be announced and completed within 12 months of the date the new license or amendment was issued.

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Deleted: To schedule the initial inspection, the date in the "next inspection date" data element in the Licensing Tracking System (LTS) shall be 12 months from the date the new license or amendment was issued. The "last inspection date" data element in the LTS shall be 0 (zero) or blank.

a. Initial inspections of all licensees. Once onsite, the inspector should interview licensee staff (management and technical) to determine if licensed material has been possessed or licensed operations have been performed. Methods for determining if licensed activities have been performed include, but are not limited to the following: performing a site tour, performing confirmatory measurements, and/or contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee. If the licensee has possessed licensed materials or performed licensed operations, then the inspector should conduct an inspection in accordance with Section 05.01 and other applicable guidance.

If it is determined that the licensee has not possessed licensed material or performed licensed operations, the inspector should:

1. Determine the licensee's plans for future possession of licensed material or plans to perform licensed operations. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.

2. Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions.

3. Request that the licensee notify the DEP before receipt of licensed material or initiation of licensed operations.

4. Document the onsite inspection. The "program scope" description should include the licensee's plans for future possession of material or plans to perform licensed operations.

5. Ensure that the date for the "next inspection date" is 12 months from the date of the onsite visit.

b. New licenses excepted from an initial inspection. There are certain circumstances that require a new license to be issued to the licensee, but an initial inspection is not warranted.

1. New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection, if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" should remain the same as for the licensee's previous license.

2. New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:

   (a) the organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety program);

   (b) the licensee significantly increases the types, quantities, or forms of radioactive materials on the license;

   (c) the licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a diagnostic nuclear medicine license);

   (d) the licensee significantly increases the number of authorized users; or

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(e) the new license authorizes one or more new facilities.

If none of these conditions applies, then the "last Inspection date" and "next inspection date" should remain the same as for the previous license.

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3. New licenses that are issued because a licensee did not file a timely application for license renewal are not required to receive an initial inspection in accordance with this section, unless more than 6 months have elapsed between the date the initial license expired and the date the renewal application was submitted. The "last inspection date" and "next inspection date" should remain the same as for the licensee's initial license.

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05.04 Routine Inspections. Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority listed in Enclosure 1. If the licensee has possessed material or performed licensed operations since the last inspection, the inspector should perform a routine inspection of the facility as defined in the program-specific inspection procedure. If the licensee has not possessed material or performed licensed operations since the last inspection, the inspector should follow the instructions in Section 05.03(a)(1) through (4).

05.05 Telephonic Contacts (Priority T). For certain licensees, the regions shall use telephone contacts at 5-year intervals in lieu of an onsite inspection, with the exception of initial or reactive inspections. Enclosure 1 designates these licensees as priority T. As defined in Section 2800-03, telephonic contacts are useful for staying in touch with priority T licensees. Procedures for using the telephonic contacts are included as Enclosure 2. A telephonic questionnaire is attached as Enclosure 2, Exhibit 1 and standard responses back to licensees contacted by telephone are included as Enclosures 4 and 5. This questionnaire should be completed, signed by the inspector, and placed in the file, and the "next inspection date" shall be changed to indicate the date of the next telephonic contact. The inspector shall brief the supervisor about the telephonic contact.

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2800-06 INSPECTION INTERVALS

06.01 Scheduling Inspections. To achieve the goals of cost saving and efficient use of staff time and travel, inspections (other than initial inspections) may be scheduled within a window around their inspection due date. Inspection of licensees in priorities 1, 2, and 3 may vary around their due date by ± 25 percent. Inspection of priority 5 licensees and telephonic contact of priority T licensees may vary around their due date by ± 1 year. Inspections will not be considered "overdue" until they exceed the scheduling window. Inspections may be scheduled before their window if the inspector receives information that warrants earlier inspection.

06.02 Combining Inspections. If a licensee holds several licenses with different Program Codes that are assigned different Priority Codes in Enclosure 1, a single inspection may be scheduled whenever practicable to aid in more effective use of the inspector's time spent in travel status. In the determination to combine inspections on a continuing basis, consideration should be given to not "over-inspect" a lower-priority license versus the need and desirability to inspect a licensee's total activities for a more complete assessment of its

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safety and compliance performance. The priority designations of the lower-priority licenses shall not be changed in these cases; the more frequent inspections of lower-priority licenses shall be handled only in the scheduling process.

06.03 Inspections After Escalated Enforcement. If escalated enforcement action has taken place for a particular licensee, a follow-up inspection to focus on significant violation(s) shall be scheduled and conducted within 6 months of the last inspection or sooner, in accordance with the guidance in this MC regarding reduction of inspection interval, after completion of the escalated enforcement action, to assess the licensee's follow-up actions in response to the previous violations. Regions may perform this follow-up inspection as a part of a routine inspection.

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06.04 Reduction of Inspection Interval

a. The inspection interval shall not be extended beyond that specified by the priority system indicated in Enclosure 1. The interval between inspections may be reduced (shortened) and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. The main consideration in reducing the inspection interval should be evidence of moderate to severe problems in the licensee's radiation safety program. Poor compliance history is one indicator of such problems. Lack of management involvement or control over the radiation safety program is another indicator. Specifically, licensees that meet the following conditions shall be considered for reduction in inspection interval if:

1. A significant violation results from the most recent inspection; or

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2. Issuance of an Order as a result of the most recent inspection; or

3. A "management paragraph" appears in the cover letter transmitting the notice of violation on the most recent inspection (i.e., a paragraph that requires the licensee to address adequate management control over the licensed program); or

4. An event requires a reactive inspection; or

5. Repetitive violations occur.

The above list is not exhaustive; the inspection interval can and should be reduced for any other reason deemed pertinent by regional management. An example would be an enforcement conference where the outcome did not include escalated enforcement action, but did indicate the need for the licensee to improve some aspect(s) of its compliance program.

Another example would be an industrial radiography licensee or a well logging licensee which is authorized to use byproduct material at temporary job sites and the current inspection was limited to an office inspection and no temporary job site inspection was completed during the current inspection. [See Section 07.04.] A licensee that meets the above criteria may have its inspection interval reduced

by any length. For example, a priority 5 licensee with a poor performance record could be rescheduled for its next inspection in 2 or 3 years, rather than 5 years, depending on the scope of licensed activities. Or a priority 2 licensee with a significant violation could be rescheduled for its next inspection in 1 year, although a follow up inspection to focus on the violation may have already been completed within 6 months. [See Section 06.03] The reduction shall be valid only until the next inspection, but regional management shall consider the results of the next inspection when determining whether the reduced interval should be continued, changed, or returned to normal.

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b. The designated inspection priority for these licensees should not be changed. However, the "next inspection date" should be changed to contain the reduced date for the next inspection.

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c. To document the reduction in the interval between inspections, a brief note (i.e., in the inspection records) should be written by the inspector, approved and signed by the inspector's immediate supervisor, and placed in the docket file.

06.05 Other Changes in Inspection Interval. At the discretion of regional management, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources and to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees. For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities.

2800-07 SPECIAL INSPECTION ACTIVITIES

07.01 Expired and Terminated Licenses and Decommissioning Activities. Notification that a license has expired or is being terminated requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by review of the licensee's transfer, disposal, and closeout survey data; by confirmation that an authorized recipient has received the material; and/or by performance of an inspection that may include confirmatory surveys. The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the DEP on termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received.

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If an inspection is performed, the inspector should also verify that the licensee is complying with regulations for timely decontamination and decommissioning, and meeting the required schedules for licensee action, as specified in the decommissioning timeliness rule.

Specific guidance for performing closeout inspections is outlined in IP 83890.

07.02 Significantly Expanded Programs. During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. A license reviewer may request a near-term onsite inspection for a significant licensing action that was recently completed. Both the inspectors and the reviewers should make the inspection and licensing supervisors aware of the following changes in a licensee's scope of use.

a. Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:

1. the licensee has recently increased the types, quantities, and uses of radioactive material;

2. the license authorizes a physical move of a facility or a new use at a temporary jobsite;

3. the license authorizes new (i.e., since the previous inspection) satellite facilities where materials will be used or stored;

4. the licensee has increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material; and

5. the number of authorized users has significantly increased or decreased.

If any of the above items demonstrates a possibility that the licensed activities have significantly changed, then the inspector should document the changes to the licensee's program in the inspection records and notify the inspection supervisor.

b. A license reviewer may request a special inspection, if, during the licensing review process, it is determined that the licensee's program has significantly expanded. [See the 5 points in the preceding paragraph.] In that case, the license reviewer shall ensure that the "next inspection date" is changed and shall post a notice in the file for the inspector [see NUREG-1556, Volume 20, Section 4.12 (Significant Licensing Actions that Warrant Onsite Inspection) and Appendix C (Checklist C.5)].

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For example, an amendment issued for a new medical therapy modality under 10 CFR 35.1000 (Program Code 02240) shall be inspected within 12 months of the date of the amendment. The reviewer shall ensure that the next inspection date was appropriately changed, the file was posted with a paper copy of the memo in Appendix C of the NUREG-1556 (Volume 20), and the inspection and licensing supervisors were notified accordingly.

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07.03 Reciprocity Inspections. 25 Pa. Code 217.203 grants a general license to any person, with a specific license from an Agreement State, Non-Agreement State or NRC authorizing use at temporary job sites, to conduct the same activity in areas under Department jurisdiction. The licensee must submit a DEP Form 241, "Reciprocity - Report of Proposed Activities in Pennsylvania in Areas of Exclusive Department Jurisdiction" 3 days before engaging in the licensed activity.

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a. The recipient of the DEP Form 241 is the Central Office Radioactive Materials Licensing Section.

b. MC 1220 details the process for scheduling the inspection of the licensee operating under reciprocity. The licensing section shall take immediate action to enter information from the form into the Reciprocity Tracking System. Before reciprocity work begins, the licensing section shall forward the form to the DEP regional office(s) having jurisdiction in the area of the licensee's proposed activities (inspecting regions).

c. The inspecting region(s) shall follow the policy and guidelines found in MC 1220, Appendix III, for performing inspections of reciprocity licensees. MC 1220 details the percentage of reciprocity licensees to be inspected each year. The inspectors shall use the program-specific procedures which are used for equivalent DEP - licensed activities.

d. The inspecting region is responsible for initiating enforcement action and taking other follow-up actions, as appropriate for the inspection. In addition, the inspecting region shall send copies of inspection and enforcement documentation to the licensing section and to the radiation control agency which issued the license that is the basis for the general license under 25 Pa. Code 217.203.

07.04 Temporary Job Site or Field Office Inspections

a. Temporary Job Sites. For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).

1. During the inspection of a licensee's principal place of business, the inspector should, through discussions with the licensee and review of licensed material utilization records, ascertain if the licensee is working at the temporary job site location(s).

