STATE OF NEW JERSEY
DEPARTMENT OF ENVIRONMENTAL PROTECTION

NEW JERSEY

AGREEMENT STATE APPLICATION

SECTIONS 4.3 & 4.4

4.3 LICENSING PROGRAM

4.3.1 MATERIALS LICENSING

4.3.1
MATERIALS LICENSING

Summary

The licensing program is outlined in the combination of the *Licensing Procedures* (Section 4.3.1 of the application), the *NJEMS Procedures Manual* (Section 4.3.2 of the application), and the *Training and Qualification Manual* (Section 4.6.2 of the application) to form a critical part of the Department's overall radioactive materials regulatory program. These procedures provide the information necessary for licensing staff to process, manage, and track licensing activities.

The New Jersey Environmental Management System (NJEMS) is a database system used by the New Jersey Department of Environmental Protection to centrally locate information regarding licenses, inspection information, enforcement actions and incidents (http://depnet/njems/index.htm). The system currently supports the Bureau of Environmental Radiation's enforcement records and documentation. Development of the portion of this system that will handle review, issuance and tracking of Licensing and Registration documentation to support the proposed Agreement State activities is continuing. An integral part of the licensing process is the Department's ability to track licensing actions. The New Jersey Environmental Management System (NJEMS) will be used by the BER to support collection and review of license applications, as well as monitoring reports and enforcement actions. Once in place (projected date early 2009), this one database will be the digital repository for licensing, inspection, enforcement, and incidents information and permit us to generate and track documents relating to these tasks.

The *Training and Qualification Manual* (Section 4.6.2) documents the license reviewer's qualification progress as well as the steps taken to qualify that individual. The *Training and Qualification Manual* contains an outline of the minimum activities expected by the BER manager and the Radioactive Materials Section (RMS) Supervisor.

The Qualified License Reviewer/Inspector (QLR/I) is required to use the *Licensing Procedures, NUREG-1556, Consolidated Guidance About Materials Licenses,* and the *NJEMS Procedures Manual* as he or she is processing and reviewing license applications, amendments, and renewals. Part of the qualified license reviewer's continuing quality assurance is the ability to demonstrate proper use and implementation of this manual and all associated procedures and guidance documents.

Legal Authority

The New Jersey Department of Environmental Protection (DEP) derives it authority from the Radiation Protection Act (New Jersey Statutes Annotated Title 26:2D-1 et seq), and its regulations are contained in the Radiation Protection Code (New Jersey Administrative Code Title 7 Chapter 28).

4.3.1 Procedures for the Technical Evaluation of Proposed Uses of Radioactive Material

The Radioactive Materials Section (RMS) of the Bureau of Environmental Radiation (BER) is responsible for establishing written licensing procedures for the safe use, storage, and possession of licensed materials. Technical procedures that have been modeled on NRC procedures along with standard review plans, checklists and policies, will assure the applications are thoroughly and equitably evaluated. Source material licensing procedures will be developed for any future Source Material licenses At such time that a facility requests a license for source material the generic licensing and inspection procedures will be modified based on the following list of documents.

NUREG-1620 Standard Review Plan for the Review of a Reclamation Plan for Mill Tailing Sites Under Title II of the Uranium Mill Tailings Radiation Control Act of 1978
NUREG-1609 Standard Review Plan for Transportation Packages for Radioactive Material
Standard Format and Content for Emergency Plans for Fuel Cycles and Materials Facilities - Regulatory Guide 3.67
Guide for the Preparation of Applications for Licenses To Process Source Material - Regulatory Guide 10.4
Division 3, Fuels and Materials Facilities
Division 4, Environmental and Siting
Division 8, Occupational Health
Consolidated Guidance About Materials Licenses (NUREG-1556) Volume 20 - Guidance About Administrative Licensing Procedures

Presently, New Jersey has only one Source Material licensee that is undergoing decommissioning and does not expect any applications for new source material licenses.

The procedures and criteria that will be used to evaluate the use of radioactive materials are included in this section. Pre-licensing guidance and the Risk-Significant Radioactive Material (RSRM) guidance are an essential component of a licensing program. The objective of RSRM guidance is to identify those licenses that require additional security requirements that are currently in Security Orders and Increased Controls. The RMS will be following the pre-licensing guidance provide in the NRC Agreement State letter dated September 22, 2008 – Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will be Used as Specified On a License and the Checklist for Risk-Significant Radioactive Material (RCPD-08-020). This document is Attachement 3 to NJDEP-BER Procedure No. 3.01 and is considered Official Use Only – Sensitive Unclassified Non-Safeguards Information (SUNSI).

The procedures included in this section of the application for processing of licensing actions are as follow:

BER 3.01 – Review of Application for License or Amendment Request
Attachment 1 – Checklist for review of license application

Attachment 2 - Guidance/Checklist for Risk-Significant Radioactive Materials (Not Provided due to Sensitive Nature)
Attachment 3 – Checklist for determining when significant licensing action has taken place that may require an additional onsite inspection
BER 3.02 – Review of Application for Renewal of a Specific License
BER 3.03 – Review of a Request for License Termination
BER 3.04 - Prioritization of Licensing Actions
BER 3.05 - Review of Annual Registration of Generally Licensed Devices
Appendix A - Licensing Forms
Appendix B – Sample Letters
License Conditions
- Fingerprinting
- Increased Control
- National Source Tracking System

Witholding Correspondence

On January 8, 2002, amendments to New Jersey's Open Public Records Act (OPRA) placed new obligations on all State agencies related to providing information to the public. The unqualified access to certain government records can threaten the lives, health, and safety of the citizens of the State and endanger public and private property. The filing of proposed new rule N.J.A.C. 13:1F-1.5 establishes standards for use at all levels of government for determining access to a government record on a record specific and/or request specific basis where there is a bona fide security concern. Since the filing of the proposed rule in 2004, the NJDEP is exempted from the OPRA requirements based on domestic security issues. The NJDEP views all information concerning radioactive material licensee activities as a domestic security issue. Therefore, no procedure regarding withholding information is required.

The required qualifications of license reviewers can be found in the *Training and Qualification Manual*, section 4.6.2 of the application.

NJDEP – BER Procedure No. 3.01
Review of Application for License or Amendment Request

1.0 PURPOSE

1.1. The purpose of this procedure is to define the process for reviewing all types of specific license requests, with the exception of applications for license renewal or request for license termination. Standard review plans, checklists and policies that shall be used during the review process will be identified. The process for issuing a specific license or an amendment to a license and standard license conditions will be provided. The process for denying (State's initiative) or abandoning (applicant's or State's initiative) a request for licensing action shall be defined.

1.2. References

1.2.1. N.J.A.C. 7:28

1.2.2. NUREG-1556, "Consolidated Guidance About Materials Licenses."

1.2.3. Title 10 Code of Federal Regulations

1.3. Computer Based Letters, Forms and Reports

1.3.1. http://www.nj.gov/dep/rpp/download/rmlicap2.pdf

1.3.2. Appendix A – Licensing Forms

1.3.3. Appendix B - Example Letters

1.4. Hardcopy Files

1.4.1. Specific License

1.4.2. License Application and/or Amendment Request Submittal

1.4.3. Deficiency Letter

1.4.4. License Transmittal Letter

1.5. Definitions

1.5.1. Application request means a request for an application for a license from a prospective licensee.

1.5.2. Licensing action means a request or application received from an applicant or a licensee as follows:

1.5.2.1. an application for a license to manufacture, produce, transfer distribute or arrange for the distribution, sell, lease, receive, acquire, own, possess or use any licensed radioactive material;

1.5.2.2. an application for renewal of a license;

1.5.2.3. a request for an amendment to a license, e.g., change in administration, authorized use and/or user(s), RSO, quantity of material, add isotopes, facilities, and etc.; and,

1.5.2.4. a request for termination of a license(s).

1.5.3. Processing means reviewing the application for license or amendment, requesting additional information, if appropriate, and either issuing or denying with or without prejudice, the requested license or amendment.

1.5.4. Denying without prejudice means that the application for license was deficient and denied, but that the applicant may reapply after correcting the deficiencies.

1.5.5. Denying with prejudice means that the applicant for license is not qualified and shall not reapply for a license, e.g., a minor applying for a license to possess and use radioactive material or a non medical qualified individual applying for a license to use radioactive material in the diagnosis and/or treatment of humans.

1.5.6. Regulatory Guide means guidance published by the NRC or the NJDEP, in which each guide defines an acceptable program or part of a program, for the possession and specific use of radioactive materials. An applicant is not obligated to follow one of these guidance documents when developing their program and applying for a license or amendment; however, if not followed, the applicant must demonstrate that the proposed program is at least equivalent to the one described in the guidance document.

1.5.7. Consolidated Guidance About Materials License means guidance published by the NRC in NUREG-1556, in which each volume defines an acceptable program for a specific type of use of radioactive material.

2.0 RESPONSIBILITIES

2.1. Administrative Assistant

The Administrative Assistant is responsible for receiving, logging and acknowledging the receipt of an application for a new license. Requests for amendments to a license shall be received and logged. The Administrative Assistant is responsible for maintaining the computer based and hardcopy files and for tracking the applications for license or amendment during processing. The Administrative Assistant is responsible for responding to requests for license applications by transmitting an application, order form and Internet address of the regulations, and a copy of, or reference to, specific guidance.

2.2. Qualified License Reviewer/Inpsector (QLR/I)

The QLR/I is responsible for reviewing the assigned application, determining if it is complete, requesting additional information as appropriate, and if appropriate, preparing the license or amendment for review and signature by the Radioactive Materials Section Supervisor. The QLR/I following the guidance in N.J.A.C. 7:28-4 and 51.1 (see 10 CFR 30)is responsible for recommending whether an application is deficient and should be denied either with or without prejudice.

2.3. Senior Qualified License Reviewer/Inspector (QLR/I)The Senior QLR/I is responsible for signing licenses and license amendments in the absence of the Radioactive Materials Section Supervisor and for reviewing and approving licenses/amendments completed by the QLR/I and transmittal to the Radioactive Materials Section (RMS) Supervisor.

2.4. Radioactive Materials Section Supervisor

The RMS Supervisor or designee is responsible for assigning a licensing action for processing to a Senior QLR/I (who may delegate to QLR/I). The Radioactive Materials Section Supervisor is responsible for performing quality assurance reviews, approving and signing licenses and license amendments. The RMS Supervisor following the guidance in N.J.A.C. 7:28-4 and 51.1 (see 10 CFR 30) is responsible for denying, with or without prejudice, an application for license or for license amendment.

3.0 PROCEDURE

3.1. **Receipt of an Application or Request**

Upon the receipt of an application for license or a request for a license amendment the following shall be performed:

3.1.1. Priority

An action priority shall be assigned to the application or request in accordance with BER 3.04, "Prioritization of Licensing & General License Registration Actions" and with concurrence of the RMS Supervisor.

3.1.2. Assignment of Reviewer

The RMS Supervisor shall assign applications or amendment requests to the appropriate Senior QLR/I. The review of an application or request shall be conducted by either the Senior QLR/I or QLR/I.

3.1.3. The Administrative Assistant will check that the fee is included, if applicable.

3.1.4. The QLR/I will check that the enclosed fee is correct (see Appendix A NJRAD Form 101). If not, the licensee will be contacted to send the correct amount.

3.1.5. The proper fee will be sent to the Department of Treasury.

3.2. **Processing an Application for License**

3.2.1. The application (Form NJRAD-313 in Appendix A) and all appended and referenced material shall be reviewed. NJDEP specific Rule and Policies, and NRC Consolidated Guidance, Regulatory Guides, Standard Review Plans, Reviewers Evaluation Forms, Technical Assistance Requests, and Checklist (Attachment 1) shall be used, as appropriate, by the reviewer to evaluate the applicant and the application. If additional information is needed, a letter denoting application deficiencies shall be sent by the reviewer or, a meeting with the applicant, and/or a visit to the proposed facility(s) shall be requested by the reviewer.

3.2.2. Sections of the application that do not conform to, or fail to address areas in the appropriate guidance, become deficiencies that must be resolved before the license is issued. The application should be reviewed against the checklist/suggested format in the appropriate NUREG-1556 volume(s). All deficiencies should be clearly documented and communicated to the applicant.

3.2.3. Reviewers should apply the guidance in the NUREG-1556 series to the extent suitable to the applicant's proposed activities and should not apply any standards or criteria for which there is no specific regulatory basis. Reviewers should accept only procedures or proposals that result in a level of safety at least equivalent to that provided for in NRC guidance.

3.2.4. Following the completion of the review of the application and any supplemental material requested by the reviewer, a recommendation to issue a license or deny the application shall be made to the Radioactive Materials Section Supervisor.

3.2.5. If the recommendation is to issue the license and the Radioactive Materials Section Supervisor concurs, the Senior QLR/I or QLR/I shall prepare the license for the Radioactive Materials Section Supervisor's signature. All submitted and referenced information shall be tied- down. Tie-down license conditions are facility-specific conditions used for procedures, radiation detection equipment, use locations, etc., that are not already generically identified on the license.

3.2.6. If the recommendation is to deny the application and the Radioactive Materials Section Supervisor concurs, the reviewer shall prepare a notification to the applicant. The notification shall state the reason for denial and if a new application would be accepted from the applicant.

3.2.7. A license that is issued or renewed should have a 10 year term limit, unless management determines , on a case -by-case basis, that a license should be issued for fewer than 10 years.

3.2.8. It is the policy of NJDEP to conduct an onsite inspection and evaluation of all new radioactive material license applications prior to the issuance of a license. Guidance and Checklists for Prelicensing Inspections and Risk Significant Radioactive Materials are provided in Attachment 2.

3.3. **Processing a Request for License Amendment or Renewal**

3.3.1. A request for an amendment to a specific license need not and probably will not be on a NJDEP form. The request may be a letter plus attachments or a formal application. The request shall be signed by the individual in the position, or higher, that signed the application for license or the request shall be returned for proper signature. Alternatively, the licensing action request may be signed by an individual delegated by the person who signed the application or higher (the Administrator or Radiation Safety Officer).

3.3.2. The initial review of the request for amendment shall determine if the request is so broad that it should be processed as a rewrite of the current license or as a new license. If it's determined that either a rewrite or a new license is appropriate and the Radioactive Materials Section Supervisor concurs, the request shall be returned to the licensee and an appropriate application shall be requested.

3.3.3. The QLR/I should focus the evaluation on only those areas that the licensee indicates need revision. If the licensee completely resubmits the entire application, the reviewer should request that the licensee specifically identify the requested changes. The licensee may opt to resubmit the request and only discuss the specific changes, or may identify the changes by marking or highlighting the modified text.

3.3.4. The first task for the QLR/I is to review the inspection and licensing correspondence, and query the New Jersey Environmental Management System (NJEMS) data base to see if the licensee has been effectively in compliance for the duration of the license. NJDEP licensing management reserves the option to request that the RMS staff perform a comprehensive review of the license even though the request for an amendment or renewal is from a licensee that has been in compliance with the applicable

regulations, but that may exhibit other characteristics warranting a comprehensive review.

3.3.5. The QLR/I should use the following guidance and document any issues with the licensee that may arise during the course of the review.

3.3.5.1. Enforcement History - A licensee that is or has been the subject of an ongoing investigation by the Department or escalated enforcement action within 5 years will be considered for a comprehensive review of the renewal application. Escalated enforcement action includes any Order, civil penalty, or Notice of Violation issued at Severity Levels IV, III, II, or I. ***Note:*** Licenses should not be renewed if they are the subject of an ongoing investigation or pending enforcement action.

3.3.5.2. Loss of Material - If the licensee has been cited with a violation for the loss of control of a reportable quantity of licensed material presumed to be in the public domain in the last 5 years, the license application will be considered for a comprehensive review.

3.3.5.3.Unauthorized Disposal or Release of Material - If the licensee has been cited with a violation regarding unauthorized disposal or release of material in the last 5 years, the license application will be considered for a comprehensive review.

3.3.5.4.Overexposure - If the licensee has been cited for a radiation exposure in excess of regulatory requirements in the last 5 years, a comprehensive review of the license application will be considered. Exposures would include those to members of the public as well as to occupationally exposed individuals.

3.3.6. A request from a medical licensee to add an authorized user to their license shall be accompanied by records of the individuals training and qualifications. Records of training shall be signed by the preceptor and shall not be just a letter stating that these procedures had been performed at another licensed facility.

3.3.7. Where appropriate, material previously received for the license may be incorporated by reference.

3.3.8. A request to add an authorized user to a license shall be accompanied by records of the individuals training and qualifications.

3.3.9. A request to add or replace a Radiation Safety Officer (RSO) or Chair of the Radiation Safety Committee (RSC) shall include training and experience records and duties, responsibilities, and if appropriate availability.

3.3.10. A request to add isotopes, quantities, physical form, use, facilities, instrumentation, or the authorized place of use shall be reviewed in the same way as a request for a partial specific license for that activity.

3.3.11. An amendment to a license is normally amended in entirety and includes new tied-down license conditions as appropriate.

3.3.12. The Radioactive Materials Section Supervisor shall sign the amendment.

3.3.13. To document processing a licensing action the author and reviewer shall use NJEMS.

3.3.14. In the event the Radioactive Materials Section Supervisor is absent, the second review shall be conducted by a Senior QLR/I and the NJEMS log shall be completed by the Senior QLR/I.

3.3.15. Use Attachment 3 to determine if significant licnesing action has taken place that may require an additional onsite inspection.

3.4 Processing of Exemptions For Material Licensees

3.4.1 Licensees may be granted exemptions from NJDEP regulations pursuant to N.J.A.C. 7:28-51, 58, 60.

3.4.2 Applicants requesting exemptions must provide sufficient information for the license reviewer to determine that the proposed exemption was approved by the Commission on Radiation Protection and in accordance with the provisions of N.J.A.C 7:28-2.8.

3.4.3 Temporary exemptions may be granted only after a determination has been made that the circumstances surrounding the request are urgent and temporary and that the exemption can be approved by the Commission on Radiation Protection and in accordance with the provisions of N.J.A.C. 7:28-2.8. Such exemptions should not be exercised repeatedly for the same set of circumstances for the same licensee.

3.4.4 Temporary exemptions may be appropriate when a normal license amendment is not appropriate because of non-recurring, short duration (normally 7 days or less) nature of exemption and the non-compliance would normally result in a Severity Level I violation per NJDEP Regulations.

3.5 Processing Reciprocity Applications

3.5.1 Guidance to the licensing staff for processing reciprocity application NJDEP Form 241 are contained in NJDEP Inspection Manual Chapter 1220 "Reciprocity-Report of Proposed Activities in New Jersey, in Areas of Department Jurisdiction" and Inspection of Reciprocity Licensees Operating Under NJAC 7:28-62" (see 10 CFR 150).

3.6 Emerging Medical Technologies

3.6.1 The specific risks associated with emerging technologies, additional regulatory requirements, and the training and experience requirements for authorized users are evaluated on a case-by-case basis. The licensing guidance for emerging technologies will be modeled on other medical uses with similar risks. Licensing guidance for each specific emerging tecdhnology is available on the Medical Uses Licensee Toolkit page of the NRC we site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

4.0 RECORDS

4.1. Hardcopy

4.1.1. Applications for license plus attachments are kept in the license file.

4.1.2. Requests for amendments are maintained in the appropriate specific license file.

4.2. Computer Based

4.2.1. NJEMS

Attachment 1: Checklist for review of license application **

OK	DEF	NA	Description
			Item 1, New License , Amendment, Renewal
			Item 2, Applicant's Name And Mailing Address
			Item 3, Address(es) Where Licensed Material Will Be Used Or Possessed
			Item 4, Person To Be Contacted About The Application
			Item 5, Radioactive Material Requested
			physical forms listed
			possession limits
			Item 6, Purpose(s) for Which Licensed Material Will Be Used
			Item 7, Individual(s) Responsible For Radiation Safety Program And Their Training
			Item 8, Training Program For Individuals Working In Or Frequenting Restricted Areas
			Item 9, Facilities And Equipment
			Item 10, Radiation Safety Program
			Item 11, Waste Management Program
			Item 12, Appropriate Fees Include
			Item 13, Certification

** In addition to this checklist, reviewers should apply the guidance in the NUREG-1556 series to the extent suitable to the applicant's proposed activities and should not apply any standards or criteria for which there is no specific regulatory basis.

Pre-licensing Guidance

Pre-licensing guidance and the Risk-Significant Radioactive Material (RSRM) guidance are an essential component of a licensing program. The objective of RSRM guidance is to identify those licenses that require additional security requirements that are currently in Security Orders and Increased Controls. The RMS will be following the pre-licensing guidance provide in the NRC Agreement State letter dated September 22, 2008 – Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will be Used as Specified On a License and the Checklist for Risk-Significant Radioactive Material (RCPD-08-020).

BER 3.01 Attachment 3

CHECKLIST FOR DETERMINING WHEN SIGNIFICANT LICENSING ACTION HAS TAKEN PLACE THAT MAY REQUIRE AN ADDITIONAL ONSITE INSPECTION

If recent licensing actions have resulted in one of the following, Radioactive Materials Group staff should determine the need for performing an onsite inspection before the next routine inspection:

1. **Does the licensing action result in increased authorization for types and quantities of radioactive material that could result in a significant potential for increased radiation exposure to the public and occupational workers?**

   ☐ **No**

   ☐ **Yes (Describe)**

   Note: This can be identified by a change to a higher priority (i.e., from a Priority 2 to a Priority 1 license) or an increase in the authorized quantity from a millicurie amount to a curie amount.

2. **Does the licensing action authorize a physical move of a facility or authorize use at a temporary job site(s)?**

   ☐ **No**

   ☐ **Yes (Describe)**

3. **Does the licensing action authorize satellite facilities where material will be used or stored?**

   ☐ **No**

   ☐ **Yes (Describe)**

4. **Does the licensing action increase the types of uses or disposal (incineration) of radioactive materials?**

   ☐ **No**

   ☐ **Yes (Describe)**

5. **Does the licensing action significantly increase the number of authorized users?**

☐ **No**

☐ **Yes (Describe)**

6. Does the licensing action involve a change in the radiation safety officer?

☐ **No**

☐ **Yes (Describe)**

NJDEP – BER Procedure No. 3.02
Review of Application for Renewal of a Specific License

1.0 PURPOSE

1.1. Applicability

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

1.2. References

1.2.1. NJAC 7:28

1.2.2. Title 10 Code of Federal Regulations

1.3. Computer Based Letters, Forms and Reports

1.3.1. NJEMS

1.4. Hardcopy Files

1.5. Definitions

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

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

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

2.0 RESPONSIBILITIES

2.1. Administrative Assistant

The Administrative Assistant is responsible for notifying a licensee that their license(s) will expire in 90 days and sending appropriate guidance document(s) based on input from the technical staff. The Radioactive Materials Section Supervisor shall be informed of licensees that have not submitted renewal applications at least 30 days prior to expiration and of any licenses that have expired. The Administrative Assistant is responsible for receiving, logging and acknowledging the receipt of an application for license renewal and ensuring the applicant is informed that the application is considered to be timely. Maintains the hardcopy file with renewal documentation.

2.2. Qualified License Reviewer/Inspector (QLR/I) The QLR/I is responsible for reviewing the application to see if it is valid and, with the concurrence of the Radioactive Materials Section Supervisor or Senior QLR/I, signing the letter informing the applicant that the application is considered to be timely, and for processing the application, as assigned.

2.3. The Senior QLR/I is responsible for signing license renewals in the absence of the Radioactive Materials Section Supervisor, once a second review has been performed.

2.4. Radioactive Materials Section Supervisor

The Radioactive Materials Section Supervisor is responsible for determining if an application for renewal is timely or if the license has expired and should be terminated. The Radioactive Materials Section Supervisor is responsible for determining if a license should be an expedited renewal form or renewal in entirety and for assigning applications for renewal to a Senior QLR/I (who may delegate to QLR/I) for processing. The Radioactive Materials Section Supervisor is responsible for reviewing, approving and signing the license renewal.

3.0 PROCEDURE

The review of an application for renewal of a specific license shall be conducted by a QLR/I.

3.1. License Expiration

3.1.1. Ninety (90) days prior to a license's expiration date, the licensee should be notified of the pending expiration date and that if an application for renewal is post marked at least 30 days prior to the expiration date, the application will be considered to be timely. If the renewal application is post marked less than 30 days prior to but not after the expiration date, the Radioactive Materials Section Supervisor or designee shall determine if the application should be considered timely.

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

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

3.1.4. The Radioactive Materials Section Supervisor must approve continued operation of any license for which the renewal application was submitted after the license's expiration date as per N.J.A.C. 7:28-51 (see 10 CFR 30).

3.1.5. Processing of terminated licenses is covered in BER 3.03, License Termination.

3.2. Renewal in Entirety

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

3.2.2. The application, all referenced material, prior applications for amendment, and inspection history shall be reviewed. The QLR/I shall use, as appropriate, NJDEP regulations, Consolidated Guidance, Regulatory Guides and/or Review Evaluation Forms. If needed, additional information should be requested from the applicant. In particular NJDEP specific rule and policy should be reviewed if only NRC guidance was utilized.

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

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

3.2.4.1. The authorized place of use and facilities are the same.

3.2.4.2. The program codes for the category-of-use have not changed.

3.2.4.3. The authorized users have not changed.

3.2.4.4. The allowable isotopes, quantities, physical form and use have not changed.

3.2.4.5. The tied down license conditions are the same.

3.2.4.6. Only instruments that will enhance performance have been added.

3.2.4.7. No items of noncompliance equal to or greater than Class IV severity have been observed during inspections of the license. Items of questionable significance that do not satisfies the above requirements, such as adding an authorized user, may be overlooked with concurrence of the Radioactive Materials Section Supervisor.

4.0 RECORDS

4.1. Hardcopy

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

4.2. Computer Based

4.2.1. NJEMS

NJDEP- BER Procedure No. 3.03

Review of a Request for License Termination

1.0 PURPOSE

1.1. Applicability

This procedure defines the process for terminating a license for such activities as possession, use, storage and disposition of licensed radioactive material. This procedure applies to the disposal of licensed material, decommissioning of the site and facilities, and surveys adequate to demonstrate that residual radioactivity is within regulatory limits at such time that a license is terminated.

1.2. References

1.2.1. N.J.A.C. 7:28-12.1 et seq..

1.2.2. NUREG-1757, Vol. 1, 2, 3, "Consolidated Decommissioning Guidance," excluding sections related to a long term control license, ALARA, and institutional and engineering controls.

1.2.3. NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination."

1.2.4. NUREG-1575 - EPA 402-R-97-016, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), August, 2000 (evaluation of residual contamination of building surfaces and in surface soil)

1.2.5. NUREG 1501, "Background as a Residual Radioactivity Criterion for Decommissioning,"

1.2.6. RaSoRS, Radioactive Soil Remediation Standards spreadsheet available at http://www.nj.gov/dep/rpp/ras/rasdown.htm

1.2.7. D & D, Dose Modeling Code (Buildings)

1.2.8. RESRAD, Dose Modeling Code (Soil Concentration Levels)

1.2.9. RESRAD-Build, Dose Modeling Code (Buildings)

1.2.10. RESRAD-Offsite, Dose Modeling Code

1.2.11. Regulatory Guide 1.86 Termination of Operating Licenses For Nuclear Reactors (1974) (provides values for acceptable levels of surface contamination, however, not dose based)

1.2.12. MARSSIM NUREG 1575, Rev.1

1.2.13. MARSAME NUREG 1575, Supplement 1

1.3. Computer Based Letters, Forms and Reports

1.3.1. Appendix A - Licensing Forms

1.3.2. Appendix B – Sample Letters

1.4. Hardcopy Files

1.4.1. Terminated License File

1.5. Definitions

1.5.1. Background radiation means radiation from cosmic sources, naturally occurring radioactive materials, including radon, (except as a decay product of source, special nuclear material, or technologically enhanced naturally occurring radioactive material); and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation

and are not under the control of a licensee or registrant. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Department, other Agreement State, or NRC.

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

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

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

1.5.5. Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental release of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with N.J.A.C. 7:28-15 or 10 CFR 20 Subpart K.

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

1.5.7. License revocation means a license is terminated because the licensee has allowed the license to expire; did not respond after being informed that the license had expired; and/or, did not request that the license be terminated or renewed. NOTE: The Department must take formal action in order to revoke a license under NJAC 7:28-4.17 and under N.J.A.C. 7:28-51.1 (see 10 CFR 30).

2.0 RESPONSIBILITIES

2.1. Administrative Assistant. The Administrative Assistant is responsible for:

2.1.1. Identifying those licenses that have expired and for notifying the Radioactive Materials Section Supervisor

2.1.2. Sending out acknowledgment letters for receipt of termination requests.

2.1.3. Maintaining hardcopy and computer based files.

2.2. Qualified License Reviewer/Inspector (QLR/I). The QLR/I is responsible for:

2.2.1. Processing requests for license termination or for processing expired licenses, as assigned.

2.2.2. Conducting final decommissioning confirmatory and verification surveys, as assigned, or

2.2.3. Overseeing contractors that are conducting final decommissioning confirmatory or verification surveys, as assigned.

2.3. Radiological Assessment Section (RAS) Supervisor. The RAS Supervisor is responsible for:

2.3.1. Assigning a request for license termination or an expired license to a QLR/I for processing. The RAS Supervisor will instruct the technical staff member in the required scope of the termination or expired license process, i.e., whether the licensee is required to submit a License Termination Plan (LTP).

2.4 The Radioactive Materials Section Supervisor. The RMS Supervisor is responsible for reviewing, approving and signing the license termination.

2.4.1 In concert with legal counsel, initiate a petition for revocation of the license or other sanction.

2.5 Bureau of Environmental Radiation (BER) Manager

2.5.1 BER Manager is responsible for reviewing and concurring or not concurring in the recommended petition for revocation of the license or other sanctions.

2.5.2 The BER Manager is responsible for approving the implementation of a revocation action and for signing the final order.

2.5.3 The initial decision to proceed with a revocation can be delegated to the Radioactive Materials Section Supervisor.

3.0 PROCEDURE

3.1. General Provisions

3.1.1. The criteria for termination of a license is listed in NJAC 7:28-12.8, Radiation dose standards applicable to remediation of radioactive contamination of all real property. Remediation standards for unrestricted and restricted use are provided in N.J.A.C. 7:28-12.9, Minimum rememdiation standards for TENORM and source materil; and N.J.A.C. 7:28-12.10, Minimum rememdiation standards for accelerator, byproduct and certain special nuclear material. Requirements pertaining to alternative remediation standards are found at N.J.A.C. 7:28-12.11, Petition for alternative remediation standards for radioactive contamination. The regulations for implementation of decommissioning are below.

N.J.A.C. Section	Description
N.J.A.C. 7:28-12.8	Radiation dose standards applicable to remediation of all real property
N.J.A.C. 7:28-12.9	Minimum standards for TENORM and source material
N.J.A.C. 7:28-12.10	Minimum remediation standards for accelerator produced, byproduct, and certain special nuclear materials
N.J.A.C. 7:28-12.11	Petition for alternative remediation standards for radioactive contamination
N.J.A.C. 7:28-12.12	Requirements pertaining to engineering or institutional controls
N.J.A.C. 7:28-12.14	Requirements pertaining to the final status survey
N.J.A.C. 7:28-12.15	Minimization of contamination

3.1.2. License termination under restricted conditions must demonstrate compliance with N.J.A.C. 7:28-12.11 (e). No credit is given for engineering or institutional controls when demonstrating compliance with the all controls fail dose criterion of 100 mrem/y.

3.1.3. The licensee shall determine the peak annual Total Effective Dose Equivalent (TEDE when calculating TEDE to the average member of the critical group.

3.2. Request for Termination

3.2.1. Following the receipt of a request for termination, a determination of the potential for residual radioactive contamination of the facility shall be made.

3.2.2. The license and inspection history shall be reviewed to determine the potential risk of residual radioactive contamination. The highest risk would be licensees that utilize significant quantities of unsealed radioactive material such as, but not limited to, nuclear pharmacies; waste disposal processing and repackaging services; manufacturing and distribution; nuclear laundries; academic, or medical Type A Broad; and, research and development, Type A Broad. The lowest risk would be licensees that utilize radioactive materials only in the form of sealed sources. Unless there has been a significant leak of a sealed source, the probability of residual contamination is essentially zero. NOTE: However, there have been a number of cases of residual contamination resulting from melting sealed sources contained in measuring gauges.

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

3.3. License Termination - Sealed Sources

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

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

3.3.1.2. Copies of the results of leak tests for each sealed source, if appropriate

3.3.1.3. Copies of the records of disposal, decay or transfer to an authorized recipient, for each sealed source.

3.3.1.4. Copies of periodic inventories, if appropriate.

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

3.3.1.6.The licensee has submitted a properly completed Form NJRAD-314 "Disposition of Radioactive Material."

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

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

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

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

3.4.1.1. A listing of licensed radioactive materials currently or last possessed including type, isotope and quantity, serial number, vendor, date received and use.

3.4.1.2. Copies of the results of leak tests for each sealed source, if appropriate.

3.4.1.3. Copies of the records of disposal, decay or transfer to an authorized recipient, for each radioactive material.

3.4.1.4. Copies of periodic inventories, if appropriate.

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

3.4.1.6. licensee has submitted a properly completed Form NJRAD-314, "Disposition of Radioactive Material".

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

3.4.3. If the information is incomplete, appears to be inaccurate, the final survey revealed radioactive contamination or the licensee has possessed unsealed radioactive material with a half life greater than 30 days, an inspection of the facility may be conducted.

3.4.4. If the inspection reveals that all radioactive material has been properly disposed of and an independent survey reveals no residual activity, the license shall be terminated.

3.4.5. However, if items of noncompliance were noted during the inspection enforcement action shall be taken prior to license termination.

3.4.6. If an independent survey reveals possible residual activity the licensee shall be requested to submit a sufficient License Termination Plan (LTP) such that the facility will be decontaminated to levels acceptable for unrestricted use or restricted use. N.J.A.C. 7:28-12.8, 12.9, 12.10, 12.11, NUREG- 1575 and the most recent version of the Department's *Field Sampling Procedures* Manual (available on the Department's web site) can be used in the development, implementation of the LTP and the termination of the license(s). NUREG 1727 can be used to evaluate the LTP by the RAS staff with the exception of chapters on Restricted Use and Alternate Criteria, Engineering controls, and Long Term Control licenses. There is no provision for ALARA in Subchapter 12. The NJDEP shall not approve alternative standard petitions that include institutional and engineering controls where failure of those controls, not including the failure of a radon rememdiation system, would result in more than 100 mrem (one mSv) total annual effective dose equivalent. Institionsal and engineering controls are defined in N.J.A.C. 7:28-12.3. In addition, other guidance and/or modeling codes may address specific issues and may be used as needed (see sub-Section 1.2 of this procedure).

3.4.7. A checklist for review of license termination is included as Attachment 1.

3.4.8. Appendix B contains the appropriate letters for either a Request for Additional Information or approval of license termination.

3.5. Expired License

3.5.1. Licensee Contacted

3.5.1.1. Within ten (10) working days following the expiration date of a license without the receipt of a request for license termination or license renewal, the licensee shall be contacted by telephone or in person and informed that the license expired.

3.5.1.2. The licensee shall be informed that any activity using radioactive material under the license shall cease, the licensed material shall be placed in storage or disposed of, and an application for license termination shall be submitted within 30 days.

3.5.1.3. If the licensee intends to continue licensed operations and states that the failure to submit an application for license renewal was just an oversight, the licensee shall be informed that operations shall cease and that an application for license renewal (extension) should be submitted as quickly as possible.

3.5.1.4. The licensee shall be informed that operation without a current license constitutes noncompliance and that appropriate enforcement action will result.

3.5.1.5. The licensee shall be informed that only the NJDEP with approval of the Commission on Radiation Protection may authorize continued use of radioactive material without a current license, i.e., grant an exemption.

3.5.1.6. The above contact shall be recorded in a Confirmatory Action Letter and transmitted to the licensee by Registered Mail, Return Receipt Requested. (Appendix B contains sample letters)

3.5.2. Licensee Not Contacted

3.5.2.1. If the licensee cannot be contacted either by telephone, visit to the address on the license or all other reasonable efforts, the authorized place of use shall be inspected and surveyed.

3.5.2.2. If no radioactive materials are found and the survey indicates the facility is free of radioactive contamination, necessary legal action may proceed in order to revoke the license.

3.5.2.3. If residual contamination is discovered, the facility shall be decontaminated to acceptable levels and the license revoked.

4.0 RECORDS

4.1. Hardcopy

4.1.1. Terminated License File

4.2. Computer Based

4.2.1. Standard Termination Letter

4.2.2. Form NJRAD-314, "Disposition of Radioactive Material"

Attachment 1 - Checklist for review of license termination

			a) a listing of licensed radioactive materials currently or last possessed including type, isotope and quantity, serial number, vendor, date received and use.
			b) copies of the results of leak tests for each sealed source, if appropriate.
			c) copies of the records of disposal, decay or transfer to an authorized recipient, for each radioactive material listed in a) above.
			d) copies of periodic inventories, if appropriate.
			e) a copy of remediation standards and documentation on how they were developed, such as computer model runs and justification of all assumptions.
			f) a copy of the results of the final survey of the area where radioactive materials were used and stored. The record should include the type of instrument(s) used, the minimum detectable activity, and the last calibration date.
			g) licensee has submitted a properly completed Form BER-103, "Disposition of Radioactive Material.

NJDEP – BER Procedure No. 3.04
Prioritization of Licensing & General License Registration Actions

1.0 PURPOSE

1.1 Applicability

The purpose of this procedure is to define the process for prioritizing each licensing or registration action received by the Radioactive Materials Section. Implementation of this procedure will assure that each licensing or registration action will be processed in a timely and efficient manner.

1.2 References

1.2.1 NJAC 7:28

1.2.2 Title 10 Code of Federal Regulations

1.3 Computer Based Letters, Forms and Reports

1.3.1 NJEMS

1.4 Hardcopy Files

1.5 Definitions

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

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

1.5.3 Registration action means a response to the receipt of quarterly shipping reports from device manufacturers that require the radioactive materials section to contact the recipient of the generally licensed device(s) to initiate registration of the device(s).

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

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

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

1.5.7 Timely Renewal means receipt of an application for renewal of a license that has been postmarked or received 30 days or more

before the license's expiration date. The license remains in effect until processing of the application for renewal has been completed.

2.0 RESPONSIBILITIES

2.1 Administrative Assistant. The Administrative Assistant is responsible for:

2.1.1 Receiving, and logging and acknowledging the receipt of a renewal, amendment, or termination request, a new application, or an annual general license registration,

2.1.2 Maintaining the hardcopy and the computer based letters, forms and report files, and

2.1.3 Updating the files, as necessary.

2.1.4 Setting initial priority.

2.2 Qualified License Reviewer/Inspector (QLR/I)

2.2.1 The QLR/I is responsible for processing the assigned licensing or general license registration actions in accordance with the priorities.

2.3 Radioactive Materials Section Supervisor. The Radioactive Materials Section Supervisor or Senior QLR/I is responsible for:

2.3.1 Assigning a priority to a licensing action when administrative assistant has questions and

2.3.2 Assigning the licensing action to a Senior QLR/I (who may delegate to a QLR/I) for processing.

3.0 PROCEDURE

3.1 Licensing Actions - Priorities

Every licensing action request is assigned a default priority of ninety days for completing the processing of the action. Notice of deficiencies of the request will be sent to the licensee within 45 days.

3.2 The priorities for licensing actions follow Priority Time Increment Licensing Action as found in the NJEMS Procedures. If there is a statement on the request for expedited processing and approved by the Radioactive Materials Section Supervisor, the Radioactive Materials Supervisor will assign a due date for completion of review that is less than ninety days.

3.3 The prioritization for general license device registrations is dictated by the receipt of the quarterly reports from the manufacturers.

4.0 RECORDS

4.1 Hardcopy

4.1.1 Requests for applications are maintained in a file.

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

NJDEP – BER Procedure No. 3.05
Review of Annual Registration of Generally Licensed Devices

1.0 PURPOSE

1.1. Applicability. The purpose of this procedure is to define the process for reviewing General License Registrations. Standard review plans, checklists and policies that shall be used during the review process will be identified. The process for handling a General License Registration will be provided.

1.2. References

1.2.1. N.J.A.C. 7:28-52.1

1.2.2. Title 10 Code of Federal Regulations

1.3. Computer Based Letters, Forms and Reports (NJEMS)

1.4. Hardcopy Files

1.4.1. General License Registration NJRAD Form 664

1.5. Definitions

1.5.1. General License Registration means the annual registration of generally licensed devices which meet the criteria set for the in N.J.A.C. 7:28-52.1 (see 10 CFR 31).

1.5.2. Registration action means a form received from a registrant as follows:

1.5.2.1. a registration form for an annual General License Registration;

1.5.3. Processing means reviewing the annual general license registration packet, and requesting additional information, if appropriate.

2.0 RESPONSIBILITIES

2.1. Administrative Assistant

The Administrative Assistant is responsible for receiving, logging and acknowledging the receipt of an annual registration packet. The Administrative Assistant is responsible for maintaining the computer based and hardcopy files and for tracking the applications for annual registrations during processing. The Administrative Assistant is responsible for responding to requests for annual registration packets by transmitting a packet, regulations, and reference to specific guidance.

2.2. Qualified License Reviewer/Inspector (QLR/I) The QLR/I is responsible for reviewing the assigned annual registration, determining if it is complete, requesting additional information as appropriate, and if appropriate, preparing the registration for review and signature by the Radioactive Materials Section Supervisor. The QLR/I is responsible for recommending whether a registration is deficient and requires additional information. The Senior QLR/I is responsible for signing registrations in the absence of the Radioactive Materials Section Supervisor.

2.3. Radioactive Materials Section Supervisor

The Radioactive Materials Section Supervisor is responsible for assigning a registration action for processing to a Senior QLR/I (who may delgate to QLR/I). The Radioactive Materials Section Supervisor is responsible for reviewing, approving and signing registrations.

3.0 PROCEDURE

3.1. Receipt of a General License Registration Packet

Upon the receipt of an application for a General License Registration the following shall be performed:

3.1.1. Priority

An action priority shall be assigned to the registration request in accordance with BER 2.04, "Prioritization of Licensing & General License Registration Actions" and concurred with by the Radioactive Materials Section Supervisor.

3.1.2. Assignment of Reviewer

The Radioactive Materials Section Supervisor shall assign a Senior QLR/I t to process the registration. The review of an application or request shall be conducted by a QLR/I or the Senior QLR/I.

3.1.3. The Administrative Assistant will check that the fee is included, if applicable.

3.1.4. The QLR/I will check that the enclosed fee is correct. If not, the appropriate responsible party will be contacted to send the correct amount.

3.2. Processing a General License Registration

3.2.1. The application (Form NJRAD-664) and all appended and referenced material shall be reviewed. NJDEP specific Rule and Policies, and NRC Consolidated Guidance, Regulatory Guides, Standard Review Plans, Reviewers Evaluation Forms and Technical Assistance Requests shall be used, as appropriate, by the reviewer to evaluate the registration. If additional information is needed, the appropriate responsible party will be contacted.

3.2.2. The reviewer shall assure that the review of the registration includes the following commonly missed items:

3.2.2.1. Application signed by the highest ranking corporate, partnership, or governmental officer or official at the facility,

3.2.2.2. Complete contact address and phone number(s) included.

3.2.3. Following the completion of the review of the application and any supplemental material requested by the reviewer, a recommendation to issue the registration shall be made to the Radioactive Materials Section Supervisor.

4.0 RECORDS

4.1. Hardcopy

4.1.1. Applications for registrations plus attachments are kept in the registration file.

4.2. Computer Based

4.2.1. NJEMS files

BER Licensing Procedures

APPENDIX A

Licensing Forms

NJ Department of Environmental Protection
BUREAU OF ENVIRONMENTAL RADIATION
RADIOACTIVE MATERIALS SECTION
PO BOX 415, TRENTON, NEW JERSEY 08625-0415
Radioactive Material License Application Instructions
Rev 3, September 2008

Regulations:

Use of radioactive material in New Jersey is governed by New Jersey Administrative Code Title 7, Department of Environmental Protection, Chapter 28, Radiation Protection Programs (N.J.A.C. 7:28). Regulations for licensing of diffuse naturally occurring or accelerator produced radioactive material are in subchapter 4. Regulations for licensing of byproduct and source material are in subchapters 52-63 inclusive (see 10 CFR 31 through 36, 39, 40, 61, 70, 71 and 150). N.J.A.C. 7:28-61.1 (see 10 CFR 71) "Packaging and Transportation of Radioactive Material" is the applicable regulation in New Jersey for the packaging and transport of radioactive material.

Assistance:
Please call the Radioactive Materials Section at 609-984-5462 with any questions regarding completion of a New Jersey radioactive material license application.

Documentation:
This guidance may be used to prepare documentation regarding licensing of radioactive material use in the State of New Jersey. Documentation includes:

- License Application – use form NJRAD-313
- License Amendment – use form NJRAD-313
- License Renewal – use form NJRAD-313
- Radioactive Material License Fee Worksheet use form NJRAD-101
- License Termination – use form NJRAD-314

NOTE: There are no provisions to apply for a NJDEP radioactive material license over the internet. Only paper applications will be accepted.

Keeping Licenses Current:

The licensee is obligated to keep the license current. If any of the information provided in the original application changes in a way that requires an amendment to the license as specified in the NUREG-1556 series, or in any way affects specific items concerning NJDEP jurisdiction, the licensee must submit an application for a license amendment to reflect the change, before the change takes place. The licensee should identify the specific changes in the amendment request and discuss the basis for the changes.

Reciprocity Application:

Refer to N.J.A.C. 7:28-62.1 (see 10 CFR 150) for recognition of licenses from other jurisdictions.

License Termination:
If a licensee wishes to terminate one or many NJDEP radioactive material licenses, the Administrator must sign and submit form NJRAD-314 to the Bureau of Environmental Radiation at the address above requesting the termination The Bureau may respond with a list of further documentation required to be submitted to the Bureau. License termination is only in effect after the licensee receives a letter stating such per NJDEP.

Completing License Application Form NJRAD-313:

- Complete page 1 of Form NJRAD-313.
- Use page 2 of NJRAD-313 or facsimile to answer items 5 through 12 and 14, as appropriate.
- Answers to each item must be preceded with the number of the item being answered.
- Do not make reference to documents previously filled with the State or any other government agency for a new license application. For license renewal or license amendment, include as attachments all necessary support information.
- Submit all documents, including drawings, if practicable, on 8-1/2 x 11 inch paper. If submission of larger documents is necessary, fold them to 8-1/2 x 11 inches.
- Identify each drawing with drawing number, revision number, title, date, scale, and applicant's name. Clearly indicate if drawings have been reduced or enlarged.
- Avoid submitting proprietary information unless it is absolutely necessary.
- Do not submit personal information about employees.
- All submittals must be typewritten text on clear paper, using 12-point Times New Roman font. Avoid formatting (bold, italics) unless absolutely necessary.
- Do not submit copies of NRC or NJDEP licenses.
- Submit an original, signed application and one copy of all the attachments.
- The NJDEP suggests that the submittal be sent return receipt so that the licensee will have a record that the NJDEP has received the submittal.
- Retain one copy of the license application for your records.

Item Number 1:
Each submittal of a new license application or renewal to an existing New Jersey radioactive material license requires the use of form NJRAD-313. It is acceptable for an amendment request to be submitted in a letter. Additional guidance may be found in guidance documents referenced for the category of license as described on page 7 of this document. See N.J.A.C. 7:28-51.1 (see 10 CFR 30) for byproduct material license applications, license renewals, and license amendments.

Item Number 2:
List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual

is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A Post Office Box number is an acceptable mailing address.

Notify NJDEP of changes in mailing address; these changes do not require a fee. See Category N in this document for bankruptcy and change of control.

Item Number 3:
Specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility at which licensed material will be used or stored (e.g., include locations for field studies or other off-site locations; list activities to be conducted at each location). A Post Office Box address is not acceptable.

Item Number 4:
Identify the individual(s) who can answer questions about the application and include telephone number(s) and email address(es). This is typically the proposed RSO, unless the applicant has named a different person. The NJDEP will contact this individual if there are questions about the application.

