ENCLOSURES

31-44

ENCLOSURE 31

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,

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.

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

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.

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.

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.

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

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 knowledgeable 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.

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 NRC, pursuant to 10 CFR 21.21.

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

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.

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.

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.

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,

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 .

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.

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.

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 addressed.

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.

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.

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.

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

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.

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.

   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.

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

system must be calibrated and checked in accordance with the requirements of 10 CFR 35.633 and 35.643. During the inspection, the inspector should review selected dosimetry worksheets from the previous full calibration and spot check measurements required by 10 CFR 35.633 and 35.643. 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 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.

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.

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.

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

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.

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.

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.

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. 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. The inspector should verify that the applicator meets the manufacture and distribution requirements for medical use in 10 CFR 35.49.

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 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 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.

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.

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. 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.

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.

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.

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.

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 - 1757. "Consolidated Decommissioning Guidance."

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.

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.

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.

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.

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 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.

For further inspection guidance, refer to MC 2800.

END

Appendices:

A. "Decay Factors for Strontium-90 Sources"

APPENDIX A

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

ENCLOSURE 32

DEP INSPECTION MANUAL

INSPECTION PROCEDURE 87133

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.

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

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.

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.

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.

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.

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.

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.

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.

   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.

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.

   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.

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.

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 addressed.

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 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.

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.

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.

   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

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.

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.

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.

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.

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

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.

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.

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

inspector should immediately contact DEP regional management for further guidance.

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.

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 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.

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.

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 - 1757. "Consolidated Decommissioning Guidance."

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.

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.

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.

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.

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.

END

ENCLOSURE 33

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.

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.

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.

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.

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.

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 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.

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.

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.

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.

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.

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 35.41. 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 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 35.3045, "Report and notification of a medical event." 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.

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.

k. Reserved.

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.

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).

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.

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.

   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:

(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; 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 35.61. 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.

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.

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.

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.

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 35.27 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.

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.

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 35.24(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.

   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 35.27(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.

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.

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.

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.

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 - 1757. "Consolidated Decommissioning Guidance."

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.

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.

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.

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.

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.

For further inspection guidance, refer to MC 2800.

END

ENCLOSURE 34

DEP INSPECTION MANUAL

INSPECTION PROCEDURE 92701

FOLLOW-UP

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.

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 Reserved.

03.04 Reserved.

END

ENCLOSURE 35

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 before the inspector arrives at the site of inspection.

0300-02 POLICY

The general policy for non-reactor 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 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 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 of the inspection until the inspector arrives at the site where the inspection is to be conducted.

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 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 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.

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.

End

ENCLOSURE 36

DEP INSPECTION MANUAL

MANUAL CHAPTER 0610

RADIOACTIVE MATERIAL SAFETY INSPECTION REPORTS

INSPECTION REPORTS

Table of Contents

0610-01 PURPOSE

To provide guidance on inspection report content, format, and style for radioactive material inspection reports.

0610-02 OBJECTIVES

To ensure that inspection reports:

02.01 Clearly communicate significant inspection results to licensees, DEP staff, and the public.

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.

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.

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.

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.

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).

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 a DEP license or permit. The provisions listed as applicable to "licensees" in this chapter are also applicable to 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 certificate holder's failure to meet a contract requirement related to DEP activities, where the DEP has not placed the requirement directly on the 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 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.

Violation. The failure to comply with a legally binding regulatory requirement, such as a statute, regulation, order, license condition, or technical specification.

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 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

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 inspection staff, the report numbers should be issued per regional instructions and should be consistent with Departmental templates.

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.

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.

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.

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.

0610-05 GUIDANCE FOR INSPECTION REPORT CONTENT

This section provides general guidance on the contents of an inspection report for radioactive materials 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.

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.

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 write-up 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 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.

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.

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.

c. 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 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.

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. 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."

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.

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.

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.

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.

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.

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."

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.

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.

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?

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.

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.

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.

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.

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.

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."