2. The inspector may contact the licensee's customer to schedule the temporary job site inspection. The licensee's customer should be requested not to notify the licensee of the inspection.

3. If an unannounced inspection of the location(s) is not possible, then the inspector should attempt to arrange an announced inspection at the temporary job site(s).

4. If a temporary job site inspection is not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the "next inspection date" may indicate a reduced inspection interval. [See Section 06.04]

b. Permanent Field Offices. Each region is responsible for requesting an assist inspection (i.e., an inspection conducted by one region at the request of another

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region) at each permanent field office to be inspected, if these locations are outside the geographical area of the region. The inspecting region should provide complete documentation and recommend enforcement action to the licensing section, which will distribute the documentation, and take other follow-up actions, as appropriate to the case. [See Section 09.02]

1. If the license authorizes licensed activities to be conducted from two or three permanent facilities (main office plus one or more field offices), only one location must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected. Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.

2. *If the license does not authorize licensed activities at the main office location*, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities.

3. If an inspection identifies significant program weaknesses (i.e., significant violation(s) or multiple violations indicative of poor program management/oversight), the licensing region should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

07.05 Team Inspections. [NOTE: This section is included solely for team inspections of materials licensees. The term "team inspections" is used here only for the purposes of this MC.]

Regional offices shall conduct team inspections of major licensees within the region on an as-needed basis. The decision on whether to conduct a team inspection involving agencies outside DEP (other than NRC) shall be made by regional management, in consultation with Central Office. Examples of situations where team inspections may be appropriate are:

a. Routine inspections of major licensees (i.e., broad-scope academic, broad-scope medical licensees, and large processor/manufacturers). A team inspection should be considered when the size or complexity of operations at a broad-scope licensee goes beyond that which one or two inspectors can cover in a week. Team inspections are also appropriate when the team will include an expert in a specialty discipline other than health physics, such as a medical physicist, human factors specialist, fire protection specialist, engineer, or other specialized fields.

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Deleted: c. . Off-Shore Waters. For a licensee working in off-shore waters, the regional staff should either make travel arrangements to accompany another federal agency to the rig to complete an unannounced inspection or contact the rig operators, or appropriate licensee contact, to request the licensee to provide travel arrangements to the rig when work is in progress. Before accepting transportation or lodging from the licensee, staff should obtain approval from the individual's immediate supervisor. This approval should be documented with a brief statement in the inspection records. NRC should reimburse the provider for the cost of transportation, lodging, or other services accepted during the course of inspections.

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b. Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors). Also, reactive inspections of any licensee where at least one of the three or more inspectors is from another region or from Central Office.

c. Routine inspections of major licensees within the year before license renewal. Team inspections are appropriate methods to assess licensees' strengths and weaknesses, and to provide feedback to the licensing process. Such team inspections should include license reviewers on the team. However, pre-licensing visits are not considered inspections, and team inspections should not take the place of pre-licensing visits.

d. Inspections of any type (routine or reactive) that include team members from outside the DEP and the NRC, such as members from the PA Department of Health, the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). For inspections of any type that involve participation by outside agencies (other than NRC), the region should coordinate through the Central Office with the outside agency.

At regional management discretion, inspection plans may be developed for all team inspections. Inspection plans should be considered for team inspections of major, broad-scope academic or medical licensees, large manufacturers, or in cases where team members from agencies outside the DEP (other than NRC) are involved. [See examples (a) and (d) in this section]

07.06 Abandonment of Licensed Activities. Returned, undeliverable mail to licensees should trigger a prompt follow-up. The follow-up should include a telephone call to the licensee to establish the licensee's physical address. If telephone contact is not established, then an inspector should be sent to the licensee's site. The regional decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material.

07.07 Inspection of Generally Licensed Devices. Routine inspections of general licensees [other than reciprocity] are not normally performed. However, if a specific licensee also possesses generally licensed devices that require registration under 25 Pa. Code 217.143 (and 10 CFR Part 31 incorporated by reference), the inspector should verify the adequacy of the licensee's control and accountability of the devices [See IP 87124, Focus Element 1]. Inspections of general licensees shall also be made to resolve issues such as allegations, incidents, or indications of unsafe practices.

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a. . For accompaniment inspections, the Assisting Region's inspectors shall implement IP 87129 while accompanying the MML's staff during routine radiation safety audits of the MML's permittees. The purpose of the accompaniment inspection is to ... [1]

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1. . IP 87129 includes forms to document the accompaniment inspections. ¶ ... [2]

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All allegations received by NRC inspectors shall be forwarded to the Lead Region MML Coordinator and ... [3]

07.09 Inspection of Licensees Holding Nuclear Materials Management and Safeguards System Accounts. The Nuclear Materials Management and Safeguards System (NMMSS) is the federal database for current and historical data on the receipt, shipment, and inventory adjustment of certain source and special nuclear materials that are listed in Enclosure 6. The United States government uses the NMMSS data to comply with certain international requirements for tracking certain source and special nuclear materials. The NMMSS database is operated by a contractor on behalf of the U.S. Department of Energy (DOE) and the NRC.

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During each routine inspection of a licensee holding a NMMSS account, the inspector will:

1. Review the licensee's inventory records of licensed materials and compare them to the information that the licensee has reported to NMMSS.

2. Compare licensee transaction data reported to NMMSS for certain source and special nuclear material (see Enclosure 6) with the receipt, transfer and disposal records maintained by the licensee in accordance with 10 CFR 40.61 or 74.19.

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3. At a minimum, physically assess the presence of a representative sample of the NMMSS-reportable material that the licensee claims to possess according to the licensee's most recent report to NMMSS.

4. Provide the licensee with the NMMSS summary of the licensee's administrative information and explain the process for making any needed changes.

Additional information about reviewing NMMSS records is contained in Enclosure 6.

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2800-08 DOCUMENTATION OF INSPECTION RESULTS

08.01 What Constitutes an Inspection. The following guidance is provided to assist in determining when activities constitute an inspection.

a. An inspection will be considered to have been performed if:

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1. the inspection involves a licensee that possesses or has possessed licensed material since the last inspection, including material possessed under a "possession-only license" or that is performing or has performed licensed activities since the last inspection; or

2. the inspection is an initial inspection that has been performed in accordance with Section 05.03.

If it is possible to inspect records or other items according to license conditions or DEP regulations, such activities should be inspected and be recorded as an inspection, whether the radiation safety officer (RSO) is present or not, including those licenses that have expired or are being processed for termination.

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If the RSO is not onsite, the inspector shall make a telephone call to contact the RSO about the inspection. At the conclusion of the inspection, the inspector shall re-contact the RSO to explain the inspection results. If the inspector is unsuccessful in announcing the inspection to the RSO, the inspector shall make a follow-up telephone call to the RSO as soon as possible after the onsite inspection.

b. An inspection will not be considered to have been performed if the licensee or licensee's representatives are not available to assist with the inspection, and the inspector is unable to perform inspection activities. The inspector will document the on-site activities by placing a note in the docket file, signed by the inspector, that briefly summarizes the attempted inspection. Together, the inspector and his or her supervisor should determine when another attempt will be made to inspect the licensee and the "next inspection date" should be changed to reflect the new date.

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c. Regions performing assist inspections will receive credit toward the operating plan goals for conducting each assist inspection.

d. No. Guidance

Deleted: The HRMS allows the time spent in gathering factual material to be charged against the time budgeted for performing routine inspections. Telephone contacts are not onsite inspections even though they involve direct inspection effort. The inspector should charge their time to HRMS, Program Code PA No. 203232E, (TAC No. A10159). The fact that a telephone contact of a Priority T licensee was made should not be entered into the LTS as an inspection; however, the date of the next telephone contact should be indicated in the "next inspection date" data element in the LTS.

e. A reactive inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.

08.02 Allegations. Allegations will be followed up and the results documented. Following is guidance about "chilling" effect.

a. In conducting interviews or other activities with licensee personnel, inspectors should be sensitive to areas where employees may be reluctant to raise concerns about the licensee's program. Even if the licensee addresses an employee's concern regarding safety issues, there could be underlying factors that could produce a "chilling" effect or reluctance for employees to report such issues. For example, the following questions will help an inspector determine if problems exist in the licensee's safety program:

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1. Has there been an unexplained change in the number or nature of valid concerns that employees have raised with the licensee or the DEP?

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2. Have there been interactions with NRC personnel that suggest that some employees may be hesitant to raise concerns or present information to DEP?

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3. Are employee concerns addressed by licensee management in a timely manner?

4. Is the licensee's corrective action successful in addressing employees' concerns?

b. If any indication of a "chilling" effect is found, the inspector shall inform regional management for further review and follow-up.

08.03 Methods of Documenting Inspection Results. Inspections shall be initially documented by completing inspection records or a narrative report.

a. Inspection results will be documented on Enclosure 5 or in a narrative report as described below, and the region will communicate the inspection findings to the licensee in a formal letter with a Notice of Violation, if appropriate. The inspection records do not have to be typed, but should be legible and should contain:

1. the procedure(s) used;
2. the focus areas examined;
3. the status of follow-up items involving prior enforcement or reported licensee events;
4. sufficient information to support cited violations, non-cited violations, and closed violations identified during a previous inspection;
5. description of completed and anticipated corrective actions to any identified violations; and
6. a succinct description of the scope of the licensee's program.; and,
7. if applicable, a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in Enclosure 6.

A different inspector should be able to use the inspection records in preparing for a subsequent inspection, and to determine whether corrective actions have been taken.

b. A narrative report is required for all team inspections and actions involving an enforcement conference or escalated enforcement. For escalated cases, the narrative report need address only the areas in which safety concerns and violations are identified (all other areas may be documented using Enclosure 5). All inspection documentation shall be filed in the licensee's docket file. Narrative inspection reports may be used to document other types of inspections at the discretion of regional management.

08.04 Methods of Transmitting Inspection Results. Results of inspections shall be reported to the licensee by regional office letter either with or without a Notice of Violation (NOV) to the licensee. Examples are:

No Guidance

A letter, signed by regional management, shall be used:

1. for repetitive violations;
2. for violations involving willfulness;
3. where a significant or problem is indicated;
4. when an enforcement conference or a management meeting is to be held;

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¶
2. . to document non-cited violations (NCVs), as discussed in the Enforcement Manual. ¶
¶
3. . When the NRC Form 591M is used to document the results of an inspection, the inspector must ensure that each cited and non-cited violation on the form includes: a brief statement of the circumstances, including the date(s) of the violation or NCV and the facts necessary to demonstrate that a requirement was not met, reference to the regulation or license condition that was violated, and a description of the licensee's corrective actions. Following are examples of cited violations on an NRC Form 591M:¶
¶
(a) . Section 20.1101(c) requires the licensee to annually review the content and implementation of the radiation protection program. During years 2002 and 2003, the license did not complete the review. The licensee will complete the review in October 2004 for the period of January 2002 through September 2004. The licensee intends to complete future reviews in October of each year by completing NUREG-1556, Volume 2, Appendix I, Radiation Safety Program Audit.¶
¶
(b) . As required by 10 CFR 34. ... [4]

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5. where the licensee needs to take extensive corrective action or make programmatic changes to address the violation;

6. where the licensee needs to perform further evaluations before taking corrective action;

7. where the corrective action includes a request for an amendment to the license;

8. when a specific message should be provided to the licensee;

9. if the inspector questions the effectiveness of the licensee's planned action or the ability of the licensee to carry out the corrective action; or

10. where it is appropriate to request a written response to the violation.