Notify the NJDEP if the contact person or his or her telephone number changes so that NJDEP can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

Item Number 5:
List the radioactive materials that will be used under this license. Include:

- For unsealed materials:
  - Element and mass number;
  - Chemical and/or physical form;
  - Maximum amount in millicuries which will be possessed at any one time;
  - Users of this material (see item 7);
  - Purpose for which the radioactive material will be used.
- For potentially volatile materials (e.g., I-123, I-125, I-131, H-3, Kr-85, Xe-133):
  - Element and mass number;
  - Chemical and/or physical form; specify whether the material will be free (volatile) or bound (non-volatile);
  - Maximum amount which will be possessed at any one time for each form;
  - Users of this material (see item 7);
  - Purpose for which the radioactive material will be used.
- For sealed materials:
  - Identify each radionuclide (element name and mass number) that will be used and specify the maximum activity per source in millicuries. Also, specify the maximum number of sources or total activity for each radionuclide;

- Provide the manufacturer's (distributor's) name, model number, and serial number for each sealed source and device requested;
- Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by the NRC or an Agreement State;
- Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by the the NRC or an Agreement State.

- Provide an Emergency Plan (if required per 10 CFR 30.72 Schedule C which is incorporated by reference at N.J.A.C. 7:28-51.1 (see 10 CFR 30)). Guidance is provided in Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," dated January 1992, and Policy and Guidance Directive 84-14, Revision 1, "Standard Review Plan for Emergency Plans for Fuel Cycle and Materials Licenses." NUREG 1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Report," dated January 1988, also contains valuable information.
- Provide a decommissioning funding plan if required per N.J.A.C. 7:28-51.1 (see10 CFR 30.35 and 10CFR 30 Appendix C). A licensee authorized to possess licensed material in excess of the limits specified in N.J.A.C. 7:28-51.1 (see 10 CFR 30.35) must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning
- For a broad scope license, see section I under "Categories".
- See appropriate NUREG guidance document for your license category for further details and information on emergency plans, decommissioning funding plans, and record keeping .
- All licensees are required to maintain records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use.

Item Number 6:
Check all categories of radioactive material use that apply. The applicant should describe in general terms the purposes for which the licensed material will be used. Sufficient information should be provided to enable the reviewer to have a clear understanding of each use and to determine the potential for exposure of workers and members of the public to radiation and radioactive materials. Additional descriptions and required information are on the following pages of this guidance.

Item Number 7:
List the name, title, training and experience of the person designated as Radiation Safety Officer. If this facility has a Radiation Safety Committee or Isotope Committee, describe the committee's responsibilities, duties, titles of the membership, and meeting frequency.

List the name(s), title, training and experience of individual(s) who will use, directly supervise or approve the use of radioactive materials. This is unnecessary for a broad scope license.

Item Number 8:

Describe the training program for each group of workers who require personal monitoring equipment. Submit a description of the radiation safety training program developed for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for assessing the success of the training; and the frequency of training and refresher training; or identify the model training program described in the appropriate NUREG document corresponding to your particular type of licensed program and submit a statement that this training program will be implemented.

Item Number 9:

Describe laboratory facilities, remote-handling equipment, storage containers, shielding, fume hoods, etc. Sample diagrams should be provided that take into consideration shielding, the proximity of radiation sources to unrestricted areas and other items related to radiation safety. When radioactive materials may become airborne, sample diagrams should take into consideration descriptions of the ventilation systems including pertinent airflow rates, pressures, filtration equipment and monitoring systems. For special application facilities, such as those facilities described above, you will need to specify their locations (i.e. buildings and room numbers).

Item Number 10:

Describe the radiation protection program at the facility as required in N.J.A.C. 7:28-6.1 (see 10 CFR 20). Include copies of all documents relating to radiation protection procedures and control measures (e.g. emergency procedures, spill control, surveys performed and their frequency, etc.). Include:

1. Audits of the program
2. Dosimetry:
    a. Describe the methods used for personnel dosimetry, including type of dosimeter, frequency of changing, methods for calibration and processing or the name of the supplier.
    b. Include any proposed bioassay program.
3. Radiation Detection
    a. List the radiation detection instrumentation to be used under this license. This list should include:
        i. Make and model of the instrument (and probe if appropriate)
        ii. Number of these units.
        iii. Type of radiation detected.
        iv. Instrument sensitivity (range in mR/hr, cpm, etc.)
    b. Describe the method and frequency of calibration of each instrument listed above. If a consultant is employed to perform this service, specify the company's name and address;
4. Material receipt and accountability
5. Occupational dose projections and control mechanisms
6. Public dose projections and control mechanisms

7. Safe use of radionuclides and emergency procedures. Include the ALARA program and all applicable procedures.
8. Surveys and their frequency
9. Transportation. Include procedures and regulations to follow for any transport of radioactive materials from or between any of the licensee sites listed above.

Item Number 11:
Describe the methods that will be used for disposing of radioactive waste and estimate the type and amount of activity involved for each method. If a commercial waste disposal service is employed, give the company's name and address.

Item Number 12:
Use form NJRAD-101 to calculate the fees required for this application.

Item Number 13:
If you answered "yes" to this question, provide details of each denial.

Item Number 14:

Form NJRAD-313 must be signed and license fee check (payable to "Treasurer, State of New Jersey") must be enclosed. To ensure adequate management involvement, **a management representative must sign the submitted application acknowledging management's commitments and responsibility** for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations
- Completeness and accuracy of the radiation safety records and all information provided to NJDEP (N.J.A.C. 7:28-51.1)(see 10 CFR 30)
- Knowledge about the contents of the license and application
- Compliance with current NJDEP and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures.
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that the public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) with responsibility for the overall radiation safety program.
- Prohibition against discrimination of employees engaged in protected activities (N.J.A.C. 7:28-51.1)(see 10 CFR 30).
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in (N.J.A.C. 7:28-51.1)(see 10 CFR 30).
- Obtaining NJDEP's prior written consent before transferring control of the license.
- Notifying NJDEP, Bureau of Environmental Radiation in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

Categories of Licensees

A. Portable Gauge:

Certain portable gauges may be exempt from NJDEP licensing requirements. N.J.A.C. 7:-52.1 (see 10 CFR 31) provides a listing of exempt devices.

The requirements for portable gauge licenses may be found at N.J.A.C. 7:28-51.1 (see 10 CFR 30). Portable gauges are of many different designs based, in part, on their intended use (e.g., to measure moisture, density, thickness of asphalt, liquid level). Because of differences in design, manufacturers provide appropriate instructions and recommendations for proper operation and maintenance. In addition, with gauges of varying designs, the sealed sources may be oriented in different locations within the devices, resulting in different radiation safety concerns. Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v1/r1/. This NUREG provides guidance to an applicant in preparing a portable gauge license application. It is not intended to address the research and development of gauging devices or the commercial aspects of manufacturing, distribution, and service of such devices. Within this document, the phrases "portable gauge" or "gauging devices," and the term "gauge" may be used interchangeably.

B. Industrial Radiography

Industrial radiography is defined in N.J.A.C. 7:28-63.1 (see 10 CFR 34)as the examination of the macroscopic structure of materials by non-destructive methods using sources of radiation. Guidance for this license application may be found in N.J.A.C. 7:28-63.1 (see 10 CFR 34) and in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v2/ . Also see: http://www.nj.gov/dep/rpp/xrm/index.htm.

C. Fixed gauge

The requirements for a fixed gauge license may be found at N.J.A.C. 7:28-51.1 (see 10 CFR 30). Typically gauges are used for process control (e.g., to measure the thickness of paper, the density of coal, the level of material in vessels and tanks, and volumetric flow rate). Additional guidance for this license application may be found in the following NUREG:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v4/ . These fixed gauges containing sealed sources of radioactive material incorporate features engineered to enhance their safety. NRC's considerable experience with these licensees indicates that

radiation exposures to workers are generally low, if workers follow basic safety procedures, and the gauges operate as designed.

D. Self-shielded irradiator

The requirements for licensing a self-shielded irradiator may be found at N.J.A.C. 7:28-56.1 (see 10 CFR 36). NJDEP uses the same definition of a self-shielded irradiator as the ANSI definition for a Category I irradiator: "[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration." These self-shielded irradiators containing sealed sources of radioactive material incorporate features engineered to enhance their safety. NRC's considerable experience with these licensees indicates that radiation exposures to workers are generally low, if the irradiators operate as designed and workers follow basic safety procedures. Irradiators are used for a variety of purposes in research, industry, and other fields. Typical uses are:

- Irradiating blood or blood products;
- Sterilizing or reducing microbes in medical and pharmaceutical supplies;
- Preserving foodstuffs;
- Studying radiation effects;
- Synthesizing and modifying chemicals and polymers;
- Eradicating insects through sterile male release programs; and
- Calibrating thermoluminescent dosimeters (TLDs).

Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v5/

E. Irradiator

The definition of and requirements for an irradiator license may be found at N.J.A.C. 7:28-56.1 (see 10 CFR 36). Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v6/ . This report addresses the variety of radiation safety issues associated with irradiators, of various designs, whose dose rates exceed 5 Gray (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable to the irradiator's design. Table 1.1 describes the characteristics of commonly authorized irradiators:

- Sources stored in pool and removed to irradiate package/product;
- Sources stored in pool and package/product lowered into pool to be irradiated;
- Dry source storage and in-air irradiation of package/product; and
- Teletherapy unit converted to non-human use.

F. Academic, research and development and other programs of limited scope including gas chromatographs and X-ray flourescence analyzers

The definitions and requirements for an academic, research and development, and other limited scope licenses may be found at N.J.A.C. 7:28-54.1 (see 10 CFR 33). Byproduct material, as defined in at N.J.A.C. 7:28-51.1 (see 10 CFR 30.4), is used for a variety of purposes in academia, research, industry, and other fields. The following are typical uses:

- *In vivo* studies (labeling cells, studies involving animals, excluding humans);
- *In vitro* studies;
- Analytical work/studies, including use of GCs and XRFs;
- Veterinary medicine;
- Calibration of applicant's instruments; and
- Field studies.

Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/. This report provides guidance to an applicant in preparing an Academic, Research and Development and Other Licenses of Limited Scope (ARDL) application including gas chromatography devices (GC) and X-RAY fluorescence analyzers (XRF). It is not intended to address licenses of broad scope, licenses for manufacturing and distribution of byproduct material, or licenses for the use of source, or special nuclear material. Within this document, the phrases or terms, "byproduct material," "licensed material" or "radioactive material," are used interchangeably.

G. Exempt distribution

Exemptions from the requirements for a NJDEP license to persons who receive, possess, use, transfer, own, or acquire byproduct material in exempt distribution products, are provided in N.J.A.C. 7:28-52.1,(see 10 CFR 31) "General Domestic Licensing of Byproduct Material" Exempt distribution products include silicon chips, electron tubes, resins, check sources, carbon-14 urea capsules, gunsights, and smoke detectors.

The following NUREG provides assistance in preparing license applications for distribution of exempt products:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v8/.

H. Medical use

Regulations for the medical use of byproduct material are found in N.J.A.C. 7:28-55.1 (see 10 CFR 35). The following NUREG provides assistance in preparing license applications for medical use of radioactive materials:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r1/

The NRC's "Procedures for Recognizing Certification Processes of Specialty Boards" may be found on the NRC's web page regarding the medical use of byproduct material:
http://www.nrc.gov/materials/miau/med-use-toolkit.html

Complementary guidance on inspection procedures for inspections of medical use licensees is contained in the following documents available at the NRC's web page on the Medical Use of Byproduct Material:
http://www.nrc.gov/materials/miau/med-use-toolkit.html .

Inspection Procedures in the 87100 series:

- "Nuclear Medicine Programs — Written Directive Not Required,"
- "Nuclear Medicine Programs — Written Directive Required,"
- "Brachytherapy Programs,"
- "Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs," and
- "Medical Broad Scope Programs."

For human use of the radioactive material, the licensed user is an individual who will possess or use radioactive substances, prescribe dosage, administer, or arrange for the administration of said substances to human beings or irradiate, or arrange for the irradiation of human beings by said substances. For application for Human-Use licenses, physicians, in lieu of documentation of training and experience, may submit proof of certification by an appropriate board or proof of certification as fellow in an appropriate College or Faculty.

I. Broad Scope

The definition of and requirements for a broad scope license for byproduct material may be found at N.J.A.C. 7:28-54.1 (see 10 CFR 33). Additional guidance for this license application may be found in the following NUREG:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v11/ . Included in this guidance document is a new option for Type A licensees of broad scope to have increased flexibility to make changes in some program areas and revise some procedures previously approved by the NJDEP without amendment of the license.

This NUREG is not intended to be used alone. Because broad scope licensees may be involved in many different program areas (e.g., medicine, research and development, manufacturing and distribution, etc.), this document frequently refers the user to other more program-specific guidance documents in the NUREG-1556 series. A single document containing all of the guidance that might be required by a broad scope licensee or an applicant for a broad scope license would be unwieldy and would quickly become obsolete as guidance in the individual program areas is revised.

For question 5:

- Applicants for a Type A broad scope license typically request any form of byproduct material with atomic numbers from 1 through 83. The applicant should state the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.
- Licensees may request source material and special nuclear material when use of these materials is directly related to the use of byproduct material under the broad scope license (e.g. laboratory-scale research and development or the use of depleted uranium as shielding). Applicants should submit separate applications

for the use of source and special nuclear materials for purposes not directly related to the use of byproduct material under the broad scope license (e.g., sub-critical assemblies and nuclear pacemakers).

- A separate listing should also be submitted for sealed sources needed in quantities larger than that described in the atomic number 1-83 request (e.g., self-contained irradiators, instrument calibrators, sealed sources used for medical therapy, portable and non-portable gauging devices, etc.).
- Applicants for a Type B or Type C broad scope license should request any chemical or physical form of byproduct material specified in N.J.A.C. 7:28-54.1 (see 10 CFR 33.100, Schedule A). The possession limit for a Type B broad scope license, if only one radionuclide is possessed, is the quantity specified for that radionuclide in N.J.A.C. 7:28-54.1 (see 10 CFR33.100, Schedule A, Column I).

For questions 9:

- Describe the criteria your RSC and/or RSO, as appropriate, will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.). Your description will need to include your method of classifying laboratories based on type, toxicity and quantity of byproduct material being requested.

J. Possession for manufacturing and distribution

The requirements for a possession for a specific license to possess certain items containing byproduct material to manufacture or transfer may be found at N.J.A.C. 7:28-53.1 (see 10 CFR 32). Materials manufacturers are those licensees that process raw material and/or sources and distribute those processed materials or manufactured products to users as finished products. Examples are:

- major radiopharmaceutical processor/manufacturers (not radiopharmacies);
- sealed source fabricators;
- device manufacturers; and
- other manufacturing licensees that possess and use bulk quantities of radioactive materials or sources.

Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v12/. This report provides guidance on three types of licenses associated with the manufacturing and distribution of radioactive materials and products containing radioactive materials.

1. Possession for manufacturing and distribution (including distribution of products to other specific licensees authorized to receive the products);
2. Possession for distribution only (with no manufacturing); and
3. Distribution (only) for medical use (transfer of radioactive drugs, sealed sources, and devices directly to medical use licensees).

Licensing for distribution to general licensees is found in section O Distribution-only licensees are not involved in the processing of raw materials or sources, nor in the manufacturing of devices. Distributors also include importers for purposes of distribution.

K. Commercial Radiopharmacy

Commercial radiopharmacy licenses are those licenses issued by the NJDEP, pursuant to N.J.A.C. 7:28-55.1 (see 10 CFR 35), for the possession and use of radioactive materials for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use.
Additional guidance for this license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/. Within this NUREG, preparation includes the making of radiopharmaceuticals from reagent kits (i.e., technetium-99m MAA (macroaggregated albumin)), and from raw materials (i.e., the compounding of radioiodine capsules for diagnostic and therapeutic medical use). Commercial radiopharmacies may also be authorized to transfer for commercial distribution *in vitro* test kits described in N.J.A.C. 7:28-53.1 (see 10 CFR 32.11), radiopharmaceuticals to licensees authorized to possess them for other than human medical use (i.e., veterinary medicine and research licensees), and radiochemicals to those licensees authorized to possess them, pursuant to N.J.A.C. 7:28-53.1 (see 10 CFR 32). In addition, N.J.A.C. 7:28-53.1 (see 10 CFR 32) authorizes radiopharmacies to redistribute (transfer) sealed sources for calibration and medical use initially distributed by a manufacturer licensed pursuant to N.J.A.C. 7:28-55.1 (see 10 CFR 35.74).

Applicants requesting to manufacture and initially distribute radioisotope generators, *in vitro* kits, radiochemicals and sealed sources should refer to section K of this document for specific licensing requirements.

Guidance to applicants requesting to possess and distribute radioactive materials produced by an accelerator located at the applicant's address may be found in NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v21/ .

L. Non-Commercial Production/Distribution

Applicants applying for authorization for the production and noncommercial distribution of Positron Emission Tomography (PET) radioactive drugs to medical use licensees in a consortium, should refer to NUREG-1556, Vol. 21, http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v21/ .

M. Well logging

Well logging is defined in N.J.A.C. 7:28-57.1 (see 10 CFR 39) as the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. N.J.A.C. 7:28-57.1 (see 10 CFR 39) does not have requirements for the issuance of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells. Byproduct material, as defined in N.J.A.C. 7:28-51.1 (see 10 CFR 30.4) is used for a variety of purposes to include: well logging and tracer applications involving both single or multiple well bores; conventional well logging and tracer operations; and, in some cases, research and development. Examples include the following applications:

- Sealed sources are used in cased and uncased boreholes;
- Tracer materials are used in single well applications;
- Tracer materials are used in multiple well applications (field flood study) for enhanced recovery of oil and gas wells;
- Sealed sources are used for calibration of applicant's survey instruments and well logging tools; and
- Sealed sources and tracer materials are used in the research and development of new techniques and equipment.

Additional guidance to an applicant in preparing a well logging, tracer, and field flood study license application may be found in the following NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v14/

N. Changes of control and bankruptcy involving byproduct, source or special nuclear materials

N.J.A.C. 7:28-51.1 (see 10 CFR 30.34(b)) requires that no change of control of any NJDEP license may be transferred, assigned or in any manner disposed of unless the NJDEP give its consent in writing. N.J.A.C. 7:28-51.1 (see 10 CFR 30.34(h)) requires immediate written notification to the NJDEP following the filing of a petition for bankruptcy. Guidance for licensees and, in some cases, license applicants to use in preparing a notification to NJDEP of a change of control or bankruptcy may be found in this NUREG: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v15/. It also contains criteria NJDEP will use for evaluating such a notification and determining whether a new or amended license is needed.

The regulations are clear that control of licensed activities cannot be transferred without prior written consent from NJDEP. It is not NJDEP's intent to interfere with the business decisions of licensees. However, it is necessary for licensees to notify NJDEP sufficiently before the actual change to allow time for appropriate review, whenever decisions are being considered that involve changes of control. NJDEP's focus is on the health and safety aspects, not on the financial intricacies, of the proposed transaction. NJDEP will only require licensees to submit business information necessary to permit the Department to determine whether a change of control will take place. NJDEP is required by law to ensure that the public's health and safety are not compromised and therefore must be confident that when a licensee's program is undergoing a change of control, all efforts are made to ensure that the radiation safety aspects of the program are not degraded.

Although the burden of notification is on the existing licensee, it may also be necessary for the transferee or the successor to provide supporting information or to independently coordinate the change of control with the NJDEP.

In the case of bankruptcy, NJDEP regulations require that a licensee notify NJDEP in writing immediately following the filing of a voluntary or involuntary petition under the Bankruptcy Code by or against the licensee, or an entity controlling the licensee or listing the license or licensee as property of the estate, or an affiliate of the licensee. This

notification must indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

No changes of control or license terminations will be authorized until all information or records concerning decommissioning of the facility, radiation doses to the public, and waste disposal (such as releases to sewers, incineration, radioactive spills, and on-site burials) have been transferred to the new licensee, if licensed activities will continue at the same location. If the license is to be terminated the owner may request the NJDEP to accept the records.

O. Authorizing distribution to general licensees

The requirements for an NJDEP general license for persons who receive, possess, use, transfer, own, or acquire byproduct material in generally licensed products are provided in N.J.A.C. 7:28-52.1 (see 10 CFR 31, "General Domestic Licenses for Byproduct Material.") Generally licensed products include static elimination devices, gauging devices, gas chromatograph detector cells, tritium signs, *in vitro* clinical or laboratory kits, and check sources. These devices/products are distributed to general licensees by companies who have a specific license from the NJDEP, NRC or other Agreement States.authorizing such distribution.

The requirements to obtain an NJDEP general distribution license for persons who distribute or initially transfer byproduct material in generally licensed products are provided in N.J.A.C. 7:28-53.1 (see 10 CFR 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.")

This NUREG provides assistance to applicants in preparing license applications for a specific license to distribute generally licensed devices:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v16/ .

P. Special Nuclear Material of less than Critical Mass Quantities

Special Nuclear Material, as defined in N.J.A.C. 7:28-60.1 (see 10 CFR 70.4), means plutonium (Pu), uranium (U)-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the NJDEP determines to be special nuclear material or any material artificially enriched by any of the foregoing. Typical uses include:

a) Experiments using sub-critical assemblies;
b) Foil activation experiments using Pu-238/Beryllium (Be) sources;
c) Instrument calibration;
d) Student instruction in radiation detection and measurement;
e) Nuclear pacemakers;
f) U-235 target foils experiments.

This NUREG provides assistance to applicants in preparing a license application for possession of special nuclear material of less than critical mass quantities:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v17/ This NUREG is intended for applicants requesting authorization to possess and use up to 2,000 grams of

plutonium, total, in the form of sealed Pu-Be neutron sources, and any special nuclear material in quantities and forms not sufficient to form a critical mass, as stated in N.J.A.C. 7:28-60.1 (see 10 CFR 70). The latter quantities are considered to be up to 350 grams of contained U-235, 200 grams of U-233, 200 grams of plutonium (in any form other than Pu-Be neutron sources), or any combination of them in accordance with the following formula:

$$\frac{\text{grams U-235}}{350} + \frac{\text{grams U-233}}{200} + \frac{\text{grams Pu}}{200} < 1$$

Q. Service Provider

Service providers provide commercial services to both specific and general licensees, and in some instances, recover both licensed and unlicensed material from the public domain. Customers who possess such radioactive material may require commercial services to manage materials at concentrations and activities they are not authorized to handle. In these unique situations, a service provider licensee is authorized to possess these radioactive materials under its license incident to performing specific services required by its customers. Optionally, licensees may elect to transfer licensed material such as radioactive waste and contaminated materials to service providers (e.g., radioactive waste brokers, decontamination and decommissioning service providers, or nuclear laundry operators).

Licensees who in the course of doing business, receive physical samples and possess equipment containing licensed materials related to the performance of service activities such as leak test and environmental sample analyses, survey instrument, and dosimetry calibration services are also included in the service provider category.

Assistance to service provider applicants in preparing a license application may be found in the following NUREG:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v18/. Service providers addressed in this NUREG are limited to licensed entities providing the following types of commercial services:

- Installation, relocation, removal from service, disposal, radiation surveys, routine and preventive maintenance, adjustment of equipment, training of personnel or repair of devices containing licensed materials.
- Installation, relocation, removal from service, disposal, radiation surveys, routine or preventive maintenance, adjustment, training or repair of Part 36 irradiators.
- Installation, radiation surveys, routine and preventive maintenance, adjustment or repair of remote afterloaders, teletherapy, or gamma stereotactic radiosurgery units that require access to the sealed source(s), driving units, or other electronic components that could expose the sealed source, reduce the shielding, or compromise the radiation safety of the device or safety systems.
- Calibration of survey instruments and personnel dosimetry equipment.
- Leak testing of sealed sources, including analyzing the leak test kits or smears.

- Environmental sample analysis.
- Training of personnel using sealed sources.
- Calibration of medical dose calibrators.
- Nuclear laundry services.
- Waste management services including:
    - Commercial incineration
    - Compaction, Super Compaction
    - Solidification or vitrification
    - Packaging and repackaging of radioactive waste for transportation.
- Decontamination and decommissioning services.
- Site characterization services.

R. Registration of Generally Licensed Devices Containing Greater Quantities of Certain Isotopes

The requirements for an NJDEP Registration for a Generally Licensed Device for persons who receive, possess, use, transfer, own, or acquire byproduct material in certain quantities in generally licensed products are provided in N.J.A.C. 7:28-52.1 (see 10 CFR 31), "General Domestic Licenses for Byproduct Material." Generally licensed products in this category include devices containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, or 37 MBq (1 mCi) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)) based on the activity indicated on the label.
These devices/products are distributed to general licensees by companies who have a specific license from the NJDEP, NRC, or other Agreement States authorizing such distribution.

S. License for Drinking Water Treatment Systems

Community Water Systems (CWS) and Non-community, non transient (NCNT) water systems that accumulate naturally occurring radioactive materials above exempt quantities (N.J.A.C. 7:28-4.5) in their treatment operations are required to obtain a specific New Jersey radioactive material license before treatment operations commence.

NJRAD Form-313 (Revised July 14, 2008)

APPLICATION for RADIOACTIVE MATERIALS LICENSE

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
P.O. Box 415, Trenton, NJ 08625
Tel. (609) 984-5462
Fax. (609) 633-2210
Website: http://www.nj.gov/dep/rpp/

INSTRUCTIONS – Complete all items in the application whether for an amendment, renewal or initial application. Read each item carefully and answer as completely as possible. The type and scope of information to be provided is described in the NJRAD licensing guidance document. Responses may be submitted on separate sheets if the appropriate section is clearly referenced. Make a copy of the completed application and all attachments for your records. Send signed original and appropriate fees to the address on the left. Make checks payable to: "Treasurer, State of New Jersey".

1. This application is for:
- ☐ New License
- ☐ Amendment to license number: _____
- ☐ Renewal of license number: _____

2. Name and current mailing address of applicant

3. Address(es) where licensed material will be used or possessed (attach additional sheets if necessary)

3a.

3b.

3c.

4. Person to be contacted about this application
Name: Telephone:
Facsimile: E-mail:

5. Radioactive Material:

	Element & Mass #	Form	Maximum possession limit	6. Proposed use
a				
b				
c				
d				
e				
f				
g				
h				
i				
j				
k				

7. Individual(s) Responsible for radiation safety program and their training and experience
☐ **Attachments Enclosed**

8. Training program for individuals working in or frequenting restricted areas
☐ **Attachments Enclosed**

9. Facilities and equipment
☐ **Attachments Enclosed**

10. Radiation safety program
☐ **Attachments Enclosed**

11. Waste Management
☐ **Attachments Enclosed**

12. License fee Categories:
Amount enclosed $ ☐ **Attachments Enclosed**

13. Certification: I, CERTIFY UNDER PENALTY OF LAW THAT THE INFORMATION PROVIDED IN THIS DOCUMENT IS TRUE, ACCURATE AND COMPLETE. I AM AWARE THAT THERE ARE SIGNIFICANT CIVIL AND CRIMINAL PENALTIES FOR SUBMITTING FALSE, INACCURATE ORINCOMPLETE INFORMATION, INCLUDING FINES AND/OR IMPRISONMENT. THE CERTIFICATION SHALL BE SIGNED BY THE HIGHEST RANKING CORPORATE, PARTNERSHIP OR GOVERNMENTAL OFFICER OR OFFICIAL AT THE FACILITYOR THE INDIVIDUAL FOR WHICH OR FOR WHOM THE SPECIFIC STATE LICENSE IS REQUESTED.

Name and Title of Certifying Official	Signature	Date

Fee Worksheet for Specific License Applications

NRC FEE CATEGOR	LICENSE TYPE	PROGRAM CODES	FEE AMOUNT	SELECT applicable items by typing "X" in this column
	N.J.A.C. 7:28-64, Table 1			
1. Special Nuclear Material				
1D	All other special nuclear material except a) licenses authorizing special nuclear material in unsealed form in combination that would constitute a critical quantity, as defined in Subchapter 62 of this chapter; b)U-235 or plutonium for fuel fabrication activities; c) spent fuel and reactor-related greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI); d) special nuclear material in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers; or e) licenses or certificates for the operation of a uranium enrichment facility.	22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22163, 22170, 23100, 23300, 23310	$4,275	
2. Source Material				
2B	Licenses that authorize only the possession, use and/or installation of source material for shielding.	11210	$575	
2C	All other source material licenses.	11200, 11220, 11221, 11230, 11300, 11800,	$9,825	
3. Byproduct material				
3A	Licenses of broad scope for possession and use of byproduct material issued under subchapters 51 and 54 for processing or manufacturing of items containing byproduct material for commercial distribution.	03211, 03212, 03213	$21,600	
3B	Other licenses for possession and use of byproduct material issued under subchapter 51 for processing or manufacturing of items containing byproduct material for commercial distribution. This category also includes licenses for repair, assembly, and disassembly of products containing radium-226.	03214, 03215, 22135, 22162	$6,225	
3C	Licenses issued under subchapter 53 authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and devices containing byproduct material. This category also includes the possession and use of source material for shielding authorized under subchapter 58 of this chapter when included on the same license.	02500, 02511, 02513	$8,850	
3E	Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units).	03510, 03520	$3,000	
3F	Licenses for possession and use of less than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes.	3511	$5,850	
3G	Licenses for possession and use of 10,000 curies or more of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes.	03521	$23,100	
3J	Licenses issued under subchapter 53 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under subchapter 52 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under subchapter 52 of this chapter	03240, 03241, 03243	$1,800	

NRC FEE CATEGOR	LICENSE TYPE	PROGRAM CODES	FEE AMOUNT	SELECT applicable items by typing "X" in this column
3K	Licenses issued under subchapter 53 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under subchapter 52 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under subchapter 52 of this chapter.	03242, 03244	$1,350	
3L	Licenses of broad scope for possession and use of byproduct material issued under subchapters 51 and 54 of this chapter for research and development that do not authorize commercial distribution.	01100, 01110, 01120, 03610, 03611, 03612	$11,000	
3M	Other licenses for possession and use of byproduct material issued under subchapter 51 of this chapter for research and development that do not authorize commercial distribution.	03620	$4,200	
3N	Licenses that authorize services for other licensees, except: Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.	03219, 03225, 03326	$6,225	
3O	Licenses for possession and use of byproduct material issued under subchapter 63 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under subchapter 58 of this chapter when authorized on the same license.	03310, 03320	$10,575	
3P	All other specific byproduct material licenses, except those in Categories 4.A through 9.D.	02400, 02410, 03120, 03121, 03122, 03123, 03124, 03220, 03221, 03222, 03800, 03810	$2,025	
3R	Possession of items or products containing radium–226 identified in subchapter 52 which exceed the number of items or limits specified in that section: (Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. This exception does not apply if the radium sources are possessed for storage only.)			
3R(1)	1. Possession of quantities exceeding the number of items or limits in subchapter 52, but less than or equal to 10 times the number of items or limits specified.	02700	$1,575	
3R(2)	2. Possession of quantities exceeding 10 times the number of items or limits specified in Subchapter 52.	02710	$2,025	
3S	S. Licenses for production of accelerator-produced radionuclides.	03210	$8,100	
5. Well Logging				
5A	Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies.	03110, 03111, 03112	$3,225	
7. Medical				
7A	Licenses issued under subchapters 51, 55, 58, and 60 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.	02300, 02310	$10,125	
7B	Licenses of broad scope issued to medical institutions or two or more physicians under subchapters 51, 55, 58, and 60 of this chapter authorizing research and development, including human use of byproduct material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Separate fees will not be assessed for pacemaker licenses issued to medical institutions who also hold nuclear medicine licenses under Category 7.B. or 7.C.	02110	$21,615	

NRC FEE CATEGOR	LICENSE TYPE	PROGRAM CODES	FEE AMOUNT	SELECT applicable items by typing "X" in this column
7C	Other licenses issued under subchapters 51, 55, 58, and 60 of this chapter for human use of byproduct material, source material, and/or special nuclear material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Separate fees will not be assessed for pacemaker licenses issued to medical institutions who also hold nuclear medicine licenses under Category 7.B. or 7.C.	02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160	$3,600	
14. Decommissioning/Reclamation				
14A	Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under subchapters 51, 58, and 60 of this chapter.		Full Cost *	
14B	Site-specific decommissioning activities associated with unlicensed sites, whether or not the sites have been previously licensed.		Full Cost *	
	N.J.A.C. 7:28-64, Table 2			
1A	Very Small Community Water Systems		$300	
1B	Small Community Water Systems		$875	
1C	Medium Community Water Systems		$1,250	
1D	Large Community Water Systems		$2,500	
1E	Non-Transient Non-Community Water Systems treating equal to or less than 1000 gallons per day.		$200	
1F	Non-Transient Non- Community Water Systems treating more than 1000 gallons per day.		$500	
6. Diffuse NARM License			$2,500	
			SUBTOTAL OF ALL FEE CATEGORIES:	**$0.00**
CALCULATION OF ADDITIONAL FEES FOR MULTIPLE SITES				
			Number of Additional Sites:	
4. Additional Use Sites (Non-contiguous)				
4A	Non-profit educational institutions (25% for each additional site)		$0	
4B	Medical Private Practice (50% for each additional site)		$0	
			SUBTOTAL FOR ADDITIONAL SITES:	**$0.00**
	* Additional Fees for Full-cost licensees will be invoice by the Department separately from the annual fee invoices.			
			TOTAL ANNUAL LICENSE FEE:	**$0.00**

NJRAD FORM-241 (Revised July 10, 2008)

RECIPROCITY APPLICATION FORM

REPORT OF PROPOSED ACTIVITIES WITHIN NEW JERSEY JURISDICTIONAL BOUNDARIES INCLUDING OFFSHORE AND STATE WATERS

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
P.O. Box 415, Trenton, NJ 08625
Tel. (609) 984-5462
Fax. (609) 633-2210
Web: http://www.nj.gov/dep/rpp/

1. NAME OF LICENSEE (Person or firm proposing to conduct the activities described below)

2. TYPE OF REPORT ☐ Initial ☐ Change

3. ADDRESS OF LICENSEE

4. LICENSEE CONTACT AND TITLE

5. TELEPHONE NUMBER

6. FACSIMILE NUMBER

7. ACTIVITIES TO BE CONDUCTED UNDER THE GENERAL LICENSE GIVEN IN N.J.A.C. 7:28-52.1 (See 10 CFR 31)

☐ WELL LOGGING ☐ LEAK TESTING AND/OR CALIBRATIONS ☐ TELETHERAPY/IRRADIATOR SERVICE
☐ PORTABLE GAUGES ☐ OTHER - Specify: _____
☐ RADIOGRAPHY - Specify: _____
REGISTERED AS USER OF PACKAGING (CERTIFICATES OF COMPLIANCE NUMBERS)

LOCATIONS OF USE - LIST ADDITIONAL WORK SITES ON SEPARATE SHEET(S)

8. CLIENT NAME & ADDRESS

9. ACTUAL PHYSICAL ADDRESS OF WORK LOCATION

10. CLIENT TELEPHONE #

11. WORK LOCATION TELEPHONE #

12. DATES SCHEDULED		**13. NUMBER OF WORK DAYS**	**14. ADD**	**15. DELETE**	**16. LOCATION ID #** (To be assigned by NJ DEP)
FROM:	TO:				

17. LIST RADIOACTIVE MATERIAL, WHICH WILL BE POSSESSED, USED, INSTALLED, SERVICED, OR TESTED
(Include description of type and quantity of radioactive material, sealed sources, or devices to be used.)

18. NRC or AGREEMENT STATE SPECIFIC LICENSE (One copy must accompany the initial NJRAD FORM 241)	**LICENSE NUMBER**	**STATE**	**EXPIRATION DATE**

19. CERTIFICATION ***(MUST BE COMPLETED BY APPLICANT)***

I, THE UNDERSIGNED, HEREBY CERTIFY THAT:

a. All information in this report is true and complete.
b. I have read and understand the provisions of the general license N.J.A.C. 7:28-52.1 (see 10 CFR 31) and I understand that I am required to comply with these provisions as to all byproduct, source, or special nuclear material which I possess and use within the jurisdictions of New Jersey, including its offshore waters, under the general license for which this report is filed with the NJDEP Bureau of Environmental Radiation.
c. I understand that activities, including storage, conducted in New Jersey under general license N.J.A.C. 7:28-52.1 (see 10 CFR 31) are limited to a total of 180 days in calendar year. With the exception of work conducted in off-shore waters, which is authorized for an unlimited period of time in the calendar year.
d. I understand that I may be inspected by NJDEP Bureau of Environmental Radiation at the above listed work site locations and at the Licensee home office address for activities performed within the jurisdictions of New Jersey, including its offshore waters.
e. I understand that conduct of any activities not described above, including conduct of activities on dates or locations different from those described above or without NJDEP Bureau of Environmental Radiation authorization, may subject me to enforcement action, including civil or criminal penalties.

CERTIFYING OFFICER - RSO or Management Representative (Name and Title)	**SIGNATURE**	**DATE**

WARNING: False statements in this certificate may be subject to civil and/or criminal penalties.

FOR NJDEP USE ONLY	REVIEWING OFFICIAL (Name and Title)	SIGNATURE	DATE	TOTAL USAGE -- DAYS TO DATE

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section

REPORT OF PROPOSED ACTIVITIES WITHIN NEW JERSEY JURISDICTIONAL BOUNDARIES INCLUDING OFFSHORE AND STATE WATERS

INSTRUCTIONS

Licensees cannot perform work in areas of exclusive New Jersey State jurisdiction without either (a) filing (and receiving approval of) NJRAD Form 241 for reciprocity in accordance with N.J.A.C. 7:28-52.1 (see 10 CFR 31) or (b) applying for (and receiving approval of) a specific New Jersey radioactive materials license. An area of exclusive New Jersey State jurisdiction is an area over which the State government exercises legal control without interference from the jurisdiction and administration of Federal law. If the work is to be performed on Federal property within New Jersey, the licensee must first determine the jurisdictional status of the area where the licensee plans to work. If the jurisdictional status of the work site is unknown to the licensee, the licensee should contact the Federal agency that controls the facility where the work is to be performed. A written statement concerning the jurisdictional status is not required in order to file for reciprocity; however, it is recommended that the licensee obtain such a statement for the file for future reference and inspection purposes.

Licensees seeking to conduct activities under reciprocity for the first time in a calendar year must submit this Form, one copy of the NRC or Agreement State specific license and one-half the fee listed in Tables 1 and 2 of N.J.A.C. 7:28-64.2. NJDEP must receive this filing at least 3 days before the licensee engages in activities permitted under the General License established by N.J.A.C. 7:28-52.1 (see 10 CFR 31). This evidence can be a copy of the check that will be mailed to the NJDEP Bureau of Environmental Radiation. The preferred method of filing is through the facsimile transmission however, the licensee may file the required information through the mail or other means as long as NJDEP receives the information at least 3 days before the licensee engages in the activity. NO ACTIVITIES MAY BE CARRIED OUT WITHOUT FIRST RECEIVING APPROVAL OF A RECIPROCITY OR SPECIFIC LICENSE APPLICATION.

In completing NJRAD Form 241, it is important that the information submitted on NJRAD Form 241 be specific regarding the location and date of use as well as the activity requested. If it is not possible to provide complete information, such as addresses for the locations of work, the licensee should provide as much information as possible. The licensee is responsible for providing additional information as revisions or clarifications as soon as such information becomes available.

Item 2:
The licensee should check the "initial" box if this is the first submission of Form 241 for the year. Licensees should check the "change" box to indicate changes to the information provided on the initial NJRAD Form 241. Changes may include modifications such to as additional work locations, changes to radioactive material, work activities, information that clarifies or deletes specific locations or work sites, modifies work site contacts, or adds or deletes dates of work, licensees should file by NJRAD Form 241 or letter, so that NJDEP receives the filing at least 3 days prior to engage in such activity. It is not necessary to resubmit the NRC or Agreement State license unless the license has been amended since the filing of the initial NJRAD Form 241. No fee is required for changes. Once one year passes from the date of initial application, a new Initial application must again be filed with the associated fees included. Additional sheets may be used, provided it includes all of the requested information in NJRAD Form 241.

Under the general license, reciprocity activities are authorized only as long as the licensee holds a valid radioactive material license. If the license expires during the year, an extension letter or a renewed license

issued by the regulating agency must be submitted to NJDEP before performing any additional work under reciprocity.

Under the general license, reciprocity activities, including storage (usage), conducted in New Jersey State jurisdiction, are limited to a total of 180 days in any calendar year. NJDEP tracks reciprocity usage on the basis of approved usage days. NJDEP will not approve any activity under the general license which causes the total usage days to exceed 180 days. It is important that licensees track the days of use and clarify or delete dates of work when applicable.

Item 12 should reference the proposed beginning and ending dates of work for each work location with the total number of days worked recorded in Item 13. Item 14 should be completed to show additional work dates different from those provided on the initial NJRAD Form 241 and Item 15 should indicate dates when work was not performed, as initially requested, that need to be deleted from the total work days. The Location ID Number in Item 16 is generated by the NJDEP for use in tracking reciprocity activities and is specific for each work location. The Location ID Number should be referenced for any revisions or clarifications to work location information.

Item 17: Licensees should identify the specific make and model numbers of sealed sources and devices.

NOTE: Inspections by NJDEP of activities performed in New Jersey or areas of New Jersey jurisdiction, including offshore waters operating under the general license in N.J.A.C. 7:28-52.1 (see 10 CFR 31) will be conducted at the listed work site location(s). Failure to file an NJRAD Form 241 may result in the issuance of formal enforcement actions.

Completed application forms may be mailed to:
New Jersey Department of Environmental Protection, Bureau of Environmental Radiation, Radioactive Materials Section, P.O. Box 415, Trenton, NJ 08625 or sent via facsimile to (609) 633-2110.

NJRAD Form-244 (Revised August 18, 2008)

REGISTRATION CERTIFICATE – USE OF DEPLETED URANIUM UNDER A GENERAL LICENSE

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
P.O. Box 415, Trenton, NJ 08625
Tel. (609) 984-5462
Fax. (609) 633-2210
Website: http://www.nj.gov/dep/rpp/

INSTRUCTIONS – Subchapter 58 of N.J.A.C. Title 7, Chapter 28 establishes a general license authorizing the use of depleted uranium contained in industrial products or devices for mass-volume applications. Submit this form within 30 days after the first receipt or acquisition of such depleted uranium. Read each item carefully and answer as completely as possible. Responses may be submitted on separate sheets if the appropriate section is clearly referenced. Make a copy of the completed application and all attachments for your records. Send signed original and appropriate fees to the address listed on the top-right of this form. Make checks payable to: "Treasurer, State of New Jersey".

1. Name and current mailing address of registrant:

Registrant Name:

Telephone:

Facsimile:

Address:

2. Individual responsible for the material(s):

Name:

Telephone:

Address:

3. Statement - I hereby file NJRAD Form 244 pursuant to Subchapter 58, for use of depleted uranium contained in industrial products or devices for mass-volume applications.

4. Certification: I hereby certify that:

A. All information in this registration certificate is true, accurate and complete.

B. I am aware that there are significant civil and criminal penalties for submitting false, inaccurate or incomplete information, including fines and/or imprisonment.

C. This registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in Subchapter 58 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.

D. I understand that NJDEP Bureau of Environmental Radiation regulations require that any changes in information furnished by a registrant on this registration certificate be reported in writing to the NJDEP Bureau of Environmental Radiation at the address listed at the top-right of this form, within 30 days after the effective date of such change.

E. I understand that the registrant is required to comply with the provisions of Subchapter 58 of the NJDEP Bureau of Environmental Radiation's regulations with respect to all depleted uranium which the registrant receives, acquires, uses, or transfers under the general license for which this registration certificate is filed with the NJDEP Bureau of Environmental Radiation.

Name and Title of Certifying Official	Signature	Date

New Jersey Department of Environmental Protection
Division of Environmental Safety & Health
Radiation Protection and Release Prevention Programs
P.O. Box 415
Trenton, New Jersey 08625-0415
Tel (609) 984-5400
Fax (609) 984-5595

TO: All New, Current, or Previous Users of Devices Subject to General License Registration

PURPOSE: To Track and Account for Certain Generally Licensed Devices for Public Protection

The New Jersey Department of Environmental Protection (DEP) requires annual registration of certain devices that are possessed under the general license issued in N.J.A.C. 7:28-52 (se 10 CFR 31). Devices subject to registration include those containing the radioactive material and activity listed in Table 1. You are receiving this notice because DEP records indicate that you have one or more such devices. Information about the general license registration program is available on the Internet at: http://www.nj.gov/dep/rpp

SUBJECT: ANNUAL REGISTRATION OF GENERALLY LICENSED DEVICES

Note that under N.J.A.C. 7:28-52 (see 10 CFR 31), the attached General Licensee Registration Package must be completed, signed, and returned to the DEP within 30 days from the date of this letter. READ ALL OF THE INSTRUCTIONS PRIOR TO COMPLETING THE PACKAGE. Mail the registration fee (check or money order payable to the Treasurer, State of New Jersey) and a copy of the completed Registration to:

Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
PO BOX 415
Trenton, NJ 08625-0415

Registration Fee: DEP regulations (N.J.A.C. 7:28-52) (see 10 CFR 31) require that you submit a registration fee with each registration on an annual basis. The registration fee is subject to change yearly, and you are required to submit the fee that is in effect as of the date of this letter. If you have any questions about the fee or payment options, call 609-984-5400.

The REGISTRATION FEE is $350.00 per registered device.

Enclosures:
1. NJRAD Form 664, "General Licensee Registration Form"

INSTRUCTIONS FOR COMPLETING NJRAD FORM 664 "GENERAL LICENSE REGISTRATION"

Review all seven sections of this registration form. If any information is incorrect or missing, make corrections [redacted]e applicable boxes or attach additional sheets, if necessary. Use the "Ø" character to represent the number [redacted] (zero). Verify information about the devices by reviewing the label on the outside of the device. **For safety reasons, DO NOT TRY TO TAKE APART any device to verify this information.** If you are uncertain how to identify the device's label, contact the device's manufacturer or an authorized service agent for this information. Also contact the manufacturer for any additional information about general license requirements. You may also review 10 CFR 31.5 and other applicable regulations on the NRC web site at http://www.nrc.gov/reading-rm/doc-collections/cfr/, or review specific information about the general licensee project at http://www.nrc.gov/materials/miau/miau-reg- initiatives/gen-license.html

Sections 1 – Indicate whether the general license registration form is for a new, amended or renewal registration.

Section 2 – Provide the requested information about you, the general licensee. The Registrant name can be a person or a corporation/organization/department – whoever owns the device.

Section 3 – Provide the name, telephone number, and mailing address of the individual designated to be responsible for maintaining the registered device(s). This individual must verify and sign the form in section 7.

Section 4 – Provide the street address/location where your device(s) are stored/used. For portable devices, provide the storage location. P. O. Box addresses are not permitted in this section. Include additional information about the exact location of storage (such as department, room number, etc.).

[redacted]ion 5 – Indicate the number of devices requiring registration and multiple by $350 to get the total annual [redacted] due for your registration.

Section 6 - Devices Subject to Registration. This section lists each device subject to registration and in your possession, according to DEP records. Devices subject to registration include those containing at least one of the radionuclides listed in Table 1, with the activity indicated, at the time of manufacture.

Table 1. Criteria for Registration

Radionuclide	Activity greater than or equal to:
Strontium-90 (Sr-90) Radium-226 (Ra-226)	3.7 megabecquerel (0.1 millicurie)
Cobalt-60 (Co-60) Curium-244(Cu-244) Americium-241 (Am-241) Californium-252 (Cf-252)	37 megabecquerel (1 millicurie)
Cesium-137 (Cs-137)	370 megabecquerel (10 millicurie)

If you do not possess a device listed, check the "not in possession of device" box, and provide the following relevant information on an additional sheet:

- Date transferred
- Location of Device
- Recipient Name, Contact Information, Address, License Number

[redacted]ection 7 - Certification and Signature. The responsible individual must certify, sign, and date Section 7.

NJRAD FORM-314 (Revised July 14, 2008)

CERTIFICATE of DISPOSITION of RADIOACTIVE MATERIALS

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
P.O. Box 415, Trenton, NJ 08625
Tel. (609) 984-5462 Fax. (609) 633-2210
Website: http://www.nj.gov/dep/rpp/

Instructions: This form is to be used to officially request termination of a Radioactive Material License as outlined in N.J.A.C. 7:28. Disclosure of this information is required. Failure to provide any information will result in this request for termination of a specific license not being processed. Retain one copy and submit original of the entire request to BER at the address above.