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.

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 certificate holder fails to meet a contract requirement related to DEP activities, the failure may result in a Notice of Nonconformance. These non-escalated enforcement actions follow a similar format to NOV's and require a similar level of report detail.

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 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.

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.

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.

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.

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

APPENDIX B

Reserved

APPENDIX C

Reserved

APPENDIX D

Reserved

Reserved.

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.

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

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).

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.

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)

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

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.....

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

ENCLOSURE 37

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.

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.

02.02 Classified Information. Information in any form outside of Commonwealth access and jurisdiction determined by federal authority to be kept secret in the national interest.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

c. Ensure that management and staff are cognizant of, and adhere to, the policies and guidance in this inspection manual chapter (IMC).

03.02 Inspector Supervisors

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.

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.

d. Review and approve extensive list of documents requested from licensees.

03.03 Inspectors

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.

03.04 Division of Radiation Control

a. Develops and interprets the information contained in this IMC.

b. Provides guidance on situations not covered in this IMC.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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)

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
4. Do I need something in writing from the licensee that says they	No.	

have reviewed the images for safeguards, personal privacy and propriety information?		
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 <u>can</u> be forwarded electronically (via email or fax) . Images that contain classified or safeguards information <u>cannot</u> 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	If the images **<u>are used</u>** to substantiate an inspection finding and they do not contain classified or safeguards information, they are considered official agency records. **Examples** of images <u>used</u> 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 **<u>are not</u>** used to substantiate an inspection finding and they contain personal privacy, classified, proprietary or safeguards information they <u>must</u> be destroyed in accordance with DEP requirements.	

destroyed? If images are not used to support inspection findings can they be retained for training purposes?	**Examples** of images <u>not used</u> to support an inspection finding include: (1) those images that are used as memory 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 <u>do not</u> 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 <u>not</u> the basis for an inspection finding.	

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. There are no agency requirements that non-sensitive photographs be labeled and dated. However, for ease of	10 CFR 2.390

	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.	

ENCLOSURE 38

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 approve the official version of record and 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 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.

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 appropriate NRC program office 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.

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. 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. Note: Publication and public distribution of PN's in this category may need to be restricted.

k. 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.

l. 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.

m. 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.

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 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."

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 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 appropriate NRC program office 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

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

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	Agreement State Liaison (opt)
Affected States	RCPD (opt)

ENCLOSURE 39

DEP INSPECTION MANUAL

MANUAL CHAPTER 1220

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

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.

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."

02.03 To provide information to appropriate regional offices and to DEP's Central Office regarding licensees operating under reciprocity.

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.

03.04 Reciprocity. Department recognition of certain Agreement State, Non-Agreement State and NRC licenses for work performed in areas of Department jurisdiction.

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.

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 an annual fee invoice for renewal of reciprocity. If there is a request for initial approval of reciprocity or if a current reciprocity requires updating for annual renewal, provide: a Procedures Letter (Appendix II) with the procedures and information required for filing an initial or updated DEP Form 241 and for withholding reciprocity information from public disclosure; the applicable regulations and Information Notices; copies of DEP Form 241; and other pertinent information.

   Note: The expiration date of licenses upon which reciprocity is based will be monitored. The status of those licenses must be current, extended or timely filed pending renewal. The licensing section will contact the licensee or issuing agency for confirmation of license status and to update documentation. Reciprocity privileges are automatically suspended when the licensee no longer satisfies all the requirements for reciprocity. The general license of reciprocity is subject to revocation if the licensee fails to maintain the requirements for reciprocity or comply with license conditions or applicable regulations.

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.)

END

Appendices:

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.)

APPENDIX I

PROCEDURES AND GUIDELINES FOR PROCESSING DEP FORM 241

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

The following points address requirements for filing the initial DEP Form 241.

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. At least three days prior to the first time that an Agreement State, Non-Agreement State or NRC licensee conducts licensed 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.

   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.