If a regional office letter and NOV are to be issued, Non Cited Violations (NCVs), if any, are to be documented in the inspection records.

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2800-09 COORDINATION OF REGIONAL RESPONSIBILITY FOR INSPECTIONS

09.01 General. When a license authorizes operations in more than one region, the responsibility for inspection shall reside with the regional office in which the licensee's main office is located. The main office means the corporate office, normally the street address listed in item 2 of the license.

09.02 Assistance in Inspections. In the interest of efficiency in use of travel time and funds, the responsible regional office may request another regional office to conduct inspections (assist inspections) of the activities of such licensees when the licensee is operating outside the geographical area of the responsible region. [See Section 07.04(b)] Because of the close proximity of a licensed facility to the responsible region's boundary, the responsible region's personnel may perform the inspection activity themselves rather than request assistance from another region. In such cases, these activities should be coordinated between regions.

09.03 Transfer of Responsibility. Notwithstanding the above (Sections 09.01 and 09.02), when a license has an address that places the inspection responsibility in one region, and operations under the license routinely or predominantly occur within another region, the inspection responsibility may be transferred to the region in which the operations are performed. This transfer shall be done with mutual agreement of the regional offices involved. The regional offices should ensure that the appropriate changes are made to the LTS to show which office has the overall responsibility for inspection and enforcement.

2800-10 COORDINATION WITH OTHER AGENCIES

10.01 Federal Agencies. DEP does not conduct inspections of licensee compliance with the requirements of other agencies, except those incorporated by reference. However,

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DEP inspectors may identify concerns that are within another agency's regulatory authority. If such concerns are significant and the licensee demonstrates a pattern of unresponsiveness, the DEP regional office, in coordination with Central Office, should inform the appropriate liaisons within the other agency about the concerns.

Except for regulations incorporated by reference, it is important that all inspectors recognize and understand that they are not to make decisions regarding activities under the purview of other agencies. Thus, in discussing the concerns with the licensee, inspectors are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations, but are to point out concerns to heighten licensee awareness. For example, if an inspector identified concerns for lack of fire protection, then it would be appropriate to encourage the licensee to advise the local fire department of conditions in the facility and to take prompt action to correct the situation. The inspector would also advise the licensee of the inspector's obligation to inform the DEP supervisor who may coordinate the information with OSHA.

In the case of complaints or allegations involving another federal agency's jurisdiction, the inspector should withhold the information from the licensee and elevate the concerns to the attention of DEP regional management while the inspector is still onsite. [see Section 08.02]

2800-11 INPUT INTO DEP TRACKING SYSTEMS

11.01 Input into the Licensing Tracking System (LTS). Enclosure 1 provides a listing of license program codes with the associated inspection priorities. Enter data promptly into the LTS at the time a new license is issued or an inspection has been performed, including the dates for initial inspections of new licensees, the last inspection date, and the next inspection date for licensees already inspected. When changes are made to the next inspection date (reductions in the inspection intervals), regions should enter the data for the correct next inspection date into the LTS and annotate the inspection file.

11.02 Input into the Nuclear Materials Events Database (NMED). Central Office manages NMED for all material-related incidents and events. The regional office is responsible for ensuring that Central Office is notified of all material-related incidents. The regional office shall also forward annotated copies of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the Central Office.

The regional office is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete."

The target for ensuring "complete" NMED records is 70 days from the date the event is reported. The regional office shall provide the information outlined in Enclosure 3 to classify a record as "complete." If there is a reason that the regional office can not obtain the required information, that reason should be forwarded to the Central Office.

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¶
a. . U.S. Department of Transportation (DOT). The NRC/DOT MOU, "Transportation of Radioactive Materials" - published in the Federal Register July 2, 1979, delineates DOT's and NRC's respective responsibilities for regulating safety in transportation of radioactive materials.¶
¶
b. . U.S. Department of Justice (DOJ)¶
¶
1. . The NRC/DOJ–Federal Bureau of Investigation (FBI) MOU, "Cooperation Regarding Threat, Theft, or Sabotage in U.S. Nuclear Industry" - published in the Federal Register May 16, 2000, provides a basis for contingency response planning, coordination, and cooperation between the FBI and the NRC, to deal effectively with threats, and with acts [5]

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2800-12 INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES FOR MATERIALS PROGRAM

The Inspection Manual Chapters (MCs) and Inspection Procedures (IPs) listed in Enclosure 4 comprise the inspection program for material licensees. This list is organized into various topics. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities. In performing an inspection, a MC in addition to several specific procedures, may be needed to adequately evaluate the licensee's program.

MCs and IPs in this section are classified into two categories: Routine (R) and As-Needed (N). "Routine" (R) means those MCs and IPs that are generally used to evaluate licensee performance. For example, the IP 87100-series includes procedures for routine inspections of certain types of use of byproduct material, i.e., industrial/academic, medical, industrial radiography, gauges, etc. However, all "routine" MCs and IPs are not appropriate for each inspection. "As-Needed" (N) means those MCs and IPs that are specifically used for a certain situation.

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END

Enclosures:

1. Inspection Priority by Program Codes

2. Telephone Contact Procedures for Priority T Licenses

   Exhibit 1 Telephone Contact Questionnaire
   Exhibit 2 Standard Response to Licensees Contacted by Telephone (Violations)
   Exhibit 3 Standard Response to Licensees Contacted by Telephone (No Violations)

3. Information for the Nuclear Materials Events Database (NMED)

4. Inspection Manual Chapters and Inspection Procedures

5. Inspection Record

6. Information for the Inspection of Licensees Holding Nuclear Materials Management and Safeguards System (NMMSS) Accounts

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ENCLOSURE 1
INSPECTION PRIORITY CODES ASSIGNED TO PROGRAM CODES

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
01100	3	Academic Type A Broad	Radiation Safety Committee (RSC)-approved users;33.13
01110	5	Academic Type B Broad	Radiation Safety Officer (RSO)-approved users; 33.14
01120	5	Academic Type C Broad	Authorized Users specifically named in the license; 33.15
02110	2	Medical Institution Broad	RSC-approved users for possession and use of a wide range of radionuclides in medical research, diagnosis, and therapy and research and development.
02120	3	Medical Institution–Written Directive (WD) Required	Used as primary code and may be used with the secondary codes for research and development, as appropriate. Used as secondary code when the license also authorizes certain medical therapy modalities.
02121	5	Medical Institution–WD Not Required	Used as primary code *only* for diagnostic nuclear medicine and diagnostic types of use under 35.1000. Used as secondary code when the license also authorizes certain medical therapy modalities.
02200	3	Medical Private Practice–WD Required	[same remark as 02120]
02201	5	Medical Private Practice–WD Not Required	[same remark as 02121]
02210	3	Eye Applicators Strontium-90 (Sr-90)	Institution or Private Practice
02220	3	Mobile Medical Service–WD Not Required	Use as a primary code if the license authorizes the mobile service *only*. Use as a secondary code if the license authorizes medical use at a central facility (i.e., institution or private practice facility) in addition to the mobile service.
02230	2	High-Dose Rate Remote After loader (HDR)	Use as a primary code.
02231	2	Mobile Medical Service–WD Required	Use as a primary code. Includes mobile HDR and non-HDR modalities under 10 CFR Part 35
02240	2	Medical Therapy–Other Emerging Technology	Medical therapy modalities used under 10 CFR 35.1000, i.e., liquid

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
			sources, microspheres, and intravascular brachytherapy devices.
02300	5	Teletherapy	Treatment of human subjects only
02310	2	Gamma Stereotactic Radiosurgery (GSR)	Treatment of human subjects *only*
02400	5	Veterinary–Nonhuman Subjects	Routine diagnosis or therapy on animals. No animal research.
02410	5	*In-Vitro* Testing Laboratories	Licenses are issued to individuals or facilities which are not included in larger programs described by Program Codes 02110 or 02120.
02500	2	Nuclear Pharmacies	Receive bulk material used to prepare single use dosages or multi-dose products which are distributed to authorized medical licensees. Sealed sources are re-distributed in the original packaging to authorized clients.
02511	5	Medical Product Distribution–32.72 Prepared Radiopharmaceuticals	Distribution of prepared radiopharmaceuticals to authorized medical licensees.
02513	5	Medical Product Distribution–32.74 Sources and Devices	Therapy sources, calibration and reference sources
03110	3	Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources	Use of sealed or unsealed sources for exploration of oil, gas, or minerals in wells.
03111	3	Well Logging Byproduct and/or SNM Sealed Sources Only	Exploration of oil, gas, or minerals in wells; study of subsurface potable aquifers.
03112	3	Well Logging Byproduct Only–Tracers Only	Exploration of oil, gas, or minerals in wells
03113	3	Field Flooding Studies	Injection of unsealed byproduct materials for tracing oil and gas reservoirs
03120	5	Measuring Systems Fixed Gauges	Non-portable gauges for measurement or control of material density, flow, level, thickness, or weight, etc.
03121	5	Measuring Systems Portable Gauges	Moisture/density gauges contain gamma and neutron sources used for measurements in soils, compacted soils and road surfacing materials.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
03122	T[1]	Measuring Systems Analytical Instruments	i.e., x-ray fluorescence analyzers
03123	T	Measuring Systems Gas Chromatographs	Quality control testing of samples from industrial process and environmental conditions.
03124	T	Measuring Systems Other	instrument calibrators, Krypton-85 (Kr-85) leak detectors
03211	2	Manufacturing and Distribution Broad–Type A	RSC-approved users under 10 CFR 33.13
03212	5	Manufacturing and Distribution Broad–Type B	RSO-approved users under10 CFR 33.14
03213	5	Manufacturing and Distribution Broad–Type C	Authorized Users specifically named in the license under 10 CFR 33.15
03214	5	Manufacturing and Distribution Other	Smaller firms that require a more restrictive license.
03218	3	Nuclear Laundry	Cleaning of protective clothing contaminated with radioactive materials.
03219	3	Decontamination Services	Cleaning of scrap materials for authorized release for unrestricted use.
03220	T	Leak Test Service Only	Commercial service organizations provide leak test kits to clients, perform measurement of leak test samples from clients, and issue reports of leak test results.
03221	5	Instrument Calibration Services Only–Source Less Than Or Equal To 100 Curies	Commercial calibration service
03222	5	Instrument Calibration Services Only–Source Greater Than 100 Curies	Commercial calibration service
03225	5	Other Services–Source Less Than Or Equal To 100 Curies	Commercial servicing for industrial gauge, and HDR licensees
03226	2	Other Services–Source Greater Than 100 Curies	Commercial servicing for teletherapy, irradiators , and GSR units containing a total activity in the unit during servicing that is greater than 100 curies.
03231	2	Waste Disposal (Burial)	Commercial and non-commercial