A. LICENSE STATUS INFORMATION

LICENSEE NAME AND ADDRESS:	LICENSE NUMBER	EXPIRATION DATE
	LICENSEE CONTACT NAME	TELEPHONE #

B. DISPOSAL OF RADIOACTIVE MATERIALS

The licensee executing this certificate certifies that:

☐ (A) No radioactive materials have ever been procured or possessed by the licensee under this license.

☐ (B) All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner:

- ☐ (i) Transfer of radioactive materials to the licensee listed below:
  License Name: License Number: Issuing Agency:
- ☐ (ii) Disposal of radioactive materials (explain):
  - ☐ (a) Directly by the licensee:
  - ☐ (b) By licensed disposal site:
  - ☐ (c) By waste contractor:
- ☐ (iii) All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of N.J.A.C. 7:28 and is ALARA.

C. SURVEYS PERFORMED AND REPORTED

☐ (A) A radiation survey was conducted by the licensee. The survey confirms:

- ☐ (i) the absence of licensed radioactive materials.
- ☐ (ii) that any remaining residual radioactivity is within the limits of N.J.A.C. 7:28 and is ALARA.

☐ (B) A copy of the radiation survey results:

- ☐ (i) is attached; or
- ☐ (ii) is not attached (provide explanation); or
- ☐ (iii) was forwarded to NJDEP RMS on:

☐ (C) A radiation survey is not required as only sealed sources were ever possessed under this license, and:

- ☐ (i) The results of the latest leak test are attached; and/or;
- ☐ (ii) No leaking sources have ever been identified.

D. RETENTION OF RECORDS

Records required to be maintained following license termination shall be available at the following address:

E. CERTIFICATION

I certify under penalty of perjury that the information contained on this form and all attachments are true and correct. It is therefore requested that the above referenced radioactive material license be terminated.

NAME & TITLE	SIGNATURE	DATE

NJRAD Form-483 (Revised August 19, 2008)

REGISTRATION CERTIFICATE – *in vitro* TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
P.O. Box 415, Trenton, NJ 08625
Tel. (609) 984-5462
Fax. (609) 633-2210
Website: http://www.nj.gov/dep/rpp/

Subchapter 51 of N.J.A.C. Title 7, Chapter 28 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under Subchapter 51 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NJRAD Form 483 and received from the Department a validated copy of NJRAD Form 483 with a registration number.

INSTRUCTIONS – Complete and submit this form to the address listed above. Use of material for the purpose specified shall not begin until approval is granted by the Department.

1. Name and current mailing address of registrant:
Registrant Name:
Telephone:
Facsimile:
Address:

2. Individual responsible for the material(s):
Name:
Telephone:
Address:

3. Application: (check one box only)
I hereby apply for a registration number pursuant to Subchapter 51, for use of byproduct materials for:
☐ Myself, a duly licensed physician authorized to disperse drugs in the practice of medicine.
☐ The above-named clinical laboratory.
☐ The above named hospital.
☐ Veterinarian in the practice of veterinary medicine.

4. Certification: I hereby certify that:

A. All information in this registration certificate is true, accurate and complete.
B. I am aware that there are significant civil and criminal penalties for submitting false, inaccurate or incomplete information, including fines and/or imprisonment.
C. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of Subchapter 51. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.
D. I understand that Department regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Bureau of Environmental Radiation within 30 days from the effective date of such change.
E. I have read and understand the provisions of Subchapter 51 and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the Bureau of Environmental Radiation.

Name and Title of Certifying Official	**Signature**	**Date**

FOR DEP USE ONLY	**Name and Title of Certifying Official** / **Signature**	**Date**	**Registration Number**
		☐ **Approved** ☐ **Denied**	

New Jersey Department of Environmental Protection
Division of Environmental Safety & Health
Radiation Protection and Release Prevention Programs
P.O. Box 415
Trenton, New Jersey 08625-0415
Tel (609) 984-5400
Fax (609) 984-5595

TO: All New, Current, or Previous Users of Devices Subject to General License Registration

PURPOSE: To Track and Account for Certain Generally Licensed Devices for Public Protection

The New Jersey Department of Environmental Protection (DEP) requires annual registration of certain devices that are possessed under the general license issued in N.J.A.C. 7:28-52 (see 10 CFR 31). Devices subject to registration include those containing the radioactive material and activity listed in Table 1. You are receiving this notice because DEP records indicate that you have one or more such devices. Information about the general license registration program is available on the Internet at: http://www.nj.gov/dep/rpp

SUBJECT: ANNUAL REGISTRATION OF GENERALLY LICENSED DEVICES

Note that under N.J.A.C. 7:28-52 (see 10 CFR 31), the attached General Licensee Registration Package must be completed, signed, and returned to the DEP within 30 days from the date of this letter. READ ALL OF THE INSTRUCTIONS PRIOR TO COMPLETING THE PACKAGE. Mail the registration fee (check or money order payable to the Treasurer, State of New Jersey) and a copy of the completed Registration to:

Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
PO BOX 415
Trenton, NJ 08625-0415

Registration Fee: DEP regulations (N.J.A.C. 7:28-52)(see 10 CFR 31) require that you submit a registration fee with each registration on an annual basis. The registration fee is subject to change yearly, and you are required to submit the fee that is in effect as of the date of this letter. If you have any questions about the fee or payment options, call 609-984-5400.

The REGISTRATION FEE is $350.00 per registered device.

Enclosures:
1. NJRAD Form 664, "General Licensee Registration Form"

INSTRUCTIONS FOR COMPLETING NJRAD FORM 664 "GENERAL LICENSE REGISTRATION"

Review all seven sections of this registration form. If any information is incorrect or missing, make corrections in the applicable boxes or attach additional sheets, if necessary. Use the "Ø" character to represent the number 0 (zero). Verify information about the devices by reviewing the label on the outside of the device. **For safety reasons, DO NOT TRY TO TAKE APART any device to verify this information.** If you are uncertain how to identify the device's label, contact the device's manufacturer or an authorized service agent for this information. Also contact the manufacturer for any additional information about general license requirements. You may also review 10 CFR 31.5 and other applicable regulations on the NRC web site at http://www.nrc.gov/reading-rm/doc-collections/cfr/, or review specific information about the general licensee project at http://www.nrc.gov/materials/miau/miau-reg- initiatives/gen-license.html

Sections 1 – Indicate whether the general license registration form is for a new, amended or renewal registration.

Section 2 – Provide the requested information about you, the general licensee. The Registrant name can be a person or a corporation/organization/department – whoever owns the device.

Section 3 – Provide the name, telephone number, and mailing address of the individual designated to be responsible for maintaining the registered device(s). This individual must verify and sign the form in section 7.

Section 4 – Provide the street address/location where your device(s) are stored/used. For portable devices, provide the storage location. P. O. Box addresses are not permitted in this section. Include additional information about the exact location of storage (such as department, room number, etc.).

Section 5 – Indicate the number of devices requiring registration and multiple by $350 to get the total annual fee due for your registration.

Section 6 - Devices Subject to Registration. This section lists each device subject to registration and in your possession, according to DEP records. Devices subject to registration include those containing at least one of the radionuclides listed in Table 1, with the activity indicated, at the time of manufacture.

Table 1. Criteria for Registration

Radionuclide	Activity greater than or equal to:
Strontium-90 (Sr-90) Radium-226 (Ra-226)	3.7 megabecquerel (0.1 millicurie)
Cobalt-60 (Co-60) Curium-244(Cu-244) Americium-241 (Am-241) Californium-252 (Cf-252)	37 megabecquerel (1 millicurie)
Cesium-137 (Cs-137)	370 megabecquerel (10 millicurie)

If you do not possess a device listed, check the "not in possession of device" box, and provide the following relevant information on an additional sheet:

- Date transferred
- Location of Device
- Recipient Name, Contact Information, Address, License Number

Section 7 - Certification and Signature. The responsible individual must certify, sign, and date Section 7.

NJRAD Form-664 (Revised August 18, 2008)

GENERAL LICENSE REGISTATION FORM

INSTRUCTIONS – Read each item carefully and answer as completely as possible. Responses may be submitted on separate sheets if the appropriate section is clearly referenced. Make a copy of the completed application and all attachments for your records. Send signed original and appropriate fees to the address listed on the top-right of this form. Make checks payable to: "Treasurer, State of New Jersey".

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
P.O. Box 415, Trenton, NJ 08625
Tel. (609) 984-5462
Fax. (609) 633-2210
Website: http://www.nj.gov/dep/rpp/

1. General License Information:
☐ **New** ☐ **Renewal**
☐ **Amended**:
GL Registration Number: _____

2. Name and current mailing address of registrant:
Registrant Name:
Telephone:
Address:

3. Individual responsible for the device(s):
Name:
Telephone:
Address:

4. Physical Location of Storage:
Address:

5. Fee Information:
Number of Registered Devices:
Annual Fee per registered device: $350.00
Total Registration Fee:

6. Device Information: (attach additional sheets if necessary)

6a. Device #1 ☐ **No longer in possession**
Distributor: License #:
Manufacturer: License #:
Device Model: Device Serial #:
Date Received: Date Transferred/Disposed:
Source(s) possessed including Isotope, Activity (mCi):

6b. Device #2 ☐ **No longer in possession**
Distributor: License #:
Manufacturer: License #:
Device Model: Device Serial #:
Date Received: Date Transferred/Disposed:
Source(s) possessed including Isotope, Activity (mCi):

6c. Device #3 ☐ **No longer in possession**
Distributor: License #:
Manufacturer: License #:
Device Model: Device Serial #:
Date Received: Date Transferred/Disposed:
Source(s) possessed including Isotope, Activity (mCi):

6c. Device #4 ☐ **No longer in possession**
Distributor: License #:
Manufacturer: License #:
Device Model: Device Serial #:
Date Received: Date Transferred/Disposed:
Source(s) possessed including Isotope, Activity (mCi):

7. Certification: I, CERTIFY UNDER PENALTY OF LAW THAT THE INFORMATION PROVIDED IN THIS DOCUMENT IS TRUE, ACCURATE AND COMPLETE. I AM AWARE THAT THERE ARE SIGNIFICANT CIVIL AND CRIMINAL PENALTIES FOR SUBMITTING FALSE, INACCURATE ORINCOMPLETE INFORMATION, INCLUDING FINES AND/OR IMPRISONMENT. THE CERTIFICATION SHALL BE SIGNED BY THE HIGHEST RANKING CORPORATE, PARTNERSHIP OR GOVERNMENTAL OFFICER OR OFFICIAL AT THE FACILITYOR THE INDIVIDUAL FOR WHICH OR FOR WHOM THE SPECIFIC STATE LICENSE IS REQUESTED.

Name and Title of Certifying Official	**Signature**	**Date**

New Jersey Department of Environmental Protection
Division of Environmental Safety & Health
Radiation Protection and Release Prevention Programs
P.O. Box 415
Trenton, New Jersey 08625-0415
Tel (609) 984-5400
Fax (609) 984-5595

TO: All New, Current, or Previous Users of Devices Subject to General License Registration

PURPOSE: To Track and Account for Certain Generally Licensed Devices for Public Protection

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- Date transferred
- Location of Device
- Recipient Name, Contact Information, Address, License Number

[illegible]ection 7 - Certification and Signature. The responsible individual must certify, sign, and date Section 7.

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Jon E. Corzine
Governor

Lisa P. Jackson
Commissioner

STATE OF NEW JERSEY
DEPARTMENT OF ENVIRONMENTAL PROTECTION
RADIATION PROTECTION PROGRAMS AND RELEASE PREVENTION
PO BOX 415, TRENTON, N.J. 08625-0415
609-984-5462

NOTICE TO EMPLOYEES
STANDARDS FOR PROTECTION AGAINST RADIATION

Your Employer's Responsibility

1. Any company that conducts activities regulated by the Department of Environmental Protection (DEP) must comply with the DEP's requirements. If a company violates DEP requirements, it may be penalized or have its license revoked.

2. Your employer must post or otherwise make available to you copies of the New Jersey Administrative Code, Title 7, Chapter 28 (NJAC 7:28), licenses, registrations and operating procedures which apply to work you are engaged in, and explain their provisions to you.

What is Covered By The New Jersey Administrative Code, Title 7, Chapter 28
(NJAC 7:28-1 et seq.)

1. Limits on exposure to radiation and radioactive material in controlled areas.

2. Measures to be taken after accidental exposure;

3. Personnel monitoring, survey and equipment;

4. Caution signs, labels, and safety interlock equipment;

5. Related matters.

Your Responsibility As A Worker

You should familiarize yourself with those provisions of NJAC 7:28 and the operating procedures which apply to the work for which you are engaged. You should observe these provisions for your own protection and the protection of your co-workers. Should you observe violations of these requirements, you are to report them to the above address.

You are Protected From Discrimination
(NJSA 34:19-1)

Under the "Conscientious Employee Act" an employer cannot discharge, suspend or demote an employee who discloses an activity or practice which he believes to be unlawful.

How Do You Report Violation?

You should report violations immediately to your supervisor. If you believe that adequate corrective action is not being taken, you may report this to a DEP inspector or the DEP office listed above.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. NJAC 7:28 requires that your employer provide you with a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in NJAC 7:28-6. This section specifies limits of exposure to radiation and exposure to concentrations of radioactive material in air and water.

2. If you work where personnel monitoring is required, and if you request information on your radiation exposures:

   (a) Your employer shall advise you annually of your exposure of radiation, and,

   (b) Your employer shall give you a written report, upon termination of your employment, of your radiation exposures, and any bioassays.

INSPECTIONS

All persons shall afford the Department an opportunity to inspect any sources of radiation and the operation associated with the source of radiation as well as the facilities and premises where the source of radiation is being used or stored (NJAC 7:28-2).

INQUIRIES

Inquiries dealing with the matters outlined above are to be made to the Radiation Protection Programs, New Jersey State Department of Environmental Protection, PO Box 415, Trenton, New Jersey 08625-0415 (609-984-5462).

POSTING REQUIREMENT

Copies of this notice must be posted where employees working in or frequenting any portion of controlled areas can observe a copy on the way to or from their place of employment.

NRC FORM 483 (6-2008) U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0038 EXPIRES: 11/30/2008

Estimated burden per response to comply with this mandatory collection request: 8 minutes. The validated registration serves as evidence to suppliers of byproduct material that the registrant is entitled to receive the byproduct material. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to INFOCOLLECTS.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0038), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

REGISTRATION CERTIFICATE -- *in vitro* TESTING WITH BYPRODUCT MATERIAL UNDER GENERAL LICENSE

Section 31.11 of 10 CFR 31 establishes a general license authorizing physicians, clinical laboratories, hospitals, and veterinarians in the practice of veterinary medicine to possess certain small quantities of byproduct material for *in vitro* clinical or laboratory tests not involving the internal or external administration of the byproduct material or the radiation therefrom to human beings or animals. Possession of byproduct material under 10 CFR 31.11 is not authorized until the physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine, has filed NRC Form 483 and received from the Commission a validated copy of NRC Form 483 with a registration number.

1. NAME AND ADDRESS OF APPLICANT *(See Instruction 3.B. below)*

TELEPHONE NUMBER (Include Area Code):

2. APPLICATION *(Check one box only)*

I hereby apply for a registration number pursuant to 10 CFR 31, Section 31.11, for use of byproduct materials for:

- ☐ Myself, a duly licensed physician authorized to disperse drugs in the practice of medicine.
- ☐ The above-named clinical laboratory.
- ☐ The above named hospital.
- ☐ Veterinarian in the practice of veterinary medicine.

INSTRUCTIONS

A. Submit this form to:

Source Safety and Security Branch (T-8 E24)
Division of Materials Safety & State Agreements
Office of Federal and State Materials
and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

(At NRC, a registration number will be assigned and a validated copy of NRC Form 483 will be returned.)

B. In the box above, print or type the name, address (including ZIP Code), and telephone number of the registrant physician, clinical laboratory, hospital, or veterinarian in the practice of veterinary medicine for whom or for which this registration

4. REGISTRATION

REGISTRATION NUMBER:

(If this an initial registration, leave this space blank -- number to be assigned by NRC. If this is a change of information from a previously registered general license, include your registration number.)

5. If place of use is different from address listed above, give complete address.

6. CERTIFICATION

I hereby certify that:

A. All information in this registration certificate is true and complete.

B. The registrant has appropriate radiation measuring instruments to carry out the tests for which byproduct material will be used under the general license of 10 CFR 31.11. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the byproduct materials.

C. I understand that Commission regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Director of Nuclear Material Safety and Safeguards within 30 days from the effective date of such change.

D. I have read and understand the provisions of Section 31.11 of NRC regulations 10 CFR 31 (reprinted on the reverse side of this form); and I understand that the registrant is required to comply with those provisions as to all byproduct material which he receives, acquires, possesses, uses, or transfers under the general license for which this Registration Certificate is filed with the U.S. Nuclear Regulatory Commission.

PRINTED OR TYPED NAME AND TITLE OF APPLICANT	SIGNATURE	DATE

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECTS. 18 U.S.C. 1001 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.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 10 CFR 31.11

§31.11 General license for use of byproduct materials for certain *in vitro* clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units no exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen 3 (tritium), in units not exceeding 50 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron 59, in units not exceeding 20 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americum-241 each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(8) Cobalt 57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NRC Form 483, "Registration Certificate - in vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and received from the Commission a validated copy of NRC Form 483 with registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under Part 35 of this chapter.

(c) A person who receives, acquires, possesses or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess, at any one time, pursuant to the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine 125, iodine 131, selenium-75, and/or iron 59 in excess of 200 microcuries.

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material, except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as required by §20.301 of this chapter.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section, as required by §20.301 of this chapter.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of §32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59 or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
NAME OF MANUFACTURER

(e) The registrant possessing or using byproduct material under the general license of paragraph (a) of this section shall report in writing to the Director of Nuclear Material Safety and Safeguards any changes in the information furnished by him in NRC Form 241, "Registration Certificate - in vitro Testing with Byproduct Material Under General License." The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Parts 19, 20, and 21 of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §20.301, 20.402, and 20.403 of this chapter.

NOTES

[1] A State to which certain regulatory authority over radioactive material has been transferred by formal agreement, pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

[2] Material generally licensed under this section prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

[3] A new triplicate set of this Registration Certificate, NRC Form 483, may be used to report any change of information furnished by a registrant as required by §31.11(e).

If larger quantities or other forms of byproduct material than those specified in the general license of 10 CFR 31.11 are required, file NRC Form 313, "Application for Byproduct Material License," to obtain a specific byproduct material license. Copies of application and registration forms may be obtained from the Medical, Academic and commercial Use Safety Branch (O-6 H3), Division of Industrial and Medical Nuclear Safety, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

NRC FORM 653 (8-2005) 10 CFR 32 — U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0001 EXPIRES: 08/31/2008

Estimated burden per response to comply with this mandatory collection request: 36 minutes. NRC requests quarterly reports to keep apprised of device movements. Send comments regarding the burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0001), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

(Continue on NRC Form 653, 653A or 653B, as appropriate)

For each "licensee" to whom a device(s) has been transferred during the reporting period, supply the following:

NAME OF VENDOR	REPORTING PERIOD FROM	TO
LICENSE NUMBER		

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE		MAILING ADDRESS AT THE LOCATION OF USE *(No P. O. Boxes, include Zip Code)*
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE		MAILING ADDRESS AT THE LOCATION OF USE *(No., P.O. Boxes, include Zip Code)*
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

NRC FORM 653 (Continued) U.S. NUCLEAR REGULATORY COMMISSION
(005)
FR 32

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE		MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*
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TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

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NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

NRC FORM 653 (Continued) U.S. NUCLEAR REGULATORY COMMISSION
(8-2005)
10 CFR 32

TRANSFERS OF INDUSTRIAL DEVICES REPORT (TO GENERAL LICENSEES)

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE		MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

INTERMEDIATE PERSON(S) (if any)

NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE
NAME OF INTERMEDIATE PERSON(S)	NAME OF RESPONSIBLE INDIVIDUAL	TITLE OF RESPONSIBLE INDIVIDUAL	TELEPHONE

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE		MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*
NAME OF RESPONSIBLE INDIVIDUAL	TELEPHONE	
TITLE OF RESPONSIBLE INDIVIDUAL		

INFORMATION ON DEVICE(S) TRANSFERRED

DATE OF TRANSFER	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	ISOTOPE	ACTIVITY AND UNITS

NRC FORM 653A
(8-2005)
CFR 32

U.S. NUCLEAR REGULATORY COMMISSION

TRANSFERS OF INDUSTRIAL DEVICES REPORT (FROM GENERAL LICENSEES)

For each "licensee" from whom a device(s) has been received during the reporting period, supply the following:

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

NRC FORM 653A (Continued)
(8-2005)
10 CFR 32

U.S. NUCLEAR REGULATORY COMMISSION

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INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

GENERAL LICENSEE INFORMATION

NAME OF GENERAL LICENSEE	MAILING ADDRESS AT THE LOCATION OF USE *(No P. O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

DATE OF RECEIPT	TYPE OF DEVICE	MODEL NUMBER	SERIAL NUMBER	MANUFACTURER OR INITIAL TRANSFEROR (IF NOT REPORTING PARTY)

NRC FORM 653B
(8-2005)
10 CFR 32

U.S. NUCLEAR REGULATORY COMMISSION

TRANSFERS OF INDUSTRIAL DEVICES REPORT (LABEL CHANGES)

For each device for which required label information has been changed, supply the following:

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

NRC FORM 653B (Continued)
(8-2005)
10 CFR 32

U.S. NUCLEAR REGULATORY COMMISSION

TRANSFERS OF INDUSTRIAL DEVICES REPORT (LABEL CHANGES)

For each device for which required label information has been changed, supply the following:

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

GENERAL LICENSEE USER INFORMATION

NAME OF GENERAL LICENSEE USER	MAILING ADDRESS AT THE LOCATION OF USE *(No P.O. Boxes, include Zip Code)*

INFORMATION ON DEVICE(S) RECEIVED

TYPE OF DEVICE	MODEL NUMBER	PREVIOUS SERIAL NUMBER	NEW SERIAL NUMBER	PREVIOUS ISOTOPE	NEW ISOTOPE	PREVIOUS LABEL ACTIVITY AND UNITS	LABEL ACTIVITY AND UNITS

BER Licensing Procedures

APPENDIX B

Sample Letters

APPENDIX B
Sample Letters

Table of Contents

Attachment 1: Sample Letter - Request for additional information

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: New Jersey Radioactive Materials License Application/Amendment Request
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]

[INSERT SALUTATION]:

The Bureau is in receipt of your ***<<application / amendment request / Decommissioning Plan>>*** dated ***<<DATE>>***. In addition to the items already submitted, please provide the following:

1. ***<<Item 1*** **- DESCRIBE THE DEFICIENCY AND INCLUDE A CLEAR STATEMENT SPECIFYING THE INFORMATION NEEDED** ***>>***
2. ***<<Item 2>>***
3. ***<<Item 3>>***
4. ***<<Item 4>>***

To continue review of your submission, we request that you respond in writing within 30 calendar days from the date of this letter. To expedite processing, please reference the program interest and activity identification numbers listed in the subject line above. Official correspondence regarding your New Jersey Radioactive Materials Licenses must be signed by the administrator or Radiation Safety Officer and submitted by fax or mail to our office.

If you have questions or require clarification on any of the information stated above, we encourage you to contact us at 609-984-5462.

Sincerely,
[INSERT NAME]
Radioactive Materials Section

Attachment 2: Sample letter - Denial due to insufficient information

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: New Jersey Radioactive Materials License Application/Amendment Request
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]

[INSERT SALUTATION]:

This letter shall serve as notification that the Department has **denied** your amendment request dated <<***DATE***>> due to insufficient information. Correspondences were sent from this office dated <<***DATE***>> and <<***DATE***>> requesting additional information. No response to either of these letters has been received. Therefore your request has been terminated. No response to this notification is necessary.

Should you have any questions, I can be reached at (609) 984-5480.

Sincerely,
[INSERT NAME]
Radioactive Materials Section

Attachment 3: Cover Letter for Licensing Actions except Terminations

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: New Jersey Radioactive Materials License [INSERT APPROPRIATE DESCRIPTIVE TEXT - NEW LICENSE, LICENSE AMENDMENT, LICENSE RENEWAL]
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]

[INSERT SALUTATION]:

Enclosed is New Jersey State Radioactive Materials License **[INSERT LICENSE #]** issued in response to your **application/amendment request** for a radioactive materials license authorizing the use of specific radioactive materials in the State of New Jersey.

This license contains conditions affecting the use of these radioactive materials. Please review each license condition. Although the Bureau has made a determination that your use of radioactive material will not constitute a hazard to health and safety, it is the licensee's responsibility to maintain compliance with NJAC 7:28-1 et seq. the New Jersey Radiation Protection Code. You should review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please contact the Radioactive Materials Section.

[THE FOLLOWING DISCUSSION MAY BE OMITTED FOR AMENDMENTS:]
NJDEP expects licensees to conduct their programs with meticulous attention to detail and high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NJDEP requirements, you must conduct your radiation safety program according to the condition of your NJDEP license, representations made in your license application, and NJDEP regulations. In particular, note that you must:

1. Operate in accordance with New Jersey Administrative Code Title 7, Department of Environmental Protection, Chapter 28, Radiation Protection Programs (NJAC 7:28) regulations and NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspections and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NJDEP in writing of any change in mailing address.
3. In accordance with N.J.A.C. 7:28-51.1, notify NJDEP, promptly, in writing, and request termination of the license:
    a. When you decide to terminate all activities involving materials authorized under the license; or
    b. If you decide not to acquire or possess and use authorized material.
4. Request and obtain a license amendment before implementing changes to the license.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NJDEP regulations.

In addition, please note that BER Form 100 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application must be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NJDEP. Failure to conduct your program in accordance with NJDEP regulations, license conditions, and representations made in your license application and supplemental correspondence with NJDEP may result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying, or revoking your license as specified in N.J.A.C. 7:28-4.16.

If you have questions or require clarification on any of the information stated above, we encourage you to contact us at 609-984-5462. Thank you for your cooperation.

Sincerely,

[INSERT NAME]
Radioactive Materials Section

Enclosure: As stated

Attachment 4: Temporary Exemption from DEP Regulation or License Condition

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: TEMPORARY EXEMPTION TO NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION (NJDEP) [REGULATION OR LIST THE SPECIFIC LICENSE CONDITION(S)]
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]

[INSERT SALUTATION]:

Pursuant to the written request dated [date of request] for temporary exemption(s) from the requirements of [NJDEP regulation or license condition] by [name and position of requestor representing the licensee], the following temporary exemption(s) is (are) granted by the Department with the approval of the Commission on Radiation Protection for the specified period of time:

[Each temporary exemption granted should be listed separately with documentation of the circumstances surrounding the request and the duration of time for that the exemption is granted.]

If your understanding of the above temporary exemption differs from that set forth above, you are to contact the Radioactive Materials Section immediately, at 609-984-5462.

Sincerely,

[INSERT NAME], Supervisor
Radioactive Materials Section

Attachment 5: Sample Letter for Expired License

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: IMPORTANT NOTICE OF LICENSE EXPIRATION
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]
Expiration Date: [INSERT DATE]

[INSERT SALUTATION]:

Our records indicate that your New Jersey State Radioactive Materials License has expired on the date shown above. A letter was sent [DATE] (copy enclosed) informing you that your license would expire in 180 days and requesting a timely renewal application within 30 days. As of the date of this letter, no renewal application has been filed in accordance with NJAC 7:28-50.

It is our understanding that you still possess material that requires a specific department license. Your possession of such material without a current license is a violation of NJAC 7:28-50. You must place your radioactive material in secure storage until such time as you acquire a valid department Radioactive Material License. No use of radioactive material or purchase of additional radioactive material is authorized.

If you currently possess licensed material but have decided not to continue your program, you must immediately do the following in order to comply with NJAC 7:28-50:

1. Transfer all radioactive material formerly authorized by the expired license. Transfer must comply with the requirements of NJAC 7:28-50. Before transferring any radioactive material, you must verify that the recipient's license authorizes the receipt of the isotope(s), type, form, and quantity of radioactive material that is to be transferred.
2. Send copies of the transfer records, a completed copy of form NJRAD-314 "Request for Termination of Specific License and Disposition of Radioactive Material", and a separate written request for termination of the license to this office within 15 days of the date of this letter, so we can close our files on the expired license.

If you do not possess licensed materials and do not desire to continue your program, you must submit copies of records documenting transfer or disposal of the material, a completed Form

NJRAD-314 "Request for Termination of Specific License and Disposition of Radioactive Material" (copy attached), and a letter confirming your decision.

Enclosed is regulatory guidance which you should utilize in preparing the application. Be advised that the guidance may not correspond to the current rule and that the rule takes precedence. Also, for your information, the Department has guidance available on the following website: http://www.nj.gov/dep/rpp/rms/index.htm

If you have questions or require clarification on any of the information stated above, we encourage you to contact us at 609-984-5462. Thank you for your cooperation.

Sincerely,

William P. Csaszar, Supervisor
Radioactive Materials Section

Enclosure: As stated

Attachment 6: Sample Renewal Letter for 90 day Notification

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: IMPORTANT NOTICE OF LICENSE EXPIRATION
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]
Expiration Date: [INSERT DATE]

[INSERT SALUTATION]:

Your NJDEP Radioactive Materials License No. [INSERT LICENSE #] will expire on [INSERT EXPIRATION DATE]. If you wish to renew your license, please submit a complete new application on Form NJRAD-313, "Application for Radioactive Material License" with all required attachments. It is not acceptable to reference any information or documents that have been previously submitted under previous application or renewal requests.

For guidance in preparing this application, Regulatory Guide NUREG 1556 (all Volumes) can be found on the US Nuclear Regulatory Commission website at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/ Please be aware that you must use the Volume which corresponds to your particular situation.

Please submit all renewal and amendment request to the following address:

Radioactive Materials Section
Bureau of Environmental Radiation
NJ Department of Environmental Protection
PO Box 415
Trenton, NJ 08625-0415

If your renewal application is submitted at least 30 days before the license expiration date, your license will remain in effect until the application has been finally determined by the Bureau of Environmental Radiation.

However, if your renewal application cannot be filed before the expiration date, you should contact NJDEP immediately to see if you can obtain a temporary extension of the expiration

date. Without NJDEP approval of that extension request, your license expires on the expiration date stated on the license. If your license expires, you no longer have a valid license, but you are required to maintain all licensed materials in safe, locked storage until your application for a license or request for termination is submitted and approved. Use of the licensed material after the expiration of your license may subject you to criminal and/or civil enforcement.

If you do not wish to renew your license, you must dispose of or transfer all licensed radioactive material in your possession in an authorized manner (see the appropriate requirements in NJAC 7:28-51.1, 58.1, or 60.1); then complete the enclosed NJRAD Form 314, "Certificate of Disposition of Materials," and return it before the expiration date of your license, with a request that your license be terminated. If you cannot dispose of or transfer all licensed radioactive material in your license before the expiration date, you must request a license renewal, for storage only, of the radioactive material, to avoid enforcement action for violations involving the possession of licensable material without a valid license. Enforcement action may include a substantial monetary civil penalty that could also include daily civil penalties until you achieve compliance.

If you have questions or require clarification on any of the information stated above, we encourage you to contact us at 609-984-5462. Thank you for your cooperation.

Sincerely,
[Name], Supervisor
Radioactive Material Section

Attachment 7: Receipt of Renewal Application – Timely Filed

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: Acknowledgement of Timely Renewal
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]

[INSERT SALUTATION]:

This acknowledges receipt of your application for renewal of New Jersey Radioactive Material License No. [INSERT LICENSE #]. In accordance with NJAC 7:28-50 your existing license shall not expire until the application has been fully determined by this office.

If you have questions or require clarification on any of the information stated above, we encourage you to contact us at 609-984-5462. Thank you for your cooperation.

Sincerely,

[NAME], Supervisor
Radioactive Materials Program

Attachment 8: Sample Letter for Termination of a Specific License

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: Notice of License Termination
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]

[INSERT SALUTATION]:

The Bureau has received your documentation on the disposition of your radioactive materials including the following:

- <list submissions i.e. as decommissioning plan, responses to RAIs, final status survey, etc.>

The Bureau has determined that <Company> has complied with all the requirements for license termination in accordance with N.J.A.C. 7:28-12.1 et seq. Therefore, as of <date>, your New Jersey State Radioactive Materials License ***<<INSERT #>>*** is hereby terminated.

Although your license is terminated, it does not relieve you of the responsibility of consequences which might arise as the result of activities not ??covered under this license. In addition, it is your responsibility to determine if the Industrial Site Recovery Act (ISRA) applies to your facility, if you have not already done so. Instructions on determining applicability are on the New Jersey Department of Environmental Protection Agency's (NJDEP) website at http://www.nj.gov/dep/srp/isra/isra_applicability.htm. Compliance with the ISRA rules, N.J.A.C. 7:26B is required when ceasing subject industrial operations or prior to sale of the property. Contact the Site Remediation Program for requirements pertaining to ISRA. If you have any questions I may be reached at <reviewer's phone number>.

Your cooperation in complying with NJAC 7:28-1 et seq. is appreciated.

Sincerely,

[NAME]
Radioactive Materials Program

Attachment 9: Letter for Follow-up on Returned Mail

Division of Environmental Safety and Health
Bureau of Environmental Radiation
Radioactive Materials Section
PO Box 415
Trenton, NJ 08625-0415
Phone (609)-984-5462
Fax (609) –633-2210

[INSERT DATE]

[INSERT NAME AND ADDRESS]

SUBJECT: New Jersey Radioactive Materials License
Program Interest ID #: [INSERT #]
Activity ID #: [INSERT #]

[INSERT SALUTATION]:

This letter concerns your New Jersey Radioactive Materials License issued by the New Jersey Department of Environmental Protection (NJDEP), identified above. Correspondence sent to the address on your license has been returned to us unopened. We have found through telephone contacts or other sources that you can be reached at the above address.

Please be advised that you must notify us of changes in your mailing address and/or location of licensed radioactive material. We would appreciate it if you would review your current license and confirm whether it correctly reflects your mailing address and locations of radioactive material. If there are changes, you should immediately submit an amendment request to the Bureau of Environmental Radiation, Department of Environmental Protection, PO Box 415, Trenton, NJ 08625-0415.

If we do not hear from you within 30 days, we plan to turn your files over to our Inspection Section for appropriate review. If you have questions or require clarification on any of the information stated above, we encourage you to contact us at 609-984-5462. Thank you for your cooperation.

Sincerely,

[NAME]
Radioactive Materials Program

License Condition for Increased Controls

The licensee will comply with the requirements for "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern" (IC) (Accession No. ML053130364) published in the Federal Register (FR) on December 1, 2005 (70 FR 72128) as Attachment B to EA-05-090, "Order Imposing Increased Controls," (Accession No. ML053130218)". The licensee will complete implementation of the IC requirements by the first day that radionuclides specified in Table 1, Radionuclides of Concern, (Accession No. ML053130250) of the IC are possessed at or above the limits specified in the table. Notwithstanding any provisions of the State regulations to the contrary, all measures implemented or actions taken in response to the IC requirements shall be maintained until the State orders otherwise in a revised license condition, or until the State explicitly modifies its regulations to reflect increased controls, and states in modifying its regulations that the revisions are to supercede Order EA-05-090.

License Condition – Fingerprinting

The licensee shall comply with the requirements described in the NRC Order EA-07-305 (the Order). The licensee shall complete implementation of said requirements by the first day that radionuclides in quantities of concern are possessed at or above the limits specified in "Table 1: Radionuclides of Concern" contained within the Order. The licensee shall notify the Department when they have achieved full compliance with the requirements described in the Order. The notification shall be made within **twenty-five (25) days** after full compliance has been achieved. This notification shall include a certification that the Trustworthiness and Reliability (T&R) Official (and any subsequent T&R Official) is themselves deemed trustworthy and reliable by the Licensee as required in paragraph B.2. of the Order. The licensee shall notify the NRC and the Department within 24 hours if the results from a criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Data Base.

PROPOSED LICENSE CONDITION FOR NSTS

XX. The licensee shall comply with the provisions of 10 CFR 20.2207 regarding the reporting of transactions involving nationally tracked sources, as defined in 10 CFR 20.1003 and Appendix E of 10 CFR Part 20.

4.3.3 LOW-LEVEL WASTE SITE LICENSING

4.3.3 Procedure for Conducting the Technical Evaluation of a Proposed License for a Low-level Radioactive Waste (LLRW) Land Disposal Site

New Jersey will develop procedures for conducting the technical evaluation of a proposed license for a LLRW land disposal site if the need arises. While New Jersey has the regulations in place to exercise the authority to license a LLRW facility, this authority may never need to be implemented, as New Jersey is currently a member of the Atlantic Compact. Documentation pertaining to the Atlantic Compact is in the section labeled 4.1.1 Authority to Establish a Program and Enter an Agreement.

4.3.5 LICENSING QUALITY ASSURANCE

4.3.5 Procedures for Assuring the Technical Quality of Licenses

New Jersey has established procedures as a means of assuring the integrity and quality of licensing actions. Included in the procedure is a requirement that all licenses will be submitted for a secondary peer review prior to being sent for final evaluation and signature. Included in this section of the application are:

BER 3.06 Licensing Quality Assurance
Attachment 1 - Licensing Casework Review Summary Sheet

NJDEP- BER Procedure 3.06
Licensing Quality Assurance

Introduction
In addition to this procedure, New Jersey's procedures addressing peer and supervisory review are found in the *Licensing Procedures*, *Inspection Procedures*, and *NJEMS Procedures Manual.*

The New Jersey Environmental Management System (NJEMS) is a database system used by the New Jersey Department of Environmental Protection to centrally locate information regarding licenses/permits, inspection information, and incidents. The system currently supports the Bureau of Environmental Radiation's enforcement records and documentation. Development of the portion of this system that will handle review, issuance and tracking of Licensing and Registration documentation to support the proposed Agreement State activities is continuing. Once in place (projected date early 2009), this one database will be the digital repository for licensing, inspection, enforcement, and incidents information and permit us to generate and track documents relating to these tasks.

The NJEMS' ability to provide for review of license and permit applications, as well as emission statements, testing documents, monitoring reports and enforcement actions, ensures a significant degree of quality assurance. The *NJEMS Procedures Manual* in conjunction with the *Licensing Procedures* will contain the specific procedures to be followed when performing licensing actions once this portion of the program is in place.

The quality assurance for licensing actions involves training of staff, use of appropriate procedures, and supervisory review of work performed. Quality review of licensing applications takes precedence over arbitrary completion deadlines. Supervisory review of all actions is required.

1.0 Objectives

A. To verify that license reviews are thorough, complete, consistent, and of acceptable technical quality with health and safety issues properly addressed.

B. To ensure that decisions regarding the issuance, denial, amendment, termination, or renewal of radioactive materials licenses are made in a technically sound fashion and in a manner consistent with approved NJDEP or NRC guidance.

C. To verify that essential elements of license applications have been submitted and that these elements meet current regulatory guidance for describing the isotopes and quantities used, qualifications of personnel who will use material, facilities and equipment, financial assurance, and operating and emergency procedures sufficient to establish the basis for licensing actions.

D. To confirm that the proper signature authority is followed.

E. To determine that license tie-down conditions are stated clearly and are inspectable.

F. To verify that deficiency letters clearly state regulatory positions and are used at the proper time.

G. To confirm that reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.

H. To verify that applicable guidance documents are available to reviewers and are followed.

2.0 Responsibilities

Administrative Assistant: The Administrative Assistant is responsible for notigying a licensee that their license(s) will expire in 180 days and sending appropirate guidance document(s) based on input from the technical staff. The Administrative Assistant shall inform the RMS Supervisor of licenseees that havfe not submitted renewal applications at least 30 days prior to expiration and of any licenses that have expired. The Administrative Assistant is responsible for receiving, logging and acknowledging the receipt of an application for license renewal and ensuring the applicant is informed that the application is considered to be timely. Maintains the hardcopy file with renewal documentation.

Qualified License Reviewer/Inspector (QLR/I): The QLR/I is responsible for reviewing licensing actions (initial application, renewals, amendments) to see if it they are valid and, with the concurrence of the Senior QLR/I, signing the letter informing the applicant that the renewal application is considered to be timely, and for processing the application as assigned.

Senior QLR/I: The Senior QLR/I is responsible for reviewing the QLR/I licensing actions and signing such actions in absence of the RMS Supervisor. The Senior QLR/I can perform the functions of the RMS Supervisor in his or her absence.

Radioactive Materials Section (RMS) Supervisor: The RMS Supervisor is responsible for determining if an application for renewal is timely or if a license has expired and should be terminated. The RMS Supervisor is responsible for determining if a renewal should be expedited or reviewed in its entirety and for assigning licensing actions to the appropriate Senior QLR/I (who may then delegate to the QLR/I). The RMS Supervisor is responsible for reviewing, approving, and signing licensing actions.

3.0 Procedure

1. All licensing actions will be reviewed by either the Senior QLR/I or RMS Supervisor.
2. To determine the technical quality of licensing actions, the following should be evaluated:

   a) Technical correctness with regard to license conditions, issue and expiration dates, and nomenclature in distribution licenses;
   b) Applications are properly completed and signed by an authorized official;
   c) Any significant errors, omissions, deficiencies or missing information in licensing action files (i.e., documents, letters, file notes, and telephone conversations). Licenses should be properly supported by information in the file. Any significant deficiencies related to health and safety should be documented, discussed with the section supervisor and communicated to the area being evaluated;
   d) Improper and/or illegal license authorizations. Any variances/exceptions to standards should receive management approval and not undermine health and safety;
   e) Appropriate financial assurance instruments are in place for licenses authorizing possession of radionuclides, quantities, or a combination thereof that meet the criteria for financial assurance requirements;
   f) Any pre-licensing visits completed for complex and major licensing actions;
   g) Procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program; licensing guides, checklists, and policy memoranda consistent with current NRC practice.
   h) Appropriate use of signature authority;
   i) Consideration of the present compliance status of licensees during reviews of licensing actions;
   j) Use of standard license conditions to expedite and provide uniformity to the licensing process, whenever practicable;
   k) Verification of specific tie-down license conditions;
   l) Implementation of licensing initiatives. In particular, the reviewer should identify these initiatives for a performance-based review (i.e., radiography certification, general licensing programs, etc.).

3.0 Each reviewer will complete Attachment 1. If there are questions, the licensing action will be returned to the QLR/I or Senior QLR/I to address.

4.0 The RMS Supervisor and/or the Senior QLR/I will keep Attachment 1 in the appropriate personnel file so that any trends can be evaluated. This file, along with the inspection evaluation reports, will be used to complete the Performance Evaluation System (PES) for each employee in the RMS.

Attachment 1

LICENSING CASEWORK REVIEW SUMMARY SHEET

A/S OR REGION: _____

FILE NO.:	_____	TYPE OF LICENSING ACTION: NEW	☐
LICENSEE:	_____	RENEWAL	☐
LOCATION:	_____	AMENDMENT	☐
LICENSE TYPE:	_____	TERMINATION	☐
DATE OF ACTION:	_____		
LICENSE NO.:	_____	LICENSE REVIEWER: _____	
AMENDMENT NO.:	_____		

NO.	COMMENTS FOR REPORT

	QUESTIONS FOR REVIEWERS

SUPERVISORY REVIEW BY: _____ DATE: _____

IMPEP REVIEW BY: _____ DATE: _____

FINDINGS DISCUSSED WITH: _____ DATE: _____

4.3.6 LICENSING ADMINISTRATIVE PROCEDURES

4.3.6 Administrative Licensing Procedures

New Jersey's administrative procedures for licensing that address receipt of licensing actions to technical evaluators, license documentation preparation, tracking of action progress, signing of completed licenses, transmittal of signed license to the licensee, and license file maintenance can be found in this section, as well as the transition from a NRC license to a New Jersey license.

BER 3.07 Licensing Administrative Procedures
BER 3.08 License Transition from NRC to New Jersey

NJDEP – BER Procedure No. 3.07
LICENSING ADMINISTRATIVE PROCEDURES

1.0 Introduction

New Jersey's administrative procedures for licensing that address receipt of licensing actions to technical evaluators, license documentation preparation, tracking of action progress, signing of completed licenses, transmittal of signed license to the licensee, and license file maintenance can be found in the *Licensing Procedures*.

All documents related to the licensing and inspection of radioactive material in New Jersey will be kept in filing cabinets in a secure area in the Bureau of Environmental Radiation. All electronic files are kept on the Department of Environmental Protection's password protected servers with restricted access.

The *Licensing Procedures* included in this application provides the licensing staff and other appropriate staff members with basic administrative procedures for processing, managing, and tracking licensing actions from the time each action is received by the Radioactive Materials Section (RMS) until the action is completed. These procedures include acknowledging requests for specific licensing actions, tracking the progress of actions, maintaining files electronically, preparing licenses, distributing documents, and other miscellaneous administrative activities.

The New Jersey Environmental Management System (NJEMS) is a database system used by the New Jersey Department of Environmental Protection to centrally locate information regarding licenses, inspection information, and incidents. The system currently supports the Bureau of Environmental Radiation's enforcement records and documentation. Development of the portion of this system that will handle review, issuance and tracking of Licensing and Registration documentation to support the proposed Agreement State activities is continuing. Once in place (projected date early 2009), this one database will be the digital repository for licensing, inspection, enforcement, and incidents information and permit us to generate and track documents relating to these tasks. A licensing tracking system, part of the New Jersey Environmental Management System (NJEMS), supports collection and review of license applications and enforcement actions. NJEMS also provides the capability to generate licenses, correspondence, and reports. By using NJEMS, the Bureau is able to create new licenses, modify existing licenses, and renew licenses.

2.0 Objective

The NJEMS system supports a standardized review process and provides licensing and inspection management reports. NJEMS allows the RMS staff and management to provide timely responses to inquiries and specialized, ad hoc queries. Consequently, all incoming licensing documents will be entered into this license tracking system.

3.0 Procedure

A. The Administrative Assistant and the QLR/I and/or the Senior QLP/I are responsible for the timely processing of materials licensing actions. All materials licenses are assigned unique numbers that are tracked in the NJEMS database for the life of the licenses. For initial applicants, a new license number will be assigned. However, this number will not be referenced in communications with the licensee until the license has been finalized. (The computer system permits licensee identification using many different queries including a facility name as well as a license number.) Each licensing action is tracked in the NJEMS database from receipt of a request for licensing action through completion.

B. The QLR/I or Senior QLR/I will complete an acceptance review, as defined in the *Licensing Procedures*, and take the appropriate actions.

C. The objective is to complete all licensing actions within 45 days of receipt. Therefore, a well-prepared license application (complete and accurate) should be processed, signed, and issued within that time. Likewise, the QLR/I should have identified any need for additional information or clarification and issued a deficiency letter within 30 days of the receiving a licensing action with flaws. When the response to the deficiency letter arrives, the 30-day timeframe begins again. The previous discussion established the time constraints for processing a licensing action. Peer review and supervisory review are included in that timeframe.

D. The 45-day completion objective should always be met when licensing actions involve health and safety related issues. However, the quality review and approval will always take precedence over an arbitrary completion deadline. A supervisory review of new, amended, and renewed licenses is required. A supervisory review is not required for deficiency letters.

E. The QLR/I will ensure that the correct program code is assigned to the license. When it becomes necessary to assign more than one program code to a license, the code with the highest inspection priority (shortest inspection cycle) will be designated the primary code.

F. To standardize and simplify the review process, QLR/Is will use all available tools, including process, criteria, and checklists, when reviewing license applications. These are included in the *Licensing Procedures*, their attachments and appendices.

G. License Authorization
When complete, each license must be signed by the QLR/I or Senior QLR/I and submitted for signature of the RMS Supervisor.

H. Issuance of Final Licensing Action
A cover letter and the original license should be sent for all completed licensing actions. The cover letter may be a form letter or individual letter. Many licensing actions require

specific information to be included in the cover letter related to the individual case. All information may be combined into a single cover letter, or QLR/Is may elect to use attachments. For licenses that are amended frequently, it is acceptable to include the standard information with every licensing action; or, if deemed appropriate, the information may be deleted if it was provided in a recent previous communication.

I. Record Retention

Paper and electronic records of inspection reports, enforcement actions, licensing documents, and routine correspondence are kept on the premises of the New Jersey Department of Environmental Protection, Bureau of Environmental Radiation. Paper documents are saved and filed according to license number and are stored in a secured entry resource room. Electronic files are kept as part of NJEMS on a network accessible to authorized Bureau staff. All records are periodically archived to effectively utilize space.