   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 will normally identify work to be conducted during a calendar year periods. But the license may identify any work over a contiguous period beyond the calendar year subject to the limitation of 180 days per calendar year. Work schedules may be subsequently revised through filing of an updated DEP Form 241 except that no fee

will be due on an active reciprocity authorization until the anniversary month of issuance.

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.

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.

i. 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.

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 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 calendar year 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 that 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.

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 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

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.

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)

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)

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.

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)

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, 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

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.

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, 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, and 70) incorporated by reference

END

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, 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 (YYYY) calendar year period commencing (MM/DD ending MM/DD), provided the licensee narrows down or deletes dates as they become known. For example: the initial DEP Form 241 may list 2007 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 DEP. 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.

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 filing of DEP Form 241 for reciprocity of a specific license requires payment of a fee. The fee will be assessed annually on the anniversary of the issuance of the reciprocity for as long as the licensee conducts reciprocity activities in Pennsylvania.

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). 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:

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, DEP 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.

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.

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.

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.

APPENDIX III

INSPECTION OF RECIPROCITY LICENSEES

A. PURPOSE

Policy and guidelines for performing inspections of licensees working under reciprocity.

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:

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.

   To determine if a reciprocity licensee should be a candidate for inspection, the central office licensing section should do the following:

   a. Determine if the reciprocity licensee has had DEP enforcement in the past 2 years.

   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.

   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.

   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.

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

ENCLOSURE 40

DEP INSPECTION MANUAL

MANUAL CHAPTER 1301

RESPONSE TO RADIATION SOURCE INCIDENTS

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.).

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.

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.

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.

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:

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.

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

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.

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

Examine regulatory significance of the incident and close out the DEP response, considering the following factors:

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"

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

[i] 61 FR 20944, May 8, 1996.

APPENDIX 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

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

ENCLOSURE 41

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

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 (See NRC Management Directive MD 8.1 Abnormal Occurrence Reporting Procedure.) 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 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.

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.

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."

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.

ATTACHMENT 1

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.

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.

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.

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.

3. Include information that the radiation dose information contained in this letter is exempt from disclosure under the Right to Know Law.

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.

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]

END

[1]REAC/TS website: www.orau.gov/reacts/resources.htm

ENCLOSURE 42

DEP INSPECTION MANUAL

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.

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, NRC Office of Federal and State Materials and Environmental Management Programs (FSME)

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.

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 NRC and NRC will 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.

b. 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.

c. 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, Low-Level Waste and Decommissioning Projects Branch (LLDP), Division of Waste Management, NMSS and submit a copy to FSME 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.

ENCLOSURE 43

DEP INSPECTION MANUAL

MANUAL CHAPTER 2602

DECOMMISSIONING OVERSIGHT AND INSPECTION PROGRAM
FOR
MATERIALS LICENSEES

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]

2602-02 OBJECTIVES

02.01 To provide general guidance for the coordination and regulatory oversight of DEP licensed materials facilities undergoing decommissioning.

02.02 To provide general guidance for planning and conducting inspections of DEP licensed materials facilities undergoing decommissioning.

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

To meet these objectives, and assist individuals involved in decommissioning nuclear facilities, DEP staff utilizes NRC NUREG-1757, Consolidated NMSS Decommissioning Guidance, Volumes 1-3, which summarize the regulations, policies, and procedures that DEP staff will use during the decommissioning of 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

[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.

facilities. Any significant deviations from this guidance shall be approved by regional management prior to performing an inspection.

2602-03 APPLICABILITY

This manual chapter applies to all DEP licensees under 10 CFR Parts 30, 40 and 70 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 and 70.38; (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 and 70.38; 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.

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 Central Office. 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.

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.

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.

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.

2602-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Director, Bureau of Radiation Protection . Provides overall direction for the materials decommissioning inspection program.

05.02 Manager, Decommissioning and Surveillance Division. Coordinates, develops, and implements materials decommissioning inspection requirements and policies.