[1] Priority T denotes a telephone contact made by an inspector to evaluate the radiation protection program for Program Codes 03122, 03123, 03124, 03220, 11210, 22130, 22160, and 22161. The telephone contact interval is 5 years.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
03232	3	Waste Disposal Service Prepackaged Only	pick up, transfer, and storage; opening packages not authorized
03233	2	Waste Disposal Service Incineration	Commercial operation
03234	2	Waste Disposal Service Processing and/or Repackaging	receipt, open, compact, re-package, and transfer to authorized burial
03235	-[2]	Incineration, Non-Commercial	(Secondary Code)
03236	2	Waste Treatment Service (Other Than Compaction)	Includes multiple, complex physical and chemical waste treatment processes
03240	5	General License Distribution - 32.51	For fixed gauges authorized under 10 CFR 31.5
03241	5	General License Distribution - 32.53	For luminous aircraft safety devices authorized under 10 CFR 31.7
03242	5	General License Distribution - 32.57	For calibration and reference sources authorized under 10 CFR 31.8
03243	5	General License Distribution - 32.61	For ice detection devices authorized under 10 CFR 31.10
03244	5	General License Distribution - 32.71	For certain *in-vitro* clinical testing kits authorized under 10 CFR 31.11
03250	5	Exempt Distribution-32.11: Exempt Concentrations and Items	For residual material in a product authorized under 10 CFR 30.14
03251	5	Exempt Distribution-32.14: Certain Items	For manufactured products authorized under 10 CFR 30.15
03252	5	Exempt Distribution-32.17: Resins	For synthetic plastic resins authorized under 10 CFR 30.16
03253	5	Exempt Distribution-32.18: Small Quantities	For individual quantities authorized under 10 CFR 30.18
03254	5	Exempt Distribution-32.22: Self-Luminous Products	For devices authorized under 10 CFR 30.19
03255	5	Exempt Distribution-32.26: Smoke Detectors	For devices authorized under 10 CFR 30.20
03256	5	Exempt Distribution - 32.21 - Carbon-14 Urea Capsules	For *in vivo* diagnostic use authorized under 10 CFR 30.21
03310	2	Industrial Radiography Fixed Location	Permanent radiographic installation (PRI) or designated field station. Use as secondary

[2] Program Code 03235 is used only as a secondary code for certain licensees authorized to operate a noncommercial incinerator to dispose of radioactive waste

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
			code, except when the license authorizes the PRI *only*.
03320	1	Industrial Radiography Temporary Job Sites	Use as primary code for multiple temporary customer locations
03510	5	Irradiators Self Shielded Less Than Or Equal To 10,000 Curies	Not external beam
03511	5	Irradiators Other Less Than Or Equal To 10,000 Curies	Panoramic (in air or under water) units; includes converted teletherapy units
03520	5	Irradiators Self Shielded Greater Than 10,000 Curies	Not external beam
03521	2	Irradiators - Other Greater than 10,000 curies	Panoramic (in air or under water) units; includes sterilization (mega-curie) units
03610	3	Research and Development Broad–Type A	RSC-approved users under 10 CFR 33.13
03611	5	Research and Development Broad–Type B	RSO-approved users under 10 CFR 33.14
03612	5	Research and Development Broad–Type C	Authorized users specifically named in the license under 10 CFR 33.15
03613	2	Research and Development Broad–Multisite–Multiregional	Master Materials Licenses
03620	5	Research and Development Other	Non-human research subjects
03710	5	Civil Defense	Instrument calibration and training
03800	3	Byproduct Material Possession Only - Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized
03810	3	Byproduct Material Standby - No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized
03900	D[3]	Decommissioning of Byproduct Material Facilities	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR

[3] The Priority D denotes a decommissioning inspection as determined under MC 2602, Decommissioning Inspection Program, for Program Codes 03900, 11900, 21325, and 22200. These inspections are scheduled at times when the licensee is performing decommissioning activities at the site.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
			30.36
11200	5	Source Material Other Less than 150 Kilograms	Research or manufacturing of consumer products
11210	T	Source Material Shielding	Possession and use
11220	5	Source Material Military Munitions Indoor Testing	Depleted Uranium (DU); results in fragmentation of DU
11221	5	Source Material Military Munitions Outdoor Testing	DU
11230	5	Source Material General License Distribution - 40.34	DU products and devices authorized under 10 CFR 40.25
11300	5	Source Material Other Greater than 150 Kilograms	Research or manufacturing of consumer products
11700	5	Rare Earth Extraction and Processing	Generates waste products containing source material not related to the nuclear fuel cycle
11800	2	Source Material Possession Only - Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized
11810	2	Source Material Standby - No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized
11900	D	Decommissioning of Source Material Facilities	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR 40.42
21310	5	Critical Mass Material - University	Greater than 350 grams of enriched Uranium-235 (U-235), greater than 300 grams of Uranium-233 (U-233), greater than 200 grams of Plutonium, or any combination thereof
21320	5	Critical Mass Material - Other Than Universities	Greater than 350 grams of enriched U-235, greater than 300 grams of U-233, greater than 200 grams of Plutonium, or any combination thereof
21325	D	Decommissioning of Critical Mass - Other Than Fuel Fabrication	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR 70.38

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
22110	3	Special Nuclear Material Plutonium - Unsealed, Less than Critical Mass	Less than 200 grams, total, for biological and chemical testing and instrument calibration
22111	3	Special Nuclear Material, U-235 and/or U-233 - Unsealed, Less than a Critical Mass	Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration
22120	5	SNM Plutonium - Sealed Neutron Sources, Less than 200 Grams	Plutonium-beryllium howitzer for instrument calibration, teaching and demonstration purposes, and industrial applications
22130	T	Power Sources with Byproduct and/or Special Nuclear Material	Heat or power generators for remote locations
22140	5	Special Nuclear Material Plutonium - Sealed Sources in Devices	Gauges
22150	5	Special Nuclear Material Plutonium - Sealed Sources Less than a Critical Mass	Less than 200 grams, total, for biological and chemical testing and instrument calibration
22151	5	Special Nuclear Material, U-235 and/or U-233 Sealed Sources, Less than a Critical Mass	Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration
22160	T	Pacemaker–Byproduct, and/or Special Nuclear Material - Medical Institution	Surgical implantation, follow up, recovery, and disposal of devices
22161	T	Pacemaker–Byproduct, and/or Special Nuclear Material - Individual	Possession of a surgically implanted device by the recipient while in the United States
22162	2	Pacemaker–Byproduct and/or Special Nuclear Material - Manufacturing and Distribution	
22170	5	Special Nuclear Material General License Distribution (70.39)	Includes calibration or reference sources authorized under 10 CFR 70.19
22200	D	Decommissioning of Other SNM Facilities - Less than Critical Mass	(See MC 2602) D&D may have been authorized according to an approved plan under 10 CFR 70.38
23300	2	SNM Possession Only (Non-Fuel)-Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
23310	2	SNM Standby (Non-Fuel)-No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized

END

ENCLOSURE 2

TELEPHONE CONTACT PROCEDURES FOR PRIORITY T LICENSEES

1. PROGRAM OBJECTIVES: The Central Office developed telephone contact procedures to maintain safety for materials possessed by certain licensees (Priority T) after the initial inspection was completed and the inspector determined that the licensee had satisfactorily implemented the radiation protection program. Thereafter, an inspector will interview the Priority T licensee at 5-YEAR intervals for the duration of the license.

2. PROCEDURES

   a. Select a Priority T licensee to interview by telephone [see Section 05.05].

   b. Obtain the license file and identify the licensee's point of contact and review pertinent details of the license that will be needed to evaluate the licensee's responses to the interview questionnaire. (Exhibit 1).

      NOTE: If the license authorizes nuclear-powered cardiac pacemaker devices that contain special nuclear material (i.e., Program Codes 22160 or 22161), the inspector should refer to the guidance contained in Enclosure 6, Section 2, "NMMSS Inspection Process," describes preparation steps and onsite steps which should be adapted to complete this telephonic contact procedure.

      For example, the inspector should request the NMMSS contractor to send the "Task 8 Inspection Package" which contains inventory data the licensee has reported to NMMSS. The inspector should also request the licensee to transmit a facsimile of their current inventory record. Compare the licensee's current record with the NMMSS report data.

      If discrepancies exist, the licensee must assess the situation and verify the fact that NMMSS-reportable quantities are lost or missing or were incorrectly reported to NMMSS. The licensee is responsible for contacting the NMMSS contractor to correct the database.

   c. Telephone the licensee and complete each item of Exhibit 1, as appropriate for the type of use authorized by the license. If a question is not applicable for the type of use, then indicate "N.A." for the answer.

   d. The inspector should promptly notify their supervisor if the licensee describes any significant problem. The supervisor should determine whether an inspection of the facility or a letter transmitting regulatory concerns is needed. If an inspection is warranted, the inspector should note that decision on Exhibit 1 and provide the completed questionnaire and license file to the supervisor for further action. Use Exhibit 2, "Standard Response to Licensees Contacted by Telephone (Concerns, Inspection to Follow)," to notify the licensee that a follow up inspection may be scheduled in the near future. Following is a list of problems which may warrant an onsite inspection.

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1. licensee is unaware of licensed material or DEP regulations for possession, use, transfer, and disposal

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2. change in ownership or bankruptcy proceedings

3. a qualified radiation safety officer or authorized user was not routinely involved

4. unsecured or unshielded material

5. doses in excess of 10 CFR Part 20 limits

6. excessive radiation levels or leaking sources

7. lost, stolen, or missing licensed material

8. non-routine event threatens safe, secure storage (i.e., special maintenance or handling, fire, explosion, or damage from a natural disaster)

9. decommissioning activities

e. If no problem is evident from the licensee's responses, use Exhibit 3, "Standard Response to Licensees Contacted by Telephone (No Concerns/Violations.)" to provide the licensee with appropriate documentation.

f. With the supervisor's concurrence, the inspector may sign the letter and provide the package to the administrative staff.

EXHIBIT 1: TELEPHONE CONTACT QUESTIONNAIRE

Instructions: Complete this questionnaire as per the program objectives and procedures for Enclosure 2.