NJDEP – BER Procedure No. 3.08
License Transition from NRC to New Jersey

1.0 Procedure

A. Upon completion of the Agreement, all active NRC licenses issued to facilities in New Jersey will be recognized as New Jersey Department of Environmental Protection licenses. New Jersey will issue a one-page licensing document with the following information included: Licensee name and address, address where licensed material is used, Radiation Safety Officer, and name and phone number of contact person.

B. A new license number (if appropriate) and expiration date will be included. The document will contain the following statements:

"This license authorizes receipt, acquisition, possession, and transfer of byproduct, source, and/or special nuclear material; the authorized use(s); purposes; and the places of use as designated on the NRC license. The licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in the NRC license. The New Jersey Department of Environmental Protection rules shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the rules."

C. Electronic copies of the licenses shall be incorporated with and stored on NJEMS. Hard copies of licenses shall be stored in file cabinet in a secured area.

4.4 INSPECTION PROGRAM

4.4.1 INSPECTION PROCEDURES

4.4.1
INSPECTION PROCEDURES

New Jersey's inspection procedures and guides can be found in this section of the application. These inspection procedures and manual chapters have been adapted from the NRC versions and modified for New Jersey's program and regulations.

The inspection program is outlined in the combination of the *Inspection Procedures*, the *NJEMS Procedures Manual*, and the *Training and Qualification Manual* to form a critical part of the Department's overall radioactive materials regulatory program. These manuals provide the information necessary for inspection staff to process, manage, and track licensing activities. These manuals are included as part of this application.

The New Jersey Environmental Management System (NJEMS) is a database system used by the New Jersey Department of Environmental Protection to centrally locate information regarding licenses/permits, inspection information, and incidents. The system currently supports the Bureau of Environmental Radiation's enforcement records and documentation. Development of the portion of this system that will handle review, issuance and tracking of Licensing and Registration documentation to support the proposed Agreement State activities is continuing. Once in place, this one database will be the digital repository for licensing, inspection, enforcement, and incidents information and permit us to generate and track documents relating to these tasks.

Included in Section 4.4.1 are:

- NJDEP Inspection Manual – Manual Chapter 1220
- NJDEP Inspection Manual – Manual Chapter 2602
- NJDEP Inspection Manual – Manual Chapter 2800
- NJDEP Inspection Manual – Inspection Procedure 83822
- NJDEP Inspection Manual – Inspection Procedure 83890
- NJDEP Inspection Manual – Inspection Procedure 84850
- NJDEP Inspection Manual – Inspection Procedure 84900
- NJDEP Inspection Manual – Inspection Procedure 86740
- NJDEP Inspection Manual – Inspection Procedure 87102
- NJDEP Inspection Manual – Inspection Procedure 87103
- NJDEP Inspection Manual – Inspection Procedure 87104
- NJDEP Inspection Manual – Inspection Procedure 87121
- NJDEP Inspection Manual – Inspection Procedure 87122
- NJDEP Inspection Manual – Inspection Procedure 87123
- NJDEP Inspection Manual – Inspection Procedure 87124
- NJDEP Inspection Manual – Inspection Procedure 87125
- NJDEP Inspection Manual – Inspection Procedure 87126
- NJDEP Inspection Manual – Inspection Procedure 87127
- NJDEP Inspection Manual – Inspection Procedure 87130
- NJDEP Inspection Manual – Inspection Procedure 87131

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- NJDEP Inspection Manual – Inspection Procedure 87132
- NJDEP Inspection Manual – Inspection Procedure 87133
- NJDEP Inspection Manual – Inspection Procedure 87134
- NJDEP Inspection Manual – Inspection Procedure 92702

NJDEP INSPECTION MANUAL
MANUAL CHAPTER 1220

PROCESSING OF NJDEP FORM 241, 'RECIPROCITY -REPORT OF PROPOSED ACTIVITIES IN NEW JERSEY, IN AREAS OF DEPARTMENT JURISDICTION, AND INSPECTION OF RECIPROCITY LICENSEES OPERATING UNDER N.J.A.C.7:28-62.1)

1220-01 PURPOSE

To establish procedures for processing New Jersey Department of Environmental Protection (NJDEP) Form 241 and changes to NJDEP Form 241; provide information to licensees for filing NJDEP Form 241; and institute the frequencies and requirements for inspection of licensees operating under reciprocity in areas of NJDEP 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 N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) "RECIPROCITY"

02.03 To provide information to NJDEP 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 N.J.A.C. 7:28-62.1 (see 10 CFR 150.20.)

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 NJDEP Form 241 filed by licensees requesting reciprocity for activities conducted in New Jersey. Filing by facsimile is considered acceptable if the facsimile includes one copy of the NJDEP 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, which will be mailed to the Department. The licensee should receive confirmation (by telephone, e-mail, or facsimile) that NJDEP has received the facsimile.

1220-04 RESPONSIBILITIES AND AUTHORITIES

04.01 Radioactive Materials Licensing Section. Maintain NJEMS reciprocity activities, in order to assist in the planning of inspections of those activities and to establish the following procedures and guidelines for use in processing NJDEP Form 241:

a. Each year, at least 60 days prior to the licensees anniversary of operating under reciprocity, provide: a Letter reminding the licensee of their approaching anniversary date. Included in the letter would be the NJDEP's website where additional information, forms, etc. are available for download.

b. Review NJDEP Form 241 when received to ensure that the proposed activities are in accordance with N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) 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 NJDEP general license requirements in N.J.A.C. 7:28-62.1 (see 10 CFR 150.20.)

c. Enter the licensee information into NJEMS. The Supervisor, Radioactive Materials Section, or his/her designee shall be the signature authority for the reviewing official of the reciprocity activities, as requested by NJDEP Form 241.

d. Maintain records of reciprocity activities.

e. Maintain Form 241 requests for at least 5 years following the year for which the Form 241 was effective.

f. Schedule, conduct, and track inspections to achieve the overall objectives of the inspection program, including the objectives of this chapter.

g. Inspect licensees operating in areas of exclusive Department jurisdiction under reciprocity using the same provisions used for equivalent NJDEP-licensed activities. Carry out enforcement actions against those licensees when violations are found during a NJDEP inspection. (See Appendix II for specific procedures and frequency.)

Appendices:

I. "Procedures and Guidelines for Processing NJDEP Form 241 and "Procedures Letter" (Appendix I provides the procedures to be followed, by the reviewers, in processing reciprocity requests from the receipt of NJDEP Form 241 to the input of data into the NJEMS to the final distribution of completed actions.)

"Procedures Letter" (Appendix I also contains a sample Procedures Letter to be sent, by the Radioactive Material Licensing Section, to licensees each year, providing information concerning filing for reciprocity (including Forms 241 and procedures for filing, applicable guidelines, and regulations).)

II. "Inspection of Reciprocity Licensees" (Appendix II provides information for use by NJDEP inspectors concerning inspection frequencies and the tracking of inspections through the NJEMS).

APPENDIX I

PROCEDURES AND GUIDELINES FOR PROCESSING NJDEP 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 NJDEP Form 241.

1. Agreement State, Non-Agreement State and NRC licensees requesting reciprocity for activities conducted in New Jersey in areas of exclusive State jurisdiction are subject to N.J.A.C. 7:28-62.1 (see 10 CFR 150.20). Prior to the first time within a 12 consecutive month period that an Agreement State, Non-Agreement State or NRC licensee conducts activities in areas of Department jurisdiction, it must file a copy of a completed NJDEP Form 241, one copy of its license, and the appropriate fee as specified in fee category N.J.A.C. 7:28- 64.1.

   Note: A licensee operating under reciprocity pursuant to N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) shall obtain affirmative authorization from NJDEP before performing activities requested on NJDEP Form 241. Licensees that do not qualify for the general license will be informed of this determination, within 3 days of receipt of NJDEP Form 241 (See Item 4, "Deficient NJDEP 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 N.J.A.C. 7:28-61.1 (see 10 CFR 71.12).

   Note: If a company has more than one license, a separate NJDEP Form 241 must be submitted for work conducted under each license used during the calendar year.

   Note: All fee payments and questions concerning fees should be referred to the New Jersey Radioactive Materials Section.

2. In completing NJDEP Form 241, the licensee must provide sufficient information to enable NJDEP to conduct inspections.

   Note: The licensee should only identify work to be conducted during a single 12 consecutive month period.

3. In general, the preferred method of filing is through the facsimile transmission of NJDEP Form 241, a copy of the 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 NJDEP has received the facsimile.

Alternatively, the licensee may file the required information through the mail or other means as long as NJDEP 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 Supervisor, Radioactive Material Licensing Section or his designee can waive the time requirements specified in N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) for the filing of NJDEP Form 241, provided the licensee:

   a. informs the Radioactive Materials Section by telephone, facsimile, NJDEP Form 241, or letter of initial activities ; and

   b. receives oral or written authorization for the activity(ies) from the Radioactive Materials Section; and

   c. files NJDEP Form 241, a copy of the Agreement State, Non-Agreement State or NRC license and evidence (as described in paragraph B.3 above) that the appropriate fee requirements will be met within 3 days.

C. PROCESSING OF NJDEP FORM 241

Reciprocity licensees are required to report their proposed activities in New Jersey to the Radioactive Materials Section. The office shall take the following actions in processing NJDEP Form 241.

1. RECEIPT

Verify that the filing is timely. Stamp or otherwise note the date of receipt on all copies of NJDEP Form 241. The form must normally be received by NJDEP Radioactive Materials Office at least 3 calendar days before the licensee's beginning work.

Note: The Supervisor, Radioactive Material Licensing Section or his designee may waive the 3-day time requirement, as discussed in B.4. above.

2. INITIAL NJDEP FORM 241

   a. Immediately upon receipt of NJDEP 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 a copy of a valid, active Agreement State, Non-Agreement State or NRC license are included with the initial NJDEP Form 241.

Note: For NJDEP 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 Radioactive Materials management for approval.

c. Review the license that was submitted with NJDEP 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 or NRC licensee cannot qualify for a general license under N.J.A.C. 7:28-62.1 (see 10 CFR 150.20), 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 7:28-62.1 apply.

d. For initial NJDEP Forms 241, enter the licensee and fee information into NJEMS.

e. Enter work location information into NJEMS.

f. If NJDEP 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 NJDEP Forms 241." When it is determined that the required information has been submitted and the fee payment has been provided, sign and date NJDEP Form 241 as the reviewing official and forward a copy to the licensee. This copy may be transmitted via facsimile.

g. Note: For cases where NJDEP Form 241 is received and the filing indicates that the licensee does not qualify for a reciprocity license under N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) , notify the licensee of this fact within 3 days of receipt of NJDEP Form 241 and return the fee to the applicant.

h. Note: Signature authority for the reviewing official of the reciprocity activities as requested by NJDEP Form 241 will reside with the Supervisor, Radioactive Materials Section, or his/her designee.

3. CHANGES TO NJDEP FORM 241

a. Verify that NJDEP 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 NJEMS for the initial NJDEP 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 NJEMS (number of days activities are conducted and/or licensed material is stored in Department Jurisdiction and record on NJDEP Form 241).

d. For new locations of work, additional dates, or different activities, enter the information into NJEMS.

e. If NJDEP Form 241 is deficient, see Item 4. ,"Deficient NJDEP Forms 241." When it is determined that the required information has been submitted, sign and date NJDEP Form 241 as the reviewing official or send a letter indicating that the revisions to the reciprocity activities submitted on the initial NJDEP Form 241 have been reviewed and found sufficient, and forward a copy of the authorized NJDEP Form 241 to the licensee. Signed NJDEP Forms 241 maybe transmitted via facsimile.

Note: For cases where changes to NJDEP 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 N.J.A.C. 7:28-62.1 (see 10 CFR 150.20), notify the licensee of this fact within 3 days of receipt of NJDEP 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 Form 241.

4. DEFICIENT NJDEP FORMS 241

a. If NJDEP Form 241 contains omissions or errors, try to first resolve them by telephone contact with the licensee within 3 days of receipt of the NJDEP 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 N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) 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 N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) 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 NJDEP Form 241 request, explaining that the licensee has not submitted the required information and thus does not qualify for a general license under N.J.A.C. 7:28-62.1 (see 10 CFR 150.20). Indicate to the licensee that work is not to be performed in Department jurisdiction until NJDEP receives the required information.

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 I, "Procedures Letter."

d. For licensees whose proposed reciprocity activities are approaching or would exceed the 180-day limit, the licensee should be notified by telephone or mail that a specific NJDEP license must be applied for and obtained if activities in Department jurisdiction in excess of 180 days are to be conducted within the calendar year.

5. APPARENT NON-COMPLIANCE WITH N.J.A.C. 7:28-62.1

If NJDEP 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 NJDEP Form 241 request, to apply to the licensing authority for a license amendment permitting temporary job site locations, or apply for a specific NJDEP license. The reviewer should note the resolution or proposed action on NJDEP Form 241.

b. Cases where activities were started before the initial NJDEP 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 N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) and should be treated in accordance with the NJDEP 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 NJDEP Form 241 was submitted) should be reviewed on a case-by-case basis when determining compliance with N.J.A.C. 7:28-62.1 (see 10 CFR 150.20).

Note: Staff should consider other instances of failure to change NJDEP Form 241 as noncompliance with the general license provisions of N.J.A.C. 7:28-62.1 (see 10 CFR 150.20).

6. NJDEP FORMS 241 -EQUIVALENCE

a. Equivalence -There may be cases where the licensee submits a letter in lieu of NJDEP Form 241. This is acceptable, provided that the submittal contains all of the information required by NJDEP Form 241, a complete copy of a valid Agreement State, Non-Agreement State or NRC license, if applicable, and the required fee.

D. WITHHOLDING RECIPROCITY INFORMATION FROM PUBLIC DISCLOSURE

Applicants that seek to withhold information contained in NJDEP Form 241 from public disclosure, must submit an application and affidavit for withholding, when the initial NJDEP Form 241 is filed. The Radioactive Material Section shall take the following actions in processing requests for withholding of information on NJDEP 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 NJDEP 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 has also been supplied in the application.

Note: If the licensee has already submitted a NJDEP Form 241, it must submit an application and affidavit within a week of NJDEP's receipt of NJDEP Form 241.

Note: Only the information contained in Items 8 to12 of NJDEP 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 3days 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 NJDEP to consider withholding the information contained in NJDEP 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 Radioactive Materials Section Supervisor 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 NJDEP Radioactive Materials Section for as long as the licensee continues to perform reciprocity activities and submit NJDEP Form 241. 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 I on the front of each document containing proprietary information.

E. RETENTION AND DISPOSAL OF RECIPROCITY LICENSING DOCUMENTS

1. All reciprocity licensing documents, the initial NJDEP Form 241, 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.

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
. Sample Letter #2-Acknowledging Disagreement With Request to Withhold Form 241 Information from Public Disclosure
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 New Jersey Department of Environmental Protection (NJDEP) to withhold, as proprietary or confidential, the information contained in Items 8 to 12 of NJDEP 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, NJDEP 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 NJDEP FORM 241

By NJDEP Form 241, "Reciprocity -Report of Proposed Activities in New Jersey 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 NJDEP Form 241, marked as proprietary, will be withheld from public disclosure. Your request for withholding will be maintained by the Bureau of Environmental Radiation, Radioactive Materials Section, indefinitely for as long as you continue to perform reciprocity activities and submit NJDEP Form 241. If you skip a year between filing reciprocity requests, you must resubmit for review an application and affidavit for withholding information contained in NJDEP 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 NJDEP may have cause to review

this determination in the future. In all review situations, if NJDEP 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 (609) 984-5462.

Sincerely,
(Supervisor, Radioactive Materials Section)

ATTACHMENT 2 (Continued)

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 NJDEP FORM 241

By NJDEP Form 241, "Reciprocity -Report of Proposed Activities in New Jersey 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, NJDEP 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 NJDEP. You should understand that NJDEP may have cause to review this

determination in the future. In all review situations, if NJDEP 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 (609) 984-5462.

Sincerely,
(Supervisor, Radioactive Materials Section)

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 NJDEP FORM 241

By NJDEP Form 241, "Reciprocity -Report of Proposed Activities in New Jersey in Areas of Exclusive Department Jurisdiction," letter from (Licensee's Name) dated _, and affidavit dated 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 NJDEP Form 241 to be proprietary.

The client information contained in Item(s) __ of NJDEP 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 Bureau of Environmental Radiation, Radioactive Materials Section indefinitely or for as long as you continue to perform reciprocity activities and submit NJDEP Form 241. If you skip a year between filing reciprocity requests, you must resubmit for review an application and affidavit for withholding information contained in NJDEP Form 241 from public disclosure.

We have also determined that, for the following reason(s), the information contained in Item(s) of NJDEP Form 241 does not contain proprietary information:

1 .

2.

Therefore, the client information contained in Items NJDEP-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.

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 NJDEP. You should understand that NJDEP may have cause to review this determination in the future.

In all review situations, if NJDEP 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 (609) 984-5462.

Sincerely,
(Supervisor, Radioactive Materials Section)

APPENDIX I

PROCEDURES LETTER TO BE SENT TO LICENSEES WITH PROCEDURES AND INFORMATION FOR FILING NJDEP 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 New Jersey in areas of exclusive Department jurisdiction, for the first time in a consecutive 12 month period, must submit NJDEP Form 241, " Reciprocity - Report of Proposed Activities in New Jersey in Areas of Exclusive Department Jurisdiction; a copy of the Agreement State, Non-Agreement State or NRC specific license; and the fee specified in N.J.A.C. 7:28-64.1. NJDEP must receive this filing at least 3 days before the licensee engages in activities permitted under the General License established by N.J.A.C. 7:28-62.1. 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.

If, in processing NJDEP Form 241, NJDEP determines that the NJDEP 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 N.J.A.C. 7:28-62.1, and work is not to be performed in New Jersey in areas of exclusive Department, Jurisdiction, until NJDEP receives the required information.

Licensees cannot perform work in New Jersey in areas of exclusive Department jurisdiction without either (a)filing NJDEP Form 241 for reciprocity in accordance with N.J.A.C. 7:28-62.1 or (b) applying for a specific NJDEP 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. NJDEP tracks reciprocity usage on the basis of approved usage days. NJDEP will not approve any activity, under the general license, that causes the total usage days to exceed 180 days. NJDEP 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 NJDEP 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 NJDEP Form 241. It is expected that licensees will review this information, as well as the regulations cited in (N.J.A.C. 7:28-62.1(see 10 CFR 150.20)), to ensure that the radiation safety program is in compliance with NJDEP regulations before conducting activities under reciprocity.

NJDEP will perform inspections of activities performed in New Jersey by licensees operating under a general license pursuant to NJDEP. 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 NJDEP Form 241, and other rules, regulations, and orders of NJDEP, now or here after in effect. Failure to comply with these regulations or to conduct your radiation safety program in compliance with NJDEP regulations before operating under reciprocity may result in NJDEP 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 NJDEP

regulations. This is the licensee's obligation. The lack of awareness of NJDEP requirements, and applicable provisions is not an acceptable justification to preclude NJDEP enforcement actions.

For your information and use in filing for reciprocity, I have enclosed, Guidelines for Filling NJDEP Form 241 (Enclosure 1), NJDEP Form 241 (Enclosure 2), and NJDEP Form, "Notice to Employees" (Enclosure 3).

If you have any questions about the regulations or the application process, please feel free to contact me at (609) 984-5462.

Sincerely,

(Reviewing Official)

Enclosures:

1. Guidelines for Filing NJDEP Form 241
2. NJDEP Form 241, "Reciprocity-Report of Proposed Activities in New Jersey in Areas of Exclusive Department Jurisdiction"
3. NJDEP Form, "Notice to Employees"

ENCLOSURE I

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 New Jersey in areas of exclusive Department jurisdiction, for the first time in a 12 consecutive month period, must submit: NJDEP Form 241, "Reciprocity - Report of Proposed Activities in New Jersey in Areas of Exclusive Department Jurisdiction ";a copy of the Agreement State, Non-Agreement State or NRC specific license; and evidence of the fee specified in N.J.A.C. 7:28-64.1, with the Radioactive Materials Licensing Section. NJDEP must receive this filing at least 3 days before the licensee engages in activities permitted under the General License established by N.J.A.C. 7:28-62.1 (see 10 CFR 150.20). Failure to file NJDEP Form 241 may result in civil or criminal penalties.

To facilitate NJDEP 's inspection of licensees working under reciprocity, it is important that the information submitted on NJDEP 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 job sites 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 NJDEP 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 NJDEP Form 241.

For the dates of work, it is acceptable to indicate that the licensee will operate under reciprocity for 180 days in the 12 month period commencing..., provided the licensee narrows down or deletes dates as they become known. For example: the initial NJDEP Form 241 may list March 1-March 31 for the site at the Bisco pipeline; however, because of rain, work was not performed on March 2 March 10. The need to delete work dates becomes important when a licensee approaches the 180 day limit; therefore, the licensee should delete the dates when work was not performed. (See Changes, below.)

In general, the preferred method of filing is through the facsimile transmission of NJDEP Form 241, a copy 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 NJDEP. The licensee should receive confirmation (by telephone, e-mail, or facsimile) that NJDEP has received the facsimile. Alternatively, the licensee may file the required information

through the mail or other means as long as NJDEP receives the information at least 3 days before the licensee engages in the activity.

In addition, the licensee must also submit, by mail, a copy of NJDEP Form 241, a copy 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 NJDEP 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 NJDEP Form 241 must be filed with the NJDEP. When submitting revision requests, file by NJDEP Form 241 or letter, so that NJDEP 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 NJDEP has received the facsimile; and (2) NJDEP receives, within 3days, NJDEP 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 N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) for the filing of NRC Form 241 if you:

a. Inform the Bureau of Environmental Radiation, Radioactive Materials Section by telephone, facsimile, a NJDEP Form 241, or a letter of initial activities or changes to the information submitted on the initial NJDEP Form 241; and

b. Receive oral or written authorization for the activity(ies) from the Bureau of Environmental Radiation, Radioactive Materials Section; and

c. Submit a copy of NJDEP Form 241, and a copy of your Agreement State, Non-Agreement State or NRC license (for initial filings).

NJDEP Receipt :

When it has been determined that the required information has been submitted and the fee payment has been provided, NJDEP will sign and date the NJDEP Form 241 and will forward a copy to the applicant.

If, however, in processing NJDEP Form 241, NJDEP determines that the NJDEP Form 241 contains omissions or errors, the NJDEP 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, NJDEP staff will inform the NJDEP of this determination and indicate that work is not to be performed in New Jersey in areas of exclusive Department jurisdiction until NJDEP receives the required information. No work is to be performed unless applicant has received approval from NJDEP.

Fees:

Under the current fee regulations in N.J.A.C. 7:28-64.1, initial filings of NJDEP Form 241 require payment of a fee.

Withholding Information:

Licensees wishing NJDEP to withhold, as proprietary or confidential, the information contained in Items 8 to 12 of NJDEP 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 NJDEP 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 NJDEP Form 241 can be considered for withholding from public disclosure as proprietary information. Therefore, if your company wishes NJDEP to withhold the information contained in NJDEP 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, NJDEP 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 NJDEP'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 NJDEP Form 241. 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 N.J.A.C. 7:28-62.1. (see 10 CFR 150.20(b)) In particular, radiographers and radiographers' assistants must, at all times during radiographic operations, wear direct reading pocket dosimeters, alarm rate meters, AND either film badges or thermoluminescent dosimeters (TLDs) as required by N.J.A.C. 7:28-63.1 (see 10 CFR 34. 47(a)). Secondly, radiographic exposure devices, sources, and associated equipment must comply with the requirements described in N.J.A.C. 7:28-63.1 (see 10 CFR 34.20). Licensees need to be aware that when exposure devices are transported, NJ Department of Transportation and US DOT regulations must be followed.

These regulations can be found in 49 CFR and N.J.A.C. 7:28-61.1 (see 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 N.J.A.C. 7:28 61.1 (see10 CFR 71 .101(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 N.J.A.C. 7:28-63.1 (see 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.

ENCLOSURE 2
NJDEP FORM 241

"Reciprocity-Report of Proposed Activities in New Jersey in Areas of Exclusive Department Jurisdiction"

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section

REPORT OF PROPOSED ACTIVITIES WITHIN NEW JERSEY JURISDICTIONAL BOUNDARIES INCLUDING OFFSHORE AND STATE WATERS

INSTRUCTIONS

Licensees cannot perform work in areas of exclusive New Jersey State jurisdiction without either (a) filing (and receiving approval of) NJRAD Form 241 for reciprocity in accordance with N.J.A.C. 7:28-52.1 (see 10 CFR 31) or (b) applying for (and receiving approval of) a specific New Jersey radioactive materials license. An area of exclusive New Jersey State jurisdiction is an area over which the State government exercises legal control without interference from the jurisdiction and administration of Federal law. If the work is to be performed on Federal property within New Jersey, the licensee must first determine the jurisdictional status of the area where the licensee plans to work. If the jurisdictional status of the work site is unknown to the licensee, the licensee should contact the Federal agency that controls the facility where the work is to be performed. A written statement concerning the jurisdictional status is not required in order to file for reciprocity; however, it is recommended that the licensee obtain such a statement for the file for future reference and inspection purposes.

Licensees seeking to conduct activities under reciprocity for the first time in a calendar year must submit this Form, one copy of the NRC or Agreement State specific license and one-half the fee listed in Tables 1 and 2 of N.J.A.C. 7:28-64.2. NJDEP must receive this filing at least 3 days before the licensee engages in activities permitted under the General License established by N.J.A.C. 7:28-52.1 (see 10 CFR 31). This evidence can be a copy of the check that will be mailed to the NJDEP Bureau of Environmental Radiation. The preferred method of filing is through the facsimile transmission however, the licensee may file the required information through the mail or other means as long as NJDEP receives the information at least 3 days before the licensee engages in the activity. NO ACTIVITIES MAY BE CARRIED OUT WITHOUT FIRST RECEIVING APPROVAL OF A RECIPROCITY OR SPECIFIC LICENSE APPLICATION.

In completing NJRAD Form 241, it is important that the information submitted on NJRAD Form 241 be specific regarding the location and date of use as well as the activity requested. If it is not possible to provide complete information, such as addresses for the locations of work, the licensee should provide as much information as possible. The licensee is responsible for providing additional information as revisions or clarifications as soon as such information becomes available.

Item 2:
The licensee should check the "initial" box if this is the first submission of Form 241 for the year. Licensees should check the "change" box to indicate changes to the information provided on the initial NJRAD Form 241. Changes may include modifications such to as additional work locations, changes to radioactive material, work activities, information that clarifies or deletes specific locations or work sites, modifies work site contacts, or adds or deletes dates of work, licensees should file by NJRAD Form 241 or letter, so that NJDEP receives the filing at least 3 days prior to engage in such activity. It is not necessary to resubmit the NRC or Agreement State license unless the license has been amended since the filing of the initial NJRAD Form 241. No fee is required for changes. Once one year passes from the date of initial application, a new Initial application must again be filed with the associated fees included. Additional sheets may be used, provided it includes all of the requested information in NJRAD Form 241.

Under the general license, reciprocity activities are authorized only as long as the licensee holds a valid radioactive material license. If the license expires during the year, an extension letter or a renewed license

issued by the regulating agency must be submitted to NJDEP before performing any additional work under reciprocity.

Under the general license, reciprocity activities, including storage (usage), conducted in New Jersey State jurisdiction, are limited to a total of 180 days in any calendar year. NJDEP tracks reciprocity usage on the basis of approved usage days. NJDEP will not approve any activity under the general license which causes the total usage days to exceed 180 days. It is important that licensees track the days of use and clarify or delete dates of work when applicable.

Item 12 should reference the proposed beginning and ending dates of work for each work location with the total number of days worked recorded in Item 13. Item 14 should be completed to show additional work dates different from those provided on the initial NJRAD Form 241 and Item 15 should indicate dates when work was not performed, as initially requested, that need to be deleted from the total work days. The Location ID Number in Item 16 is generated by the NJDEP for use in tracking reciprocity activities and is specific for each work location. The Location ID Number should be referenced for any revisions or clarifications to work location information.

Item 17: Licensees should identify the specific make and model numbers of sealed sources and devices.

NOTE: Inspections by NJDEP of activities performed in New Jersey or areas of New Jersey jurisdiction, including offshore waters operating under the general license in N.J.A.C. 7:28-52.1 (see 10 CFR 31) will be conducted at the listed work site location(s). Failure to file an NJRAD Form 241 may result in the issuance of formal enforcement actions.

Completed application forms may be mailed to:
New Jersey Department of Environmental Protection, Bureau of Environmental Radiation, Radioactive Materials Section, P.O. Box 415, Trenton, NJ 08625 or sent via facsimile to (609) 633-2110.

NJRAD FORM-241 (Revised July 10, 2008)

RECIPROCITY APPLICATION FORM

REPORT OF PROPOSED ACTIVITIES WITHIN NEW JERSEY JURISDICTIONAL BOUNDARIES INCLUDING OFFSHORE AND STATE WATERS

New Jersey Department of Environmental Protection
Bureau of Environmental Radiation
Radioactive Materials Section
P.O. Box 415, Trenton, NJ 08625
Tel. (609) 984-5462
Fax. (609) 633-2210
Web: http://www.nj.gov/dep/rpp/

1. NAME OF LICENSEE (Person or firm proposing to conduct the activities described below)	2. TYPE OF REPORT ☐ Initial ☐ Change
3. ADDRESS OF LICENSEE	4. LICENSEE CONTACT AND TITLE
	5. TELEPHONE NUMBER / 6. FACSIMILE NUMBER

7. ACTIVITIES TO BE CONDUCTED UNDER THE GENERAL LICENSE GIVEN IN N.J.A.C. 7:28-52.1 (See 10 CFR 31)

☐ WELL LOGGING ☐ LEAK TESTING AND/OR CALIBRATIONS ☐ TELETHERAPY/IRRADIATOR SERVICE
☐ PORTABLE GAUGES ☐ OTHER - Specify: _____
☐ RADIOGRAPHY - Specify: _____
REGISTERED AS USER OF PACKAGING (CERTIFICATES OF COMPLIANCE NUMBERS)

LOCATIONS OF USE - LIST ADDITIONAL WORK SITES ON SEPARATE SHEET(S)

8. CLIENT NAME & ADDRESS	9. ACTUAL PHYSICAL ADDRESS OF WORK LOCATION
	10. CLIENT TELEPHONE # / 11. WORK LOCATION TELEPHONE #

12. DATES SCHEDULED		13. NUMBER OF WORK DAYS	14. ADD	15. DELETE	16. LOCATION ID # (To be assigned by NJ DEP)
FROM:	TO:				

17. LIST RADIOACTIVE MATERIAL, WHICH WILL BE POSSESSED, USED, INSTALLED, SERVICED, OR TESTED
(Include description of type and quantity of radioactive material, sealed sources, or devices to be used.)

18. NRC or AGREEMENT STATE SPECIFIC LICENSE (One copy must accompany the initial NJRAD FORM 241)	LICENSE NUMBER	STATE	EXPIRATION DATE

19. CERTIFICATION *(MUST BE COMPLETED BY APPLICANT)*

I, THE UNDERSIGNED, HEREBY CERTIFY THAT:

a. All information in this report is true and complete.
b. I have read and understand the provisions of the general license N.J.A.C. 7:28-52.1 (see 10 CFR 31) and I understand that I am required to comply with these provisions as to all byproduct, source, or special nuclear material which I possess and use within the jurisdictions of New Jersey, including its offshore waters, under the general license for which this report is filed with the NJDEP Bureau of Environmental Radiation.
c. I understand that activities, including storage, conducted in New Jersey under general license N.J.A.C. 7:28-52.1 (see 10 CFR 31) are limited to a total of 180 days in calendar year. With the exception of work conducted in off-shore waters, which is authorized for an unlimited period of time in the calendar year.
d. I understand that I may be inspected by NJDEP Bureau of Environmental Radiation at the above listed work site locations and at the Licensee home office address for activities performed within the jurisdictions of New Jersey, including its offshore waters.
e. I understand that conduct of any activities not described above, including conduct of activities on dates or locations different from those described above or without NJDEP Bureau of Environmental Radiation authorization, may subject me to enforcement action, including civil or criminal penalties.

CERTIFYING OFFICER - RSO or Management Representative (Name and Title)	SIGNATURE	DATE

WARNING: False statements in this certificate may be subject to civil and/or criminal penalties.

FOR NJDEP USE ONLY	REVIEWING OFFICIAL (Name and Title)	SIGNATURE	DATE	TOTAL USAGE -- DAYS TO DATE

ENCLOSURE 3

NJDEP FORM "NOTICE TO EMPLOYEES"

P-14

Jon E. Corzine
Governor

Lisa P. Jackson
Commissioner

STATE OF NEW JERSEY
DEPARTMENT OF ENVIRONMENTAL PROTECTION
RADIATION PROTECTION PROGRAMS AND RELEASE PREVENTION
PO BOX 415, TRENTON, N.J. 08625-0415
609-984-5462

NOTICE TO EMPLOYEES
STANDARDS FOR PROTECTION AGAINST RADIATION

Your Employer's Responsibility

1. Any company that conducts activities regulated by the Department of Environmental Protection (DEP) must comply with the DEP's requirements. If a company violates DEP requirements, it may be penalized or have its license revoked.

2. Your employer must post or otherwise make available to you copies of the New Jersey Administrative Code, Title 7, Chapter 28 (NJAC 7:28), licenses, registrations and operating procedures which apply to work you are engaged in, and explain their provisions to you.

What is Covered By The New Jersey Administrative Code, Title 7, Chapter 28 (NJAC 7:28-1 et seq.)

1. Limits on exposure to radiation and radioactive material in controlled areas.

2. Measures to be taken after accidental exposure;

3. Personnel monitoring, survey and equipment;

4. Caution signs, labels, and safety interlock equipment;

5. Related matters.

Your Responsibility As A Worker

You should familiarize yourself with those provisions of NJAC 7:28 and the operating procedures which apply to the work for which you are engaged. You should observe these provisions for your own protection and the protection of your co-workers. Should you observe violations of these requirements, you are to report them to the above address.

You are Protected From Discrimination
(NJSA 34:19-1)

Under the "Conscientious Employee Act" an employer cannot discharge, suspend or demote an employee who discloses an activity or practice which he believes to be unlawful.

How Do You Report Violation?

You should report violations immediately to your supervisor. If you believe that adequate corrective action is not being taken, you may report this to a DEP inspector or the DEP office listed above.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. NJAC 7:28 requires that your employer provide you with a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in NJAC 7:28-6. This section specifies limits of exposure to radiation and exposure to concentrations of radioactive material in air and water.

2. If you work where personnel monitoring is required, and if you request information on your radiation exposures:

   (a) Your employer shall advise you annually of your exposure of radiation, and,

   (b) Your employer shall give you a written report, upon termination of your employment, of your radiation exposures, and any bioassays.

INSPECTIONS

All persons shall afford the Department an opportunity to inspect any sources of radiation and the operation associated with the source of radiation as well as the facilities and premises where the source of radiation is being used or stored (NJAC 7:28-2).

INQUIRIES

Inquiries dealing with the matters outlined above are to be made to the Radiation Protection Programs, New Jersey State Department of Environmental Protection, PO Box 415, Trenton, New Jersey 08625-0415 (609-984-5462).

POSTING REQUIREMENT

Copies of this notice must be posted where employees working in or frequenting any portion of controlled areas can observe a copy on the way to or from their place of employment.

APPENDIX II

INSPECTION OF RECIPROCITY LICENSEES

A. PURPOSE

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

B. INSPECTION

The Radioactive Materials Section shall take the following action:

1. Frequency Inspections of licensees operating under general licenses under N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) should be conducted using the same provisions used for equivalent NJDEP-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 NJDEP 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, you should do the following:

a. Determine if the reciprocity licensee has had NJDEP 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 NJDEP 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.. 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.

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.

NJDEP 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 NJDEP- licensed materials facilities and non-licensed materials facilities.

2602-02 OBJECTIVES

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

02.02 To provide general guidance for planning and conducting inspections of NJDEP-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 to an unacceptable level.

02.06 To provide for effective allocation of resources for the inspection of NJDEP- licensed materials facilities undergoing decommissioning. 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 NJDEP oversight.

The NRC's NUREG-1757, Consolidated Decommissioning Guidance, Volumes 1-3, summarizes policies, and procedures that the NJDEP staff shall use during the decommissioning of licensed materials facilities. This manual chapter summarizes the basic framework for the inspection of these decommissioning facilities, while NUREG-1757 provides the framework for the overall regulatory oversight process used to ensure an adequate and consistent decommissioning of the decommissioning facilities.

2602-03 APPLICABILITY

This manual chapter applies to all NJDEP licensees under N.J.A.C. 7:28-51.1, 58.1, and 60.1 (see 10 CFR 30, 40, and 70)undergoing decommissioning. The principal regulations and policy governing such decommissioning are N.J.A.C. 7:28- 12.1 et seq.

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 licensed materials in the public interest. The NJDEP regulations at N.J.A.C. 7:28-12.1 et seq. do not consider ALARA.

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 the headquarters program 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 legal interest.

04.03 Confirmatory Survey. A survey conducted by NJDEP, or its contractor (authorized by the NRC, NJDEP or another Agreement State), 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 termination of the license and (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 restricted or unrestricted use.

04.05 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 NJDEP's regulations and termination of the license, and to demonstrate that the facility meets NJDEP's requirements for release. A remedial action workplan in combination with a remedial selection report under N.J.A.C. 7:28-7:26E are considered equivalent to a DP.

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 NJDEP 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 Assistant Director, Radiation Protection and Release Prevention Programs. Provides overall direction for the decommissioning materials inspection program.

05.02 Manager, Bureau of Environmental Radiation. Coordinates, develops, and implements decommissioning materials inspection requirements and policies.

05.03 Supervisor, Radiological Assessment Section. Directs the implementation of the inspection program for decommissioning materials facilities and sites. Ensures, within budget limitations, that the 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 NJDEP personnel implementing the decommissioning oversight and inspection program for materials facilities undergoing decommissioning shall use the guidance identified in this manual chapter and NRC's NUREG-1757 with the exception of chapters that are not required or allowed under N.J.A.C. 7:28-12. For example, chapters on ALARA, long-term control licenses, or NEPA requirements. This includes formerly licensed sites where the license was terminated, and sites involving diffuse NORM, source, special nuclear, or byproduct material subject to NJDEP regulation for which a license was never issued. Significant deviations from this guidance shall be employed only after review and approval by the appropriate NJDEP management.

05.05 The responsibility for managing inspection activities and conducting inspections resides with the Radioactive Materials Section and Radiological Assessment Section within the Bureau of Environmental Radiation. The Bureau is responsible for developing the inspection program for each decommissioning facility or site under its jurisdiction.

2602-06 DECOMMISSIONING PROGRAM OVERSIGHT

06.01 Timing of Decommissioning. NJDEP regulations at NJAC 7:28-51.1, 58.1 and 60.1 (see 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 NRC's 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. The criterion for termination with unrestricted release is found in NJAC 7:28-12.8.

06.03 Decommissioning Records Management. NRC regulations prescribe recordkeeping responsibilities for NJDEP licensees. During licensed operations NJDEP 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 NJDEP regulation prescribe the disposition of these records. Finally, NJDEP staff is responsible for maintaining decommissioning records following license termination. NJDEP staff should refer to Section 3 of the NRC's NUREG-1757 Vol. 3 for information on recordkeeping requirements for decommissioning facilities.

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 NJDEP will evaluate the decommissioning of materials 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 N.J.A.C. 7:28-12.1 et seq. Group 3 sites may require an abbreviated DP, without a site-specific dose modeling analysis. Groups 4 through 7 sites are required to submit a DP with site-specific dose modeling in accordance with N.J.A.C. 7:28-51.1, 58.1, and 60.1 (see 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 NRC 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 NJDEP management and documented in writing prior to their implementation. NUREG-1757 Vol. 1, Rev 2, Sections 7 through 14, contain guidance for the determination of the appropriate decommissioning review process and the actions and oversight required by each group.

06.04 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 NJDEP criteria in sufficient detail to allow NJDEP 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. NJDEP regulations at N.J.A.C. 7:28-51.1, 58.1 and 60.1 (see 10 CFR 30, 40, and 70) require that certain information be provided by licensees in the DP. The NRC's 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 NJDEP requirements.

a. Site Characterization. NJDEP requirements for decommissioning under N.J.A.C. 7:28-51.1, 58.1 and 60.1 (see 10 CFR 30.36(f)(4), 40.42(f)(4), and 70.38(f)(4) 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 NJDEP staff during characterization planning. For these licensees it may be appropriate for NJDEP staff to meet with the licensee prior to, or during, site characterization. NJDEP staff should refer to NRC's NUREG-1757 Vol. 2 for additional discussion of site characterization.

b. Financial Assurance for Decommissioning. NJDEP regulations at N.J.A.C. 7:28-4, 51.1, 58.1 and 60.1 (see 10 CFR 30.35, 40.36, and 70.25) 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 NJDEP 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. NJDEP staff should refer to Section 4 of NRC's NUREG-1757 Vol. 3 for additional discussion of financial assurance.

c. Final Status Survey Plans. Licensees wishing to terminate their licenses must demonstrate to NJDEP that residual radioactive material at their facility attributable to past licensed operations does not exceed NJDEP criteria for release of the facility. NJDEP regulations at N.J.A.C. 7:28-4, 51, 58 and 60 (see 10 CFR 30.36(f)(4), 40.42(f)(4), and 70.38(f)(4)) require that all DPs contain a description of the planned final radiation survey to demonstrate that the facility meets NJDEP's criteria for release and termination of the license. In addition, NJDEP regulations at NJAC 7:28-51.1, 58.1 and 60.1 (see 10 CFR 30.36(I), 40.42(I), 70.38(l)) describe the information that must be submitted to NJDEP 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 NJDEP's requirements. If the licensee has satisfied all of the conditions for remediating its site, NJDEP staff terminates the license for the site. For sites with non-radiological contamination, NJDEP should inform the Site Remediation Program and/or the U.S. Environmental Protection Agency about the intent to terminate the license. In addition, if the

Industrial Site Recovery Act (ISRA) does not apply to the facility, the termination is intended as final State action and should include appropriate language in the termination letter to reflect this intent. If it is determined that ISRA applies to the facility, the Site Remediation Program will issue a No Further Action (NFA) Letter. Information on the applicability of ISRA is found at http://www.nj.gov/dep/srp/isra/isra_applicability.htm.

e. Restricted Use and Alternate Criteria. NJDEP 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 NJAC 7:28-12.11 and 12.12 for those licensees who intend to request termination of their radioactive materials licenses using either the restricted use or alternate criteria provisions of Subchapter 12. The basic requirement for license termination under restricted conditions is that the licensee provides institutional and/or engineering controls that limit the calculated dose to 0.15 mSv/y (15 mrem/y). Further, the licensee must reduce residual radioactivity so that if all these controls fail, the calculated dose would not exceed 1 mSv/y (100 mrem/y). Additional institutional controls would be established to meet regulatory requirements.

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 N.J.A.C. 7:28-4, 51.1, 58.1 and 60.1 (see 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 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. Most of the materials licensees have facilities which, for the most part, will not require submittal of a formal decommissioning plan for NJDEP review and approval and will not be a major effort. However, because of a possible wide range of decommissioning activities and safety considerations, this manual chapter describes inspection program requirements and guidance necessary to provide reasonable assurance that NJDEP 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. NJDEP 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.

07.02 Timing and Frequency of Inspections. The decommissioning inspection program is formally initiated when the licensee is required to begin decommissioning under NJDEP regulations. The inspection program continues until the site, including all buildings and other structures and outdoor areas, are remediated in accordance with NJDEP requirements and the appropriate licensing action is completed, which could be license termination or amendment, NFA letter, 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 the NJDEP 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 interest exists, inspections and visits may be warranted to ensure that management has 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. 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 inspection schedule provided in the MIP should be reviewed every 6-12months 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, NJDJEP 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 NJDEP maintains an "open door" policy with regard to access by the public or local officials to the NJDEP staff or to publicly available electronic documentation concerning a licensee's performance. Some local officials or community groups may desire increased interaction with

the NJDEP's staff and inspectors. The degree of interaction that is considered necessary to ensure openness in the NJDEP'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, 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. Facilities 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 NJDEP inspection staffs. For these decommissionings, activities should be inspected using IP 87104, and supplemented with other procedures as necessary. Section 07.13 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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1801), and posted in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902). Containers of contaminated materials shall be labeled in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1904 and 1905). Contaminated materials in buildings shall be secured and controlled by locking buildings, rooms, or areas. Contaminated materials in outside areas shall be secured and controlled by fencing or soil covers. Eight foot cyclone-type fencing is generally acceptable. Other fencing types, such as barbed wire fences, may be sufficient in low population, rural areas. Three to four foot thick soil covers over contaminated soil, slag, or tailing piles are also generally acceptable. Access to buildings, rooms, or indoor and outdoor areas having contaminated materials shall be limited only to individuals having the licensee's or responsible party's permission for access. Normally, decommissioning activities will not involve materials subject to safeguards requirements. On decommissioning sites that do involve materials subject to safeguards requirements, safeguards inspections should be coordinated with decommissioning inspections on an as needed basis.

07.07 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 indicates 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 NJDEP standards and requirements. Airborne and liquid effluents should meet NJDEP 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 NJDEP maximum contamination levels for radionuclides in public drinking water systems, NJDEP hydrological staff should be consulted to evaluate the significance of the groundwater contamination and the need for further groundwater monitoring programs.

07.08 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 NJDEP-approved site characterization plans; 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.

07.09 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 NJDEP regulations, approved decommissioning plans, and license conditions for key decommissioning activities that are important for health and safety. These activities may include: physical security; 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.

07.10 Scope of Inspections after Remediation. Decommissioning activities after remediation of the site include a licensee-conducted final status survey and in some cases, a NJDEP 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 NJDEP 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. As necessary to ensure confidence in the licensee's survey results, the inspection may include independent NJDEP 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 an NJDEP 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 NJDEP of the desire to release the areas for unrestricted use, so this is not possible.

b. Confirmatory Surveys. The purpose of the NJDEP 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, NJDEP 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 interest exists; or (4) in-process inspections were not conducted. NJDEP confirmatory surveys should not be used to demonstrate, for the licensee, compliance with NJDEP 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 NJDEP or its contractor (authorized by NRC, NJDEP or another Agreement State.) Licensee surveys and NRC confirmatory surveys may be conducted in phases as decommissioning proceeds.

c. 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 before conducting a confirmatory survey. Confirmatory surveys may be performed by 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 NJDEP 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. 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.

d. 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 the NRC's NUREG-1575, (Rev 1) Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM). As an alternate, facilities may use the NJDEP's Sampling Procedures Manual (http://www.nj.gov/dep/rpp/ras/rasdown.htm). 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 licensee's 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.

07.11 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. Site visits and inspections should be coordinated 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 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. Although unique plant conditions may exist following the permanent cessation of operations, NJDEP 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. 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 they 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.

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.

07.12 Documentation of Inspections The inspection staff shall fully document in the form of 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).

07.13 IMCs and IPs for the Decommissioning Program. The NJDEP 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.

IMC 2800 "Materials Inspection Program".
IP 83822 "Radiation Protection".
IP 83890* "Closeout Inspection and Survey".
IP 84850 "Radioactive Waste Management - Inspection of Waste Generator Requirements of NJAC 7:28-6 and 7:28-59.
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".

In addition to the procedures described above, inspection staffs should also use other existing parts of the NJDEP Inspection Manual that are routinely used on typical inspections and which are included in IMC 2800.

NJDEP 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 New Jersey Department of Environmental Protection (NJDEP) 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 NJDEP (i.e. , report of a medical event, other Federal 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 2800-07 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 NJDEP. 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 Telephone Contacts. These are contacts, made by telephone and documented in the licensee 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 Assistant Director, Radiation Protection and Release Prevention Element. Provides overall program direction for the DEP materials inspection program.

04.02 Chief, Bureau of Environmental Radiation

a. Manages the implementation of the inspection program elements performed in the State.

b. Ensures, within budget limitations, that the Bureau 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 other state agencies, to obtain technical assistance, as necessary.

e. Recommends changes to the materials inspection program to the Assistant Director, Radiation Protection and Release Prevention Element.