05.03 Regional Program Manager. In concert with Central Office, 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.

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.

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.

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 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 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.

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.

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:

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.

4. Licensee radiation and radioactivity measurement programs provide accurate quantification and classification of radioactivity.

Management oversight of the decommissioning program is conducted by Central Office. The management of specific decommissioning sites may be shared between the regions

and the Central Office. Normally, Central Office will project manage the complex materials decommissioning sites and draw on regional offices for support as needed. Non-complex materials decommissioning sites may be managed in the regional offices and Central Office will provide support as needed.

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.

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, 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 Central Office 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.

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 Central Office 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.

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 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.

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.

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 Central Office, 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.

- 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.

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.

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.

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.

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.

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.

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

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 Central Office 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 DEP 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 DEP 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.

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".

END

ENCLOSURE 44

DEP INSPECTION MANUAL

MANUAL CHAPTER 2800

MATERIALS INSPECTION PROGRAM

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.

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.

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.

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.

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.

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.

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

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

a. Manages the implementation of the inspection program elements performed in a Regional Office.

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.

e. Recommends changes to the materials inspection program to the Central Office Chief, Division of Radiation Control.

04.05 Regional Radiation Protection Supervisor(s)

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.

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.

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].

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.

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].

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 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.

   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.

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.

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.

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.

   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.

(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.

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].

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. 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.

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 the composition of an appropriate team response if the event warrants. 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.

Reactive inspections will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy."

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].

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.

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

(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.

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.

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.

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 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.

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

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.

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.

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.

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)].

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.

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.

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 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.

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 the program manager's or regional director's 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.

07.07Inspection 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.

07.08 Reserved.

07.09 Reserved.

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:

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.

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.

c. Regions performing assist inspections will receive credit toward the operating plan goals for conducting each assist inspection.

d. Reserved.

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:

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?

2. Have there been interactions with DEP personnel that suggest that some employees may be hesitant to raise concerns or present information to DEP?

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.

A letter, signed by regional management (supervisor or higher), 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;

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.

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 Environmental Facility Application Compliance Tracking System (eFacts) to provide necessary security clearance to regional personnel for creating and modifying applicable

facility, inspection and enforcement records.

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, 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 Materials Licensing Application Database. Enclosure 1 provides a listing of license program codes with the associated inspection priorities. Enter data promptly into the database at the time a new license is issued. Client, site, facility and inventory records are also created in eFacts. Compliance records are created in eFacts when an inspection has been performed. The compliance record includes as a minimum, 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, regions should enter the data for the correct next inspection date into eFacts 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.

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.

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. Reserved

ENCLOSURE 1
INSPECTION PRIORITY CODES ASSIGNED TO PROGRAM CODES

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	Use as a primary code.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
		loader (HDR)	
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 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.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
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.
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

[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
			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
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 -	For *in vivo* diagnostic use

[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
		Carbon-14 Urea Capsules	authorized under 10 CFR 30.21
03310	2	Industrial Radiography Fixed Location	Permanent radiographic installation (PRI) or designated field station. Use as secondary 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

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
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 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	Greater than 350 grams of

[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
		Than Universities	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
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

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix
			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
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).

   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.

      1. licensee is unaware of licensed material or DEP regulations for possession, use, transfer, and disposal

      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.

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 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

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.

(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:

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

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.

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.

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
2. Source/Radioactive Material:
   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

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

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
IP 87104	"Decommissioning Inspection Procedures for	N

MC/IP No.	Inspection Manual Chapter/Inspection Procedure Title	Routine (R) or As Needed (N)
	Materials Licenses"	
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
IP 92701	""Follow-up"	R

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)
( ) Followup on previous violations

Inspector(s) _____ Date _____ (Name(s))

_____
(Signature(s))

Approved _____ Date _____
(Name)

_____
(Signature)

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)

AMENDMENT #	DATE	SUBJECT

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.)

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)

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.)

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

-END-

ENCLOSURE 6

Reserved