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Name and title of Interviewer Signature of Interviewer	
Date of this Interview Date of Previous Interview	
QUESTIONS	**ANSWERS**
Licensee Name, Address, and URL	
Licensee's Point of Contact (Name, Address, Phone and FAX Numbers, and URL)	
License Number Docket Number	
1. Name and Title of person responsible for radiation safety program:	
2. Describe how you prevent: (a) use by unauthorized personnel and (b) loss or theft.	
3. Describe how you maintain shielding, restrict access, and control contamination from unsealed material to prevent individuals from becoming exposed to radiation.	
4. Describe how you determine radiation doses to workers and members of the public from licensed activities. What was the maximum dose received since the last DEP or NRC telephone contact or inspection?	
5. Describe radiation area surveys around licensed activities. What survey instrument (SI) was used? SI's last calibration date? What were the typical radiation levels and at what distance?	
6. Describe leak testing of the sealed source(s). How often and who analyzed the leak test samples? What were the most recent results?	

7. Describe physical inventory of all byproduct material and NMMS reportable materials in your possession. When was the last inventory completed? Were all the sources located?	
8. Describe your provisions for repair and maintenance of your device or source holder.	
9. Describe any unusual events involving the byproduct material or the device(s) in which it is used (i.e., fire, explosion, natural disaster.)	

EXHIBIT 2
STANDARD RESPONSE TO LICENSEES CONTACTED BY TELEPHONE
(CONCERNS, INSPECTION TO FOLLOW)

Licensee Name _____[License No.]
Address _____

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ATTENTION: [Licensee Point of Contact, Title]

SUBJECT: TELEPHONE INTERVIEW TO EVALUATE THE RADIATION SAFETY PROGRAM

Sir or Madam:

This refers to the interview by telephone on [date]. The interview was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Department of Environmental Protection (DEP) rules and regulations and with the conditions of your license. As a result of this examination of your licensed activities, we noted regulatory concerns that are specified below. These concerns may be further evaluated during an onsite inspection at your facility in the near future.

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(List regulatory concerns. For any concern that appears to rise to a violation or otherwise to indicate lack of programmatic oversight, the region should promptly conduct an inspection and take enforcement action, as appropriate, based on the results of the inspection.)

In particular, you should examine your license and the DEP's regulations to determine how you can correct the apparent regulatory concerns listed above. The points listed below are especially important for your radiation safety program:

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1. control access to and prevent loss of licensed material, ensure proper transfers and disposal of licensed material, and promptly report to NRC loss or theft of licensed material
2. maintain shielding of licensed material to reduce radiation exposure
3. implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material evaluate radiation exposures to workers and members of the public
4. use properly calibrated survey instruments to monitor radiation levels
5. ensure that workers are knowledgeable, skilled, and empowered to implement the radiation protection program
6. ensure that upper level managers are aware of the radiation protection program, that annual audits of the program are completed, and that appropriate action is taken for past performance, present conditions, and future needs

If you have any questions about this matter, please contact me at [phone, fax, email address].

Sincerely, [Inspector Name, Title]

EXHIBIT 3
STANDARD RESPONSE TO LICENSEES CONTACTED BY TELEPHONE
(NO CONCERNS / VIOLATIONS)

Licensee Name _____[License No.]
Address _____

Deleted: [Docket No.]

ATTENTION: [Licensee Point of Contact, Title]

SUBJECT: TELEPHONE INTERVIEW TO EVALUATE THE RADIATION SAFETY PROGRAM

Sir or Madam:

This refers to the interview by telephone on [date]. The interview was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Department of Environmental Protection rules and regulations and with the conditions of your license. No regulatory concerns were identified.

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If you have any questions about this matter, please contact me at [phone, fax, email address].

Sincerely,

[Inspector Name, Title]

ENCLOSURE 3
INFORMATION FOR THE NUCLEAR MATERIALS EVENTS DATABASE (NMED)

The regional office shall forward copies of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the Central Office.

The regional office is responsible for ensuring that sufficient information is provided for the NMED item to be considered "complete." The basic information along with the additional specific information for certain types of events, outlined below, constitutes the "complete" record.

The target for ensuring "complete" NMED records is 70 days from the date the event is reported. The information identified below must be provided to classify a record as "complete." If there is a reason that required information can not be obtained, that reason should be forwarded to the Central Office.

Deleted: NMED contractor and the NMED Project Manager, NMSS

Deleted: For publicly available documents, entry into ADAMS meets the requirement for forwarding the documents. For documents that are not publicly available, the regional office must forward paper copies to the NMED contractor and the NMED Project Coordinator, NMSS.

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Deleted: NMED contractor and the NMED Project Manager

Basic Information:

1. Essential Details
   a. narrative event description
   b. report identification number
   c. event date and notification date
   d. licensee/reporting party information (name, license number, and address)
   e. site of event
   f. whether the event is DEP reportable and the applicable reporting requirement
   g. cause and corrective actions
   h. number of persons involved, consequences
   I. notifications: local police, FBI, other States, as needed
   j. identify any possible generic safety concerns/potential for others to experience the same event

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2. Source/Radioactive Material:

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   a. isotope and activity
   b. manufacturer
   c. model and serial number

3. Device/Associated Equipment:
   a. manufacturer
   b. model and serial number

Additional information is required for the specific event types listed below:

1. Release of Licensed Material or Contamination (NMED CODE: RLM):
   a. release type (air or water)
   b. contamination (person or surface)
   c. isotope and activity released

2. Medical event (NMED CODE: MD2):
   a. procedure administered
   b. dose intended and dose administered
   c. isotope and activity administered
   d. organ targeted
   e. notifications: patient, physician

3. Overexposure (EXP):
   a. radiation source and activity
   b. exposure dose
   c. exposure type (whole body, extremity, etc.)

4. Transportation (TRS):
   a. type of transport
   b. identity of shipper
   c. package type and ID number

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ENCLOSURE 4

INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES

MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
	MATERIALS SAFETY PROGRAMS	
MC1220	"Processing of DEP Form 241,'Reciprocity - Report of Proposed Activities in Pennsylvania, in Areas of Department Jurisdiction,' and Inspection of Reciprocity Licensees Operating Under 25 PA Code Chapter 217 Subchapter J"	N
MC2815	"Construction and Pre-Operational Inspection of Panoramic, Wet-Source Storage Gamma Irradiators"	N
IP 87121	"Industrial Radiography Programs"	R
IP 87122	"Irradiator Programs"	R
IP 87123	"Well Logging Programs"	R
IP 87124	"Fixed and Portable Gauge Programs"	R
IP 87125	"Materials Processor/Manufacturer Programs"	R
IP 87126	"Industrial/Academic/Research Programs"	R
IP 87127	"Radiopharmacy Programs"	R
IP 87130	"Nuclear Medicine Programs–Written Directive Not Required"	R
IP 87131	"Nuclear Medicine Programs–Written Directive Required"	R
IP 87132	"Brachytherapy Programs"	R
IP 87133	"Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs"	R
IP 87134	"Medical Broad-Scope Programs"	R
	CONDUCT OF INSPECTIONS	
MC 0300	"Announced and Unannounced Inspections"	R

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MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
MC 1246	"Formal Qualification Programs in the Bureau of Radiation Protection Program Area."	R
INCIDENT RESPONSE		
MC 1301	"Response to Radiation Source Incidents"	N
MC 1302	"Follow-up Actions and Action Levels for Radiation Exposures Associated with Incidents Involving Members of the Public"	N
MC 1303	"Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)"	N
MC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
IP 87103	"Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing"	N
LOW-LEVEL WASTE/WASTE MANAGEMENT		
IP 84850	"Radioactive Waste Management - Inspection of Waste Generator Requirements of 25 PA Code Chapters 219 and 236"	R
IP 84900	"Low-Level Radioactive Waste Storage"	R
DECOMMISSIONING INSPECTIONS		
MC 2602	"Decommissioning Oversight and Inspection Program For Materials Licensees"	N
IP 83890	"Closeout Inspection and Survey"	N

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MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
IP 87104	"Decommissioning Inspection Procedures for Materials Licenses"	N
	RADIATION PROTECTION	
IP 83822	"Radiation Protection"	R
IP 87102	"Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)"	R
	TRANSPORTATION	
MC 1330	"Response to Transportation Accidents Involving Radioactive Materials"	N
IP 86740	"Inspection of Transportation Activities"	R
	REPORTS/COMMUNICATIONS/FOLLOW-UP	
MC 0610	"Radioactive Material Safety and Safeguards Inspection Reports"	R
MC 0620	"Inspection Documents and Records"	R
MC 1120	"Preliminary Notifications"	N
MC 1232	"Collection Preparation and Shipment of Independent Measurement Samples"	N

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ENCLOSURE 5

INSPECTION RECORD

____Region ___ Inspection Report No.____ License No.____

____Licensee (Name and Address):

_____Location (Authorized Site) Being Inspected

_____Licensee Contact: _____ Telephone No.____

_____Priority: _____ Program Code:

_____Date of Last Inspection: _____ Date of This Inspection:

_____Type of Inspection: ( ) Initial ( ) Announced ( ) Unannounced
( ) Routine ( ) Special

_____Next Inspection Date: _____ ( ) Normal ( ) Reduced
Justification for reducing the routine inspection interval:

_____Summary of Findings and Actions:

( ) No violations cited.
( ) Non-cited violations (NCVs)
( ) Violation(s).
( ) Violation(s).
( ) Followup on previous violations

Inspector(s) _____ Date
_____(Name(s))

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(Signature(s))

Approved _____ Date _____
(Name)

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(Signature)

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PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

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2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events reported to DEP since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

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PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

2. SCOPE OF INSPECTION:
(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used:

Focus Areas Evaluated:

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

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4. VIOLATIONS, Non Cited Violations (NCV's), AND OTHER SAFETY ISSUES:
(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

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5. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

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ENCLOSURE 6

INFORMATION REGARDING INSPECTION OF LICENSEES HOLDING NUCLEAR MATERIALS MANAGEMENT AND SAFEGUARDS SYSTEM ACCOUNTS

1.0 Background:

The Nuclear Materials Management and Safeguards System (NMMSS) is the U.S. Government's database for current and historical data on the receipt, shipment, and inventory adjustment of certain source and special nuclear materials (SNM). NMMSS data is also used to satisfy the reporting requirements of international agreements that the United States is part of regarding the tracking of certain source and special nuclear materials. The NMMSS database is operated by a contractor on behalf of the U.S. Department of Energy (DOE) and the NRC.

NRC and Agreement State licensees are required by 10 CFR Parts 40, 72, 74, and 150 to submit reports to NMMSS if they ship, receive, or adjust their onsite inventories for materials that are equal to or greater than the quantities shown in Table 1 on page 5.