04.03 Radioactive Materials Section Supervisor

a. Proposes changes to the radioactive materials inspection program.

b. Implements the radioactive materials inspection program.

c. Reviews and approves inspection schedules.

d. Ensures that radioactive materials inspectors achieve and maintain qualifications.

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.

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.

Inspection plans should be developed for complex, non-routine inspections. Inspection plans may also be developed for any other inspections. After the inspection, the inspection plan may be discarded. It need not be filed or kept.

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 6 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 NJDEP.

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.

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].

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. 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. 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. Inspection Preparation on NJEMS

1. As assigned, either via the inspector's **TO DO LIST** or by direct assignment as established by a program supervisor, the inspector will create a new **Standard Compliance Inspection** activity within the **Central File** of the assigned PI. From the **Central File,** select location based upon the assigned facility PI. Click the **Create New Document** button, **Activity Category** - Enforcement; **Activity Class** - Standard Compliance Inspection; **Activity ID** - New; **Activity Type** - Standard Compliance Insp; **Document Type** - form; **Document Template - Compliance Evaluation; Title** - consistent with program guidelines. Click OK to create.

2. The inspector will review all relevant data for the program interest. This will include, but not be limited to, existing NJEMS permits, historic compliance evaluations, the **Violation List Screen** and historic enforcement actions. Some or all of the data pertaining to the facility/program interest may exist in paper files or preexisting computer systems that must also be accessed. The inspector should also note other programs' activities at the site.

3. The inspector will prepare an inspection checklist utilizing **the compliance Evaluation** screen by entering an intended start date and including all appropriate **Program Interests** and **Subject Items/Requirement Sets.** Since subject items/requirement sets are specific to each program, inspectors must follow program policy as to what subject items/requirement sets are to be included in inspections. Inspectors are not authorized to omit individual requirements unless directed otherwise by their programs. The sets developed for inspection were meant to help the inspector to look at all applicable requirements deemed appropriate for the inspection.

4. The inspector will go to **Activity Tracking** and enter a completed date for the "**prepare checklist**" task and enter the hours to complete this task.

5. The inspector will print the inspection checklist and use that to perform the inspection in accordance with all Department policies and procedures. At this point the inspection will be performed as directed by program specific guidelines. All information obtained and observations made during the inspection shall be recorded on the checklist for input into NJEMS upon return to the office.

c. 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 included in this manual.

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 NJDEP requirements should be based on direct observation of work activities, interviews with licensee workers,demonstrations by appropriate workers performing tasks regulated by NJDEP, 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 radioactive 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.

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 NJDEP 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 NJDEP 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 NJDEP's presence on site, and apprise 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 Enforcement Action 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 radioactive 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 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.

(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 NJDEP'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 NJDEP requirements and the inspector's understanding of the licensee's corrective action plan for each violation.

To avoid the formal disputed violation process, 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, management should be notified immediately.

Although deficiencies identified in some areas 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 Enforcement Action.

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, it is particularly important that the inspector keep 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 understands 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 management. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to management. The licensee's next opportunity to discuss the findings will be after the management has reviewed these matters.

d..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 in accordance with guidance in this manual.

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. Management shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary. 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 involving a medical event will be performed using the guidance in Management Directive 8.10, "NRC Medical Event Assessment Program." All other 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.

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.

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 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 NJDEP before receipt of licensed material or initiation of licensed operations.

4. Document the onsite inspection

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.

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.

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.

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, 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 3-03, 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 Exhibits 2 and 3 of Enclosure 2. This questionnaire should be completed, signed by the inspector, and placed in the file. 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 the Severity Level III or above violation(s) shall be scheduled and conducted within 6 months of the last inspection or sooner, in accordance with this guidance 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.

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 Severity Level I, II, or III 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 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 who 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 Severity Level III or above violation could be rescheduled for its next inspection in 1 year, although a follow up inspection to focus on the Severity Level III or above violation may have already been completed within 6 months. [See Section 06.03] The reduction shall be valid only until the next inspection, but management shall consider the results of the next inspection when determining whether the reduced interval should be continued, changed, or returned to normal.

b. 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 file.

06.05 Other Changes in Inspection Interval. At the discretion of 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 NJDEP on termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received. 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.]

For example, an amendment issued for a new medical therapy modality under N.J.A.C. 7:28-55.1 (see 10 CFR 35.1000) (Program Code 02240) shall be inspected within 12 months of the date of the amendment.

07.03 Reciprocity Inspections. N.J.A.C. 7:28-4.2 and N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) grant a general license to any person, with a specific license from an Agreement State Non-Agreement State or NRC authorizing use as 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 New Jersey in Areas of Exclusive Department Jurisdiction" at least 3 days before engaging in a licensed activity.

a. The recipient of the NJDEP Form 241 is the 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 NJEMS Tracking System before reciprocity work begins.

c. The Radioactive Materials Licensing Section 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 NJDEP-licensed activities.

d. The Radioactive Materials Licensing Section is responsible for initiating enforcement action and taking other follow-up actions, as appropriate for the inspection.

07.04 Temporary Job Site or Field

a. 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.

07.05 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 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.

07.06 Inspection of Generally Licensed Devices. Routine inspections of general licensees (other than reciprocity N.J.A.C. 7:28-4.2 and N.J.A.C. 7:28-62.1 (see 10 CFR 150.20) are not normally performed. However, if a specific licensee also possesses generally licensed devices that require registration under N.J.A.C. 7:28-4.2 and N.J.A.C. 7:28-52.1 (see 10 CFR Part 31), the inspector should verify the adequacy of the licensee's control and accountability of the devices. Inspections of general licensees shall also be made to resolve issues such as allegations, incidents, or indications of unsafe practices.

07.07 Inspection of Licensees Holding Nuclear Materials Management and Safeguards System (NMMSS) Accounts. The NMMSS is **not** a program under New Jersey's Agreement State authority and therefore should not be included in inspections of these licensees. However, New Jersey does encourage our licensees to fulfill their obligation to report to NMMSS.

07.08 Inspection of Increased Controls (IC) (see Enclosure 5) for Licensees Authorized to Possess Risk Significant Radioactive Material. During routine, unannounced health and safety inspections of licensed facilities authorized to possess radioactive materials in quantities greater than or equal to values described in Table 1: Radionuclides of Concern (see Enclosure 5, Exhibit 1), inspectors should evaluate IC compliance. The evaluation will include the fingerprinting and criminal history records check requirements (see Enclosure 6) for unescorted access to the Table 1 materials. Procedures for processing fingerprint checks can be found in Enclosure 7 and guidance for evaluating the FBI identification and criminal history records checks is outlined in Enclosure 8.

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 NJDEP 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 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 .

c. 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 and transmitted. No reference to follow-up of an allegation or employee concern will be entered in the inspection records, inspection reports, or other documents that will be filed in the file for the licensee. Following is further 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 NJDEP?

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

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 management for further review and follow-up.

08.03 Methods of Documenting Inspection Results. Inspections shall be initially documented by completing inspection records.

a. 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

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.

08.04 Methods of Transmitting Inspection Results. Results of inspections are to be entered into the New Jersey Environmental Management System (NJEMS).

1. Upon return to the office from the inspection, the inspector will enter today's date as the **completed date** for the **"site visit"** task in **Activity Tracking,** for that activity and enter the **Hours to Complete** this task.

2. The inspector will document all observations in the **Compliance Evaluation** screen prepared for that inspection. For evidentiary purposes, the inspector must be sure to capture all of the data in the **Compliance Evaluation** screen. The data must be in sufficient detail to substantiate the case and enable you to remember and understand five years later what you observed during your visit in the event the case goes to litigation. Any information in NJEMS should be factual and relevant to the case. You should not be entering your opinion or non-relevant observations.

3. If the start date of the inspection is different than the intended date entered when creating the inspection checklist, change the date to reflect the actual date of inspection. Enter the correct **start time, end date** and **end time**. Many inspections start and end on the same day. However, many programs perform inspections that span several days. One **Compliance Evaluation** screen is created for each separate and distinct inspection, not for every site visit. Therefore, if an inspection covers multiple days and multiple site visits but is considered all part of the same inspection, it should be documented in only one **Compliance Evaluation** screen. The **end date** field on the **Description Tab** will reflect the last date that the inspector performed a site visit. In order to capture each site visit in NJEMS, the inspector must add the task **"Site visit"** to **Activity Tracking** for each individual site visit.

4. Enter all appropriate data on the **Description Tab** (inspector names, person(s) interviewed, witnesses, multimedia checkbox, attributes, substances and impacts and if the inspection involves a Pesticide program interest the pesticide pop up data). Note: that only the inspectors listed in the **compliance evaluation** and supervisors will be able to edit that document.

5. The **multimedia checkbox** will be checked whenever a subject item/requirement set from more than one program is included in the inspection checklist. This includes screening checklists.

6. The inspector will enter general inspection observations related to the facility/program interest in the **General Comment** field. This field is intended to capture data related to the program interest(s) and inspection as a whole, not to individual violations. Any supporting documentation or reports obtained during the inspection that are not stored in NJEMS should be referenced with its location in this field.

7. The inspector will enter subject items/requirement set and specific requirement compliance and violation information on the **Checklist** and **Non-Checklist** tabs. The inspector may have to modify his original inspection checklist to include subject items/requirement sets not originally included but which were observed during the inspection.

8. The inspector will capture data related to each subject item/requirement set in the subject item comments field or in any checklist items that have a **Compliance Status**. For subject item/requirement sets which are automatically given the Compliance Status of **H** for Heading, no information is required. This is general information that relates to the Subject Item or group of checklist items as whole and not individual requirements.

9. The inspector will record relevant observations made during the inspection as they relate to individual requirements as listed as individual rows in the **Checklist** or **Non-Checklist tab.**

10. The documentation will include completion of each of the individual requirement's **Compliance Status** field. Compliance status will be chosen from the drop-down list associated with the field. For individual requirements not inspected, the inspector will mark the compliance status as not inspected in accordance with the appropriate program policy. Note: compliance status - Out of Compliance or OC will refer the inspected requirement and associated data contained within the row as a violation to the **Violation List** when the screen is approved by a program supervisor and the screen is locked and referred (see #22 to follow). **See Enforcement Action SOP.**

11. The **Results or Comments** field will be used to support the determination noted for compliance status. In the case of a complaint determination, relevant observations or supporting data should be noted in this field. For all requirements, which are marked out of compliance, the inspector must clearly document the findings in the requirement's results or comments field. The inspector must be very accurate and fully document each violation. This data will eventually become the **Description of Noncompliance (DNC)** which is used in the enforcement action to address the violation. A standard description or noncompliance will default into this field, when the requirement is marked out of compliance, if it is available in the requirement library. This field is editable to allow for the addition of relevant information needed to fully describe the violation, but the default language is to remain unchanged so that violation wording is standardized.

12. Grace days and non-minor reason fields will be utilized in accordance with the Grace Period Policy/Rule in the event a violation is noted.

13. The **Non-Checklist** tab is used to record individual violations that are not addressed in the **Checklist.** The **Non-Checklist** tab can be used along with the **Checklist** tab or instead of the **Checklist** tab. The **non-Checklist** tab is used for permit violations where the permit requirements have not been entered into NJEMS (i.e., multiple APEDS converted permit violations). Violations which need to be addressed after the inspector has completed his checklist data entry will also be documented on the **Non-Checklist** (i.e., supervisor discovers a requirement not included in the **Checklist** which should have been and was determined out of compliance).

14. Completion of the **Non-Checklist** tab shall be consistent with completion of the **Checklist** tab.

15. The inspector should save all relevant supporting documentation and reports obtained during the course of the inspection in NJEMS wherever possible. This would include photographs taken, sketches drawn, reports collected, etc...

16. Once the inspector has completed the **Compliance Evaluation,** the inspector will check in all documents related to this activity.

17. The inspector will enter today's date in the **Completed Date** column for the task, submit report, and enter the **Hours to Complete** field. The inspector should be sure that all relevant tasks have been completed and that the supervisor's name appears in the assigned to field for the review and approve task so that it appears on the supervisor's **To Do List.**

18. The supervisor will then review the **Compliance Evaluation** to make sure that all of the necessary data has been accurately captured, all supporting documentation saved to the correct activity in **Central File**, and all NJEMS SOPs and policies have been followed. The supervisor is responsible for making sure that the data captured in NJEMS is accurate not just for ensuring that the inspection data is collected correctly. The supervisors have primary responsibility for data integrity.

19. If the **Compliance Evaluation** is incomplete, the supervisor will add the **"correct and resubmit"** task and enter the inspector's name in the **Assigned-To** field. The supervisor must also include comments for this task explaining why the compliance evaluation is being returned. If the due date must be revised, because the correction must be expedited, the supervisor will enter a revised due date. The supervisor may also send a **system tickler** to let the inspector know what PI and Activity number was returned. Note: The supervisor should evaluate whether or not it is necessary to revise the system due date for the **"review & approval"** task assigned to him or her.

20. The inspector will correct and resubmit to the supervisor by adding the **"review and approve"** task for reassignment to the supervisor, and enter the time taken in the **hours to complete** field. The process of resubmitting and reviewing will continue until the **Compliance Evaluation** is considered complete.

21. Once the **Compliance Evaluation** is complete and accurate, the supervisor will **Refer and Lock** the screen. This will forward any of the violations documented and marked Out of Compliance (OC), to the **Violation List** for inclusion in an Enforcement Action. This will also set the activity's status to **conducted.** The supervisor will also lock any related documents for this activity. It's important not to **refer and lock** the **compliance evaluation** until the supervisor is sure there will be no need for modification. Unlocking the document in the system can only be done by the system administrator and under limited conditions.

22. The supervisor will enter today's date for the **Completed Date** for the task **"review and approve"** in **Activity Tracking** and enter the time taken in the **Hours to Complete** field.

If no violations were identified, no further action is needed. If violations were identified, refer to the **Enforcement Action SOP** for instruction on documenting the violation in an **Enforcement Action.**

2800-09 COORDINATION WITH OTHER AGENCIES

09.01 Federal Agencies. NJDEP does not conduct inspections of licensee compliance with the requirements of Federal agencies, except the U.S. Department of Transportation (DOT). However, NJDEP 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 NJDEP should inform the appropriate liaisons within the other agency about the concerns.

Except for DOT regulations, 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 NJDEP supervisor.

In the case of complaints or allegations involving federal agency's jurisdiction, the inspector should withhold the information from the licensee and elevate the concerns to the attention of NJDEP management while the inspector is still onsite.

2800-10 INPUT INTO New Jersey Environmental Management System **(NJEMS)**

10.01 Input into NJEMS.

Enclosure 1 provides a listing of license program codes with the associated inspection priorities. Staff should enter data promptly into the NJEMS at the time a new license is issued or an inspection has been performed, including the dates for initial inspections of new licensees, the last inspection date, and the next inspection date for licensees already inspected. When changes are

made to the next inspection date (reductions in the inspection intervals), staff should enter the data for the correct next inspection date into the NJEMS

10.02 Input into the Nuclear Materials Events Database (NMED).
The Radioactive Materials Section (RMS) manages NMED for all material-related incidents and events. The RMS 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 RMS shall provide the information outlined in Enclosure 3 to classify a record as "complete."

2800-11 INSPECTION MANUAL CHAPTERS AND INSPECTION PROCEDURES FOR MATERIALS PROGRAM

The Inspection Manual Chapters (MCs) and Inspection Procedures (IPs) provided in this Manual, 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.

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 Chapter/Inspection Procedure Titles
5. Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern
    Exhibit 1 Table 1
    Exhibit 2 Definitions
6. Specific Requirements Pertaining to Fingerprinting and Criminal History Records Check
7. Procedures for Processing Fingerprint Checks
8. Guidance for Evaluating FBI Identification and Criminal History Records Checks

ENCLOSURE 1
INSPECTION PRIORITY CODES ASSIGNED TO PROGRAM CODES

Program	Priority	Category Title	Remarks
01100	3	Academic Type A Broad	Radiation Safety Committee (RSC)-approved users;7:28-54
01110	5	Academic Type B Broad	Radiation Safety Officer (RSO)-approved users; 7:28-54
01120	5	Academic Type C Broad	Authorized Users specifically named in the license; 7:28-54
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 7:28-55. Used as secondary code when the license also authorizes certain medical therapy modalities.
02200	3	Medical Private Practice - WD Required	(same remark as 02120)
02201	5	Medical Private Practice - WD Not Required	(same remark as 02121)
02210	3	Eye Applicators Strontium-90 (SR-90)	Institution or Private Practice
02220	3	Mobile Medical Service - WD Not Required	Use as a primary code if the license authorizes the mobile service only. Use as a secondary code if the license authorizes medical use at a central facility (i.e., institution or private practice facility) in addition to the mobile service
02230	2	High-Dose Rate Remote After Loader (HDR)	Use as a primary code
02231	2	Mobile Medical Service - WD Required	Use as a primary code. Includes mobile HDR and non-HDR modalities under 7:28-55

Program	Priority	Category Title	Remarks
02240	2	Medical Therapy - Other Emerging Technology	Medical therapy modalities used under 7:28-55, 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 redistributed in the original packaging to authorized clients
02511	5	Medical Product Distribution - 32.72 Prepared Radiopharmaceuticals	Distribution of prepared radiopharmaceuticals to authorized medical licensees
02513	5	Medical Product Distribution - 32.74 Sources and Devices	Therapy sources, calibration and reference sources
03110	3	Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources	Use of sealed or unsealed sources for exploration of oil, gas, or minerals in wells
03111	3	Well Logging Byproduct and/or SNM Sealed Sources Only	Exploration of oil, gas, or minerals in wells; study of subsurface potable aquifers
03112	3	Well Logging Byproduct Only - Tracers Only	Exploration of oil, gas, or minerals in wells
03113	3	Field Flooding Studies	Injection of unsealed byproduct materials for tracing oil and gas reservoirs
03120	5	Measuring Systems Fixed Gauges	Non-portable gauges for measurement or control of material density, flow, level, thickness, or weight, etc.
03121	5	Measuring Systems Portable Gauges	Moisture/density gauges contain gamma and neutron sources used for measurements in soils, compacted soils and road surfacing materials
03122	T 1	Measuring Systems Analytical Instruments	i.e., x-ray fluorescence analyzers. Priority T denotes the radiation

			protection program for Program Codes 03122, 03123, 03124, 03220, 11210, 22130, 22160, and 22161. The telephone contact interval is 5 years
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 7:28-54
03212	5	Manufacturing and Distribution Broad - Type B	RSO - approved users under 7:28-54
03213	5	Manufacturing and Distribution Broad - Type C	Authorized Users specifically named in the license under 7:28-54
03214	5	Manufacturing and Distribution Other	Smaller firms that require a more restrictive license
03218	3	Nuclear Laundry	Cleaning of protective clothing contaminated with radioactive materials
03219	3	Decontamination Services	Cleaning of scrap materials for authorized release for unrestricted use
03220	T	Leak Test Service Only	Commercial service organizations provide leak test kits to clients, perform measurement of leak test samples from clients, and issue reports of leak test results
03221	5	Instrument Calibration Services Only-Source Less Than Or Equal To 100 Curies	Commercial calibration service
03222	5	Instrument Calibration Services Only-Source Greater Than 100 Curies	Commercial calibration service
03225	5	Other Services - Source Less Than Or Equal To 100 Curies	Commercial servicing for industrial gauge, and HDR licensees
03226	2	Other Services-Source Greater than 100 Curies	Commercial servicing for teletherapy, irradiators, and GSR units containing a total activity in the unit during servicing that is greater than 100 curies
03231	2	Waste Disposal (Burial)	Commercial and non-commercial
03232	3	Waste Disposal Service Prepackaged Only	Pick up, transfer, and storage; opening packages not authorized
03233	2	Waste Disposal Service Incineration	Commercial Operation

Program	Priority	Category Title	Remarks
03234	2	Waste Disposal Service Processing and/or Repackaging	Receipt, open, compact, repackage, and transfer to authorized burial
03235	2	Incineration, Non-Commercial	Program Code is used only as a secondary code for certain licensees authorized to operate a noncommercial incinerator to dispose of radioactive waste
03236	2	Waste Treatment Service (Other Than Compaction)	Includes multiple, complex physical and chemical waste treatment processes
03240	5	General License Distribution - 7:28-53	For fixed gauges authorized under 7:28-52
03241	5	General License Distribution - 7:28-53	For luminous aircraft safety devices authorized under 7:28-52
03242	5	General License Distribution 7:28-53	For calibration and reference sources authorized under 7:28-52
03243	5	General License Distribution - 7:28-53	For ice detection devices authorized under 7:28-52
03244	5	General License Distribution - 7:28-53	For certain in-vitro clinical testing kits authorized under 7:28-52
03250	5	Exempt Distribution - 7:28-53: Exempt Concentrations and Items	For residual material in a product authorized under 7:28-51
03251	5	Exempt Distribution - 7:28-53: Certain Items	For manufactured products authorized under 7:28-51
03252	5	Exempt Distribution - 7:28-53: Resins	For synthetic plastic resins authorized under 7:28-51
03253	5	Exempt Distribution - 7:28-53: Small Quantities	For individual quantities authorized under 7:28-51
03254	5	Exempt Distribution - 7:28-53: Self-Luminous Products	For devices authorized under 7:28-51
03255	5	Exempt Distribution- 7:28-53: Smoke Detectors	For devices authorized under 7:28-51
03256	5	Exempt Distribution - 7:28-53- Carbon-14 Urea Capsules	For in vivo diagnostic use authorized under 7:28-51
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
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 (megacurie) units
03610	3	Research and Development Broad - Type A	RSC - approved users under 7:28-54
03611	5	Research and Development Broad - Type B	RSO-approved users under 7:28-54
03612	5	Research and Development Broad - Type C	Authorized users specifically named in the license under 7:28-54
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.
21320	5	Critical Mass Material - Other Than Universities	Greater than 350 grams of enriched U-235, greater than 300 grams of U-233, greater than 200 grams of Plutonium, or any combination thereof
21325	D	Decommissioning of Critical Mass - Other Than Fuel Fabrication	(See MC 2602) D&D may have been authorized according to an approved plan under 7:28-60
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 U0233 - 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 7:28-60
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 7:28-60
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

ENCLOSURE 2

TELEPHONE CONTACT PROCEDURES FOR PRIORITY T LICENSEES

1. PROGRAM OBJECTIVES:

The telephone contact procedures maintain safety for materials possessed by certain licensees (Priority T) after the initial inspection has been completed and the inspector determines that the licensee has 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. Using the NJEMS report of licensees due for inspection, select a Priority T licensee to interview by telephone.

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 N.J.A.C. 7:28-6.1 (see 10 CFR 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	
Licensee's Point of Contact (Name, Address, Phone and FAX Numbers)	
License 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 NJDEP 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 your provisions for repair and maintenance of your device or source holder.	
8. 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 [LicenseNo.]
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 New Jersey DEP (NJDEP) 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, an inspection should be conducted and take enforcement action, as appropriate, based on the results of the inspection.)

In particular, you should examine your license and the NJDEP'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 NJDEP 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.

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

7. Evaluate radiation exposures to workers and members of the public.

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
Address [License No.]

ATTENTION: [Licensee Point of Contact, Title]

SUBJECT: TELEPHONE INTERVIEW TO EVALUATE THE RADIATION SAFETY PROGRAM

Sir or Madam:

This refers to the interview by telephone on [date]. The interview was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the NJDEP 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 Radioactive Materials Section (RMS) shall forward copies of all documentation regarding a material incident (i.e., "Preliminary Notifications," reports of medical events, follow-up inspection reports) to the NMED contractor and the NMED Project Manager. The RMS 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 RMS.

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) site of event
    e. whether the event is NJDEP reportable and the applicable reporting requirement
    f. cause and corrective actions
    g. number of persons involved, consequences
    h. notifications: NRC, local police, FBI, other States, as needed
    i. 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 CHAPTER/INSPECTION PROCEDURE TITLES

	Inspection Manual Chapter/Inspection Procedure Title	**Routine (R) or As Needed (N)**
MC 1220	Reciprocity Processing and Inspecting	N
MC 2602	Decommissioning Inspection Program for Materials Licensees	N
MC 2800	Materials Inspection Program	R
IP 83822	Radiation Protection	R
IP 83890	Closeout Inspection/Survey	R
IP 84850	Radioactive Waste Management – Inspection of Waste Generator Requirements of N.J.A.C. 7:28-6.1 (see 10 CFR 20 and 7:28-59.1 (see 10 CFR 61)	R
IP 84900	Low Level Radioactive Waste Storage	R
IP 86740	Transportation Activities	N
IP 87102	Maintaining Effluents from Materials Facilities As Low As Is Reasonably (ALARA)	R
IP 87103	Materials Licensees Involved in an Incident or Bankruptcy	N
IP 87104	Decommissioning for Materials Licensees	N
IP 87121	Industrial Radiography	R
IP 87122	Irradiator	R
IP 87123	Well Logging	R
IP 87124	Fixed and Portable Gauges	R
IP 87125	Material Processor/Manufacturer	R
IP 87126	Industrial/Academic/Research Programs	R
IP 87127	Radiopharmacy	R
IP 87130	Nuclear Medicine (No Written Directive)	R
IP 87131	Nuclear Medicine (Written Directive)	R
IP 87132	Brachytherapy Programs	R
IP 87133	Gamma Knife/Teletherapy	R
IP 87134	Medical Broad Scope	R
IP 92702	Followup on Enforcement Actions	N

ENCLOSURE 5

INCREASED CONTROLS FOR LICENSEES THAT POSSESS SOURCES CONTAINING RADIOACTIVE MATERIAL QUANTITIES OF CONCERN

AND

ENCLOSURE 6

SPECIFIC REQUIREMENTS PERTAINING TO FINGERPRINTING AND CRIMINAL HISTORY RECORDS CHECK

ENCLOSURE 5

INCREASED CONTROLS FOR LICENSEES THAT POSSESS SOURCES CONTAINING RADIOACTIVE MATERIAL QUANTITIES OF CONCERN

The purpose of the increased controls (IC) for radioactive sources is to enhance control of radioactive material in quantities greater than or equal to values described in Table 1 (Exhibit 1 of this Enclosure), to reduce the risk of unauthorized use of radioactive materials, through access controls to aid prevention, and prompt detection, assessment, and response to mitigate potentially high consequences that would be detrimental to public health and safety. These increased controls for radioactive sources are established to delineate licensee responsibility to maintain control of licensed material and secure it from unauthorized removal or access. The following increased controls apply to licensees which, at any given time, possess radioactive sources greater than or equal to the quantities of concern of radioactive material defined in Table 1.

IC 1. In order to ensure the safe handling, use, and control of licensed material in use and in storage each licensee shall control access at all times to radioactive material quantities of concern and devices containing such radioactive material (devices), and limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.

a. The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern and devices. The licensee shall approve for unescorted access only those individuals with job duties that require access to such radioactive material and devices. Personnel who require access to such radioactive material and devices to perform a job duty, but who are not approved by the licensee for unescorted access, must be escorted by an approved individual.

b. For individuals employed by the licensee for three years or less, and for nonlicensee personnel, such as physicians, physicists, house-keeping personnel, and security personnel under contract, trustworthiness and reliability shall be determined, at a minimum, by verifying employment history, education, and personal references. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the employee (i.e., seeking references not supplied by the individual). For individuals employed by the licensee for longer than three years, trustworthiness and reliability shall be determined, at a minimum, by a review of the employees' employment history with the licensee.

c. Service providers shall be escorted unless determined to be trustworthy and reliable by an NRC-required background investigation as an employee of a manufacturing and distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the manufacturing and distribution licensee providing the service.

d. The licensee shall document the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable, and does not

constitute an unreasonable risk for unauthorized use of radioactive material quantities of concern. The licensee shall maintain a list of persons approved for unescorted access to such radioactive material and devices by the licensee.

IC 2. In order to ensure the safe handling, use, and control of licensed material in use and in storage, each licensee shall have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material quantities of concern and devices. Enhanced monitoring shall be provided during periods of source delivery or shipment, where the delivery or shipment exceeds 100 times the Table 1 values.

a. The licensee shall respond immediately to any actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices. The response shall include requesting assistance from a Local Law Enforcement Agency (LLEA).

b. The licensee shall have a pre-arranged plan with LLEA for assistance in response to an actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices which is consistent in scope and timing with a realistic potential vulnerability of the sources containing such radioactive material. The pre-arranged plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources. Prearranged LLEA coordination is not required for temporary job sites.

c. The licensee shall have a dependable means to transmit information between, and among, the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.

d. After initiating appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the devices, the licensee shall, as promptly as possible, notify NJDEP. The Bureau of Environmental Radiation shall be contacted during business hours at (609) 984-5462 and the NJDEP Hotline shall be notified 24-hours-a-day at 1-877-927-6337.

e. The licensee shall maintain documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access.

IC 3.

a. In order to ensure the safe handling, use, and control of licensed material in transportation for domestic highway and rail shipments by a carrier other than the licensee, for quantities that equal or exceed those in Table 1 but are less than 100 times Table 1 quantities, per consignment, the licensee shall:

1. Use carriers which:
   A. Use package tracking systems,
   B. Implement methods to assure trustworthiness and reliability of drivers,
   C. Maintain constant control and/or surveillance during transit, and
   D. Have the capability for immediate communication to summon appropriate response or assistance.

The licensee shall verify and document that the carrier employs the measures listed above.

2. Contact the recipient to coordinate the expected arrival time of the shipment;
3. Confirm receipt of the shipment; and
4. Initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined the shipment has become lost, stolen, or missing, the licensee shall make the following notifications. The Bureau of Environmental Radiation shall be contacted during business hours at (609) 984-5462 and the NJDEP Hotline shall be contacted 24 hours a day at (877) 927-6337.

b. *Domestic highway and rail shipments of material that exceeds 100 times the quantities in Table 1 per consignment are under the NRC's authority to protect the common defense and security. This authority has not been relinquished to the Agreement States.*

c. If a licensee employs an M&D licensee to take possession at the licensee's location of the licensed radioactive material and ship it under its M&D license, the requirements of 3.a. and 3.b above shall not apply.

d. If the licensee is to receive radioactive material greater than or equal to the Table 1 quantities, per consignment, the licensee shall coordinate with the originator to:

1. Establish an expected time of delivery; and
2. Confirm receipt of transferred radioactive material. If the material is not received at the expected time of delivery, notify the originator and assist in any investigation.

IC 4. In order to ensure the safe handling, use, and control of licensed material in use and in storage each licensee that possesses mobile or portable devices containing radioactive material in quantities greater than or equal to Table 1 values, shall:

a. For portable devices, have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

b. For mobile devices:

1. that are only moved outside of the facility (e.g., on a trailer), have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

2. that are only moved inside a facility, have a physical control that forms a tangible barrier to secure the material from unauthorized movement or removal when the device is not under direct control and constant surveillance by the licensee.

c. For devices in or on a vehicle or trailer, licensees shall also utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee.

IC 5. The licensee shall retain documentation required by these increased controls for three years after they are no longer effective:

a. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years after the individual's employment ends.
b. Each time the licensee revises the list of approved persons required by 1.d., or the documented program required by 2, the licensee shall retain the previous documentation for three years after the revision.
c. The licensee shall retain documentation on each radioactive material carrier for three years after the licensee discontinues use of that particular carrier.
d. The licensee shall retain documentation on shipment coordination, notifications, and investigations for three years after the shipment or investigation is completed.
e. After the license is terminated or amended to reduce possession limits below the quantities of concern, the licensee shall retain all documentation required by these increased controls for three years.

IC 6. Detailed information generated by the licensee that describes the physical protection of radioactive material quantities of concern, is sensitive information and shall be protected from unauthorized disclosure.

a. The licensee shall control access to its physical protection information to those persons who have an established need to know the information, and are considered to be trustworthy and reliable.
b. The licensee shall develop, maintain and implement policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, its physical protection information for radioactive material covered by these requirements. The policies and procedures shall include the following:

1. General performance requirement that each person who produces, receives, or acquires the licensee's sensitive information, protect the information from unauthorized disclosure,

2. Protection of sensitive information during use, storage, and transit,

3. Preparation, identification or marking, and transmission,

4. Access controls,

5. Destruction of documents,

6. Use of automatic data processing systems, and

7. Removal from the licensee's sensitive information category.

ENCLOSURE 5
EXHIBIT 1

TABLE 1:
RADIONUCLIDES
OF CONCERN

Radionuclides of Concern		
Radionuclide	Quantity of Concern (TBq)	Quantity of Concern (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239/Be	0.6	16
Ra-226	0.4	11
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations of radioactive materials listed above[3]	See Footnote Below[4]	

[1] The aggregate activity of multiple, collocated sources of the same radionuclide should be included when the total activity equals or exceeds the quantity of concern.

[2] The primary values used for compliance with this Order are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

[3] Radioactive materials are to be considered aggregated or collocated if breaching a common physical security barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

4 If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n, $A_{(i,n)}$, to the quantity of concern for radionuclide n, $Q_{(n)}$, listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) ÷ (quantity of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) ÷ (quantity of concern for radionuclide B)] + etc..... >1

ENCLOSURE 5
EXHIBIT 2

DEFINITIONS

Access Control - A means to allow only those individuals approved by the licensee, unescorted access to radioactive material.

Assessment - Licensee's capability to ascertain cause of alarm condition.

Approved Individual - Those individuals who the licensee has determined are trustworthy and reliable based on an appropriate verification.

Consignment - A package or group of packages of radioactive material that a licensee offers for transport in the same shipment.

Delay - To impede or hinder the progress of an intruder.

Dependable means to Transmit Information - Intrusion detection system and components which are used to detect, inform assessor(s), and summon responder(s), such that the system and components have continuous or alternate communication capability, even in the event of the loss of primary power or the loss of primary communication means.

Detect - To discover all unauthorized access to the radioactive material quantities of concern or device.

Immediately detect, assess, and respond - Detect, assess, and respond without delay.

LLEA - Any local law enforcement agency at the State level and below to include local jurisdictions.

Mobile device - A device containing licensed radioactive material that is mounted on a permanent base with wheels and/or casters for moving while completely assembled. Portable equipment means a device containing licensed radioactive material that is designed to be hand carried, and stationary equipment means a device containing licensed radioactive material which is installed in a fixed location.

Monitor - Capability to observe and detect unauthorized access.

Need-to-know - means a determination, by a person having responsibility for protecting the licensee's sensitive information, that a proposed recipient's access to the licensee's sensitive information is necessary in the performance of official, contractual, or licensee duties of employment.

Plan with LLEA - A plan which is consistent in scope and timing with realistic potential vulnerability such that the LLEA acknowledges they can provide a timely response to thwart unauthorized actions.

Radioactive material quantities of concern - Licensed radioactive material that individually or in aggregation is greater than the quantities in Table 1. The unity rule is used to determine if the activity of aggregated sources of different radionuclides is greater than the Table1 quantities (see discussion following Table 1).

Reliable and Trustworthy - An individual who is considered consistently dependable in judgment, character, performance, and does not constitute an unreasonable risk to the public health and safety.

Timely Response - Arrival of LLEA or armed responder to thwart unauthorized access and unauthorized actions associated with radioactive material quantities of concern or device.

ENCLOSURE 6

SPECIFIC REQUIREMENTS PERTAINING TO FINGERPRINTING AND CRIMINAL HISTORY RECORDS CHECK

The new fingerprinting requirements supplement previous requirements issued by the Increased Controls Order (EA-05-090) issued by the U.S. Nuclear Regulatory Commission. Licensees currently have a program to grant unescorted access to individuals. As required by Condition A.1 of the Order, licensees shall modify their current trustworthiness and reliability program to include the following:

1. Each licensee subject to the provisions of this attachment shall fingerprint each individual who is seeking or permitted unescorted access to risk significant radioactive materials equal to or greater than the quantities listed in Table 1. The licensee shall review and use the information received from the Federal Bureau of Investigation (FBI) identification and criminal history records check and ensure that the provisions contained in the subject Order and Enclosures 9 and 10 are satisfied.

2. The Licensee shall notify each affected individual that the fingerprints will be used to secure a review of his/her criminal history record and inform the individual of the procedures for revising the record or including an explanation in the record, as specified in the "Right to Correct and Complete Information" section of this attachment.

3. Fingerprints for unescorted access need not be taken if an employed individual (e.g., a licensee employee, contractor, manufacturer, or supplier) is relieved from the fingerprinting requirement by 10 CFR § 73.61, or any person who has been favorably-decided by a U.S. Government program involving fingerprinting and an FBI identification and criminal history records check (e.g. National Agency Check, Transportation Worker Identification Credentials in accordance with 49 CFR Part 1572, Bureau of Alcohol Tobacco Firearms and Explosives background checks and clearances in accordance with 27 CFR Part 555, Health and Human Services security risk assessments for possession and use of select agents and toxins in accordance with 42 CFR Part 73, Hazardous Material security threat assessment for hazardous material endorsement to commercial drivers license in accordance with 49 CFR Part 1572, Customs and Border Patrol's Free and Secure Trade Program[1]) within the last five (5) calendar years, or any person who has an active federal security clearance (provided in the latter two cases that they make available the appropriate documentation[2]). Written confirmation from the

[1] The FAST program is a cooperative effort between the Bureau of Customs and Border Patrol and the governments of Canada and Mexico to coordinate processes for the clearance of commercial shipments at the U.S. - Canada and U.S. - Mexico borders. Participants in the FAST program, which requires successful completion of a background records check, may receive expedited entrance privileges at the northern and southern borders.

[2] This documentation must allow the T&R Official to verify that the individual has fulfilled the unescorted access requirements of Section 149 of the AEA by submitting to fingerprinting and an FBI identification and criminal history records check.

Agency/employer which granted the federal security clearance or reviewed the FBI criminal history records results based upon a fingerprint identification check must be provided. The Licensee must retain this documentation for a period of three (3) years from the date the individual no longer requires unescorted access to certain radioactive material associated with the Licensee's activities.

4. All fingerprints obtained by the Licensee pursuant to this Order must be submitted to the Commission for transmission to the FBI. Additionally, the Licensee shall submit a certification of the trustworthiness and reliability of the T&R Official as determined in accordance with paragraph B.2 of this Order.

5. The Licensee shall review the information received from the FBI and consider it, in conjunction with the trustworthiness and reliability requirements of the IC Order (EA-05-090), in making a determination whether to grant unescorted access to certain radioactive materials.

6. The Licensee shall use any information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access to risk significant radioactive materials equal to or greater than the quantities listed in Table 1.

7. The Licensee shall document the basis for its determination whether to grant, or continue to allow unescorted access to risk significant radioactive materials equal to or greater than the quantities listed in Table 1.

Prohibitions

A licensee shall not base a final determination to deny an individual unescorted access to certain radioactive material solely on the basis of information received from the FBI involving: an arrest more than one (1) year old for which there is no information of the disposition of the case, or an arrest that resulted in dismissal of the charge or an acquittal.

A licensee shall not use information received from a criminal history check obtained pursuant to this Order in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall the licensee use the information in any way which would discriminate among individuals on the basis of race, religion, national origin, sex, or age.

Right to Correct and Complete Information

Prior to any final adverse determination, the Licensee shall make available to the individual the contents of any criminal records obtained from the FBI for the purpose of assuring correct and complete information. Written confirmation by the individual of receipt of this notification must be maintained by the Licensee for a period of one (1) year from the date of the notification.

If, after reviewing the record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, or update the alleged deficiency, or to explain any matter in the record, the individual may initiate challenge procedures. These

procedures include either direct application by the individual challenging the record to the agency (i.e., law enforcement agency) that contributed the questioned information, or direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Assistant Director, Federal Bureau of Investigation Identification Division, Washington, DC 20537-9700 (as set forth in 28 CFR Part 16.30 through 16.34). In the latter case, the FBI forwards the challenge to the agency that submitted the data and requests that agency to verify or correct the challenged entry. Upon receipt of an Official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. The licensee must provide at least ten (10) days for an individual to initiate an action challenging the results of an FBI identification and criminal history records check after the record is made available for his/her review. The Licensee may make a final unescorted access to certain radioactive material determination based upon the criminal history record only upon receipt of the FBI's ultimate confirmation or correction of the record. Upon a final adverse determination on unescorted access to certain radioactive material, the Licensee shall provide the individual its documented basis for denial. Unescorted access to certain radioactive material shall not be granted to an individual during the review process.

Protection of Information

1. Each licensee who obtains a criminal history record on an individual pursuant to this Order shall establish and maintain a system of files and procedures for protecting the record and the personal information from unauthorized disclosure.

2. The Licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his/her representative, or to those who have a need to access the information in performing assigned duties in the process of determining unescorted access to certain radioactive material. No individual authorized to have access to the information may re-disseminate the information to any other individual who does not have a need-to-know.

3. The personal information obtained on an individual from a criminal history record check may be transferred to another licensee if the licensee holding the criminal history record check receives the individual's written request to re-disseminate the information contained in his/her file, and the gaining Licensee verifies information such as the individual's name, date of birth, social security number, sex, and other applicable physical characteristics for identification purposes.

4. The Licensee shall make criminal history records, obtained under this section, available for examination by an authorized representative of the NRC to determine compliance with the regulations and laws.

5. The Licensee shall retain all fingerprint and criminal history records from the FBI, or a copy if the individual's file has been transferred, for three (3) years after termination of employment or determination of unescorted access to certain radioactive material (whether unescorted access was approved or denied). After the required three (3) year period, these documents shall be destroyed by a method that will prevent reconstruction of the information in whole or in part.

ENCLOSURE 7

PROCEDURES FOR PROCESSING FINGERPRINT CHECKS

For the purpose of complying with this Order, Licensees shall:

1. Submit one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ) for each individual seeking access to unescorted access to certain radioactive material.

2. Submit to the NRC's Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program, Mail Stop T-6E46, Rockville, MD 20852. Overnight mail is preferred.

3. Include the name and address of the individual (T&R Official) to whom the criminal history records should be returned.

4. Fingerprints for unescorted access need not be taken if an employed individual (e.g., a Licensee employee, contractor, manufacturer, or supplier) is relieved from the fingerprinting requirement by 10 CFR § 73.61, or any person who has been favorably-decided by a U.S. Government program involving fingerprinting and an FBI identification and criminal history records check (e.g. National Agency Check, Transportation Worker Identification Credentials in accordance with 49 CFR Part 1572, Bureau of Alcohol Tobacco Firearms and Explosives background checks and clearances in accordance with 27 CFR Part 555, Health and Human Services security risk assessments for possession and use of select agents and toxins in accordance with 42 CFR Part 73, Hazardous Material security threat assessment for hazardous material endorsement to commercial drivers license in accordance with 49 CFR Part 1572, Customs and Border Patrol's Free and Secure Trade Program[1]) within the last five (5) calendar years, or any person who has an active federal security clearance (provided in the latter two cases that they make available the appropriate documentation[2]). Written confirmation from the Agency/employer which granted the federal security clearance or reviewed the FBI criminal history records results based upon a fingerprint identification check must be provided. The Licensee must retain this documentation for a period of three (3) years from the date the individual no longer requires unescorted access to certain radioactive material associated with the Licensee's activities.

Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (301) 415-5877, or by e-mail to forms@nrc.gov. The Licensee shall establish procedures to ensure that the quality of the fingerprints taken results in minimizing the rejection rate of fingerprint cards due to illegible or incomplete cards.

[1] The FAST program is a cooperative effort between the Bureau of Customs and Border Patrol and the governments of Canada and Mexico to coordinate processes for the clearance of commercial shipments at the U.S. - Canada and U.S. - Mexico borders. Participants in the FAST program, which requires successful completion of a background records check, may receive expedited entrance privileges at the northern and southern borders.

[2] This documentation must allow the T&R Official to verify that the individual has fulfilled the unescorted access requirements of Section 149 of the AEA by submitting to fingerprinting and an FBI identification and criminal history records check.
Licensees must have their fingerprints taken by local law enforcement (or a private entity authorized to take fingerprints) because an authorized official must certify the identity of the person being fingerprinted.

The NRC will review submitted fingerprint cards for completeness. Any Form FD-258 fingerprint record containing omissions or evident errors will be returned to the licensee for corrections. The fee for processing fingerprint checks includes one re-submission if the initial submission is returned by the FBI because the fingerprint impressions cannot be classified. The one free re-submission must have the FBI Transaction Control Number reflected on the re-submission. If additional submissions are necessary, they will be treated as initial submittals and will require a second payment of the processing fee.

Fees for processing fingerprint checks are due upon application (Note: other fees may apply to obtain fingerprints from your local law enforcement agency). Licensees shall submit payments electronically via http://www.pay.gov. Payments through Pay.gov can be made directly from the Licensee's credit/debit card. Licensees will need to establish a password and user ID before they can access Pay.gov. To establish an account, licensee requests must be sent to paygo@nrc.gov. The request must include the licensee's name, address, point of contact, e-mail address, and phone number. The NRC will forward each request to Pay.gov and someone from Pay.gov will contact the licensee with all of the necessary account information.

Licensees shall make payments for processing before submitting applications to the NRC. Combined payment for multiple applications is acceptable. Licensees shall include the Pay.gov payment receipt(s) along with the application(s). For additional guidance on making electronic payments, contact the Facilities Security Branch, Division of Facilities and Security, at (301) 415-7404. The application fee (currently $36) is the sum of the user fee charged by the FBI for each fingerprint card or other fingerprint record submitted by the NRC on behalf of a Licensee, and an NRC processing fee, which covers administrative costs associated with NRC handling of Licensee fingerprint submissions. The Commission will directly notify Licensees subject to this regulation of any fee changes.

It is necessary for a licensee to resubmit fingerprints only under two conditions:

1. The FBI has determined that the fingerprints cannot be classified due to poor quality in the mechanics of taking the initial impressions; or,

2. The initial submission has been lost.

If the FBI advises the fingerprints are unclassifiable based on conditions other than poor quality, the Licensee must submit a request to NRC for alternatives. When those search results are received from the FBI, no further search is necessary. The Commission will receive and forward to the submitting licensee all data from the FBI as a result of the licensee's application(s) for criminal history records checks, including the FBI fingerprint record(s).

ENCLOSURE 8

GUIDANCE FOR EVALUATING FBI IDENTIFICATION AND CRIMINAL HISTORY RECORDS CHECKS FOR ALLOWING UNESCORTED ACCESS TO CERTAIN RADIOACTIVE MATERIAL

Each licensee is responsible for determining whether to grant an individual unescorted access to certain radioactive materials. The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern (listed in Table 1 – Enclosure 5, Exhibit 1 of MC 2800) and devices containing that radioactive material. The T&R determination, to grant an individual unescorted access to certain radioactive materials, is made by the licensee's T&R Official, based on information gathered from all four elements of the background check and evaluated by the T&R Official. The minimum four background check elements are: 1) fingerprinting and a Federal Bureau of Investigation (FBI) identification and criminal history records check, 2) verifying employment history, 3) verifying education, and 4) personal references. The purpose of this guidance is to address the fingerprinting component of the T&R determination.

Unescorted access determinations require an evaluation of a person's trustworthiness and reliability. When a person's life history shows evidence of unreliability or untrustworthiness, questions arise whether the person can be relied on and trusted to exercise the responsibility necessary for working with risk-significant radioactive materials. The purpose of the T&R determination requirement, for unescorted access, is to provide reasonable assurance that those individuals are trustworthy and reliable, and do not constitute an unreasonable risk to the public health and safety, including the potential to commit or aid theft and/or radiological sabotage. This is a licensee's business decision as to what criteria it uses for the bases of the trustworthiness and reliability determination. Some indicators that licensees should consider for what may be a trustworthiness and reliability concern can be found in the NRC's Increased Control guidance in Q and A #22 at the following web address:
http://www.nrc.gov/reading-rm/doccollections/enforcement/security/2005/ml053130233.pdf.

In evaluating the relevance of an individual's conduct, the T&R Official should consider the following factors:

(1) The nature, extent, and seriousness of the conduct;
(2) the circumstances surrounding the conduct, to include knowledgeable participation;
(3) the frequency and recency of the conduct;
(4) the individual's age and maturity at the time of the conduct;
(5) the extent to which participation is voluntary;
(6) the presence or absence of rehabilitation and other permanent behavioral changes;
(7) the motivation for the conduct;
(8) the potential for pressure, coercion, exploitation, or duress; and
(9) the likelihood of continuation or recurrence

Each case must be judged on its own merits, and final determination remains the responsibility of the licensee. In every case, the T&R Official should evaluate trustworthiness and reliability based on an accumulation of information which supports a positive finding, prior to granting unescorted access. Items to consider include:

1. The T&R Official should evaluate the information collected for consistency and adequacy.

2. True identity should be evaluated by comparing applicant provided identification and personal history data to pertinent information from the background check, and other data sources.