NMMSS is also used to provide information to the U.S. Department of State to satisfy agreements with other nations that require the accounting of foreign-obligated source material and SNM imported to and exported from the United States. Foreign-obligated source material is source material that is tracked by NMMSS in accordance with treaty or agreement obligations that the United States has with other nations to treat nuclear materials in a manner consistent with that treaty or agreement. For example, certain source material may be sold by or to the United States with the understanding that the material will only be used for peaceful purposes such as power generation and not used in a nuclear weapons program.

In practice, all foreign-obligated source material in the United States is located at

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fuel cycle facilities. It is not expected that any foreign-obligated material would be found at a licensee facility inspected under IMC 2800. However, if an inspector identifies source material with documented foreign obligations, then the inspector should immediately notify the Office of Nuclear Security and Incident Response, Division of Nuclear Security (NSIR/DNS), NMMSS Project Manager. The inspector should include the material within the scope of the inspection under IMC 2800 until further notice.

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While the license and licensee records typically use units of radioactivity to quantify NMMSS-reportable materials, NMMSS uses units of mass (i.e., "grams") for inventory data in records and reports

NOTE: An inspector can readily identify foreign-obligated source material because NMMSS reports the quantity as "kilograms."

SNM is the focus of the remainder of the inspection guidance in this enclosure. NMMSS tracks quantities of subject material by material type (MT) and does not track licensee inventories of NMMSS-reportable material down to the item level. For example, NMMSS cannot provide information regarding the model number and serial number of devices or sources containing NMMSS-reportable material at a particular facility. Table 2 on page 5 indicates the MT codes for the materials that NRC requires to be reported to NMMSS.

In preparing for the inspection, the inspector should sum the masses for each MT reported by NMMSS, and be prepared to do the same during the inspection when examining the licensee's inventory records. Table 3 on page 6 indicates the specific activities for the materials likely to be seen during an inspection. These factors may be used to convert between grams and activity units (curies) when comparing licensee and NMMSS records.

2.0 NMMSS Inspection Process

02.01 Preparation: If the licensee is authorized to possess NMMSS-reportable quantities of materials, the inspector will contact the NMMSS contractor (telephone (678) 328-1116) and request a "Task 8 Inspection Package." If unable to contact the NMMSS contractor, the inspector should notify the NSIR/DNS NMMSS Project Manager. A minimum of seven calendar days should be allowed prior to the start of the inspection trip to allow sufficient time for the package to be mailed to the inspector.

The Task 8 Inspection Package contains three documents which are described in Table 4, on page 6:

a. DOE/NRC Form 742, "Material Balance Report,"
b. NMMSS Report TJ-45
c. NMMSS Report D-3

Inspectors are cautioned that at a minimum, NMMSS data is Sensitive-Unclassified Official Use Only (OUO) information. Since it will generally be necessary to take

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NMMSS data on the inspection, inspectors must be familiar with, and comply with, the OUO information storage and handling requirements specified in NRC Management Directive (MD) 12.6, "NRC Sensitive Unclassified Information Security Program." Any loses or compromise of OUO data must be reported to the NRC's Division of Facility Security in accordance with NRC MD 12.6. Inspectors must also be cautious with regard to handling licensee information that may be classified, sensitive, or proprietary. For more information, contact the appropriate NRC regional or NSIR security advisor, or refer to the security services web page at http://www.internal.nrc.gov/ADM/DFS/dfs.html.

02.02 On-Site Inspection: During each inspection of a licensee holding a NMMSS account, the inspector shall:

a. Discuss the location of all NMMSS-reportable material possessed by the licensee. Obtain and review the most recent record of physical inventory of SNM performed by the licensee. Compare the licensee's inventory records with the information documented in the licensee's NMMSS account on the DOE/NRC Form 742, "Material Balance Report," provided by the NMMSS contractor.

b. Review the records documenting the receipt, transfer and disposal of material maintained by the licensee in accordance with 10 CFR 74.19(a)(1). Compare these records to the data in the NMMSS Report TJ-45 and determine that the licensee has accounted for the quantities of materials received, possessed, transferred, and disposed since the licensee submitted the most recent DOE/NRC Form 742, "Material Balance Report."

c. Verify the information listed on the licensee's inventory record by walking down the licensee's facility and (if practicable) visually identifying, at a minimum, a representative sample of the materials that the licensee reported to NMMSS on the most recently submitted DOE/NRC Form 742. If appropriate, verify the presence of the subject material with a radiation survey instrument. The intent of the measurement is to verify the presence of radioactive material rather than to determine the quantity or specific isotopic identity of the material present.

NOTE: An inspector should not ask licensee personnel to open any container or otherwise change the container's shielding to facilitate this survey.

If the licensee possesses NMMSS-reportable material in sufficient quantity to be subject to NMMSS requirements (i.e., Table 1) and has not reported the material, or if discrepancies exist between the licensee's inventory records and the most recently submitted DOE/NRC Form 742, the licensee's corrective actions must include contacting the NMMSS contractor to revise and reconcile their reported holdings of NMMSS-reportable material. The licensee must adequately evaluate any discrepancy to determine if, in fact, NMMSS-reportable materials are lost or otherwise missing. The inspector must collect sufficient information to support potential short-term NRC regulatory actions, such as the preparation of a

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confirmatory action letter or an order, and potential longer term escalated enforcement actions.

d. Provide responsible licensee personnel with a copy of NMMSS Report D-3 which summarizes the administrative information contained in NMMSS about the licensee. Review the administrative information listed in the NMMSS Report D-3 with licensee personnel to ensure that the information is up to date. This information includes, but is not limited to:

1. mailing address
2. physical or shipping address (for transmitting information via nonpostal methods that cannot use a post office box)
3. telephone number, FAX number, and e-mail address for primary technical point of contact
4. telephone number, fax number, and e-mail address for primary management point of contact
5. the license numbers of NRC or Agreement State licenses that authorize the possession of subject material

e. If corrections to any NMMSS data are needed, the licensee should contact the NMMSS contractor directly by telephone. Specifically, for corrections to NMMSS Report D-3, the licensee may update their administrative information by using the link to the On-Line RIS Update Application which is available on the NMMSS web page (lower left corner) at:

http://www.nmmss.com/NMMSST1.nsf/mainFS?OpenFrameSet.

By using the link, a licensee can keep their administrative information at NMMSS up to date. The NMMSS contractor will verify the licensee's changes before updating the NMMSS database.

02.03 Inspection Documentation: If applicable, the inspector should include a statement that the licensee's reporting to NMMSS was reviewed in accordance with the procedures described in NRC IM 2800 Enclosure 7. The statement should be recorded under the "Program Scope" of the Safety and Compliance Inspection report along with the results of the overall inspection.

Since inspection findings and much of the data used in these inspections are "Business Proprietary" or "Sensitive-Unclassified Official Use Only," inspection documentation must be properly protected at all times. Information discussing the quantities and forms of NMMSS-reportable materials possessed by the licensee shall not be included in the inspection report or in any other inspection documentation unless the information is vital to adequately document any violations or other issues that require corrective or other follow-up action by the licensee or the NRC. Any inspection records that must contain information about quantities and forms of NMMSS-reportable materials will be profiled in ADAMS as "non-publically available" documents.

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Provide a copy of any inspection report or narrative report that documents a violation of NMMSS reporting requirements to the NRC NSIR/DNS, NMMSS Project Manager.

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a. For accompaniment inspections, the Assisting Region's inspectors shall implement IP 87129 while accompanying the MML's staff during routine radiation safety audits of the MML's permittees. The purpose of the accompaniment inspection is to determine whether or not the MML's staff are inspecting the permittees in accordance with NRC's inspection policies and procedures [See Enclosure 4]. In addition, the inspectors shall obtain information deemed necessary by the Lead Region for special issues relating to the inspection.

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1. IP 87129 includes forms to document the accompaniment inspections.

2. The inspector shall provide the completed forms to the Lead Region's MML Coordinator as per the established timeliness goal.

b. For independent inspections, the Assisting Region's inspectors shall implement the program-specific guidance contained in the inspection procedures in Enclosure 4. In addition, the inspectors shall obtain information deemed necessary by the Lead Region for special issues relating to the inspection.

1. The inspections shall be unannounced by NRC or the MML.

2. Inspection report numbers will be provided by the Lead Region.

3. Inspectors will provide completed inspection documentation to the Lead Region MML Coordinator within the established timeliness goal. [See Section 2800-08]

(a) NRC Form 591M shall not be issued to the MML permittee's management. Section Break (Continuous)

(b) The Lead Region shall issue all inspection-related correspondence to the MML.

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All allegations received by NRC inspectors shall be forwarded to the Lead Region MML Coordinator and Office Allegation Coordinator for action by the Lead Region. If independent follow up by NRC is needed, the Lead Region may request the Assisting Region to assist with the follow up for the allegation.

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1. to document clear inspections and inspections resulting in Severity Level IV violations (that are neither willful nor repetitive) that can be corrected while the inspector is present, or that the licensee is able to correct easily; and

2. to document non-cited violations (NCVs), as discussed in the Enforcement Manual.

3. When the NRC Form 591M is used to document the results of an inspection, the inspector must ensure that each cited and non-cited violation on the form includes: a brief statement of the circumstances, including the date(s) of the violation or NCV and the facts necessary to demonstrate that a requirement was not met, reference to the regulation or license condition that was violated, and a description of the licensee's corrective actions. Following are examples of cited violations on an NRC Form 591M:

   (a) Section 20.1101(c) requires the licensee to annually review the content and implementation of the radiation protection program. During years 2002 and 2003, the license did not complete the review. The licensee will complete the review in October 2004 for the period of January 2002 through September 2004. The licensee intends to complete future reviews in October of each year by completing NUREG-1556, Volume 2, Appendix I, Radiation Safety Program Audit.

   (b) As required by 10 CFR 34.29, the licensee did not perform a quarterly physical inventory during the period from February 25, 2003, to October 24, 2003, to account for all sealed sources and devices containing depleted uranium. The licensee will implement an automated reminder system to notify the Radiation Safety Officer to perform the inventories.

4. The inspector must also ensure that the findings are documented in the inspection records in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement, and when it was violated. If the licensee provides corrective action for the violations, this information should also be included in the inspection records.

5. For NCVs, the inspection records should document why the violation was not cited and the corrective action taken or planned.

6. The inspector will present NRC Form 591M to the licensee at the conclusion of the exit interview, or, on rare occasions where consultation with regional management is necessary, the inspector may transmit NRC Form 591M from the regional office by facsimile. Other forms of distribution, i.e., electronic mail, may be used at the discretion of regional management. All non-willful, non-repetitive Severity Level IV violations may be cited on NRC Form 591M.

7. The NRC Form 591M, "Safety Inspection Report", shall include the name of the responsible inspector. The inspector shall sign the completed Form 591M and will usually provide the signed form to the administrative staff without further management review, unless instructed otherwise by the supervisor.