3. The T&R Official should determine whether inconsistencies determined through review or investigation, are intentional, innocent, or an oversight. Willful or intentional acts of omission or untruthfulness could be grounds for denial of unescorted access.

When a licensee submits fingerprints to the NRC pursuant to an NRC Order, it will receive a FBI identification and criminal history record since the individual's eighteenth birthday. The licensee will receive the information from the criminal history check of those individuals requiring unescorted access to radioactive materials, and the licensee T&R Official should evaluate that information using the guidance below.

The licensee's T&R Official is required to evaluate all available information in making a T&R determination for unescorted access to radioactive materials, including the criminal history records information pertaining to the individual as required by the NRC Order. The FBI identification and criminal history records check is used in the determination of whether the individual has a record of criminal activity that indicates that the individual should not have unescorted access to radioactive materials subject to this Order. Each determination of T&R for unescorted access to radioactive materials, which includes a review of criminal history information, must be documented to include the basis for the decision made. Licensees shall not make a final determination made solely on the basis of criminal history checks information involving an arrest more than 1 year old for which there is not information on the disposition of the case, or an arrest that resulted in dismissal of the charge or an acquittal.

All information collected is to be considered by the licensee in making a trustworthiness or reliability determination for unescorted access. Potentially disqualifying information obtained from confidential/unnamed sources must be substantiated and documented, and should not be used as a sole basis to deny access authorization unless corroborated. Licensees should establish criteria that would disqualify someone from being granted authorized access. In every case, the licensee should evaluate trustworthiness and reliability based on an accumulation of information which supports a positive finding.

The FBI identification and criminal history records check is used to evaluate whether the individual has a record of criminal activity that may compromise his or her trustworthiness and reliability. Identification of a criminal history through the FBI criminal history records check does not automatically indicate unreliability or lack of trustworthiness of the employee. The licensee will have to judge the nature of the criminal activity, length of employment, and recency of the criminal activity. The licensee can authorize individuals with criminal records for unescorted access to radioactive materials, based on a documented evaluation of the basis for determining that the employee was reliable and trustworthy notwithstanding his or her criminal history. Each evaluation conducted in review of criminal history and other background checks information, should be documented to include the decision making basis.

At a minimum, the licensee should consider the following elements when evaluating the results of the FBI Identification and Criminal History Records check:

1. Committed, attempted to commit, aided, or abetted another who committed or attempted to commit any act of sabotage, espionage, treason, sedition, or terrorism.
2. Publicly or privately advocated actions that may be inimical to the interest of the United States, or publicly or privately advocated the use of force or violence to overthrow the Government of the United States or the alteration of the form of government of the United States by unconstitutional means.
3. Knowingly established or continued a sympathetic association with a saboteur, spy, traitor, seditionist, anarchist, terrorist, or revolutionist, or with an espionage agent or other secret agent or representative of a foreign nation whose interests may be inimical to the interests of the United States, or with any person who advocates the use of force or violence to overthrow the Government of the United States or the alteration of the form of government of the United States by unconstitutional means. (Ordinarily, the licensee should not consider chance or casual meetings or contacts limited to normal business or Official relations.)
4. Joined or engaged in any activity knowingly in sympathy with or in support of any foreign or domestic organization, association, movement, group, or combination of persons which unlawfully advocates or practices the commission of acts of force or violence to prevent others from exercising their rights under the Constitution or laws of the United States or any State or any subdivisions thereof by unlawful means, or which advocate the use of force and violence to overthrow the Government of the United States or the alteration of the form of government of the United States by unconstitutional means. (Ordinarily, the licensee should not consider chance or casual meetings or contacts limited to normal business or official relations.)
5. Deliberately misrepresented, falsified or omitted relevant and material facts from documentation provided to the licensee.
6. Has been convicted of a crime(s) which, in the T&R Official's opinion, indicate poor judgment, unreliability, or untrustworthiness.

These indicators are not meant to be all inclusive nor intended to be disqualifying factors. Licensees can also consider how recent such indicators occurred and other extenuating or mitigating factors in their determinations. Section 149.c.(2)(B) of the AEA requires that the information obtained as a result of fingerprinting be used solely for the purposes of making a determination as to unescorted access suitability. Unescorted access suitability is not a hiring decision, and the NJDEP does not intend for licensees to use this guidance as such. Because a particular individual may not be suitable for Unescorted Access does not necessarily mean that he is not suitable for escorted access or some other position that does not involve NJDEP-regulated activities. Licensees shall notify the NRC's Headquarters Operations Office at 301-816-5100 within 24 hours if the results from a FBI identification and criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Database.

NJ.DEP INSPECTION MANUAL
INSPECTION PROCEDURE 83822

RADIATION PROTECTION

83822-01 INSPECTION OBJECTIVE

To determine whether the licensee's performance is in accordance with regulatory requirements related to radiation protection, and to evaluate the adequacy of certain aspects of the licensee's radiation protection program.

83822-02 INSPECTION REQUIREMENTS

02.01 Radiation Protection Program. Verify that the performance of the radiation protection program, commensurate with the potential risk involved in the licensee's activities, is being implemented and documented. Verify that program performance is being reviewed at least annually, both for content and implementation.

02.02 Radiation Protection Procedures. Verify that performance due to changes in the radiological protection procedures made since the last inspection are consistent with regulations and license requirements.

02.03 Instruments and Equipment. Verify that the performance of radiation protection instruments and equipment is in accordance with license requirements and licensee procedures.

02.04 Exposure Controls

a. External Exposure. Determine that the licensee's performance is in accordance with the following regulatory requirements:

1. N.J.A.C. 7:28-6.1 surveys and monitoring (see 10 CFR 20.1501 and 20.1502)
2. N.J.A.C. 7:28-6.1 occupational dose limits (see 10 CFR 20.1201)
3. N.J.A.C. 7:28-6.1 planned special exposures (see 10 CFR 20 .1206)
4. N.J.A.C. 7:28-6.1 exposure of minors (see 10 CFR 20.1207)
5. N.J.A.C. 7:28-6.1 dose to an embryo/fetus (see 10 CFR 20.1208)
6. N.J.A.C. 7:28-6.1 external dose from airborne material (see 10 CFR 20.1203)
7. N.J.A.C. 7:28-6.1 prior occupational dose (see 10 CFR 20.2104)
8. N.J.A.C. 7:28-6.1 records of monitoring results (see 10 CFR 20.2106)
9. N.J.A.C. 7:28-6.1 records of planned special exposures (see 10 CFR 20.2105)
10. N.J.A.C. 7:28-6.1 records of radiation protection program (see 10 CFR 20.2102)
11. N.J.A.C. 7:28-6.1 dose to the public (see 10 CFR 20.1301)
12. N.J.A.C. 7:28-6.1 ALARA (see 10 CFR 20.1101(b) and (d)

b. Internal Exposure. Determine that licensee's performance is in accordance with the following regulations:

1. N.J.A.C. 7:28-6.1 surveys and monitoring (see 10 CFR 20.1501 and 20.1502)
2. N.J.A.C. 7:28-6.1 exposure limits (see 10 CFR 20.1201)
3. N.J.A.C. 7:28-6.1 use of engineering and other controls (see 10 CFR 20.1701 and 20.1702)

4. N.J.A.C. 7:28-6.1 summation of external and internal doses (see 10 CFR 20.1202)
5. N.J.A.C. 7:28-6.1 determination of internal dose (see 10 CFR 20.1204)
6. N.J.A.C. 7:28-6.1 dose to the public (see 10 CFR 20.1302)

c. Respiratory Protection. For facilities with a respiratory protection program, determine if licensee's performance is in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1703).

02.05 Posting, Labeling, and Control

a. Posting and Labeling. Determine if licensee's performance is in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902, 20.1903, 20.1904, 20.1905, 20.1501, and 20.1502) other posting and labeling requirements specified in the license or licensee procedures.

b. Control. Determine if licensee's performance is in accordance with the license requirements, licensee procedures, and the following regulations:

1. N.J.A.C. 7:28-6.1 high radiation area access (see 10 CFR 20.1601)
2. N.J.A.C. 7:28-6.1 very high radiation area access (see 10 CFR 20.1602)
3. N.J.A.C. 7:28-6.1 security of stored material (see 10 CFR 20.1801)
4. N.J.A.C. 7:28-6.1 control of material not in storage (see 10 CFR 20.1802)

c. Posting of Notices. Determine if licensee's performance is in accordance with N.J.A.C. 7:28-50.1 (see 10 CFR 19.11).

02.06 Surveys

a. Requirements. Determine if licensee's performance is in accordance with the following regulations:

1. N.J.A.C. 7:28-6.1 surveys (see 10 CFR 20.1501(a) & (b))
2. N.J.A.C. 7:28-6.1 survey records (see 10 CFR 20.2103)

b. Leak Tests. Verify if licensee's performance is in accordance with license requirements or other NJDEP regulations for leak testing of radioactive sealed sources.

02.07 Notifications and Reports

a. To the NJDEP. Determine if licensee's performance is in accordance with the following regulations and license requirements:

1. N.J.A.C. 7:28-6.1 loss of control or theft of material (see 10 CFR 20.2201 & 20.2202(b))
2. N.J.A.C. 7:28-6.1 incidents, and exposures (see 10 CFR 20.2202 and 20.2203)
3. N.J.A.C. 7:28-6.1 overexposure (see 10 CFR 20.2202(a) & 20.2203)
4. Other radiation protection reports required by the license and by applicable provisions of N.J.A.C. 7:28-51 through 57, 58, and 60 (see 10 CFR 30-39, 40, 70 and 72).

b. To the Individual. Determine if licensee's performance is in accordance with N.J.A.C. 7:28-50.1 (see 10 CFR 19.13).

02.08 As Low As Is Reasonably Achievable (ALARA). N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101(b)) states that persons engaged in NJDEP licensed activities shall, to the extent practicable, maintain occupational doses and doses to members of the public ALARA. During inspections:

a. Determine if high level management has made a commitment to minimize exposure to workers and has clearly defined procedures and policies to implement the ALARA philosophy.

b. Determine that licensee personnel are made aware of management's commitment to keep occupational exposures ALARA.
c. Ascertain that the radiation protection staff has been given authority to make certain that ALARA policies are carried out and that workers have been adequately trained to understand the ALARA philosophy and how it should be implemented at their work places.
d. Determine that management and its designees perform periodic (at least annual) audits of its program (special attention should be given to methods to lower internal and external exposure and to determine that effluents released are ALARA.
e. Determine if licensee's performance is in accordance with N.J.A.C. 7:28-50.1 (see 10 CFR 19.12) with respect to workers' understanding of radiation protection in their work place, and how the training received includes an understanding of ALARA as it pertains to the work place.
f. Determine whether modifications to equipment, facilities, and procedures, have been made where practicable to significantly reduce exposures at a reasonable cost. The benefits gained should outweigh the cost of modifications. Also determine if the licensee has considered the ALARA philosophy during the engineering phase for changes in facilities, equipment, or processes and whether an ALARA review was performed during initial implementation of changes.
g. Determine if the RSO and radiation protection staff's performance includes:
    1. Identification of the origins of radiation exposures by location and job category and have noted trends in the amounts of radiation at the locations.
    2. Consideration of ways to reduce exposures in those locations where exposure to personnel are significant.
    3. Periodically reviewing operating procedures that affect radiation safety and have made surveys of operations to identify situations where radiation exposures can be reduced.
h. Determine if licensee's performance includes a program in which workers can make suggestions on radiation protection (feedback).
i. Determine if licensee's performance includes the use of adequate equipment and supplies in the radiation protection program, and if procedures are available for proper use of these supplies and equipment.

83822-03 INSPECTION GUIDANCE

03.01 Radiation Protection Program. Review the outcome of the licensee's implementation of its radiation protection program to determine if licensee's performance ensures safety and compliance with regulatory requirements. Determine if the program content and implementation are being reviewed at least annually. Inspect the documentation for these reviews.

Review of the licensee's Health Physics (HP) log book or file on HP problems may be useful to identify areas deserving special attention. Particular attention should be directed toward identifying trends and ascertaining whether corrective actions were directed toward the cause and not merely the symptoms.

Regulatory Guides 8.8 and 8.10 may be discussed in terms of providing useful guidance to the licensee regarding ALARA. If the licensee has a documented commitment to ALARA,

implementation of the program should be discussed with management. Verify that the ALARA goals are adequate and realistic.

The licensee may have submitted certain of his radiation protection procedures, or his radiation protection manual, along with the license application and, in some cases, those procedures or the manual may be incorporated into license requirements. There are references to licensee procedures throughout this inspection procedure; however, this is not done for all inspection areas. The absence of a notation regarding licensee procedures is not intended to preclude the inspector from inspecting a given area against licensee procedures if there is an applicable license requirement.

03.02 Radiation Protection Procedures. Review any substantive changes to procedures which have been implemented since the last inspection if problems are identified in a specific program area; verify that limits, precautions, controls, etc., specified in the procedures are consistent with regulations and license requirements.

03.03 Instruments and Equipment.

a. Randomly select instruments of each major type and examine them to verify operability and proper alarm settings, if alarm settings are applicable. These may include portable survey instruments, fixed monitoring equipment, constant air monitors, portable air samplers, pocket dosimeters, and alarming dosimeters.
b. Review the most recent calibration records of the instrument(s) selected for inspection to assure that the calibration and surveillance program for these instruments are being accomplished in accordance with license requirements or licensee procedures.
c. Verify that the licensee has a system (a schedule, card file, etc.) which identifies all the instruments and identifies when they are due for calibration or functional testing.
d. Verify that the procedures used to calibrate the instruments selected above contain: review and approval requirements of the licensee's procedural system or license requirements, acceptance criteria including values for trip settings that conform to license requirements, if applicable, and detailed stepwise instructions.
e. Verify that the licensee uses survey instruments that are appropriate for the type and intensity of radiation measured.

03.04 Exposure Controls

a. External Exposure
    1. Examine any changes made in procedures for control and use of personnel monitoring equipment; verify that limits, precautions, controls, etc., specified in the procedures are consistent with regulations and license requirements. Examine the type of monitoring devices used, the period of use or exchange period, and the number used to determine if these aspects seem consistent with the monitoring program. Determine who the supplier is, and if the service has been changed since the last inspection, determine the reasons for the change. Verify that the personnel dosimetry processor is accredited by NVLAP. NOTE: If applicable to the facility being inspected, verify that processor is DOELAP accredited. For pocket dosimeters or pocket chambers, determine when they are read and recharged, the number used, and review the calibration procedure or leak test

procedure. Evaluate the adequacy of the licensee's procedures or system for evaluating and using personnel monitoring data to control and minimize exposures. The licensee should account for occupational radiation doses to personnel resulting from exposures to licensed material and other unlicensed radiation sources (e.g. x-ray machines).

2. Review reports of exposure summaries generated since the last inspection to determine that licensee's performance is in accordance with regulatory requirements.
3. Review the records of all persons who received planned special exposures since the last inspection. Determine that exposure histories are on file for these individuals.
4. Determine, by discussion with supervisory personnel, if minors have been permitted to work in restricted areas and, if so, determine that licensee's performance is in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1207) by review of exposure records.

b. Internal Exposure

1. During review of exposure evaluations in 03.03b4 below, verify that the licensee's performance is in accordance with internal exposure limits.
2. Review randomly selected air sampling and bioassay records.
3. By observation, discussion, and review of documentation, verify that engineering controls are considered and used to the extent practicable. Evaluation of process and engineering controls incorporated as part of the facility or equipment as licensed will be performed in the licensing process; the inspection program will evaluate the use of other engineering controls. In situations where a review for licensing is not applicable, such as medical licensees, review these items to the extent practicable to ensure that they comply with descriptions in license applications, or conform to license conditions. Discuss with NJDEP management prior to inspection.
4. Review documentation of evaluations performed as the result of unplanned exposures. Verify the appropriateness of preventive measures instituted following an unplanned exposure.

c. Respiratory Protection

1. Determine that the equipment is certified by NIOSH/MSHA.
2. Determine proper selection of equipment.
3. Determine by review of records and by discussions that a maintenance and training program is conducted and that it is administered and conducted in accordance with written procedures. Determine by review of records, discussions, and observations that respirator users are individually fitted for respirators and that respiratory equipment is operationally tested immediately prior to each use.
4. Randomly select several control requirements and determine compliance; by review of records, by discussions, or observation.
5. In taking credit for the protection provided by the use of respiratory protective equipment, N.J.A.C. 7:28-6.1 (see 10 CFR 20.1703) requires that the protection factor be greater than the multiple by which peak concentrations are expected to exceed the values of 10 CFR 20 Appendix B, Table 1, Column 3 (incorporated by reference into N.J.A.C. 7:28-6.1), unless ALARA considerations indicate otherwise. Verify that this criterion is considered in selecting respirators.

03.05 Posting, Labeling, and Control

a. Posting and Labeling. Inspect representative areas to verify compliance; pay particular attention to "temporary" work areas that may be required for maintenance activity, newly established work areas, etc. Inspect a random sampling of containers in work or storage areas.

b. Control

1. Randomly select high radiation or very high radiation areas to verify that access is controlled in accordance with regulations or license requirements.
2. Inspect areas where radioactive material is located or stored in an unrestricted area.
3. Review a random selection of records (e.g., radiation level surveys, interlock tests, audible & visible alarm test results) and inspect work areas to verify licensee's controls ensure the safety of workers and members of the public.

c. Posting of Notices. Determine, by questioning of management, how the licensee performs in accordance with the requirements of N.J.A.C. 7:28-50.1 (see 10 CFR 19.11); inspect bulletin boards or other places where notices are posted; question a few individuals to determine if they are aware of the posting of notices.

03.06 Surveys

a. Requirements. Verify that the licensee has established schedules for periodic surveys of work areas of the plant and facility site; verify that surveys are conducted using approved procedures; review a random selection of survey records to see that surveys are being performed according to schedules; verify that the survey results are reviewed by appropriate supervision; verify that corrective actions have been taken, as appropriate. Attempt to observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys. Verify specifically that schedule and procedural requirements for surveys appear adequate to demonstrate compliance with the following aspects of the regulations and with pertinent license requirements.

1. N.J.A.C. 7:28-6.1 (permissible doses) (see 10 CFR 20.1201). Determine whether due consideration is given to energy, beta exposure, and extremity exposure, and whether neutron surveys are performed, if appropriate.

2. N.J.A.C. 7:28-6.1(exposure to airborne radioactivity) (see 10 CFR 20.1203 and 20.1204). Determine whether both particulates, non-noble gases and vapors are considered, if appropriate.

3. N.J.A.C. 7:28-6.1 (posted areas) (see 10 CFR 20.1902).

4. N.J.A.C. 7:28-6.1 (radiation in unrestricted areas) (see 10 CFR 20.1301)

b. Leak Tests. Inspect a random selection of records of leak tests of radioactive sealed sources.

03.07 Notifications and Reports

a. To the NJDEP. The objective is to determine if the licensee is reporting all the events and data required by the regulations and the license. The inspector should have reviewed those reports submitted since the last inspection; therefore, a determination should be made whether log books, and other data during the course of the inspection should aid in this determination.

b. To the Individual. Determine by discussion with individuals selected at random (identified during the course of inspection of other requirements) whether they were notified in accordance with N.J.A.C. 7:28-50.1 (see 10 CFR 19.13).

03.08 ALARA. Materials licensees there may have a very active ALARA programs for the higher inspection priorities that are identified in the license applications or license conditions. For lower priority licensees with inspection frequencies of once every 5 or 7 years, limited ALARA programs may exist; for licensees with 7 year inspection frequencies, ALARA programs may be nonexistent.

The depth of the ALARA programs will depend on the quantities of radioactive materials possessed and used, and whether the potential for radiation exposures can be significant. For example, licensees such as users of gas chromatographs may have no formal ALARA program because radiation exposures are very small. Nevertheless, even in such cases, consideration should be given to minimizing exposures. The following guidance should be used as applicable or at the inspector's discretion (compare to guidance outlined in Section 02.08).

a. Facility personnel should be made aware of management's commitment to keep exposures to workers ALARA. The commitment should appear in policy statements, instructions to personnel, and similar documents. As a minimum, workers should be familiar with the ALARA commitment so that they can explain what the commitment is, what ALARA means, why it is recommended, and how they have been advised to implement it on their jobs. Examine a selection of policy standards and instructions (if they exist) and interview workers to determine if they understand the ALARA philosophy and what it means at the work place.
b. As a minimum, management should be able to discuss which operating procedures were reviewed, in which locations most exposures are being received, what groups of workers are receiving the highest exposures, what discussions they have had with the radiation protection staff or outside consultants, and what steps have been taken to reduce exposures. Examine a random sample of records and interview personnel to determine what has been done to reduce exposures.
c. No guidance.
d. No guidance.
e. Radiation workers should understand how radiation protection relates to their job and should be retrained at least annually, or as otherwise stated in the license application. Training should be sufficient to ensure that workers can correctly answer questions on radiation protection as it relates to their jobs. Interview workers (consistent with the size of the program) to determine if the workers understand radiation protection as it relates to their jobs and if they have an opportunity to discuss radiation safety with the radiation protection staff.
f. Inquire if modifications have been made to facilities and equipment to reduce exposures. Randomly examine any procedures or records that reflect modifications and attempt to determine the extent of the benefits gained through modifications (for example, modifications may have been beneficial if exposures of 50 mrems/hour were reduced by a factor of 10 to 5 mrems/hour. It may not be beneficial to reduce 1 mrem/hour to 0.1 mrem/hour, considering cost and risk. In both of the above examples, consideration must be given to costs of modification and risk to the population). Verify that ALARA measures do not disproportionately increase the risks from non-radiological hazards, such as industrial

hazards.

g. Examine Radiation Safety Committee records or other records on ALARA policies to determine whether source-term surveys have been conducted and actions taken to reduce significant exposures.

h. No guidance.

i. Examine equipment and supplies to determine if they adequately protect personnel from unnecessary radiation. Such equipment and supplies may include, but are not limited to, decontamination supplies, survey meters, protective clothing, ventilation systems, air sampling equipment, and supplies used for posting areas, such as radiation areas.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 83890

CLOSEOUT INSPECTION AND SURVEY

83890-01 INSPECTION OBJECTIVE

01.01 To ensure that Final Surveys performed at material licenses are conducted as stated in the licensee's decommissioning plan (DP).

01.02 To verify that the sites have been decontaminated to acceptable radiological levels for unrestricted or restricted use as per N.J.A.C. 7:28-12.

83890-02 INSPECTION REQUIREMENTS

02.01 Preliminary Review. Review the licensee's Decommissioning Plan to determine the scope of site contamination and the licensee's decontamination and final survey program.

02.02 Inspection of Final Surveys and Disposition of Materials

a. Verify, by inspection, the licensee's implementation of the final survey program to confirm the acceptability of the final survey results. See Appendix A, "Final Survey Program Inspection Area," for a detailed inspection checklist for the licensee's final survey program.

b. Confirm, by inspection of records (inventory, transfer, disposal, etc.), that licensed material is being, or has been, transferred to an authorized recipient. Verify that licensee is in compliance with the licensed disposal facility's Waste Acceptance Criteria (WAC).

c. Confirm, by inspection of records, that materials and equipment are released in accordance with all applicable regulations and license conditions.

d. Verify, by inspection of the licensee's facility that licensed material and radioactive/contaminated equipment, materials, scrap, etc. are not being used or stored. This should be done following receipt and evaluation of reports of the facility's status as required by N.J.A.C. 7:28-51, 58 and 60.

02.03 Confirmatory Surveys. NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual" (MARSSIM) includes independent (third-party) measurements, sampling, and analyses to verify the findings of a final status survey. Surveys and sampling should be conducted simultaneously with the licensee during the licensee's final status surveys. The inspector should collect side-by-side or split samples with the licensee for comparative purposes, as well as comparing infield instrument readings and sensitivity. Where practical, counting samples previously collected and counted by the licensee is also acceptable. In areas where work-in-process surveys cannot be conducted, or samples collected, after-the-fact confirmatory surveys and

sampling may be performed. Sites where NJDEP's work-in-process surveys and sampling have not identified significant weaknesses in the final survey program may not require after-the-fact surveying and sampling. However, after-the-fact confirmatory surveys may be required for sites where significant unresolved weaknesses were previously identified or where repetitive violations were identified. The goal is to conduct sufficient confirmatory surveys and sampling so that the NJDEP can conclude that the licensee's survey program is being implemented in a manner that provides confidence in the results. The in-process approach has resulted in significant savings in cost, assured a more accurate final status survey, and helped the licensee in maintaining its release schedule.

NJDEP will review each proposed retirement of expired, superseded, or terminated license to determine the necessity of performing a confirmatory survey. The review will be on a case-by-case basis using the following criteria.

A. Those facilities that meet the following criteria do not require a confirmatory survey:
   1. An adequate closeout survey has been conducted by the licensee.
   2. Use has been limited to small quantities of radionuclides with half-lives of 120 days or less.
   3. The use of sealed sources only (if leak tests have been <0.005 uCi).
   4. The use of limited materials that pose a very low risk to public health and safety.

B. Those facilities that meet the following criteria do require a confirmatory survey:
   1. Partial site release where in-process inspection is not practical.
   2. Repetitive Violations.
   3. Significant lack of confidence with clean-up efforts at the site.
   4. Significant unresolved weaknesses identified during the inspection of the licensee's final survey program.

02.04 The Conduct of Confirmatory Surveys. If a confirmatory survey is necessary, it should be performed to determine if the licensee's results are accurate and sufficient to demonstrate that the facility meets NJDEP requirements.

02.05 Reports and Records

a. For licensees subject to the reporting requirements, verify by reviewing records and files that:
   1. Personnel exposure and monitoring reports required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.2206) have been submitted to the NJDEP for the calendar year in which the license has expired or is being terminated, and

   2. Reports of personnel exposures for terminated employees or employees no longer working with radioactive materials required by N.J.A.C. 7:28-50.1 (see 10 CFR 19.13) have been submitted to both the NJDEP and the employee.

b. Determine what plans or arrangements have been made for preserving records required by N.J.A.C. 7:28-6.1.

02.06 Burial of Waste. Determine if waste has been buried onsite. If burial has occurred, review the licensee's actions to historically assess, characterize, survey, and model the burial site. The licensee should model its former burial sites for compliance with N.J.A.C. 7:28-6.1 and 12.

02.07 Final Inspection Report. Prepare a final inspection report which summarizes the actions taken under this inspection procedure and the findings and evaluations of the inspection staff.

83890-03 INSPECTION GUIDANCE

03.01 Preliminary Review. Review the general licensing history of the facility and the regulations for license termination.

03.02 Inspection of Final Survey. Review any license conditions related to decontamination of the facility, the decommissioning plan, any approved final survey programs, and/or final survey reports, as applicable. The inspection of the licensee's final survey program should occur while the licensee is in the process of performing the final survey. The purpose of this "in-process' final survey inspection is to provide confidence that the licensee's survey results are accurate and representative of the condition at the facility. See Appendix A, "Final Survey Program Inspection Area," for detailed inspection checklist for the licensee's final survey program.

03.03 Confirmatory Survey Preparation. Review license records such as the DP for types of radioactive material used onsite, the occurrence of any significant safety issues, and any special concerns about the site expressed by stakeholders. Also review NUREG-1575, MARSSIM.

03.04 Conduct of Confirmatory Surveys. It may be necessary for NJDEP, or an NJDEP contractor to conduct confirmatory measurements to provide supplemental information after the licensee has completed its final survey, in addition to the findings of the in-process inspection, to ensure that the survey results reported by the licensee are accurate and representative of the conditions at the facility. Contractors must be authorized by the NJDEP, NRC, or other Agreement State. However, comprehensive confirmatory surveys should only be necessary if there is significant doubt about the licensee's final survey results. For example, a confirmatory survey would be needed if an in-process inspection of the licensee's final survey program identifies significant, unresolved weaknesses that are not administrative in nature (i.e., measurement results and/or soil concentration levels in units not comparable to the release criteria, inadequate classification of an area, or improper instrument calibration), licensee has a history of repetitive violations that reduce confidence in the survey results; significant lack of public or Congressional confidence in clean-up efforts at the site; or the site is too small (e.g., partial site release) for an in-process inspection. Note that the inspector may perform limited measurements (split samples, "side-by-side," direct measurements, etc.) as part of the in-process inspection of a licensee's ongoing final survey program. During the inspection, buildings, rooms, furniture, systems and equipment; ventilation ducts, filters, sinks, drains, traps and sumps; overhead fixtures, walls and floors, etc., should all be considered as areas to be surveyed.

03.05 Reports and Records. Although certain licensees are not required to report personnel exposures, and the limitations of a license removes the legal obligation to maintain the records required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.2101 and 20.2110), the licensee should be informed

that retention of these records is highly recommended. Licensee should be informed of the record keeping requirements for decommissioning.

03.06 Final Inspection Report. The final inspection report becomes the official certification of the disposal of licensed material. The final inspection report forms the basis for retiring and eventually disposing of both the licensing and inspection files.

APPENDIX A

FINAL SURVEY PROGRAM INSPECTION AREA

I. CONSIDERATION FOR DESIGNING FINAL STATUS SURVEY INSPECTION

a. Has the final survey report been submitted to the New Jersey Department of Environmental Protection?

b. Has the licensee final survey program been previously inspected?

c. If the final survey report is not submitted, is the licensee's final survey in-process?

d. Has the final survey plan been submitted and approved by an NJDEP license reviewer?

II. INSPECTION AREAS FOR LICENSEE FINAL SURVEYS

a. Inspections should be made against commitments in the DP and the licensee's final survey plan (which would have been approved during Decommissioning Plan (DP) review).

b. For facilities that require a significant decontamination effort, all the inspection areas listed below should be inspected while the licensee's final survey program is in progress. For facilities that do not require a significant decontamination effort, only some of the inspection areas below may apply, and it may not be practical to inspect these areas until after the licensee's final survey is completed and the licensee's final survey report has been submitted to NJDEP.

c. Inspection of a licensee's final survey may include independent confirmatory measurements by the inspector or contractor. The extent of the confirmatory measurements, and whether the use of a contractor is warranted, depends on a number of factors that are discussed in Section II.B. In most cases, limited in-process confirmatory surveys should be sufficient.

d. For each inspection, the inspector should identify which inspections (listed below) are covered.

III. LICENSEE FINAL SURVEY PLANS AND PROCEDURES

a. Determine if all potential contaminants have been identified.

b. Review the Organization and Responsibilities for adequacy/completeness:
1. Survey program documentation
2. Responsibilities and qualifications of the survey staff

c. Review the Quality Assurance/Quality Control program for adequacy/completeness:
1. Organizational structure
2. QA Program
3. Document Control/Records Management program
4. Equipment Maintenance and Control program
5. Audits and Corrective Action program

d. Determine if the laboratory analytical procedures, including QA/QC, are acceptable, and if the results are adequately documented. The laboratory must be certified by the NJDEP Office of Quality Assurance.

e. Determine if the licensee prepared an adequate Final Status Survey (FSS) plan in accordance with guidance documents (NJDEP Field Sampling Manual and MARSSIM).

f. Determine if the field and laboratory instrumentation used, or planned to be used, were adequate/appropriate for scanning, direct measurements, and analysis for the radionuclides of concern (ROCs).

g. Determine if the calibration accounted for the ROCs.

h. Review ROCs, area classification, survey unit size, estimated mean and standard deviation.

i. Review the methods used to address the impact of multiple ROCs in FSS planning.

j. Review instrument use procedures:
1. Minimum Detectable Concentration (MDC) calculations
2. Actual vs. required scan sensitivity; and

3. Calibration, including accounting for multiple radionuclides and any environmental factors that may influence instrument performance.

k. Select survey units/areas for confirmation:

1. Determine scan coverage based on classification.
2. Review analytical procedures for appropriateness for measuring the ROCs.
3. Cross-check FSS data packages against plan requirements.

l. For soil sampling, determine sampling depth requirements and sampling intervals. At a minimum, samples should be collected from anomalous or other judgmental areas, together with selected licensee-archived samples, for confirmatory analysis.
The necessity for, and the specific numbers of, other random/systematic samples should be separately evaluated, using the Data Quality Objectives (DQO) process.

m. For structure surfaces, direct measurements should include, at a minimum, anomalous or judgmental areas and comparative measurement locations. The necessity for, and the specific numbers of, other random/systematic samples should be separately evaluated, using the DQO process.

n. If project documentation is complete, accurate, and represents current radiological conditions relative to the release criteria, then recommend acceptance; if insufficient, then provide technical comments.

o. Calculate action levels to investigate anomalies identified during verification/confirmatory surveys.

p. Evaluate each anomaly identified during verification/confirmatory surveys, for compliance.
1. Is it acceptable relative to size and concentration?
2. Has the licensee adequately addressed it?
3. Is it within the bounds of survey unit classification?

q. Review if confirmatory analyses or measurements agree with the site's reported results.

r. Review if systematic agreement (randomly selected) and judgmental (location selected using professional judgment based on site knowledge) samples and measurements are less than the Derived Concentration Guidance Level.

IV. NJDEP CONFIRMATORY SURVEY

a. Review whether or not a confirmatory survey is justified.
1. Significant, unresolved, weaknesses identified during the inspection of the licensee's final survey plan.
2. Repetitive violations
3. Significant public or Congressional interest
4. Partial site release where an in-process inspection is not practical

b. If a confirmatory survey is justified, determine if a NJDEP Contractor should be used. Contractors must be authorized by the NJDEP, NRC, or other Agreement State. Meeting one or more of the three criteria listed below will, in general, justify the use of a contractor.
1. Licensee's final survey involves unique or complex technical issues.
2. Confirmatory survey is expected to require more than a person-week effort to complete field surveys and sampling.
3. Confirmatory survey is very high priority project that cannot be completed by staff in a timely manner.

NOTE: If licensees are decommissioning under the NRC's NUREG/CR-5849, NUREG 1575 Rev.1 should not be applied to them.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 84850

RADIOACTIVE WASTE MANAGEMENT - INSPECTION OF WASTE GENERATOR REQUIREMENTS OF N.J.A.C. 7:28-6 and 7:28-59

84850-01 INSPECTION OBJECTIVE

01.01 To determine whether the licensee has established and is maintaining adequate management-controlled procedures and quality assurance that reasonably ensure compliance with the requirements of N.J.A.C. 7:28-6.1 (see 10 CFR Part 20) and 7:28-59.1 (see 10 CFR Part 61) applicable to low level radioactive waste form, classification, stabilization, and shipment manifests/tracking.

84850-02 INSPECTION REQUIREMENTS

02.01 Management Controls. Review the licensee's written procedures for radioactive waste processing, specifically identifying the primary documentation thereof. Verify that the following aspects are adequately addressed:
a. That the individual(s) and organizational entities that have been assigned the responsibility for radioactive waste processing for low-level land burial have been clearly designated in writing;
b. That there has been a clear delineation of the authorities and responsibilities of those individuals and organizational entities;
c. That written management-approved instructions have been established to carry out the various radioactive waste processing and packaging activities, including authorized changes thereto, and the promulgation/distribution of such instructions to the appropriate line/staff organization.

02.02 Quality Assurance (QA). Verify that the licensee has established and maintains an adequate QA program to ensure compliance with the waste classification and characterization requirements of N.J.A.C. 7:28-59.1 (see 10 CFR 61.55 and 61.56). Verify whether the QA program includes the required audits and management evaluation of such audits. Review the results of the most recent audit and corrective actions as per N.J.A.C. 6.1 (see Subsection IIIA.3 of Appendix G to 10 CFR Part 20).

02.03 Waste Manifests. Review the licensee's procedures and records to verify that each shipment of radioactive waste intended for offsite disposal to a broker or a licensed land disposal facility is accompanied by a shipment manifest that includes all the required information [N.J.A.C. 7:28-6.1 (see 10 CFR 20.2006 (b) and (c)].

02.04 Waste Classification. Review the licensee's documentation and records of activities that have been established and are being maintained, to ensure that all low-level radioactive wastes are properly classified according to N.J.A.C. 7:28-59.1 (see 10 CFR 61.55). Verify whether such efforts reasonably ensure that a realistic representation has been accomplished.

02.05 Waste Form and Characterization. Review the licensee's documentation and records of activities, which have been established and are being maintained, to ensure that all low-level radioactive waste meets the waste characteristics of N.J.A.C. 7:28-59.1 (see 10 CFR 61.56). Verify whether the methods and determinations of the licensee provide reasonable assurance that the waste form requirements are met.

02.06 Waste Shipment Labeling. Review the licensee's procedures and records to verify that each package of radioactive waste intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of N.J.A.C. 7:28-59.1 (see 10 CFR 61.55).

02.07 Tracking of Waste Shipments. Review the licensee's procedures and records, to verify that a system has been established to forward to recipients or deliver to waste collectors, at the time of shipment, a copy of the waste manifest. Verify that acknowledgment of receipt of the manifest is obtained. Verify that the licensee has a procedure in place to effect an investigation in any instances wherein acknowledgment of receipt of shipment has not been received within the specified period. Verify that procedures are in place to report such investigations to the NJDEP and file the required written report.

02.08 Disposal Site License Conditions. Review the licensee's procedures and records to verify that the applicable disposal site license conditions are being met. Verify that the licensee has on file a current version of the disposal site license.

84850-03 INSPECTION GUIDANCE

Guidance for inspectors as well as licensees has been provided by the United States Nuclear Regulatory Commission (NRC) Low Level Waste Management Branch in the form of branch technical positions (BTPs) on "Waste Classification," dated May 1983 (see Federal Register, Vol. 48, No. 110, June 7, 1983), and "Waste Form," dated January 1991 (see Federal Register, Vol. 56, No. 18, January 28, 1991). In addition to the BTPs, NMSS has stated publicly (48 FR 40512, Vol. 48, No. 175, Sept. 8, 1983) that "topical reports" of licensees that have been reviewed by NMSS may be useful in demonstrating compliance with the requirements. Inspectors should be aware of and be prepared to accept results referenced in such topical reports as demonstration of compliance in specific inspection cases.

03.01 Specific Guidance.
a. Inspection Requirement 02.01, Management Controls. Inspection effort should be directed at verifying that written procedures have been established in a manner approved by management. The procedures should be readily available to any persons having responsibility for low-level waste classification and preparation for transfer of such wastes to land disposal facilities. The inspector should confirm that the written procedures include provisions for all of the applicable activities pertaining to Section 84850-02 requirements.

b. Inspection Requirement 02.02, Quality Assurance (QA). The written operating procedures and QA procedures of the licensee collectively are intended to accomplish compliance with the N.J.A.C. 7:28-6.1 (see 10 CFR Part 20) and N.J.A.C. 7:28-59.1 (see 10 CFR Part 61) regulatory requirements. The nature and scope of the licensee's QA program will vary depending on the nature and complexity of the specific waste stream. Inspectors should observe whether the program and procedures are effective in causing the licensee to perform the required waste form classification and characterizations when changes to the waste stream occur.

c. Inspection Requirement 02.03, Waste Manifests. Inspectors should be aware that it is permissible for the licensee to use the same shipping paper documents that are required to meet U.S. Department of Transportation shipping paper and U.S. Environmental Protection Agency hazardous waste requirements, as the waste-manifest, provided that the combined documentation contains all of the information required by N.J.A.C. 7:28-6.1 (see Appendix G to 10 CFR Part 20.) Additional waste manifest information may also be required by the operator of the land disposal facility.

d. Inspection Requirement 02.04, Waste Classification. The inspector should review whether the method used by the licensee is adequate to determine radionuclide concentrations, in order to classify his waste. The NMSS BTP on waste classification describes four acceptable methods for classifying wastes. The inspector should use this BTP as his basic guidance in implementing this inspection requirement.
1. For those licensees who use correlation factors for classifying wastes, correlation factors should be based on actual waste stream analysis.
3. If generic scaling factors are not appropriate for an individual waste stream, scaling factors should be based on the specific waste stream data.
4. It is acceptable to base correlation factors on a single set of analyses, repeated annually.
5. If sample analyses have not been completed, calculational methods for scaling factors are acceptable while analyses are in progress. Samples should be off site for analysis to be considered in progress. After receipt of the sample analyses, calculational methods may continue to be used provided the results correlate with the actual sample analyses.
6. NJDEP-approved topical reports for waste classification are acceptable for demonstrating compliance with N.J.A.C. 7:28-59.1 (see 10 CFR 61.55).

e. Inspection Requirement 02.05, Waste Form and Characterization. The inspector should determine the test methods and acceptability of such tests used by the licensee to characterize his waste stream. In cases where a "high integrity container" is used to stabilize the waste, the type and acceptability of the specific container should be verified. The inspector should use the NMSS BTP on waste form as his basic guidance in implementing this inspection requirement. In addition:
1. Classes B and C solidified waste programs should contain test data on compressive strength, leaching, irradiation stability, biodegradation, and thermal stability. Results of tests should be consistent with the BTP on waste form. Test data packages that do not address all of the above areas may be acceptable, provided that testing is under way to

complete the data package. A schedule for completion of the testing should be available for NJDEP inspection. Solidification media currently being used (cement, vinyl-ester-styrene, asphalt) are acceptable waste forms for shipment and burial, provided that qualification testing is in progress and there are procedures and controls in use to ensure the consistent production of waste capable of existing as a free-standing monolith.
2. The licensee's solidification process control program should incorporate the testing information from the solidification agent stability qualification.
3. NJDEP-approved topical reports on high integrity containers and solidification agents are acceptable for demonstrating compliance with N.J.A.C. 7:28-59.1 (See 10 CFR 61.56(b)).
4. A Certificate of Compliance issued by a State for a high integrity container is acceptable for demonstrating compliance for waste shipped to that State.

f. Inspection Requirement 02.06, Waste Shipment Labeling. Inspectors as well as the licensee should be aware that Classes A, B, & C wastes bear no relationship to Types A or B packaging for transport purposes under 49 CFR Part 173 or N.J.A.C. 7:28-61.1. The labeling of waste packages pursuant to this requirement is, therefore, in addition to any other package markings and labels required by the transport regulations.

g. Inspection Requirement 02.07, Tracking of Waste Shipments. Inspectors should be aware of the differences in the requirements of N.J.A.C. 7:28-6.1 (see Appendix G to 10 CFR Part 20)on waste manifest tracking for shipments by generators to waste collectors, as opposed to shipments directly to land disposal facilities. There are also some differences in the specific requirements of a waste collector who processes the waste before shipping it to the disposal facility, as contrasted with a collector who simply stores the material before transferring it to the land disposal facility.

84850-04 REFERENCES

04.01 Regulations. N.J.A.C. 7:28, 10 Code of Federal Regulations 61

04.02 Other References. Federal Register, Vol. 48, No. 110, June 7, 1983, NRC Notice, "Low-level Waste Licensing Branch Technical Position Papers on Radioactive Waste Classification and Waste Form; Availability."
Federal Register, Vol. 56, No. 18, January 28, 1991, NRC Notice, "Staff Technical Position on Radioactive Waste Form; Availability."
"Technical Position on Radioactive Waste Classification," mailed to all NRC licensees on May 11, 1983, by NMSS, Low-level Waste Management Branch.
"Waste Form Technical Position Paper, Revision 1," mailed to all NRC licensees on January 24, 1991, by NMSS, Low-level Waste Management Branch.
Federal Register, Vol. 48, No. 175, Sept. 8, 1983; NRC Notice "Topical Reports in Support of the Implementation of Waste Classification and Waste Form Requirements."

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 84900

LOW-LEVEL RADIOACTIVE WASTE STORAGE

84900-01 INSPECTION OBJECTIVES

The objective of this procedure is to determine whether materials licensees who store low-level radioactive waste (LLW) are doing so safely and in accordance with license conditions. This procedure may be applied to any licensee who stores LLW, regardless of when the storage facility was established. The requirements of this procedure are separate from and in addition to those of Inspection Procedure 84850, which addresses the establishment and maintenance of procedures and quality assurance with respect to the waste form, classification, stabilization and manifest requirements of N.J.A.C. 7:28-6.1 (see 10 CFR Part 20) and N.J.A.C. 7:28-59.1 (see 10 CFR Part 61.)

84900-02 INSPECTION REQUIREMENTS

02.01 Management Controls and Surveys. Review the license file and identify any special authorizations and requirements for LLW storage. Determine where LLW is being stored. Review how long the LLW has been stored and examine the licensee's accountability and security procedures for the waste. Determine whether the licensee is within the authorized possession limits. Review the licensee's procedures for safe placement, inspection and repackaging of LLW in storage. Determine whether or not the licensee has conducted and properly documented: (1) inspections of LLW packages to assure they maintain integrity; (2) radiation surveys of individual packages and the storage area, in general; and (3) any required effluent sampling. Review the licensee's records for waste placed in storage, and determine whether they are adequate to account for the LLW stored.

02.02 Adequacy of Storage Area. Inspect the storage area(s) to assure its adequacy with respect to:

a. Access control and security.
b. Access to, and housekeeping around waste packages. Adequate lighting should be provided to permit identification of unsafe radiological and non-radiological conditions.
c. Stable placement of waste or waste packages.
d. Protection from environmental elements, fire and flooding, avoidance of temperature/humidity extremes, and ventilation considerations.
e. Posting and labeling.

02.03 Package Integrity and Labeling. Examine several waste packages to determine whether the packages are adequate for the expected term of storage. Determine whether the type of packaging maintains the package integrity and that the packages are properly labeled.

84900-03 INSPECTION GUIDANCE

General Guidance

As noted in NRC Information Notice 90-09, LLW storage areas or facilities are being added by licensees as interim measures until their States or Regional Compacts construct LLW disposal facilities. Some licensees already have LLW storage facilities. Depending on the specific situation of a State or Compact, LLW may be in storage for anywhere from several months to several years. Long term storage is not expected in New Jersey since it is a member of the Atlantic Compact. In general, because the safety hazard of LLW storage facilities--especially for dry LLW storage--is low, extensive inspection efforts are not warranted. The inspection effort, therefore, should be geared toward assuring that licensees who are storing LLW for such periods are in compliance with possession limits and license conditions, and do not develop an "out-of-sight, out-of-mind" attitude. This will best be done by examining the licensee's records to ensure that the required surveys, inspections and accountability checks are being done and then following up with a physical examination of the storage area and waste containers/packages.

Specific Guidance

03.01 Management Controls and Surveys. Determine whether the procedures for placement, inspection and repackaging of LLW are clear and available to all who need to use them, and that they have been approved by management. Confirm that inspections and surveys of stored LLW have been performed at the required frequency and properly documented, and that the licensee has conducted and properly documented all required effluent sampling. Review the results of inspections and surveys of LLW in storage focusing on licensee follow-up actions to problems identified. Check the licensee's records on LLW storage, determine whether the records provide accountability and determine how long LLW has been in storage. Confirm that the licensee is within authorized possession limits.

03.02 Adequacy of Storage Area. Confirm that LLW is stored in a restricted area and is secured against unauthorized removal. Check that waste containers are visible to allow routine inspection and that they are readily accessible to licensee personnel. Confirm that the placement or stacking of containers is stable and that containers are not deformed under load, or likely to fall. Determine that ALARA considerations are used in the placement of the higher activity waste containers in the storage area. Check that the storage area is posted in accordance with the requirements of N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902). Confirm that the containers are protected from reasonably expected environmental conditions, including fire and flooding, and that the storage location is not subject to extremes of temperature or humidity (i.e., near a boiler room, laundry area, etc.) Check ventilation of the storage area to determine if it is sufficient to prevent build-up of any gases produced by waste decomposition.

03.03 Package Integrity and Labeling. Examine a representative number of packages for signs of swelling, leakage, deformation or deterioration (i.e., rusting or other corrosion which may lead to

breach). Check to determine that the licensee's packages are clearly and properly labeled in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1904 and 1905) and that low level radioactive waste is transferred or disposed in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.2006). Most licensees currently have access to a low level waste disposal facility, and it is therefore expected that most of these licensees will not require extended storage of their generated wastes. Therefore, the resources required to implement this procedure are expected to be minimal, unless access to LLW storage facilities becomes unavailable to licensees.

84900-05 REFERENCES

NRC Information Notice No. 89-13, "Alternative Waste Management Procedures in Case of Denial of Access to Low-Level Waste Disposal Sites," February 8, 1989.

NRC Information Notice No. 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees," February 5, 1990.

NRC Information Notice No. 93-50, "Extended Storage of Sealed Sources."

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 86740

INSPECTION OF TRANSPORTATION ACTIVITIES

86740-01 INSPECTION OBJECTIVES

To determine whether the licensee has established and is maintaining an effective management-controlled program, to ensure radiological and nuclear safety in the receipt, packaging, delivery to a carrier and, as applicable, the private carriage of licensed radioactive materials; and to determine whether transportation activities are in compliance with N.J.A.C. 7:28-6.1 and 7:28-61.1 (see 10 CFR Parts 20 and 71) and U.S.Department of Transportation (DOT) (49 CFR Parts 171-178) transport regulations. This inspection procedure is organized into two sections: Section 1 covers basic transportation requirements found in N.J.A.C. 7:28-6.1 and 7:28-61.1 (see 10 CFR Part 20 and 10 CFR Part 71, Subpart A), and 49 CFR Parts 171-177. Section 2 covers additional transportation requirements found in N.J.A.C. 7:28-61.1 (see 10 CFR 71, Subparts C, G, and H), and corresponding parts of 49 CFR. Use Section 1 to inspect all licensees. Determine whether the licensee meets the exemption criteria in N.J.A.C. 7:28-61.1 (see 10 CFR 71 Subpart B). If the licensee meets the exemption criteria, the inspection may be concluded after conducting Section 1; Section 2 does not apply. If the licensee does not meet the exemption criteria, use both Sections 1 and 2 to conduct the inspection.

86740-02 INSPECTION REQUIREMENTS

SUBSECTION A BASIC REQUIREMENTS

02.01 Preparation of Packages for Shipment. Examine the licensee's written procedures and shipment records. As the situation allows, observe actual package preparations and operations so as to:

a. Preliminary Determinations. Verify that before the initial use of any packaging, the licensee performs the required preliminary determinations and quality control relating to construction of the packaging (49 CFR 173.474).

b. Routine Determinations. Verify that before each use of any packaging the licensee performs the required routine determinations and quality control (49 CFR 173.475 and N.J.A.C. 7:28-61.1 (see 10 CFR 71.87).

c. Liquid Package Requirements
1. Verify that for non-low specific-activity (LSA) Type A packages with liquid contents, the licensee has provided for the required special testing, double containment system, and absorbent material, as appropriate (49 CFR 173.412(k)).

2. Verify that when required for packages containing liquid contents exceeding a Type A quantity and destined for air shipment, a test for leakage is performed on the containment system (49 CFR 173.475(g)).

d. Packaging Marking. Verify that the licensee has marked the package with the applicable general and specific package markings that are required (49 CFR 172.300-310). Note that 49 CFR 172.324 addresses reportable quantity (RQ) markings on packages).

e. Package Labeling. Verify that for non-exempted packages, the licensee provides for and accomplishes labeling of each package with the appropriate category of RADIOACTIVE (White-I, Yellow-II, or Yellow-III) label, one each on two opposite sides of the package; and accurately completes the entry of the required information in the blank spaces thereon (49 CFR 172, Subpart E).

f. Radiation Monitoring. Verify that the licensee provides for and accomplishes monitoring of each completed package, to ensure that external radiation and removable surface contamination are within the allowable limits (49 CFR 173.441, 49 CFR 173.443, 49 CFR 173.475(i), and N.J.A.C. 7:28-61.1 (see 10 CFR 71.87(i) and (j)).

02.02 Delivery of Completed Packages to Carriers. Examine the licensee's written procedures, shipment records, and as the situation allows, observe actual transport operations.

a. Shipping Paper Documentation. Verify whether the licensee prepared the required shipping paper documentation, and accurately included all the applicable required elements of information, including the shipper's certificate. [NOTE: for licensee private motor vehicle shipments, the certificate is not required (49 CFR 172.204(b)]. In the case of low-level solid radwaste shipments to licensed land burial sites as per N.J.A.C. 7:28-59.1 (see 10 CFR Part 61),verify that the shipping paper documentation also includes the required additional "waste manifest" information (N.J.A.C. 7:28-6.1 (see Appendix G to 10 CFR 20)).

b. Loading and Placarding Non-Exclusive-Use Shipments. Verify that the licensee provides to a highway carrier, or applies directly to a rail vehicle, the required placards, whenever the licensee delivers any quantity of RADIOACTIVE-Yellow-III labeled packages to such carrier for transport (49 CFR 172.506 and 508).

c. Loading and Placarding Exclusive-Use Shipments
1. Verify that the licensee ensures that the package and vehicle radiation/contamination levels are within the regulatory limits (49 CFR 173.441 and 443).
2. Verify that, except for uranium or thorium ores, the transport vehicle is placarded by the licensee when delivering to a carrier any exclusive-use shipment for which placarding is required (49 CFR Part 172, Subpart F, and 49 CFR 173.427(a)(6)(v)).

3. Verify that shipping paper documentation provided by the licensee to the carrier contains satisfactory instructions for maintenance of exclusive-use shipment controls (49 CFR 173.441(c) and (e) and 49 CFR 173.427(a)(6)(iv)).
4. Verify that for exclusive-use shipments of LSA materials, the licensee has provided for the additional specific requirements (49 CFR 173.427(a), (b), or (c)).

d. HAZMAT Employee Training. Verify that persons involved in the packaging |preparation and transport have received proper and adequate training, and that this training has been appropriately documented (49 CFR 172.700 - 704).

02.03 Receipt of Packages. Examine the licensee's procedures and records of incoming shipments to verify compliance with the applicable requirements relating to pickup from a carrier, receiving, and safe opening of packages (N.J.A.C. 7:28-6.1 (see 10 CFR 20.1906)).

02.04 Records and Reports. Review licensee's records and procedures for recordkeeping and reports to verify that a system is in place to:

a. DOT Specification 7A Type A Packaging. Maintain, on file, for at least one year after shipment, the documentation of DOT Spec. 7A safety analysis/testing and/or special form testing (49 CFR 173.415(a), 49 CFR 173.469, and 49 CFR 173.476).

b. Special Form Documentation. Verify that for packages where the licensee relies on a special form determination, to qualify the package as either a limited or Type A quantity, the licensee maintains on file, for at least one year after any shipment, and provides, on request, the documentation demonstrating that the special form material meets the applicable test requirements (49 CFR 173.469 and 173.476).

c. Incident Reporting. Immediately report to DOT, when transporting licensed material as a private carrier, any incident that occurs in which, as a direct result of the radioactive material, any person is killed, receives injuries requiring hospitalization; property damage exceeds $50,000; or fire, breakage, spillage, or suspected radioactive contamination occurs (49 CFR 171.15 and 49 CFR 171.16).

SUBSECTION B ADDITIONAL REQUIREMENTS

02.05 General License Requirements. Determine which general license(s) in N.J.A.C. 7:28-61.1, (see 10 CFR 71 Subpart C), the licensee uses to ship radioactive material packages (e.g., N.J.A.C. 7:28-61.1 (see 10 CFR 71.12, 71.14, 71.16, etc.). Verify that:

a. The licensee has copies of the specific license, DOT specification, or other approval of the package.

b. Complies with N.J.A.C. 7:28-61.1 (see 10 CFR 71 Subparts A, G, and H), as applicable.

c. Has a quality assurance (QA) program approval issued by the Department, as applicable.

d. Complies with other requirements specific to the general license(s) used.

02.06 Management Controls. Review the system of management controls for transportation activities and verify that:

a. Transportation authorities and responsibilities are delineated among individuals and/or organizational entities, and designated in writing.

b. Written management-approved instructions have been established to carry out the various transportation activities, including authorized changes.

02.07 Indoctrination and Training Program. Verify implementation of the indoctrination and training program for persons involved in the licensee's transport activities:

a. Discuss the program with the licensee's representative charged with the responsibility for the training. Identify the major elements of the program: the basis used for selection of personnel to be trained; the schedules and performance of training; and methods used to ensure qualification of competence; and methods to keep people informed of changes in procedures and requirements.

b. Examine records of training completion for all employees involved in transport activities.

c. Discuss the training with one or two supervisors and one to five employees, selected at random, to verify their participation in the training program. In addition to discussions, inspectors may review licensee shipping records, and observe licensee activities to check supervision and/or employee knowledge of licensee-related specific procedural requirements.

02.08 Quality Assurance Program. Review the licensee's documented quality assurance (QA) program, to ensure that the licensee has fulfilled all commitments made in the licensee's QA program application, including development of written QA procedures for transporting radioactive material.

02.09 Audit Program. N.J.A.C. 7:28-61.1 (see 10 CFR 71.137). Review the report of the most recent audit of transport activities conducted by the licensee and, if possible, discuss the audit program with one to five employees, selected at random, to check their degree of knowledge of the program and to aid in ensuring that the licensee is conducting an adequate program. Employee knowledge may also be evaluated by review of shipping records and directly observing transportation activities. Verify whether:

a. The most recent audit was conducted in accordance with the licensee's published procedures, and

b. Identified deficiencies (if any) were corrected, or are being corrected, before any more shipments are made.

02.10 Procurement and Selection of Packagings. For packagings that are used by the licensee to transport or to deliver licensed material to a carrier for transport, review the procedures and records for the following:
a. Fabrication of Packagings. Verify, by physical examination and examination of records, whether new packagings have been fabricated in accordance with the approved design (i.e DOT specification). For packagings supplied by, procured or leased from a vendor or supplier, verify that the licensee has obtained a written statement from such supplier, certifying that the package has been fabricated in accordance with DOT approved quality assurance program.

b. DOT Revalidation of Foreign-Approved Packagings. Verify that for foreign approved packaging used by the licensee, such designs have been revalidated by DOT, and the licensee possesses a copy of the applicable foreign certificate, DOT revalidations, and documentation referenced therein, which relate to the use and/or maintenance of the packaging and actions to be taken before shipment as per 49 CFR 173.473 and N.J.A.C. 7:28-61.1 (see 10 CFR 71.16.)

02.11 Preparation of Packages for Shipment

a. Package Marking. Verify that, for DOT-revalidation packages of foreign origin, the outside of the package is durably and legibly marked with the package identification marking indicated in the DOT Competent Authority Certificate.

b. Advance Notification to Consignee. Verify that the licensee provides, for notification to the consignee before shipment: the dates of shipment and expected arrival, and any special loading/unloading or operating instructions whenever any non-exempt fissile materials and/or packages containing "highway route controlled quantities" are involved (49 CFR 173.22(c) and N.J.A.C. 7:28-61.1 (see 10 CFR 71.89)).

c. Advance Notification to States. Verify that the licensee provides advance notification to the Governor of a State, or his designee, when required, as described in N.J.A.C. 7:28-61.1 (see 10 CFR 71.97).

02.12 Periodic Maintenance of Packagings. For reusable DOT specification, or DOT revalidated foreign-made packaging, examine the licensee's procedures and records for shipments, to verify that, before reuse, all the initial and periodic maintenance required by the certificate, specification, or revalidation has been performed. If possible, observe such maintenance activities (49 CFR 173.474, 49 CFR 173.475, N.J.A.C. 7:28-61.1 (see 10 CFR 71.85, and 71.87). For multi-user packages supplied by another party, the licensee-user should obtain written certification that required periodic maintenance and quality control measures have been conducted in accordance with a NRC-approved quality assurance program.

02.13 Records, Reports, and Notifications. Review the licensee's records and procedures for recordkeeping and reports to verify that a system is in place to:

a. Record of Shipment. Maintain on file for three years after any shipment, a record of each shipment of licensed material (which is not exempt there from) and that such records contain the required information (N.J.A.C. 7:28-61.1 (see 10 CFR 71.91(a))).

b. Quality Assurance Records - Components and Services. Maintain, for three years after the life of any packaging, sufficient quality assurance records documenting evidence of the quality of packaging components and those services that are of safety significance, including the results of required preliminary determinations before first use of any packaging N.J.A.C. 7:28-61.1 (see 10 CFR 71.85 and 71.91(c)).

c. Quality Assurance Records - Other. Maintain, for three years after the last shipment, sufficient quality assurance records that furnish documented evidence to support the activities affecting quality assurance of transport packages. N.J.A.C. 7:28-61.1 (see 10 CFR 71.135).

d. Notification of Excess Contamination or Radiation Level. Immediately notify the appropriate regional office and the delivery carrier for instances in which removable radioactive surface contamination and/or external radiation levels on packages received in a shipment exceed the applicable reporting limits (N.J.A.C. 7:28.6.1 (see 10 CFR 20.2203)).

86740-03 INSPECTION GUIDANCE

03.01 General Guidance. In fulfilling the inspection requirements and objectives of this procedure, the inspector should assess the adequacy of the various aspects of the licensee's program in view of the licensee's total program. That is, he should consider for the various transportation activities such factors as the volume, quantity, and types of radioactive material involved, the inherent potential radiological hazards, the complexity of the packaging required, the number of shipments made and received over a period of time, the number of licensee employees involved in the activities, etc. In other words, a "graded approach" should be used in assessing the adequacy of the licensee's program, with the smaller programs requiring complete but less complex and extensive controls than larger programs. In the same context, the extent and scope of the inspection coverage may be adjusted accordingly. For example, inspection of the transportation program of a licensed processor/supplier of medical isotopes would require much broader inspection coverage: i.e., package procurement, preparation, delivery to carrier, radwaste shipments, etc., as contrasted with the inspection of a radiography user, wherein the primary focus would be on the transport of devices in private carriage. Correspondingly, the transport program of a typical nuclear utility would focus on the package preparation and delivery to carriers of large volumes of radwaste materials and spent fuel shipments.

03.02 Specific Guidance

SUBSECTION A GUIDANCE FOR BASIC REQUIREMENTS

a. Inspection Requirement 02.01(c). Preparation of Packages for Shipment: Liquid Packaging Requirements. These requirements are very important in examining the packaging configurations used by suppliers of medical and industrial isotopes. Inspectors should verify that in the Type A testing of a given design, the license has considered the requirements of 49 CFR 173.412(k) relative to use of absorbent materials and/or a double containment system. For packaging exceeding 50 cc liquid volume, either option is allowed, whereas for less than 50 cc the use of an absorbent material is required. The configuration should be examined visually to verify that the absorbent material is suitably positioned to contact the liquid in the event of leakage. The package testing must also address the results of the additional requirement of 49 CFR 173.466 for liquids, i.e., a 30-ft drop test. For packages containing liquid greater than A2 amounts and destined for air shipments, the licensee is required to perform a leakage assessment on each package before shipment. Leakage testing methods are described in the NRC's Regulatory Guide 7.4.

b. Inspection Requirement 02.01(d). Preparation of Packages for Shipment: Package Marking. The specific requirements for marking of packages include:
1. DOT proper shipping name (49 CFR 172.101 and 49 CFR 172.301).
2. Identification number (e.g., UNXXXX or NAXXXX, 49 CFR 172.101 and 49 CFR 172.301).
3. Gross weight, if greater than 110 pounds, "Type A" or "Type B" as appropriate and radiation symbol for Type B, Type B(U) or Type B(M) packages (49 CFR172.310(a), (b), and (c)).
4. For DOT 7A Type A packages, the words "USA DOT 7A Type A" and "Radioactive Material" (49 CFR 178.350).
5. US NRC packaging approval number (49 CFR 173.471(b)).
6. For DOT specification packages within a non-specification outer overpack, a statement, such as, "Inside Package(s) Comply with Prescribed Specification(s)" (49 CFR 173.25(a)).
7. "RADIOACTIVE -LSA," or "Radioactive-SCO" in the case of LSA or SCO packages transported as exclusive-use (49 CFR 173.427(a)(6)(vi)).
8. Name and address of the consignee or consignor (49 CFR 172.301(d)).
9. "USA," in conjunction with the DOT-specification marking, if the package is destined for export (49 CFR 172.310 (d)).
10. An appropriate arrow symbol to indicate upward positioning, where liquid contents are involved in a combination package (49 CFR 172.312(a)).
11. "RQ" if reportable quantity of hazardous substance (49CFR172.324 (b)). The physical requirements for legibility and location of package markings are found in 49 CFR 172.304. Inspectors should not consider marking requirements as a less important requirement, since they constitute a very important element of the Hazardous Materials "Communications" requirements, along with labels, placards, and shipping papers. Marking deficiencies quite often indicate that the licensee is generally unaware of other

regulatory requirements and are often accompanied by more serious packaging deficiencies.

c. Inspection Requirement 02.01(e). Preparation of Packages for Shipment: Radiation Monitoring. Licensees who package and offer for transportation large numbers of small medical radiopharmaceuticals often use an "assembly-line" process, in which the loaded package travels past a fixed, preset radiation detector. Inspectors should carefully examine such systems, to ensure that they, in fact, are effective in ensuring compliance with the regulatory limits for radiation levels. Another question that frequently arises is the placement of a specification package (e.g., such as a radiography projector within an outer box or other type of enclosure during transportation). The question involves whether the radiation levels at the surface of the outer box and at 1 meter from the outer box may be used to establish the label requirements for the overall "package." Since DOT regulations do not address this, it is therefore permissible to apply labels, to the outer box, that reflect radiation levels around the outer box. The inner package, which is the authorized package, must be labeled to reflect radiation levels from that package, without the outer box.

Assuming that the inner package (the device) is labeled and marked as a specification package, the outer enclosure would, however, need to be further marked with a statement such as "Inside Packages Complies with Prescribed Specification" (49 CFR 173.25), and labeled as required, based on the radiation levels on the outer enclosure. (See also the USNRC IE Information Notice 81-02.)

In instances where the licensee consolidates more than one inner package into outer overpacks, such as bags or cartons, certain rules for transport index (TI) determination, label entries, and markings are provided in 49 CFR 173.448(g).

On an open, exclusive use vehicle, a package may not exceed the 200-mrem/ hr surface limit (i.e., a 1000-mrem/hr package must be in a closed transport vehicle (49 CFR 173.441(b)(1)(i) and 177.842(g)). Inspectors, as well as licensees, should also be aware that the 1000-mrem/hr package limit applies at the surface. Further discussion on radiation limits and other requirements for exclusive-use shipments is provided in USNRC IE Information Notice 80-32 (August 29, 1980) and Rev. 1 thereto (February 12, 1982).

Preparation of Packages for Shipment: Contamination Monitoring. In 49 CFR 173.443, Table 11, the expressed limits applicable to a "wipe" sample are stated in terms of the actual limit on the wipe, itself. A "factor of 10" higher limit is allowed for packages shipped as exclusive use. Such packages are required to be at a "factor of 1" (2200 d/m/100 cm2 beta/gamma) at the start of transportation, but may rise to a "factor of 10" during transportation (22,000 d/m/100 cm2 beta/gamma). Exclusive-use vehicles in which the "factor of 10" higher-contamination packages are transported must be surveyed.

NOTE: For packages shipped in closed, exclusive-use vehicles dedicated only to radioactive materials shipments and so marked, the "factor of 10" limits may apply at the start of transport (49 CFR 173.443(d) and 177.843(b)). This provision does not exist in N.J.A.C. 7:28-61.1 (see 10 CFR 71.87(i)); however, inspectors should be aware that licensees may still apply this provision even though it is not contained in N.J.A.C. 7:28-61.1 (see 10 CFR Part 71.) A question sometimes arises concerning the performance of contamination surveys in those cases where a package, such as a cask, is provided with an external heat barrier or screen to achieve compliance with the heat limits of 49 CFR 173.442(b). The question is whether the contamination limits, as measured by wipe tests, may be taken at the surface of the external barrier or at the surface of the cask within the barrier screen. Monitoring of contamination levels at the outer barrier screen might not disclose the existence of contamination from the package or on the package. Monitoring of the surface contamination of the cask inside the barrier is therefore a regulatory requirement, whereas monitoring of both the cask surface and the outer barrier, would constitute a better health physics practice. (See USNRC IE Information Notice 83-10, March 11, 1983.)

d. Inspection Requirement 02.01(f). Preparation of Packages for Shipment: Package Labeling. If possible, the inspector should examine one or more samples of completed, labeled packages to verify the adequacy of this requirement. The proper category of "RADIOACTIVE" label to be applied to each package is based principally, but not solely, on the measured dose rates at the package surface and at 1 meter (TI). Inspectors are also reminded that the TI assigned to the package label may be assigned on the basis of either nuclear safety for fissile materials or radiation, whichever number is higher. What this means is that in inspecting and surveying a package with a recorded TI, the radiation level reading at 1 meter from a fissile package may not be consistent with the recorded TI on the label. This is not a violation if the TI had been assigned on the basis of the nuclear safety value and is a larger number than it would be based on the actual radiation level at 1 meter. (See also 49 CFR 173.403 Transport Index definition). Inspectors are also reminded that LSA or SCO packages in other-than-exclusive use are required to be labeled, whereas for exclusive use, they only are required to be marked "RADIOACTIVE-LSA", or "RADIOACTIVE-SCO," as appropriate.
NOTE: The package labeling requirements of 49 CFR Part 172, for purposes of transport, should not be confused with the requirements for marking packaged radwaste as Classes A, B, or C, for purposes of shallow land disposal, pursuant to N.J.A.C. 7:28-59.1 (see 10 CFR Part 61). Further, the designators Classes A, B, or C waste bear no direct basis to Types A or B packages, for transport purposes.

e. Inspection Requirement 02.02(a). Delivery of Completed Packages to Carriers: Shipping Paper Documentation. Requirements for shipping paper descriptions constitute a very important part of the hazardous materials regulatory "communications" requirements, the others being labels, marking, and vehicle placards. Generally speaking, as is the case for marking, observation of shipping paper deficiencies may be symptomatic of more serious deficiencies in packaging; therefore, inspectors should be familiar with the detailed shipping paper requirements. Generally speaking, a shipping paper may be any type of transportation document, i.e., bill of lading, shipping invoice,

radioactive waste shipment record, etc. However, it must contain the following elements of applicable information (49 CFR 172.201, 172.202, and 172.203 (d)):
1. The applicable DOT proper shipping name and hazard class, "Radioactive Material," 49 CFR 172.101 (unless the words "Radioactive Material" are already contained in the name). Letters RQ or X in column captioned "HM" (49 CFR 172.203(c)(2)).
2. The applicable identification number (UNXXXX or NAXXXX) from 49 CFR 172.101.
3. The name of each radionuclide. Abbreviations, as taken from 49 CFR 173.435, are authorized.
4. A description of the physical and chemical form of the material. (For special form sources, this description is "SPECIAL FORM.")
5. The activity contained in each package, measured in SI units.
6. The category of label applied to each package ("RADIOACTIVE WHITE-I," "RADIOACTIVE YELLOW-II or RADIOACTIVE YELLOW-III").
7. The TI (dose rate at 1 meter) assigned to each package bearing "RADIOACTIVE YELLOW-II" or "RADIOACTIVE YELLOW-III" labels.
8. For shipments tendered to a common carrier, the appropriate signed shipper's certification; and for shipments by aircraft, the additional statement as to acceptability for either passenger-carrying or cargo-only aircraft. For shipments by passenger-carrying aircraft, the additional statement of intended use in research or medical diagnosis or treatment must also be included (49 CFR 172.204(a); 49 CFR 172.204(c)(3), 49 CFR 172.204(c)(4), 49 CFR 172.204(d)).
9. The words "Highway Route Controlled Quantity" for any shipments containing such quantity (49 CFR 172.203(d)(4)).
10. Any other descriptive information may be included after the basic description, provided it is not inconsistent therewith (49 CFR 172.201(a)(4)). In shipments where both non-hazardous and radioactive materials are described on the same shipping paper, the radioactive materials must appear as the first entry, or be designated by an "X" in columnar fashion, or be highlighted in a contrasting or other distinguishing fashion from the non-hazardous materials.

NOTE: N.J.A.C. 7:28-6.1 (see 10 CFR 20 Appendix G), requires that each shipment of radioactive waste to a land disposal facility be accompanied by a manifest that describes the shipment contents. The waste shipment receiver (e.g., the disposal facility operator) also requires specific additional information. In addition to shipper identification requirements and a certification, the manifests required by N.J.A.C. 7:28-6.1 (see 10 CFR 20 Appendix G), must include the following information as a minimum:
(a) The waste class, pursuant to N.J.A.C. 7:28-59.1 (see 10 CFR 61.55);
(b) A radiological description; and
(c) A physical and chemical description.
11. Emergency response information that can be used in the mitigation of an incident involving hazardous material. The information includes immediate precautions to be taken in case of an accident or incident (49 CFR 172.602). The information may be on a separate document, but must be maintained in the same manner as the shipping papers.

12. Emergency response telephone number. The number must be monitored at all times that the hazardous material is in transportation, including storage incidental to transportation (49 CFR 172.604).

f. Inspection Requirement 02.02(b). Delivery of Completed Packages to Carriers: Loading and Placarding of Non-Exclusive-Use Shipments. The licensee/shipper's responsibilities in these cases mainly relate to furnishing the required placards (based on the presence of any "RADIOACTIVE YELLOW-III"-labeled packages) to a highway carrier or applying the placards to a rail vehicle. The basic responsibility for blocking and bracing packages within the vehicle rests with the carrier, as well as storage distance controls based on the TIs. Packages bearing a total TI value of more than 50 (49 CFR 177.842(a)) are not to be shipped in a single non-exclusive-use vehicle.

g. Inspection Requirement 02.03. Receipt of Packages. NRC Regulatory Guide 7.3 provides additional guidance on these requirements found in N.J.A.C. 7:28-6.1 (see 10 CFR 20.1906), which includes provisions for the following:
1. Arrangements for package receipt or expeditious pickup.
2. Monitoring external surfaces and radiation levels for certain packages.
3. Notification of carrier and NRC when package limits or levels are exceeded.
4. Requirements for package-opening procedures.

h. Inspection Requirement 02.04(a). Procurement and Selection of Packagings: DOT Specification 7A. DOT regulations require that each shipper of a Specification 7A package maintain, on file, a written documentation of the tests and engineering evaluation or comparative data showing that the packaging complies with the specification. If the shipper of a Specification 7A package is not the original designer or user of that package, it is necessary for that shipper to obtain the package evaluation report data from the original supplier/user or to perform the tests himself and document the results. Further, if a shipper makes any changes to the packaging or its maximum authorized contents, from the description on the original test report furnished by another person, it will be necessary to perform and document a supplemental evaluation, addressing such changes and demonstrating that the package will continue to meet the appropriate performance requirements. In any case, the "bottom line" of the Specification 7A documentation is that the results of how the package meets the applicable environmental and test conditions must be addressed. In this regard, inspectors may find some shippers furnishing and relying on test results and data extracted from several technical reports by the former agency, Energy Research and Development Administration (ERDA), entitled, "Certification of ERDA Contractors Packaging with Respect to DOT Specification 7A Performance Requirements," Report MLM-2228, June 12, 1975, with one Supplement, (April 15, 1976) and MLM-2324 (October 8, 1976). A question may then arise about the sufficiency of the test data from these reports in any given case. Judgment will then have to be exercised in assessing whether the licensee's specific package falls within the parameters of the tests as reported, with respect to such aspects as maximum package weight tested, type of closure, tested content versus actual content, and content limitations. The licensee's documentation should include an evaluation concluding how the package meets the Spec. 7A test requirements based on the recorded data, or any

other independent package tests that have been performed. In any case, inspectors should reject any rationale used by the licensee that the marking alone of "DOT Spec. 7A" on the outside of the package is sufficient fulfillment of this requirement.

i. Inspection Requirement 02.04(b). Procurement and Selection of Packagings: Special Form Requirements. Radioactive sealed sources classified as "special form" material must meet the physical integrity requirements, as defined in 49 CFR 173.469 and 49 CFR 173.476. These requirements call for each shipper of a special form source to maintain, on file, a supporting safety analysis or documentation containing the results of the testing performed on the source, to demonstrate that it meets the special form requirements. This does not mean that each shipper has to actually perform the tests, only that he must obtain and retain the documentation of these tests. As a practical matter, each licensee should establish a file of such data for each source design in his inventory. It may be necessary, therefore, for the licensee to procure the required information from the source manufacturer. In many instances, qualification of the material as special form will have no direct bearing on the type of packaging required, relative to content limit -- for example, where A1 = A2 (as in the cases of Co-60, Mn-54, and P-32), Type A packaging for A1 or A2 quantities is required, regardless of "form." In such cases, when the material has been encapsulated as a sealed source, but is not described on the shipping paper documents as "special form," the documentation of special form testing is not required (49 CFR 173.476(d)). If the material however, is described as special form, the backup documentation is required.

SUBSECTION B GUIDANCE FOR ADDITIONAL REQUIREMENTS

j. Inspection Requirement 02.06. Management Controls. The inspection effort should be directed at certifying that written procedures have been established in a manner approved by management. The procedures should be readily available to all those having responsibility for any phase of the licensee's transportation activity. The inspector should confirm that the procedures include provisions for all of the applicable transport activities addressed in the Inspection Requirements Section 2 of this procedure. In reviewing the adequacy of the licensee's program for management controls and associated written documentation thereof, inspectors are reminded to concurrently review, as a cross-check, the licensee's written, approved QA program, which incorporates the elements of N.J.A.C. 7:28-61.1 (see 10 CFR 71, Subpart H). In reviewing the program, it will be necessary to review the licensee's procedures that satisfy commitments made in the QA program application.

k. Inspection Requirement 02.11(a). Preparation of Packages for Shipment: Preliminary and Routine Determinations and Package Marking. Inspection of the required preliminary and routine determinations will have some overlap with the inspection of the licensee's QA activities on transport packages. In reviewing the licensee's preliminary and routine determinations, the following additional guidance is offered:

1. In determining whether a package has any significant damage, the package should be considered to have significant damage if such damage would be likely to preclude the

package from meeting the applicable requirements of N.J.A.C. 7:28-61.1 (see 10 CFR Part 71) and/or its approved design.
2. In reviewing the adequacy of package closures, closures that involve attempts at sealing with gaskets having visible or obvious imperfections, field splices that are not part of an approved design, caulking, and rusty or dirty sealing surfaces would not be considered to be free from defects.
3. The loading and closing of packages in accordance with written procedures should include a determination that the packaging is authorized for the specific intended contents, and that any lid/closure to the main body is properly aligned, with its bolts properly torqued to the specified values in the prescribed pattern.
4. A record should be established by the licensee for each reusable packaging. Because many packagings are procured in lots and without serial numbers, the record may exist for a large quantity of packagings specified, as in a purchase order. Special emphasis should be placed on records that show that components important to safety have been inspected for conformance to NJDEP or NRC approved design. Depending on the type of package, this may include structural, thermal, shielding, containment, closure, and criticality control systems. The records may include visual observations and physical test results.
5. For NRC-certified packaging, the inspector should give special attention to any applicable terms and conditions of the certificate relating to preliminary and routine determinations and routine maintenance.
6. Package-marking requirements include "TYPE A "or "TYPE B" as appropriate, and NRC certificate number.

l. Inspection Requirement 02.11(b). Delivery of Completed Packages to Carriers: Loading and Placarding of Exclusive-Use Shipments. The requirements herein will relate very frequently to shipments of low-level radwaste to licensed burial sites, quite frequently as LSA materials. Many of the questions that arise concerning these shipments are addressed in USNRC IE Information Notice 80-32 (August 29, 1980) and Rev. 1 (February 12, 1982).

m. Inspection Requirement 02.11. Delivery of Completed Packages to Carriers: Advance Notice to States. A list of the names and mailing addresses of the Governor's designees who are to receive such advance notification of transportation of nuclear waste is published annually in the Federal Register (around June 30). The reporting quantities for the report required by NJDEP pursuant to N.J.A.C. 7:28-61.1 (see 10 CFR 71.97) are currently the same as the quantities designated by DOT as "Highway Route Controlled Quantities."

86740-04 RESOURCE ESTIMATE

Transportation safety inspection resource requirements vary greatly depending on facility size and shipping activity. On-site inspection hours can range from less than 1 hour at material licensee facilities with limited shipping activity, to more than 8 hours at reactor or other large facilities with significant shipments.

86740-05 REFERENCES

05.01 Regulations

a. 49 CFR Parts 100-178, "Hazardous Materials Regulations," of the US Department of Transportation, revised annually, as of October 1.
b. 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
c. US Postal Service Publication No. 6, Dec. 1975 "Radioactive Material," as amended by US Postal Bulletin, June 30, 1982, pp. 2-5.
d. International Atomic Energy Agency, "Regulations for the Safe Transport of Radioactive Material," Safety Series No. 6, 1985(As Amended 1990). IAEA, Vienna, Austria.

05.02 NRC Information Notices

a. 79-21 "Transportation and Commercial Burial of Radioactive Waste," Sept. 7, 1979.
b. 80-24 "Low-Level Waste Burial Criteria," May 30, 1980.
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c. 80-25 "Transportation of Pyrophoric Uranium," May 30, 1980.
d. 80-32 "Clarification of Certain Requirements for Exclusive-Use Shipments of Radioactive Materials," Aug. 29, 1980.
e. 80-32 Rev. 1, Feb. 12, 1982.
f. 81-02 "Transportation of Radiography Devices," Jan. 1981.
g. 81-32 "Transfer and/or Disposal of Spent Generators," Oct. 23, 1981.
h. 82-24 "Water Leaking From UF6 Overpacks," July 20, 1982.
i. 82-47 "Transportation of Type A quantities of Non-Fissile Radioactive Material," Nov. 30, 1982.
j. 83-10 "Clarification of Several Aspects Relating to Use of NRC-Certified Transport Packages," Mar. 11, 1983.
k. 84-14 "Highlights of Recent Transport Regulatory Revisions by DOT and NRC," March 8, 1984.
l. 84-50 "Clarification of Scope of Quality Assurance Programs for Transport Packages Pursuant to 10 CFR 50, Appendix B."
m. 84-72 "Clarification of Conditions for Water Shipments Subject to Hydrogen Gas Generation."
n. 85-46 "Clarification of Several Aspects of Removable Radioactive Surface Contamination Limits for Transport Packages."
o. 86-18 "NRC On-Scene Response during a Major Emergency."
p. 86-67 "Portable Moisture/Density Gauges: Recent Incidents and Common Violations of Requirements for Use, Transportation, and Storage."
q. 86-86 "Clarification of Requirements for Fabrication and Export of Certain Previously Approved Type B Packages."
r. 87-2 "Cracks in Stiffening Rings on 48-inch Diameter UF6 Cylinders."
s. 87-31 "Blocking, Bracing, and Securing of Radioactive Materials Packages in Transportation."
t. 87-37 "Compliance with the General License Provisions of 10 CFR Part 31."
u. 87-47 "Transportation of Radiography Devices."
v. 87-55 "Portable Moisture/Density Gauges: Recent Incidents of Portable Gauges

Being Stolen or Lost."
w. 88-06 "(Bulletin) Actions to be Taken for the Transportation of Model No. SPEC 2-T Radiographic Exposure Device."
x. 88-16 "Identifying Waste Generators in Shipments of Low-Level Waste to Land Disposal Facilities."
y. 88-18 "Malfunction of Lockbox on Radiography Device."
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z. 88-33 "Recent Problems Involving the Model SPEC- 2T Radiographic Exposure Device."
aa. 88-62 "Recent Findings Concerning Implementation of Quality Assurance Programs by Suppliers of Transport Packages."
bb. 88-66 "Industrial Radiography Inspection and Enforcement."
cc. 88-101 "Shipment of Contaminated Equipment Between Nuclear Power Stations."
dd. 89-24 "Nuclear Criticality Safety."
ee. 89-74 "Clarification of Transportation Requirements Applicable to Return of Spent Radiopharmacy Dosages from Users to Suppliers."
ff. 90-24 "Transportation of Model SPEC 2-T Radiographic Exposure Device."
gg. 90-27 "Clarification of the Recent Revisions to the Regulatory Requirements for Packaging of Uranium Hexafluoride (UF6) for Transportation."
hh. 90-35 "Transportation of Type A Quantities of Non-Fissile Radioactive Materials."
ii. 90-50 "Minimization of Methane Gas in Plant Systems and Radwaste Shipping Containers."
jj. 90-66 "Incomplete Draining and Drying of Shipping Casks."
kk. 90-82 "Requirements for Use of NRC-Approved Transport Packages for Shipment of Type A Quantities of Radioactive Material."
ll. 91-39 "Compliance with 10 CFR Part 21, "Reporting of Defects and Noncompliance."

05.03 NRC Regulatory Guides
a. 7.1 "Administrative Guide for Packaging and Transporting Radioactive Material," 06/74.
b. 7.2 "Packaging and Transportation of Radioactively Contaminated Biological Material," 06/74.
c. 7.3 "Procedures for Picking Up and Receiving Packages of Radioactive Materials (For Comment)," 06/75.
d. 7.4 "Leakage Tests on Packages for Shipment of Radioactive Materials (For Comment)," 06/75.
e. 7.5 "Administrative Guide for Obtaining Exemptions From Certain NRC Requirements Over Radioactive Material Shipments," 06/75 or 05/77.
f. 7.6 "Design Criteria for the Structural Analysis of Shipping Cask Containment Vessels," 02/77 or 03/78.
g. 7.7 "Administrative Guide for Verifying Compliance With Packaging Requirements for Shipments of Radioactive Materials (For Comment)," 08/77.
h. 7.8 "Load Combinations for the Structural Analysis of Shipping Casks (For Comment)," 05/77.
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i. 7.9 "Standard Format and Content of Part 71 Applications for Approval of

Packaging of Type B, Large Quantity, and Fissile Radioactive Material," 03/79 or 01/80.
j. 7.10 "Establishing Quality Assurance Programs for Packagings Used in the Transport of Radioactive Material," 01/83.
k. 7.11 "Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Maximum Wall Thickness of 4 Inches (0.1 m)."
l. 7.12 "Fracture Toughness Criteria of Base Material for Ferritic Steel Shipping Cask Containment Vessels with a Wall Thickness Greater than 4 Inches (0.1 m) But Not Exceeding 12 Inches (0.3 m)."

05.04 Other Publications
a. U.S. Department of Transportation, " 2000 Emergency Response Guidebook,"
b. U.S. Department of Transportation, "Radioactive Material Regulations Review," RAMREG 001-98.
c. NUREG-1608, "Categorizing and Transporting Low Specific Activity Materials and Surface Contaminated Objects."
d. NUREG-1660, "U.S. Specific Schedules of Requirements for Transport of Specified Types of Radioactive Materials Consigments."
e. Generic Letter 96-07, "Interim Guidance on Transportation of Steam Generators."

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87102

MAINTAINING EFFLUENTS FROM MATERIALS FACILITIES AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

87102-01 OBJECTIVES

01.01 This procedure is to be implemented at any facility for which accurate and current effluent information is not available, and at all facilities whose effluents are known to exceed 20 percent of NJAC 7:28-6.1 (see 10 CFR 20, Appendix B, Table 2 values). Licensees are exempt from this requirement if they do not use unsealed sources, and if they do not possess sufficient amounts of unsealed radioactive materials to cause effluents to exceed the aforementioned 20 percent criterion. Implementation of this procedure, where applicable, is to be at the frequency used for routine inspections at the facility. The objective of the procedure is to determine whether the licensee effectively maintains effluents within applicable limits, constraints, As Low As Is Reasonably Achievable (ALARA) as required by N.J.A.C. 6.1 (see 10 CFR 20.1101(b)), and the constraint on air emissions, as is required by NJAC 7:28-6.1 (see 10 CFR 20.1101(d)). Effluents include both air and water effluents, but do not include releases to public sewers.

87102-02 INSPECTION REQUIREMENTS

02.01 Management Commitment. Review management's written policy statements on ALARA, and the authority of managers and line personnel to implement this policy. Review the methods used by management to supervise implementation of the program. Determine if management and technical personnel are informed of industry developments in the area of ALARA.

02.02 Audits and Appraisals. Review the results of audits and appraisals of the ALARA program since the last inspection. Determine if effluent ALARA was explicitly considered during these audits and appraisals. Review the adequacy of the licensee's responses to findings.

02.03 Procedures, Engineering Controls, and Process Controls. Determine the quality of the relevant procedures and the degree to which ALARA techniques are incorporated into them. Determine the extent to which process and engineering controls are used to minimize effluents.

02.04 Instrumentation. Determine whether effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with manufacturers' recommendations and good practices.

02.05 Surveys and Effluent Monitoring. Determine if all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented.

02.06 Worker Training. Determine if the ALARA concept, including its application to effluents, is included in worker training and periodic retraining. Determine if the workers understand their roles and responsibilities in the ALARA program.

02.07 Changes. Review changes in equipment, processes, personnel, and procedures that may have had an effect on effluents, and determine the licensee's understanding of the impact of these changes on effluent ALARA.

87102-03 INSPECTION GUIDANCE

General Guidance

The US Nuclear Regulatory Commission (NRC) Referral Form to the U.S. Environmental Protection Agency (EPA) is provided in Enclosure 1 of this procedure. The form is intended to inform the EPA through the NRC of the inspection and to provide the EPA and the NRC with data on the magnitude of air emissions from the licensee's facilities. Fill out the form at the end of the inspection and ensure that all the data required in the form are entered. The form is mostly self-explanatory, but the following are some items to note when entering the information. The "Contact" entry in the top box of the form refers to a licensee representative who would be able to answer questions related to the licensee emission information if the NRC or EPA were to contact the licensee for additional information or clarification. In the second box, document the licensee's ALARA goal, as defined in its radiation protection program (typically as a percentage of the Appendix B values in 10 CFR 20). If the licensee has an ALARA goal greater than 20 percent of Appendix B, determine if the NJDEP has approved this goal. Finally, check to determine whether the licensee's air emissions met or exceeded its ALARA goal, and also the ALARA constraint as established under NJAC 7:28-6.1 (see 10 CFR 20.1101(b)). If, for any reason, the licensee is unable to provide the dose to the nearest member of the public, then indicate this in the space provided for insufficient information. Inability to provide the dose may indicate a weakness in the licensee's program because this value is needed to allow evaluation of the extent to which the licensee met their ALARA goal for effluents.

EPA Referral in Enforcement Cases. If the inspection findings lead to enforcement action for violations of NJDEP air emission regulations, such as those in NJAC 7:28-6.1, a copy of the inspection report will be sent to the appropriate NJDEP Air Quality office. A copy of the report will also be sent to the NRC Federal & State Materials & Environmental Management (FSME) regional State Liaison officer for possible referral to the EPA.

Specific Guidance

03.01 Management Commitment

a. Determine whether the licensee has incorporated the ALARA philosophy in its radiation protection program supported by a policy statement issued by a level of management sufficient to ensure that the program is properly carried out. The policy statement should make clear that all personnel are responsible for ensuring that the work they supervise or perform is in accordance with ALARA procedures and practices.

b. Review the licensee's ALARA goals, and determine if they are sufficiently challenging yet realistic. Past experience from NJDEP licensing and inspection activities, effluent information reported to the NJDEP staff, and data provided by the EPA from field studies, all indicate that release goals of less than 20 percent of N.J.A.C. 7:28-6.1 (see 10 CFR 20 Appendix B) values can be achieved by almost all material facility licensees. Determine if the licensee understands and implements these goals. A licensee that does not achieve these goals should provide reasons for not doing so. Ensure that the reasons provided justify deviation from regulatory guidance. Determine if the licensee has calculated annual doses resulting from air effluents and if the doses are: (i) within the ALARA constraint as required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101(d)); (ii) within the licensee's ALARA goals (as described in its radiation protection program); or (iii) uncertain because there is insufficient information or basis for determination. Review the licensee's history in meeting ALARA goals, and its corrective actions when the goals were not met.

c. Determine if investigation levels for releases are established and used, and the rationale for selecting these levels. The levels chosen to initiate corrective actions are usually those that represent normal and expected releases. Review the investigations initiated when such levels are exceeded, and also review the corrective actions taken.

<u>03.02</u> Audits and Appraisals

a. Review reports of audits conducted since the last inspection. Assess the quality of the reports and the depth of the audits. Determine whether the auditors who performed these audits were qualified for the task.

b. Determine whether the licensee's radiation safety committee (RSC), or radiation safety officer (RSO), if no RSC exists, has conducted periodic or at least annual ALARA effluent reviews as part of the required overall examination of the radiation protection program. If a consultant performs the reviews, determine whether the reviews are examined and approved by the RSC/RSO. The purpose of the ALARA review is to compare operating experience against ALARA goals, and to adjust these goals or operating procedures or equipment, if necessary, to improve performance. Determine if the results of these reviews are sent to senior management with recommendations for changes, and review the responses to these reviews and recommendations. Determine whether the ALARA effluent reviews are considered within the context of the overall site ALARA program and the radiation protection program.

<u>03.03</u> Procedures, Engineering Controls, and Process Controls

a. Identify the methods used by the licensee to control and minimize effluents to the environment and whether additional or alternative options were considered. Common control practices for effluents include filtration, encapsulation, adsorption, containment, and the storage of materials for decay. Practices for large, diffuse sources such as contaminated soils or surfaces include covers, wetting during operations, and the application of stabilizers. Verify that, when practicable, unmonitored releases do not exceed 30 percent of the total estimated effluent

releases, as suggested in NRC Regulatory Guide 8.37. Verify that, when ever effluent levels were high compared with the desired goals, the licensee considered additional ALARA measures such as recycling process fluids, leakage reduction, and modifications to facilities, operations, and procedures. Verify that the licensee considered collective exposures (i.e., both occupational and general public exposures) and not just effluent levels, when selecting effluent- reduction techniques.

b. If the licensee rejected a control practice as unreasonable, review the licensee's analysis of the practice. Quantitative or qualitative analyses may be used to justify such practices. For quantitative cost/benefit analyses, $2,000 per person-cSv (person-rem) may be used as a guide to determine whether a change is reasonable. A qualitative analysis is used in situations where assigning monetary values to the various factors involved in the analysis would be very difficult or not meaningful.

03.04 Instrumentation

a. If continuous effluent monitors are used, ensure that the licensee performs calibrations at least annually, or more frequently, if bound by license condition, or if the manufacturer suggests more frequent calibration. Calibrations should be performed according to manufacturer suggested protocols or other written procedures that implement accepted industry good practices. If flow meters are used, ensure that they are calibrated at least annually or according to the manufacturer's recommendations. Ensure that counting efficiencies are appropriate for the samples being counted, and that corrections are applied for the various factors that may distort the results, such as absorption of alpha and beta radiations, filter efficiency, sampling errors, and any other factors that may affect the accuracy of sampling and measurement. Review the licensee's techniques to quantify the releases and verify some of the calculations.

b. Ensure that samples are collected using proper media. Liquid samples should be transferred to a container for counting with the same geometry as the calibration standard. Air samples should be collected using methods appropriate for the type of activity being sampled. If, for any reason, a collection medium's efficiency falls below about 95 percent for the material to be collected, a correction factor should be applied. Charcoal cartridge collection efficiency tables/graphs (i.e., sample flow rate versus collection efficiency) should be available on site. In the case of charcoal cartridges, if the collection efficiency drops below 85 percent, the counting geometry of the cartridge (face loaded or homogeneous) should be investigated.

c. Ensure that laboratory equipment has been properly calibrated and that the sources and standards used in these calibrations are appropriate for the types of radiations and geometries used at the site. Calibrations should be conducted at least annually or more frequently if required by a license condition. Calibrations should also be performed after 2 repairs or modifications. Review the licensee's laboratory quality assurance/quality control program.

d. Ensure that laboratory equipment has sufficient sensitivity for the radionuclides being measured. Check that the counting efficiencies, background counts, sample volumes, sample count times, etc. for each measurement protocol permit achievement of the desired or required lower limit of detection (LLD). If LLD values are not clearly specified in the licensee's procedures or clearly

displayed in the laboratory, investigate the reasons and verify that the licensee's methods are capable of attaining these limits. Verify that the measurement procedures provide methods to check attainment of the LLDs. Verify that LLD values are routinely checked and recorded. Determine whether the licensee participates in outside programs to periodically verify the accuracy of its methods. These programs usually consist of measuring unknown samples sent to the licensee by an accredited organization, such as the National Institute of Standards and Technology. Review the results of participation in such programs, and enquire as to the reasons for nonparticipation, if that is the case.