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NRC has entered into several Memoranda of Understanding (MOUs), with other Federal agencies, that outline agreements regarding items such as exchange of trade-secret information and evidence in criminal proceedings. These MOUs are published in the NRC Rules and Regulations (Volume IV) and copies may be obtained from the regional office or

IMNS. The following MOUs contain information that is relevant to inspection activities:

a. U.S. Department of Transportation (DOT). The NRC/DOT MOU, "Transportation of Radioactive Materials" - published in the Federal Register July 2, 1979, delineates DOT's and NRC's respective responsibilities for regulating safety in transportation of radioactive materials.

b. U.S. Department of Justice (DOJ)

1. The NRC/DOJ–Federal Bureau of Investigation (FBI) MOU, "Cooperation Regarding Threat, Theft, or Sabotage in U.S. Nuclear Industry" - published in the Federal Register May 16, 2000, provides a basis for contingency response planning, coordination, and cooperation between the FBI and the NRC, to deal effectively with threats, and with acts associated with theft or sabotage attempts against NRC-licensed nuclear facilities and activities.

2. The NRC/DOJ MOU published in the Federal Register December 14, 1988, provides for coordination between the two agencies for matters that could lead to NRC enforcement action, as well as DOJ criminal prosecution. The MOU also facilitates exchange of information on matters within their respective jurisdictions.

c. U.S. Department of Labor (DOL)

1. The NRC/DOL MOU, "Cooperation Regarding Employee Protection Matters"

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published in the Federal Register October 27, 1998, provides coordination of employee protection provisions in Section 211 of the Energy Reorganization Act of 1974. Section 211 prohibits a licensee, applicant, or contractor or subcontractor of same from discriminating against any employee who assisted or participated, or is about to assist or participate, in an NRC inspection.

2. The NRC/DOL–Mine Safety and Health Administration (MSHA) MOU, "Facilitation of Coordination and Cooperation in Areas of Mutual Jurisdiction and Concern," published in the Federal Register January 4, 1980, clarified the regulatory roles for NRC and MSHA for milling of source material, including inspection of an operating uranium mill.

3. The NRC/DOL–Occupational Safety and Health Administration (OSHA), MOU, "Worker Protection at NRC-licensed Facilities" - published in the Federal Register October 31, 1988, was designed to ensure that there will be no gaps in the protection of workers at NRC-licensed facilities where the OSHA also has health and safety jurisdiction. At the same time, the MOU is designed to avoid NRC and OSHA duplication of effort in those cases where it is not always practical to sharply identify boundaries between the NRC's responsibilities for nuclear safety and the OSHA's responsibilities for industrial safety.

Specific guidance on the responsibilities and interfacing activities for reporting non-radiological hazards to OSHA can be found in MC 1007. There are 4 categories of hazards that may be associated the licensed materials:

(a) radiation risk from radioactive materials,

(b) chemical risk from radioactive materials,

(c) facility conditions that affect the safety of radioactive materials and thus present a risk to workers or members of the public, and

(d) facility conditions that result in an occupational risk but do not affect the safety of licensed materials.

Generally, NRC has jurisdiction over categories (a), (b), and (c). OSHA has authority and responsibility for category (d). Through this MOU, NRC supports OSHA by reporting category (d) conditions to the licensee, NRC, and OSHA so appropriate action(s) can be taken.

Time spent on meeting the requirements of MC 1007 for category (d) conditions are to be charged to IP 93001, "OSHA Interface Activities." Time spent on category (a), (b), and (c) conditions are to be charged to the program-specific inspection procedure.

d. U.S. Environmental Protection Agency (EPA)

1. The NRC/EPA MOU, "Regulation of Radionuclide Emissions", published in the Federal Register November 3, 1980, defines in general terms the respective roles of the two agencies and establishes a framework of cooperation for avoiding unnecessary duplication of effort and for conserving resources in establishing, implementing, and enforcing standards for airborne radionuclide emissions from sources and facilities licensed by the NRC.

2. The NRC/EPA MOU published in the Federal Register November 16, 1992, was designed to foster NRC/EPA cooperation in protecting health and safety and the environment on issues relating to the regulation of radionuclides in the environment.

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3. The NRC/EPA MOU published in the Federal Register December 22, 1992, concerns "Clean Air Act Standards for Radionuclide Releases from Facilities Other than Nuclear Power Reactors Licensed by NRC or its Agreement States." The MOU was designed to ensure that facilities other than nuclear power reactors, licensed by the NRC, will continue to limit air emissions of radionuclides to levels that result in protection of the public health with an ample margin of safety.

e. U.S. Department of Health and Human Services (DHHS)

The NRC/DHHS–FDA MOU published in the Federal Register December 23, 2002, renewed with minor changes the MOU signed by NRC and FDA on August 26, 1993. The MOU coordinates existing NRC and FDA regulatory programs for medical devices, drugs, and biological products using byproduct, source, or special nuclear material.

f. U.S. Department of Energy (DOE)

The NRC/DOE–Office of Waste Management MOU, "Concerning the Management of Sealed Sources," published in the Federal Register January 7, 2000, addresses the problem of unwanted and uncontrolled radioactive materials ("orphan" sources) and defines agreed-upon roles and responsibilities of the NRC and DOE in situations where the NRC is the lead Federal agency, where immediate health and safety hazards have been addressed, and where assistance with the transfer of radioactive material is determined to be necessary for continued protection of public health and safety and the environment.

10.02 State Agencies. For routine NRC inspections in both Agreement and non-Agreement States, State radiation control program personnel shall be notified of the inspection at least 1 week in advance, by telephone, e-mail, or facsimile.

State personnel interested in participation may do so as observers as long as their presence does not affect NRC's inspection program. State personnel should be informed that information gathered during the inspection is confidential and predecisional and shall not be disclosed.

Whenever possible, for reactive inspections in Agreement States, State radiation control program personnel should be notified before the start of the inspection so that any public inquiries that may come to the State radiation control agency may be referred to the appropriate regional office.

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enter the Special Inspection Code on the Inspection and Enforcement Screen, as described in Section 06.04(b)

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For documents that are publicly available, entry into ADAMS meets the requirement for forwarding documents. For documents that are not publicly available, the regional office must forward paper copies to the NMED contractor and the NMED Project Manager, NMSS

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"Augmented Inspection Team."

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"Special Inspection."

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oactive Material Incidents That Do Not Require Activation of the NRC Incident Response Center" see E-Plan

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"Use of Physician and Scientific Consultants in the Medical Consultant Program"

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"Near-Surface Low-Level Radioactive Waste Disposal Facility Inspection Program"

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10 CFR Part 20 and 10 CFR Part 61

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"Interfacing Activities between Regional Offices of NRC and OSHA"

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"OSHA Interface Activities"

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ENCLOSURE 5

NRC FORM 591M PART 1 (10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

2. NRC/REGIONAL OFFICE

REPORT NUMBER(S)

3. DOCKET NUMBER(S)

4. LICENSEE NUMBER(S)

5. DATE(S) OF INSPECTION

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy to exercise discretion, were satisfied.

Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR			

NRC FORM 591M PART 1 (10-2003)

Section Break (Next Page)

U.S. NUCLEAR REGULATORY COMMISSION

NRC FORM 591M PART 2
(10-2003) 10 CFR 2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE	
REPORT NUMBER(S)		
3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION

(Continued)

NRC FORM 591M PART 2 (10-2003)

NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

DOCKET FILE INFORMATION

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE

2. NRC/REGIONAL OFFICE

REPORT NUMBER

3. DOCKET NUMBER(S)

4. LICENSE NUMBER(S)

5. DATE(S) OF INSPECTION

6. INSPECTION PROCEDURES 7. INSPECTION FOCUS AREAS

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 2. PRIORITY 3. LICENSEE CONTACT 4. TELEPHONE NUMBER

☐ Main Office Inspection Next Inspection Date: _____

☐ Field Office _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

NRC FORM 591M PART 3 (10-2003)

DEP INSPECTION MANUAL

MANUAL CHAPTER 2815

CONSTRUCTION AND PREOPERATIONAL INSPECTION
OF PANORAMIC, WET-SOURCE-STORAGE GAMMA IRRADIATORS

2815-01 PURPOSE

To determine whether panoramic, wet-source-storage gamma irradiators (large irradiators) are constructed and equipped and can be operated in accordance with: (a) the license application, including any modifications made in response to DEP findings; and (b) Department regulations, with special emphasis on 10 CFR Part 36, incorporated by reference.

2815-02 BACKGROUND

The Food and Drug Administration expanded authorizations for gamma irradiation for the preservation of foodstuffs. This, along with other market and economic factors, has increased interest in large irradiators. In some cases licensees are having custom-made facilities designed and constructed for or by the firm instead of purchasing "turn-key" facilities from established irradiator manufacturers. Thus, there are needs to ensure that systems and procedures important to safety at large irradiator facilities are adequate when operations begin and will continue to be adequate over years of operation. The Central Office and the Regions will evaluate the initial assurance of worker and public health and safety at large irradiators by conducting construction and pre-operational inspections.

Large irradiator construction can not begin before a license application and the associated fee required by Chapter 218 are received. It is necessary for central office licensing and regional management and staff to work together as soon as a license application is received. A critical part of this effort is the licensing staff's early preconstruction examination of license applications to identify potential engineering and inspection problems that might be averted by the licensing staff's interaction with the applicant.

2815-03 DEFINITIONS

The following lists the systems that are important to safety and defines the related engineering and safety concerns associated with each:

Access Control: Adequacy of access control systems using interlocks and radiation monitors to prevent inadvertent entry to areas where radiation sources are unshielded; to provide emergency exits; and to ensure compliance with all the requirements of 10 CFR 36.23. For computer-controlled access-control systems, licensing staff should consider expert evaluation of the software/system logic before to operational testing.

Site: Potential need for protection against flooding and earth slides.

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Base (soil, rock) for the Pool and Shielding Structures: Strength, settlement, liquefaction, ground water, soil compaction.

Footers and Foundations for the Pool and Shielding Structures: Strength and reinforcement, alignment with pool and shielding structures.

Pool and Shielding Structures: Strength and reinforcement, proper density of shielding materials, correct dimensions, minimization of voids in concrete or other shielding.

Pool Liner: Contact with pool structure, penetrations in the liner, leak-tight welds.

Pool Plumbing: Makeup water system; water cleanup system; effect of construction materials on pool-water chemistry; drainage system (potentially contaminated spilled water should flow into the pool); siphon breakers; radiation detection and alarm systems.

Penetrations Through Shielding: Any significant effect on structural strength, shielding, or both.

Source-Rack Mechanical Positioning System: Strength and stiffness of the rack and positioning cables or chains, source shroud will not interfere with source positioning, adequacy of motive power, potential for jamming.

Source-Rack Movement and Position-Sensing System: Structural attachments for electrical and mechanical transducers, adequacy of transducers for interacting with the source-rack control system.

Source-Rack Electrical Control System: Adequacy of the design of logistical and operational electrical circuitry and electromechanical components, to ensure unambiguous response of the system, which includes programmable controllers or computers and their interaction with operations, interlocks, doors, signals, and alarms.

Source-Leak Detection: Adequacy of systems for detecting and isolating leaking sources.

Hard Wiring: Adequacy of wire gauge and insulation to safely carry design currents and to withstand radiation and ozone damage if exposed; locating and attaching wiring to prevent fretting, wear, and exposure to potential fire hazards; accessibility to wiring for inspection and repair.

Uninterruptable Electrical Power Supply: Adequate and reliable power capability to operate all electrical systems that are important to safety (including backup power sources); compatibility of the power supply with the electrical system.

Fire Protection System: Adequacy to detect fire and smoke and to be manually as well as automatically initiated; must ensure that raised sources are immediately lowered into the pool.

Emergency Systems for Returning an Up-stuck Source Rack to the Pool: Capability of the electrical control system to sense and signal the occurrence of an up-stuck source-rack; adequacy of mechanical or electrical means for personnel to safely release and lower the rack; need for, and adequacy of, a system to cool the source-rack until it can be released and lowered.

Ozone Ventilation System: Capability of the system to be properly initiated and to provide adequate volume flow rate of air to protect personnel and components.

System for Transferring Sources from and to Transport Vehicles: Adequately sized openings in the shield-structure roof if sources are roof-loaded; structural adequacy of the

roof-shield plug and its supports for its removal and replacement; structural and mechanical adequacy of systems for moving shipping containers into and out of the pool area.

Other Potential Technical Safety and Operational Problems: Potential safety and operational problems not specifically covered by this instruction, but which are identified by regional licensing and engineering support staff.

2815-04 RESPONSIBILITIES AND AUTHORITIES

Before initial operation of a large irradiator, central office and regional inspection management and staff will conduct construction and pre-operational inspections in a joint cooperative effort to accomplish the purpose of this Chapter.

04.01 Director, Bureau of Radiation Protection Approves the inspection program.

04.02 Chief, Division of Radiation Control in coordination with Regional Program Management. Develops, implements, and assesses the effectiveness of the inspection program. Ensures that central office staff cooperate with regional staff in implementation of the inspection program.

04.03 Regional Program Manager. Ensures that regional inspection staff cooperate with central office in implementing this instruction.

04.04 Chief, Radioactive Material Licensing Section

a. Arranges for engineering support to perform reviews and inspections as required by this instruction and as requested by the regional materials staff.

b. Ensures that management is made aware of any construction or preoperational problems as soon as possible.

04.05 Chief, Division of Radiation Control. Has project management responsibility and ensures coordination between the central office inspection and materials licensing staff and regions so that the objectives of the program are accomplished.

04.06 Supervisor, Regional Radioactive Materials Program. Ensures that inspections are planned and conducted by appropriately qualified inspectors and coordinated with the central office licensing staff, and that inspection reports are prepared, approved, and a copy forwarded to central office.

2815-05 BASIC REQUIREMENTS

Basic requirements apply only to systems that are important to safety and their attendant engineering and safety concerns (see 2815-03, Definitions).

The engineering support staff should: (a) execute the instructions for preconstruction activities (05.01); (b) perform the construction inspections (05.02); (c) document any inadequacies or uncertainties in systems that are important to safety; and (d) recommend to the licensing staff what should be done before a license is granted or denied.

05.01 Preconstruction Activities (Engineering)

a. Examine the license application to determine whether there are apparent or potential structural, seismic, construction, or operational engineering problems with

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systems that are important to safety. Document any problems and discuss them with the licensing staff. (The licensing staff will calculate the radiological adequacy of shielding.)

b. Examine the license application to determine whether systems important for safety are engineered to adequately meet the design and performance requirements of Part 36 Subpart C.

c. Examine the license application to determine whether the applicant has provided a construction plan and a schedule that will allow DEP to keep informed of construction progress and make inspections at appropriate points. If a plan and a schedule have not been submitted or are inadequate to cover construction activities, recommend to the licensing staff that this information is needed if construction is to be properly inspected. Deleted: NRC

d. Examine the license application to determine whether the applicant has made adequate arrangements to ensure (independently of its construction and equipment contractors) that its facility is constructed according to design requirements. If the applicant has not provided adequate information, recommend to the licensing staff that this information is needed. Independent construction inspections are adequate only if inspections are conducted at critical points during construction. Inspection of only finished foundation and structural work is unacceptable.

e. If local building inspectors or independent engineering firms are involved, examine their construction inspection procedures, holdpoints, and documentation requirements to determine to what extent their inspections would be adequate to ensure that the facility is constructed as designed. Ask the licensing staff to request the applicant to provide this information if it is not included with the application.

f. The activities and results of preconstruction activities are to be documented as memoranda from engineering support to licensing management, with copies to regional management. Deleted: management Deleted: MSIB

05.02 *Construction Inspections (Engineering)*

a. If the engineering support staff decides that the applicant has made adequate arrangements to determine (independently of its construction and equipment contractors) whether its facility is constructed as designed, the DEP inspection requirements are to: Deleted: NRC

(1) Inspect the facility once during construction, preferably when construction is being inspected by the applicant's inspectors;

(2) Determine whether the applicant's inspections are adequately conducted and documented;

(3) Review inspection documentation to determine whether all systems important to safety thus far constructed were inspected and if the construction was as designed; and

(4) Complete the review initiated in (3),above, after construction is completed.

b. If the engineering support staff decides that the applicant cannot, by its choice or by necessity, arrange for adequate independent construction inspections, the requirements are to:

(1) Take advantage of any independent construction inspections that are conducted by following the requirements of 06.02a, where applicable;

(2) Inspect the facility at least twice during construction to determine whether all systems important to safety are constructed as designed;

(3) Report any deviations and the need for corrective actions to the licensing staff; and

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(4) Inspect the adequacy of any corrective actions.

c. If construction deviations are detected by the applicant's or DEP's inspectors, the DEP licensing staff is to determine the need for and the adequacy of any corrective actions proposed by the applicant and is to inspect the results of the corrective actions.

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d. The activities and results of construction inspections are to be documented as Inspection Reports.

05.03 Preoperational Inspections (Engineering and Radiation Safety)

a. Before Sources Are Installed. The requirement is to have the licensee and its trained, qualified personnel successfully exercise all operational systems that are important to safety. Here, "successful" means that any equipment, control, personnel, or procedural problems are corrected, and that the exercise is repeated successfully, with reasonable assurance that the operational system will continue to be satisfactory.

The detailed inspection should be conducted before the applicant has received sources, to ensure that the following criteria for acceptance testing, required by 10 CFR 36.41, are met:

Shielding - verify construction met design.

Foundations - verify construction met design.

Pool Integrity - verify construction met design and that the pool integrity has been tested.

Water-Handling System - verify that water purification system, conductivity meter, and water-level indicator systems operate properly.

Source-Rack - verify movement of source racks for proper operation, including source-rack lowering because of simulated loss of power; verify that the conveyor system movement meets the requirements of 10 CFR 36.35; and verify testing of any limit switches and interlocks used to protect the source-rack and mechanism that moves the source rack from moving product carriers.

Access Control - verify that the complete access control functions as designed and ensure that all alarms, controls, and interlocks work properly. If the emergency exit relies on power, or involves a time delay, notify the licensing reviewer, Central Office and Regional Management for further review.

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Fire Protection System - verify ability of heat and smoke detectors to detect a fire, activate alarms, and cause the source rack to become fully shielded.

Source Return - verify licensee's ability to return source racks to fully shielded position on loss of offsite power.

Computer Systems - for access-control systems that are computer-controlled, verify that access control will work with loss of offsite power and that the computer has security features which prevent operators from overriding the access-control system when it is required to be operable.

Wiring - verify construction met design.

Systems for Transferring Sources from and to Transport Vehicles - verify construction met design.

b. When First Sources Are Installed. The first requirement is to witness:

(1) Unloading of a simulated and then an actual source- shipping container from the transport vehicle, and radiological monitoring for contamination;

(2) Transferal (by crane or other means) of a simulated and then an actual source into the pool area; and

(3) Transferal of sources into pool racks from shipping containers, and attendant radiological monitoring to determine whether the operations are successfully conducted and comply with all license conditions and pertinent NRC regulations incorporated by reference.

The second requirement is, with the facility now equipped with radioactive sources, to repeat the requirements of 05.03(a) above, and to determine whether radiation levels outside of the shielding (sources raised) are within requirements.

c. Other Preoperational Requirements

(1) Determine whether enough operators are trained in accordance with the DEP-approved training requirements in the application to be able to safely operate the irradiator in accordance with the applicant's plan for initial operation.

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(2) Determine whether the DEP-approved radiation safety program has been implemented at the irradiator site.

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05.04 The results of construction and preoperational inspections should be documented in formal inspection reports and distributed in accordance with a standardized distribution list.

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END

4.4

The Program as adapted many NRC Inspection Manual Chapters (MC) and Inspection Procedures (IP) for state use. While the original of these MCs and IPs where taken from the NRC they have been modified to suit state needs. The intent is to continue similar procedure so the transition from NRC regulation oversight to state is as seamless transparent as possible.

4.4.2 & 4.4.3

When an inspection occurs, the inspector makes field notes of his visit, the items, procedures, licensee actions, etc., he/she looked at during the inspection, and also notes individuals met or interviewed as part of the inspection. The inspector then drafts an inspection report, which is forwarded to his/her supervisor for review.

If several staff conduct the inspection, the lead inspector will designate who will draft the inspection report.

The supervisor reviews the inspection report, makes comments as necessary, and returns it to the inspector for further action, if necessary, or to finalize it. If further action is needed, the (lead) inspector makes the appropriate coordinating activities to conclude the inspection and its report and then finalizes it. The supervisory review also ensures that confidentiality is protected (e.g., by being so marked and kept separate) while public access to the non-confidential material is guaranteed.

When the inspection report is being finalized, the results letter is also drafted for supervisor review and comment. The (lead) inspector makes preliminary entry of the inspection results into the Department's eFACTS (Environment, Facilities, Applications and Compliance Tracking System) computerized database. (The acronym describes what this database is and does; for further information see eFACTS description and information.)

If necessary, the supervisor makes contact with counsel for review of any legal actions that may arise from the inspection.

The results letter, upon being finalized, is signed and mailed to the licensee, with copies made after signature but before mailing, for regional (and central office) files. Any attachments to the letter are similarly copied so that complete documentation of the mailed packet is accomplished. If necessary, the inspection report in eFACTS is amended.