03.05 Surveys and Effluent Monitoring releases to storm sewers or runoff from contaminated soil.

a. Review effluent release reports for obvious mistakes, anomalous measurements, omissions, and trends. Identify any occasions where the licensee exceeded internal investigation levels. Determine if the licensee identified these events, and review the corrective actions.

b. Ensure that the licensee has identified the significant sources of radioactive materials that contribute to effluent releases, and also has identified the pathways from these sources to the points of release. Also ensure those significant sources are appropriately monitored.

c. Determine whether the licensee's sampling procedures are adequate. Ensure that all samples taken are representative. Stack and vent samples should be taken isokinetically, if necessary. Non-isokinetic sampling will not introduce significant sampling errors if the effluents contain particulates smaller than 5 um aerodynamic diameter or noble gases. In the case of batch liquid releases, holdup tanks should be thoroughly mixed before samples are taken. Identify dilution volumes to be used. Ensure that the licensee knows or has measured the efficiencies of filters or absorbers through which effluents are passed. Note effluent release frequencies, and check whether the licensee has considered possible leakage pathways.

d. For liquid releases, note that releases to a public sanitary sewer system, in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20) requirements, are not considered liquid effluents.

e. Verify that the licensee has considered all reasonably expected release pathways and identified any potential unmonitored release pathways. Potential pathways include doors on exterior walls, open windows, exhaust vents, and unfinished corrugated metal construction. Inquire as to any releases to storm sewers or runoff from contaminated soil.

03.06 Worker Training. Verify that ALARA is included in the annual employee radiation protection training. Verify that employees have a thorough understanding of the ALARA program's principles and goals. Determine if they understand the role of engineering controls, and their role in the ALARA effort. Do this by conducting interviews with selected employees. Review training lesson plans and some examination questions and answers.

03.07 Changes. Tour the facilities and discuss changes in equipment and procedures with cognizant management. Determine whether changes have been made that will affect the types of effluents produced, effluent monitoring, sample collection, or laboratory analyses. Verify that the licensee understands the effects of these changes on effluents and the ALARA program. For

planning purposes, the direct inspection effort to complete this inspection procedure for the first time at a licensee's facility is estimated to average from 2 hours for small licensees to up to 6 hours for larger licensees, such as holders of broad scope licenses. Subsequent implementation of the procedure at the same facility is expected to require less direct inspection effort than the above averages.

87102-05 REFERENCES

N.J.A.C. 7:28 Radiation Protection Programs Code
U.S. Code of Federal Regulations, Title 10, Part 20
U.S. Code of Federal Regulations, Title 40, Part 61
U.S. Nuclear Regulatory Commission Regulatory Guide 1.109, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Compliance with 10 CFR Part50, Appendix I."
U.S. Nuclear Regulatory Commission Regulatory Guide 3.51, "Calculational Models for Estimating Radiation Doses to Man from Uranium Milling Operations."
U.S. Nuclear Regulatory Commission Regulatory Guide 8.25, "Air Sampling in the Workplace."
U.S. Nuclear Regulatory Commission Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities."
U.S. Environmental Protection Agency, "Background Information Document: Procedures Approved for Demonstrating Compliance with 40CFR Part 61, Subpart I," EPA 520/1-89-001, Office of Radiation Protection Programs, Washington DC, October 1989.
U.S. Environmental Protection Agency, "EPA Guidance Document for Facilities Subject to 40 CFR Part 61, Subpart I: Procedures for Determining Compliance with the Standard and Qualification for Exemption from Reporting," EPA 520/1-89-002, Office of Radiation Protection Programs, Washington DC, October 1989.
U.S. Environmental Protection Agency, "User's Guide for COMPLY," EPA 520/1-89-003, Office of Radiation Protection Programs, Washington DC, October 1989.
International Commission on Radiological Protection, "Limits for Intakes of Radionuclides by Workers," ICRP No. 30, 1978.
NMSS Licensee Newsletter, "Update on U.S. Environmental Protection Agency's Standard for Radionuclide Emissions from Facilities Licensed by the U.S. Nuclear Regulatory Commission", NUREG/BR-0117, No. 93-4, Dec. '93/Jan. '94.

Enclosure 1
INSPECTION REFERRAL FORM

To: FSME State Liaison Officer, US Nuclear Regulatory Commission

From: New Jersey Bureau of Environmental Radiation

Inspector: _____Phone: (____) _____

Inspection Dates: _____ License No(s):

Licensee:

Contact: _____ Phone: (____) _____

Address: _____

_____

_____

Licensee's ALARA goal if greater than 20 percent of N.J.A.C. 7:28-6.1 (see 10 CFR 20 Appendix B):

% N.J.A.C. 7:28-6.1 (10 CFR 20 Appendix B) [_____ (mrem)]

If more than 20 percent Appendix B, has the NJDEP approved this goal? (Yes) (No)

Classification of Effective Dose Equivalent:

Above licensee's ALARA goal? ___ (Yes) ___ (No)

Above NJAC 7:28-6.1 ALARA constraint requirement? ___ (Yes) ___ (No)
[0.1 mSv/yr (10 mrem/yr)]

Insufficient information to estimate dose? ___ (Yes) ___ (No)

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87103

INSPECTION OF MATERIAL LICENSEES INVOLVED IN AN INCIDENT OR BANKRUPTCY FILING

87103-01 INSPECTION OBJECTIVES

01.01 This inspection procedure is applicable to the inspection of incidents that occur at nuclear materials facilities and for those cases where the New Jersey Department of Environmental Protection (NJDEP) is concerned that material may not be properly controlled, such as when a licensee files for bankruptcy. NJDEP management must determine the need to dispatch one or more inspectors to conduct a special inspection following occurrence of an incident, either immediately following notification, or before the next routine inspection. This procedure is intended for use in such special inspections. The incidents to be inspected under this procedure include those that are considered serious enough to warrant a special inspection to determine causes and corrective actions. Typically, the procedure will be used in response to medical events, overexposures, losses or releases of significant quantities of radioactive materials, and situations where the NJDEP is concerned that material may be abandoned, such as in cases where the licensee has filed for bankruptcy, but it is not limited to these type of incidents. Guidance for inspection of materials licensees who have filed for bankruptcy is available in NUREG-1556, Volume 15.

01.02 The objective of the procedure is to assist inspectors in analyzing the sequence of events leading to the incident, and the conditions that existed at the time these events occurred. This analysis should lead to the identification of contributing factors and root causes, and to the formulation of corrective actions to prevent recurrence. The primary emphasis of the inspection is safety, not compliance. Issues of compliance are addressed after all safety issues and program weaknesses are identified and clearly understood.

01.03 The steps presented in the procedure should be followed in the order they are presented; some of the steps may be repeated in alternating fashion as data accumulates and hypotheses are refined. Experience shows that accidents generally have multiple contributing factors that are interconnected in complex ways. Therefore, a disciplined, organized, and thorough approach to the inspection is essential. Organization and correlation of the findings should start early in the inspection. Charts should be used if the data is complex. The initial organization of the data will necessarily be sketchy and incomplete, but this early start will help direct the inspection and also help identify areas where data is lacking or is inconsistent.

87103-02 DEFINITIONS

02.01 Cause. This is the action or condition that led to the occurrence of the incident. Causes are labeled, according to their proximity to the incident, as direct, contributing, or root causes.

02.02 Direct Cause. This is the event or failure that led directly to the incident, without any additional intervening action or failure. An example is a technician improperly measuring a dose in a dose calibrator. A possible direct cause for the incorrect dose is improper setting of the radionuclide or energy selection dial on the calibrator.

02.03 Contributing Cause. This is a cause that does not necessarily lead to an incident, but it does make the incident more probable. In the example of the dose calibrator mentioned in the Direct Cause definition, a contributing cause may have been a radionuclide or energy selection dial with illegible markings at the various settings. This does not in itself necessarily lead to errors in measuring doses, since a trained and attentive technician may know from experience where the settings are, without reference to the markings. However, the fact that the markings are not legible makes it much easier to make an error, and hence may be a contributing factor, or cause, when an error does occur.

02.04 Root Cause. This is the cause whose existence establishes the conditions that allow contributing causes to develop and which, in turn, increases the probability of the occurrence of an incident. In the example of the calibrator mentioned in the Direct Cause definition, a root cause may be an organization with a poor maintenance program. The poor maintenance program may be due to an unqualified maintenance manager who fails to set routine maintenance schedules, set maintenance priorities, or respond to maintenance requests. In this case, the root cause may be the presence of the unqualified manager, which results in a poor maintenance program.

87103-03 INSPECTION REQUIREMENT

03.01 Conduct an inspection to: 1) determine the causes of the incident and the corrective actions, taken or planned, to prevent recurrence; or 2) address the accountability and control and health and safety issues associated with a licensee filing for bankruptcy or instances where material may have been abandoned.

87103-04 GENERAL GUIDANCE

04.01 Pre-Inspection Notifications. NJDEP management and staff involvement early in the incident assessment is critical in determining the scope of the proposed inspection activities and future actions. As soon as the decision is made to inspect the incident, notify the licensee's management that an inspection of the incident is to be conducted. When notifying the licensee, make sure that the incident has been brought under control

and that there are no ongoing safety issues. If there are, immediately notify management of the situation. Request that the licensee preserve any physical evidence connected with the incident, if that is possible. Request in advance that the licensee be prepared to submit the necessary documents at the initial licensee meeting.

04.02 Pre-Inspection Preparations. Prepare all materials and documents that may be needed during the inspection, based on your knowledge of the nature of the incident, types of exposures, and the availability of technical support and equipment at the site.

04.03 Initial Licensee Meeting. Meet with the licensee's management as soon as possible upon reaching the site. Explain the purpose of the inspection, the techniques to be used in conducting the inspection, the scope of the work, and the expected duration.

04.04 Facility Inspections. A tour of the facility or a specific area should be performed at the beginning of the inspection since it may be necessary for the inspector to observe proper control of licensed material affected by the incident. If possible have licensee representatives guide the tour, then arrange personnel interviews when the tour is completed. Inspect equipment, tools, work areas, storage areas, and anything else directly or indirectly involved in the incident.

04.05 Interviews. Interview all personnel directly or indirectly involved in the incident, as well as all levels of management whose area of responsibility is in any way connected with the persons involved in the incident or who have any responsibility for the facilities or equipment connected with the incident.

04.06 Documentation. Obtain copies, or originals if copies are not available, of all documentation that may be needed in the inspection. Ensure that proprietary materials are appropriately safeguarded and original material handled carefully and returned at the end of the inspection. In any case where documentation supports or is needed to support an inspection finding, the inspector must make a copy of the document and include it as an attachment to the inspection report. The licensee should be advised of each document that will be included as part of the report.

04.07 Review of the Data. Review the notes of the interviews and tours, and the relevant documents. Establish a time line for the incident. If the data does not produce a coherent, internally consistent narrative, repeat interviews, tours, and document reviews until all inconsistencies and information gaps are addressed.

04.08 Establishing Causes. Once satisfied that all the relevant information has been obtained, ordered in proper temporal and logical sequence, and verified to be consistent, technically correct, and coherent, identify contributing factors and root causes. Correlate these findings with weaknesses in the licensee's program, and formulate ideas on what the appropriate corrective actions to prevent recurrence should be. Compare with the licensee's corrective actions and evaluate their adequacy. If the licensee's corrective actions are determined to be acceptable, a commitment and schedule for implementation should be made by the licensee and submitted to the NJDEP.

04.09 Licensee Briefings. Meet periodically with the licensee's management and key personnel involved in the incident. Review the sequence of events and specify the suspected causes. Provide the licensee with opportunities to modify or correct the data, sequence of events, or conclusions. Obtain further data if warranted by the discussions, and make corrections to the conclusions, as necessary.

04.10 Exit Meeting. Prepare notes summarizing the sequence of events and the conclusions. Identify possible items of noncompliance. Meet with the licensee's management and present these findings.

04.11 Post Inspection Actions. Any follow-up actions that the inspector takes on a reported incident should be summarized in writing, discussed with his/her appropriate NJDEP supervisor, and maintained in an official file.

87103-05 DETAILED GUIDANCE

05.01 Pre-Inspection Notifications. As soon as the decision is made to travel to the licensee's facility to conduct an inspection, call the licensee to notify them of the upcoming inspection. Make sure to speak with a licensee official who is high enough in the organization to ensure prompt execution of any necessary arrangements. During this call, provide the licensee with the following information:

a. Expected time of arrival at the licensee's facility.

b. Purpose of the inspection.

c. Expected duration of the inspection.

d. Request a meeting with appropriate staff, including the responsible licensee management, very soon after the anticipated arrival time.

e. Identify individuals to be interviewed. Have the licensee make arrangements for these persons to be available when needed, and ensure that the radiation safety officer (RSO) will be available. If the licensee uses a consultant, request that the consultant be present during part of the inspection. If that is not possible, then arrangements should be made for him/her to be available by telephone during a specified time period.

f. Specify a time and date on which the exit meeting is expected to be held. Make it clear that this is a rough estimate that depends on the course of the inspection. Also make it clear that the highest level of facility management (e.g., the company president, CEO, or plant manager) is expected at this meeting, including the RSO.

g. Request that copies or, if not possible, originals of all documents that may be needed during the inspection be prepared and ready following the initial meeting. These

documents usually include data on surveys and various radiological measurements, log books, calibration and traceability records, training and qualification records, an organization chart, procedures, and any other documents that may seem relevant (see also Section 05.07). If in doubt about the utility of a document, request it anyway. Emphasize the importance of providing all the requested documents as soon as you arrive at the facility.

h. Request that a knowledgeable person be available to accompany you on a tour of the facility.

i. Request that physical evidence connected with the incident be preserved, if possible. Examples of physical evidence may include: a survey instrument that gave erroneous readings or malfunctioned (useful in determining why the instrument malfunctioned); a dosimeter that gave a much higher than expected dose reading (may be tested to determine if the dosimeter is defective); contamination smears and air sample filters (may be recounted or subjected to more sophisticated analysis, if necessary); instrument settings as they were found after the incident, etc.

j. Make sure that access is available to any part of the licensee's facility that is involved in any way, directly or indirectly, with the incident. If there appear to be any difficulties, stress to the licensee that unescorted access must be arranged, escorted if need be. Notify management immediately of any potential difficulties in gaining access to areas or information. If a certain level of security clearance is required and you do not have that clearance, or if you do not have the required unescorted access training, immediately inform management and request guidance.

05.02 Pre-Inspection Preparations. Before leaving on the inspection, make sure to take all documents, calculators, computer disks, references, radiation safety equipments, etc., that may be needed. A portable computer may be very useful, as would a small hand-held tape recorder to record observations and ideas (not interviews). Arrange for personnel to provide technical assistance over the telephone, in case information that is needed is not available at the site, or if it is desirable to run a computer program to check calculations. When preparing for the inspection, consider taking at least the following items:

a. Writing pads, notebooks, and other stationary needed to record interviews, data, and findings, and to perform calculations and draw charts.

b. Calculator.

c. Computer discs with programs to perform various radiological calculations, if available, and if the licensee can provide the necessary computer, or a portable computer with the necessary software. Word processing software may be helpful if you can type at a reasonably rapid pace.

d. References, handbooks, etc., that contain the basic radiological equations and the values of frequently used constants. For example, if the incident involved external

radiation exposures, equations to convert fluence to dose may be needed. A variety of source geometries should be anticipated, such as a point, line, disk, sphere, or cylinder, etc. Quantities normally needed in such calculations include attenuation and energy absorption coefficients at various energies, densities of a variety of materials, buildup factors, organ depths, and so on. Skin dose calculations require skin dose equations applicable to a variety of source geometries. Internal dose calculations will require organ masses, intake retention functions, intake to committed dose conversion factors for organs, and so on.

In addition to the technical references, regulatory references should also be taken, including regulations that may apply, such as transportation regulations for transportation-related incidents.

e. Appropriate radiation safety equipment (instrument, dosimetry) to ensure areas are safely controlled.

05.03 Initial Licensee Meeting. Upon arrival at the site, meet with licensee management. If a sufficiently high level of management commensurate with the severity of the incident is not present, explain the situation to the licensee, terminate the meeting, and contact NJDEP management immediately. Await instructions before proceeding. The importance of this step is that it is necessary to ensure that a licensee representative who has the authority to make changes in the program has first-hand knowledge of the inspection and its findings. During the initial meeting, present the following items briefly, but clearly:

a. The purpose of the inspection.

b. The expected duration of the inspection.

c. The level of support you expect from the licensee.
Request a brief description of the incident including the names of the personnel directly involved. Request that the licensee make available the personnel to be interviewed. Request that the interviews start immediately after the meeting. Set an approximate time and date for the exit meeting. Make it clear that this is tentative and may change, depending on the progress of the inspection. Request that the licensee provide you with the documents you requested during the pre-inspection telephone conversation described in section 04.01. Find out the name of the person to accompany you on the tours. Request the name of a management person to contact in case you experience difficulties or you do not get the necessary level of support.

05.04 Interviews. Interview everyone connected in any way with the incident, either directly or indirectly. The interviews should follow a widening circle, from the small number of people directly involved, to an increasing number of people less and less directly involved. Persons directly involved are those whose actions directly led to the incident, such as, for example the person who dropped the syringe, or the person who was using the radiography source when it got stuck in the unshielded position. Persons

indirectly involved are usually a larger class, but no less important. These include the assistants to the directly involved persons, supervisors of those persons, maintenance people, health physics or safety people, warehouse personnel, drivers, and so on. Also included in persons indirectly involved are the supervisory and management staff whose responsibilities are connected in any way with the persons directly or indirectly involved in the incident or to the facilities, hardware, software, supplies, or anything else involved in the incident. This list can be very long, but the depth of the interviews will vary depending on the closeness of the person's activities or responsibilities to the incident. Although some of the personnel indirectly involved may not know much about the incident itself, they may contribute invaluable information about the morale of the staff, the quality of management at the facility, the level of training, the degree of attention to detail normally observed at the facility, audit and appraisal practices, involvement of consultants and the quality of their work, the quality of procedures in general, and the degree to which management insists that personnel adhere to applicable procedures. During these interviews, try to get a clear impression of the extent to which the persons interviewed are aware of the circumstances directly or indirectly connected to the incident, and whether their knowledge and awareness are commensurate with their responsibilities in the organization. When conducting the interviews, observe the following guidelines:

a. Interview only one or, at most, two people at a time. A worker's union representative may be present if the worker requests it. However, unless there is a compelling reason, avoid interviewing people in the presence of the supervisors.

b. Start the interview by stating clearly, but not too specifically, what you expect to learn from the person.

c. Make it clear that the purpose of the interview is not to find fault or assign blame, but to learn what happened and if there were any contributing factors so that any weaknesses in the program may be corrected. Be very courteous and realize that the person being interviewed is helping you in your inspection.

d. Do not interrupt, but ask questions when a statement is not clear. Ask questions that elicit useful details rather than questions that call for yes or no answers. Also, do not ask leading questions, i.e., questions that imply the expected answer, such as "you did follow proper procedure, didn't you?". As long as the person is talking about issues relevant to the incident, let the person talk. Keep the conversation focused and end the interview as soon as it becomes clear that no further useful information can be obtained.

e. Make sure to ask open-ended questions that will produce all the information the person being interviewed is expected to provide. The person interviewed may forget something or may believe that a piece of information is not relevant and may therefore not state it. You must be alert to this selectivity and ask questions to compensate.

f. Write down all information discussed during the interviews, such as times, places, recalled conversations, names of people, equipment, sources, reagents, supplies used, procedures involved, surveys done, and any information presented, even if it does not seem to be very relevant at the time. Keep the notes clear and orderly so that they may be used later to reconstruct the information obtained in the interview.

05.05 Facility Inspections. The purpose of a facility inspection is to help reconstruct the events leading to the incident, to place all items and persons involved in proper spatial perspective, and to attempt to identify any factors, relating to the facility or equipment, that may have contributed to the incident. Have a knowledgeable licensee representative take you on a tour of the facility. Ask that person to point out all relevant items involved in the incident and to show you the path followed by the persons involved, the layout of equipment and materials at the time of the incident, and any equipment settings that may be relevant to the inspection.
Upon arrival at the facility, proceed to make a tour of the facility or the area and remind the licensee of the need to provide unescorted access (escorted, if need be) to NJDEP inspectors. Keep in mind that you must abide by all of the licensee's rules and procedures as provided in their site access training. Take time to absorb all detail, and retrace the paths followed by the persons involved in the incident. Remember, however, that this is an event follow-up inspection, and includes only those items that may have a bearing on the event.

During these tours, look for the following, among other things:

a. Postings and Access Control: Are all radiation areas properly posted with the correct postings? Are radiation postings clearly visible and clean, and do they provide the necessary information? Is access to restricted areas properly controlled? Are dosimeters issued to the proper personnel, and are they worn properly?

b. Equipment and Facilities: Does the equipment, including radiation measuring instruments, look well maintained and properly handled? Do instruments have calibration stickers showing valid calibration dates? Is shielding provided where needed?

05.06 Reenactment of the Incident. Incidents that involved a complicated series of movements may be difficult to visualize on the basis of descriptions provided by the licensee. In this case, a reenactment may prove very helpful. The reenactment consists in having the persons directly involved in the incident go through all the motions that ultimately led to the incident. NJDEP management and staff should encourage the licensee to perform and record the event reenactment for later and repeat viewing. Prior arrangements and authorizations by the licensee and NJDEP management must be made to record the reenactment. In any case, where the licensee records the reenactment. The inspector should obtain a copy of the licensee's recording. If the equipment or facility involved in the incident is no longer available, or is unsafe for use in the reenactments, a mockup of the equipment or facility may be used, if warranted. A mockup is a model that is used in place of the equipment during the reenactment. The mockup does not have to be an exact replica of the equipment, but should include the essential features that are

significant in determining the outcome of the incident, such as the general shape or size, distances, and the weight if carrying the item was involved. Reenactments are very important, and sometimes essential, in cases where exposures at high dose rates in complicated configurations were involved. In such cases, differences of a few seconds in the estimated exposure times can result in large differences in the doses assessed for the persons involved. Reenactments, with time and- motion studies, allow refinement of estimates of exposure times, and also provide the basis for calculating the dose rates at different phases of the incident by observation of the relative positions of the personnel and radiation source during the incident.

If the dose calculations show that any person involved in the incident was exposed to high doses (i.e., above 20 Rem), management should consider the need for cytogenetic studies. Such studies may confirm, in some cases, that a high dose was received.

05.07 Documentation. The documentation needed for the inspection includes documents that indicate the overall quality of the licensee's operation, as well as those that are directly related to the incident. Obtain for review at least the following documents:

a. Procedures for all activities directly and indirectly related to the incident. If applicable, review these procedures and determine their adequacy in terms of clarity of presentation, completeness of information, logical flow of steps to accomplish the desired end, and clarity of decision points. If the procedures are found to be weak, determine who wrote them, the qualifications of those persons, and how the procedures were tested to ensure that they are correct and complete. If availability of procedures appears to be a problem, verify that there are procedures for all of the important activities. Check on the method used by the licensee to keep all procedure copies in the facility updated, and how controlled and uncontrolled procedures are used. Check on the availability of copies of relevant procedures at the locations where they are supposed to be used. Determine the procedure review schedule and verify that procedures were reviewed on schedule by qualified personnel.

b. Training and Qualifications Records. Obtain records of the qualifications of all persons directly or indirectly connected with the incident, including technicians, safety personnel, supervisors, and managers. Review these records and verify that all personnel meet at least the minimum qualification requirements for their positions and are qualified for their respective functions. Review training records and check the training schedules to verify that they meet minimum training requirements. Verify that persons scheduled for training within the past year or two have attended that training. Review the qualifications of the persons who provide the training, and review some of the lesson plans. Review some examination questions and some answers to these questions.

c. Calibration and Quality Control Records. Check the calibration records and verify that all equipment that should have been calibrated was indeed calibrated. Check that all instruments scheduled for calibration during the past year or two have been calibrated at the proper time, using approved procedures and sources. Check records of traceability of

calibration sources or instruments. Verify that personnel performing the calibrations are properly qualified and trained for the job. Check the quality control program and schedules. Verify that daily or periodic quality control checks were made as scheduled, that the results of these checks were recorded, that instruments that did not pass the tests were taken out of service, and that these checks are routinely reviewed and signed by a sufficiently high level of management.

d. Records of the Incident. Obtain and review all records that bear directly and indirectly on activities leading to the incident. These include the names of persons involved, the dates and times they entered and left the relevant areas, the type of dosimetry and the readings of these dosimeters, any protective clothing worn, and any equipment or sources issued to them. Check log books to determine the record of activities that were performed and that eventually led to the incident. Check the records of any radiation surveys that may have been made before, during, or after the incident.

e. Records of Recovery. Obtain all records that show the activities taken to recover from the incident. Check on who initiated corrective actions, who was notified, who responded and how, who came to the site of the incident, what they did, and when an investigation was initiated. Determine the scope of the licensee's investigation, who was in charge of it and who was involved, who reviewed and approved the results, and what corrective actions were recommended and what actions were actually implemented.

05.08 Review of the Data. A final reconstruction of the incident must now be attempted, and must include all available details. Start as far back in time from the incident as may seem relevant to the ensuing events. Note where the staff members were at the time, what they were doing, and what was said. Proceed forward in this manner until the time of the incident, and then proceed to the recovery phase in the same manner. Note on a time line all relevant detail, such as what doors were open or closed, what postings were in the area, instrument readings, room occupancy, clothing worn, procedures and equipment used, when equipment was turned on or off, and what the thoughts of the persons involved were, relevant to the events that were taking place (e.g., the technician might have thought that the source was in the shield, but, in fact it was not). Try to note why certain actions were taken and certain others were not. For example, the technician did not perform the required survey because he thought the room had been surveyed by someone else, or because the battery in the survey instrument was dead, etc. At the end of this review, the inspector should understand the incident and relevant factors as well as, if not better than, anyone on site. All detail must fall in place, and the flow of decisions, actions, and responses must be quite clear. If any gaps exist, or if any item is not quite clear, return to the notes or documents, interview more people, or interview again some of those already interviewed, tour the facility again, or request additional records. If the data and events are complex, consider using charts. Make up your own system or use standard charting techniques, such as those used in event and causal factors analysis. The inspector can refer to NUREG-1303, "Incident Investigation Manual," as a guide on how to collect data.

Although primarily used for an Incident Investigation Team, NUREG-1303 is the reference document based on inspection experience that provides good follow-up information on how to conduct an investigation and interview, collect information, write a preliminary notification, and prepare a report.

05.09 Establishing Causes. Most incidents usually have direct causes, as well as several contributing causes, and one or more root causes. Direct causes are the obvious ones that led directly to the incident. Contributing causes are those that facilitated, or did not prevent, the direct cause. Direct causes usually point to contributing causes which in turn point to root causes. A common direct cause is failure to follow procedures or good practices. Failures to follow procedures may have a number of causes, including, lax discipline, poor management supervision, poorly written procedures, procedures that are difficult or impractical to implement, unavailability of procedures, and so on. These contributing causes may point to other contributing causes, such as poor training, poor morale, no management oversight, etc. For incidents involving a complex interaction of events, or a long sequence of events, charts may prove to be very useful in identifying causes. It should be remembered that causes must be sought not only for the direct causes, but also for every contributing factor. One may view the incident as a series of incidents each with its own set of causes, and each leading to, or failing to prevent, the subsequent action. All these contributing causes may have one or a few root causes in common, such as, for example, an unqualified program manager, or poor management practices.

After identifying the causes, express them in a logical hierarchy, one leading to the next. State the cause in a manner that suggests how the action should have proceeded if it had been done properly. For example, it is better to say that the bottle slipped out of the technician's hand because the technician was not wearing gloves, causing his or her hand to be slippery, rather than that the bottle slipped because the technician's hand was slippery. The incorrect action is in this way directly tied to the consequence of that action, and at the same time clearly implies the correct action that should have been taken, in this case, to wear gloves. Finally, the inspector should review the direct and root causes against the licensee's causes and corrective actions to determine whether the licensee's response was appropriate.

05.10 Licensee Briefings. Once the events and data are properly ordered and understood, and causes identified, discuss with the licensee, at a pre-established time, the status of findings and communicate the issues as they develop. Schedule a brief meeting that includes all persons directly and indirectly involved in the incident. Ensure that key licensee staff is represented in the meeting, and certainly the supervisory and management personnel directly responsible for the area involved in the incident. If brief meetings are held with the licensee to discuss issues as they develop, reasonable assurance can be made that the licensee will be aware of problematic areas at the time the exit meeting is held. Present your findings in a clear and logical order. Review your understanding of the incident, the sequence of events that led to it, the persons involved, their actions, and how these actions contributed to the incident. After your presentation, which should not last more than 30 minutes for a complex incident, allow the licensee to

comment and to express disagreement. Make sure you understand the reasons for the disagreement, and clearly separate those that stem from differences of opinion from those that arise out of disagreements on matters of fact. For the former, try to understand the licensee's point of view and note it for later consideration. For the latter, ensure that disagreements on fact are resolved, either at the meeting, or later. All factual disagreements must be resolved at this stage. If factual disagreements are extensive, reschedule the meeting and allow time to review and correct any factual errors. This phase of the inspection should not end until all disagreements on matters of fact are resolved to the extent possible and to your satisfaction.

05.11 Management Briefing. Keep NJDEP management informed of the progress of the inspection. Periodically, summarize the findings and call the NJDEP supervisor, and discuss the findings. This is especially important if there are, or are expected to be, controversial issues arising from the findings. It is also important to discuss the merits of any items of apparent noncompliance with NJDEP management before discussing them with licensee representatives. Notify NJDEP management of any suspected falsification of records, providing false information to the NJDEP, or any other willful wrongdoing. If the inspector identifies serious or controversial issues which cannot be immediately resolved then NJDEP management should consider if their on-site presence is warranted.

05.12 Event Analysis Data. In accordance with its responsibility for evaluating and analyzing operational data for material licensees, NMSS/IMNS collects, reviews, and codes material license event data, and maintains a database - the Nuclear Material Events Database (NMED) - of non-reactor events. The purpose of reviewing operational event data is to identify systemic causes of licensee problems that are significant to licensee and public health and safety. In addition to maintaining this incident database, NMSS/IMNS also provides computer programs to search the database and classify incidents in a variety of ways, depending on the user's needs. For example, incidents may be classified by dose received, body part exposed, type of license, and many other variables. To accomplish this goal, NMSS/IMNS must be provided with a minimum amount of information for each incident. This minimum information is shown in Enclosure 3 of the NJDEP Manual Chapter 2800 in the form of a listing of the variables needed. Review the list and record the data for each variable, as it pertains to the incident. At this stage of the inspection, all listed information should be readily available to you. If not, attempt to obtain any missing information from the licensee before the exit meeting.

05.13 Exit Meeting. The exit meeting is the concluding meeting of the inspection, and its purpose is to provide the licensee with a summary of the findings and any items of noncompliance. Schedule the meeting for a time just before leaving the site, and leave immediately after the meeting. Make sure the meeting is attended by the highest level of facility management (e.g., the company president, CEO, or plant manager), including the RSO. The exit meeting is your meeting, held at your request, and you must conduct the meeting. Open the meeting by explaining the reasons for coming on site, what you did, and what your findings were. Explain what you believe were the causes of the incident and the program weaknesses that they indicate. Present your conclusions regarding

contributing and root causes. List the potential violations of regulatory requirements or license conditions, and note that these are apparent violations to be reviewed and approved by management. Ask if everything is clear and if there are any questions. Do not enter into any discussions but note any disagreements and inform the licensee that you will convey their disagreements to management. Thank the licensee for their cooperation during the inspection, end the meeting, and leave the site.

05.14 Post Inspection Actions. The inspector will review his or her inspection findings with NJDEP management to determine what follow-up actions must be taken. The inspector should discuss the findings in detail, commensurate with the scope of the licensee's program. Violations, items of concern, and unresolved items should be discussed in sufficient depth for management to make appropriate decisions regarding enforcement actions, referral to other State and Federal agencies, and decisions on the scheduling of future inspections of the licensee's facility.

Discussion of the inspection findings with licensing staff can be particularly useful if the licensee is having its license renewed or has recently submitted a license amendment request. Licensing information requested by the licensee should also be discussed with the licensing staff. The inspector will prepare a formal report of the results of the inspection. The findings should be documented in the inspection record, in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement, and when it was violated. Copies of all licensee documents needed to support the violation should be attached to the inspection record. The inspection record should be used to describe what procedures or activities were observed and/or demonstrated by the licensee during the inspection, and any items of concern identified that were not cited as a violation of regulatory requirements.

87103-06 BIBLIOGRAPHY

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NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87104

DECOMMISSIONING FOR MATERIALS LICENSEES

87104-01 INSPECTION OBJECTIVES

01.01 To determine if licensed decommissioning activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed decommissioning programs are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

01.03 To provide inspection requirements and guidance for facilities needing a significant decommissioning effort and where licensee submittal of a Decommissioning Plan (DP) for NJDEP approval may be required.

87104-02 INSPECTION REQUIREMENTS

A determination regarding safety and compliance with NJDEP requirements will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NJDEP, and independent measurements of radiation conditions at the facility, in addition to a review of licensee records.

All decommissioning activities performed by the licensee and its contractors should be considered for inspection. Contractors shall be authorized by the NJDEP, NRC, or an Agreement State. Inspection findings for contractor activities conducted under the site operator's license and supervision shall be documented against the site operator's program. Inspection findings for contractor activities conducted under the contractor's license and supervision shall be documented against the contractor's program. If it is unclear what radiation safety program governs a contractor activity, that activity shall be viewed as falling under the site operator's license and supervision.

In discussing issues with the licensee and reviewing records, cover the period back to the last inspection. Older records or issues preceding the last inspection should be reviewed if warranted by circumstances such as a history of incidents, non-compliance, or high radiation exposures.

The inspection program should be tailored to each specific licensee. Most materials licensees will not require submittal of a formal DP for NJDEP review and approval. Some materials licensees, such as medical teletherapists, well loggers, and radiographers, will not require any actual decontamination or dismantlement of facilities. For this type

of licensee and licensees requiring limited decontamination, the inspector may use Inspection Procedure (IP) 83890 for the closeout inspection.

An increased level of NJDEP inspector oversight, as well as coordination with Radiological Assessment Section staff, is needed for licensees that may require extensive remediation and a detailed final survey, such as manufacturers of radiochemicals and certain academic and research institutions or TENORM facilities such as mining or manufacturing. For these licensees, apply the requirements and guidance in this IP, The NJDEP Field Sampling Procedures Manual, and MARSSIM, including the field notes in Appendices A and B.

For those facilities which require extensive decontamination and remediation, the licensee shall adhere to the requirements set forth in NJAC 7:28-12 and shall follow the technical guidance provided in the most recent version of the Department's "Field Sampling and Procedures Manual" and/or MARSSIM.

02.01 Applicable Inspection Requirements from the Operational Program. The inspector should review all inspection procedures that were applicable to the licensee's operational program, and select those portions that carry over to the licensee's decommissioning program. The inspector should develop an inspection plan that will focus on the adequacy of routine activities that can significantly affect the health and safety of workers and the public and the environment around the licensee's facility. Refer to Inspection Manual Chapter (IMC) 2800 and the IP 87100 series for materials licensees.

Some of the most important inspection elements should include: security and control of contaminated material; radiation protection for workers; radioactive waste generation, storage, transportation, and disposal; effluent releases and environmental monitoring; management organization and controls; occupational safety and health; essential systems and services to support decommissioning; and final survey.

In addition to the inspection activities described above, the inspector should also use other parts of the NJ DEP Inspection Manual that are routinely used on typical inspections and which are included in IMC 2800 and the IP 87100 series of IPs.

02.02 Inspection of Key Decommissioning Activities. The inspector should develop an inspection plan to observe key decommissioning activities being performed by the licensee and its contractors. Key decommissioning activities, occur in all phases of the decommissioning process. Key decommissioning activities for facilities requiring a significant decommissioning effort, such as building remediation and dismantlement, soil removal, and groundwater remediation, are identified below.

a. Inspections before Dismantlement. This is the decommissioning planning stage after the shutdown of operations and before dismantlement and remediation. Key activities and conditions may include: verification that the DP has been reviewed and approved (if required); identification and demarcation of areas in operation and areas undergoing decommissioning, where only part of a facility is being

decommissioned; removal of licensed materials from the facility (if required by license condition); verification that security and control of contaminated material are in compliance with NJAC 7:28-6.1 (see 10 CFR 20.1801 and 1802); compliance with decommissioning timeliness requirements; compliance with recordkeeping requirements for decommissioning; implementation of the licensee's decommissioning organization; site characterization; and construction of site features to support decommissioning.

b. Inspections during Dismantlement and Remediation. This is the stage when the Site is actively being decommissioned. Key activities include: maintenance of security and control of contaminated material; decontamination and dismantlement of structures; remediation of soil, sediment, surface waters, and groundwater; survey measurements and analytical methods, waste management and on-site storage; transportation and offsite disposal of wastes; on-site disposal of waste if authorized under N.J.A.C. 7:28-6.1 (see 10 CFR 20.2002); restoration of the site; and inspection activities identified during the license review of the licensee's DP. Inspectors should consider the use of in-process inspections. In-process inspections have been shown to be more efficient than one-time confirmatory surveys. In-process inspections allow NJDEP to take side-by-side measurements, collect water and soil samples, and address survey issues early in the decommissioning process.

c. Inspections after Remediation. Key activities in this stage include: licensee final survey, NJDEP confirmatory survey, and confirming final site status.

87104-03 INSPECTION GUIDANCE

General Guidance:

Observations of licensee decommissioning activities in progress, equipment in use, facilities and use areas, and the implementation of specific license conditions and approved DPs and procedures will be primary indicators of the quality of the licensee's overall radiation safety program.

Review of licensee records related to decommissioning will also contribute to the evaluation of the licensee's program. In reviewing records, look for trends - such as increasing doses, effluent releases, or groundwater contamination - that may indicate areas of potential concern. Records of surveys, waste disposal, effluent release, receipt and transfer of radioactive materials, training, instrument calibrations, source checks, quality assurance/quality control audits, use logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety, such as personnel dose-monitoring records and incident reports, should be examined in greater detail. The planning and field conduct of an inspection should be coordinated with the NJDEP Licensing Supervisor and in coordination with the Radiological Assessment Section.

Many of the inspection activities required during decommissioning are similar to inspection activities conducted at operating facilities. The guidance given in this section, therefore, includes references to other sections of the NJDEP Inspection Manual that are applicable to materials decommissioning. The inspector should refer to IMC 2602 for general policies and guidance for decommissioning inspections. A major part of inspection activities will be related to evaluating the licensee's final survey program for release of the site under N.J.A.C. 7:28-12. For facilities that will require a final survey, the inspector should begin this activity early in the decommissioning process, starting during site characterization, to ensure that the site will be remediated in accordance with NJDEP requirements and the licensee's approved DP. Confirmatory surveys, by the inspector or a NJDEP contractor (authorized by the NJDEP, NRC, or Agreement State), may be necessary. Inspectors should consider the use of in-process inspections. In-process inspections have been shown to be more efficient than one-time confirmatory surveys. In-process inspections allow NJDEP to take side-by-side measurements, collect water and soil samples, and address survey issues early in the decommissioning process. The extent of the confirmatory surveys will depend on the inspector's and the Licensing Project Manager's confidence in the quality of the licensee's final survey program. In general, minimal, or no confirmatory surveys are necessary for licensee's that have demonstrated, through NJDEP inspection or other means, that their final survey program is comprehensive, well-documented, and of high quality.

03.01 Applicable Inspection Requirements from the Operational Program. Many inspection activities will follow directly from those used during the licensee's operational program. Review the licensee's DP and supporting documents for licensee activities that are similar to those that were performed as part of the operational program. Develop the inspection plan to carry over to decommissioning the applicable inspection activities used during the operational phase of the licensee's program. Tailor the inspection plan to meet licensee-specific conditions. See IMC 2800 and the IPs listed therein for the materials safety inspection program. Some of the operational program's inspection requirements that carry over to decommissioning of licensed activities are described below:

a. Security and Control of Contaminated Material. Security and control of radioactive material at the site shall be maintained, per NJAC 7:28-6.1 (see 10 CFR 20.1801 and 1802). Confirm that licensee security and control of contaminated material are in compliance with the DP throughout the decommissioning process. Verify that the posting requirements of NJAC 7:28-6.1 (see 10 CFR 20 1902) are met for any contaminated material. Containers of contaminated materials shall be labeled in accordance with NJAC 7:28-6.1 (see 10 CFR 20.1904 and 1905). Contaminated materials in buildings should be secured and controlled by the licensee in such a manner as to prevent unauthorized access or theft of radioactive material.

In some situations, especially for materials licensees, the only way to prevent unauthorized access or theft is to lock all access points to the material. However,

mechanisms needed to prevent access are usually dependent upon the nature of the situation at the licensee's facility, such as the physical layout of the facility and the movement patterns of people within that facility. Other possibilities for securing against unauthorized removal include having a person present who could prevent such removal of material. The need to lock access to the licensed material must be determined on a case-by-case basis, after reviewing the details of the licensee's decommissioning program.

At sites undergoing decommissioning, contaminated materials in outside areas may be secured and controlled by fencing (different types, depending on facility location and human populations around the facility, for example), soil covers, or other means. (Three-to 4-foot-thick soil covers over contaminated soil, slag, or tailing piles are generally acceptable just to secure and control material.

Access to buildings, rooms, or indoor and outdoor areas where contaminated materials are present shall be limited only to individuals having the licensee's permission for access. See IP 83822, "Radiation Protection," and applicable sections of 87100 series IPs.

b. Radiation Protection for Workers. Inspect the licensee's approved health physics procedures, as implemented in the field, to determine that the approved program is being implemented and to establish the degree of potential for exposures. Tailor subsequent inspections to concentrate on identified areas of risk. See IP 83822, "Radiation Protection."

c. Effluent Releases/Environmental Monitoring. Verify that licensee offsite monitoring and sampling locations and frequencies are sufficient to demonstrate that the effluent limits in NJAC 7:28-6.1 (see 10 CFR 20 Appendix B) are being met. The potential for offsite release may be lower during decommissioning than during operations, but inspections for offsite releases should continue to be performed during decommissioning. Verify instrument calibrations are being performed as required.

d. Management Organization and Controls. Review licensee implementation of approved plans and programs, regulatory requirements, and license conditions for the management and control of decommissioning of the facility, including: the licensee organization in place for the decommissioning project; designation and qualification of the radiation safety officer; the QA program and annual review; records control and storage; internal review and audit; safety committee; procedure control for cleanup operations; and the decommissioning procedures to be implemented.

e. Essential Systems and Services to Support Decommissioning. Verify, through observations in the facility and review of licensee records, that the support systems needed for cleanup and dismantlement efforts are functional. These systems include: electrical power; heating, ventilation, and air conditioning

systems; water supply; in-plant communications systems; liquid and solid contaminated waste systems; and in-plant lighting.

f. Occupational Health and Safety. Decommissioning activities often involve work practices, such as deep excavating and dismantlement of buildings that present non-radiological safety hazards. NJDEP inspectors, although not OSHA inspectors, should be aware of, and identify to both the licensee and OSHA (through the regional OSHA liaison), non-radiological health and safety issues that are caused by licensee decommissioning activities.

g. Documentation of Inspections. Fully document - by the field notes in this IP, the field notes in the applicable 87104 IP for the licensee's operational program, or, if necessary for complex sites, a written report -all visits to and inspections of each site undergoing decommissioning. Radioactive materials at the site present potential health and safety hazards until the site is remediated and the license is terminated.

03.02 Inspection of Key Decommissioning Activities. Identify all significant or key licensee activities of a particular site undergoing decommissioning, including before, during, and after remediation. Develop an inspection plan to focus on activities where potential health and safety problems may occur, especially accounting for high-risk activities. The frequency of inspections should be based on the particular set of decommissioning activities to be performed by the licensee. Typical key decommissioning activities are given below. Complete the checklist of key decommissioning activities in Appendix A as part of your inspection report.

a. Inspections before Dismantlement

1. Facility Conditions: Verify that all requirements preceding actual facility remediation are in place, including: the DP has been reviewed and approved (if required); licensed material used during operations has been removed from the site (if required by license condition); specific license conditions pertaining to the planning and preparation stage of decommissioning have been put in place by the licensee; and essential systems and services to support decommissioning activities are in place.

2. Timeliness Requirements: Verify that decommissioning schedules are consistent with decommissioning timeliness requirements in NJAC 7:28-51, 7:28-58 and 7:28-60, or that the licensee has submitted an alternative decommissioning schedule for NJDEP approval.

3. Recordkeeping: Verify that recordkeeping for information important to the safe and effective decommissioning of the facility is consistent with the recordkeeping requirements in N.J.A.C. 7:28-51.1 (see 10 CFR 30.36, N.J.A.C. 7:28-58.1 (see 10 CFR 40.42) and N.J.A.C. 7:28-60.1 (see 10 CFR 70.38).

4. Financial Assurance: Verify that the financial assurance requirements, including financial instruments are being maintained in accordance with N.J.A.C. 7:28-4.16, N.J.A.C. 7:28-51.1 (see 10 CFR 30.35), N.J.A.C. 7:28-58.1 (see 10 CFR 40.36) and N.J.A.C. 7:28-60.1 (see 10 CFR 70.25).

5. Site Characterization: Verify that site characterization activities are being conducted in accordance with all applicable radiation protection procedures. The inspector may want to conduct an inspection with the licensee (or licensee's representative) while the licensee is performing characterization. Where possible and warranted, conduct side-by-side measurements with the licensee and take independent measurements for comparison with licensee results. Under special circumstances, the inspector should split samples with the licensee during site characterization, where necessary, to confirm the adequacy and validity of licensee measurements. Evaluate how the results of the planned site characterization will lead to successful site remediation and the licensee's final survey. The inspector should request that the licensee review all available historical records of material use, safety event reports, aerial photographs of the site, as-built facility drawings or blueprints, etc., to aid in the identification of activities that may have resulted in contamination at the site. Interviews with employees and former employees may also be useful to identify previous activities and former locations where licensed material was used or disposed.

6. Construction of Site Features to Support Decommissioning: Verify that the construction of new loading docks, roads, rail spurs, drainage ditches, U.S. Environmental Protection Agency (EPA) storm water management units, and other features to support decommissioning, are in accordance with NJDEP-approved DPs (if required) and do not compromise health and safety considerations of workers and the public.

7. Other License Conditions and Approved Plans: Verify that licensee activities conform to specific license conditions, the approved DP, and licensee programs and procedures. Audit licensee performance on high-risk activities, as needed.

8. Resource Conservation and Recovery Act (RCRA) Facilities: The inspector should be aware of any ongoing U.S. EPA-mandated RCRA facility investigations required by EPA's Hazardous and Solid Waste Amendments permit to identify potential releases to soil and surface water.

b. Inspections during Dismantlement and Remediation

1. Decontamination and Dismantlement of Structures: Verify, by field

observation and record reviews, that licensee activities to decontaminate and dismantle structures are being performed in accordance with NJDEP-approved plans. If a decommissioning plan is not required, verify that the remediation activities are being performed in accordance with applicable NJDEP regulations and guidance. Structures include buildings, above- and below-ground utilities, treatment lagoons, and other man-made structures used or affected by the licensee.

2. Decontamination and Remediation of Soil, Sediment, Surface Waters, and Groundwater: Verify, by field observation and reviews of licensee records, that decontamination and remediation of soil, sediment, surface waters, and groundwater are being performed in accordance with NJDEP-approved plans. If a decommissioning plan is not required, verify that the remediation activities are being performed in accordance with applicable NJDEP regulations and guidance. Inspect licensee activities on-site, and inspect off-site areas that may have been contaminated by licensee operations.

3. Radioactive Waste Management: Confirm that the licensee is maintaining adequate waste management controls related to the release and disposal of liquid, airborne, and solid wastes. Radioactive wastes generated during decommissioning must be disposed of in a manner approved by NJDEP. Some of the radioactive wastes generated during decommissioning include: building materials; process and facility equipment; concrete rubble; filters, trash, and sludge; material from the waste treatment lagoons; soil and vegetation; groundwater; and surface water. Discharges to ground or surface water shall be in compliance with the N.J.A.C. 7:28-12.8 Radiation dose standards applicable to remediation of radioactive contamination of all real property.

4. Low-Level Radioactive Waste Storage: During decommissioning, large quantities of low-level waste may be temporarily stored on-site before shipment to a licensed disposal facility. Confirm that the waste is stored in accordance with license conditions and the guidance in IP 84900, "Low-Level Radioactive Waste Storage."

5. Transportation of Wastes: Review the specifics of the licensee's packaging and transportation activities to determine which elements of the following IPs will be used during the inspection: IP 86740, "Inspection of Transportation Activities," and IP 84850, "Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR 20 and 10 CFR 61." For facilities that have large amounts of contaminated materials to ship offsite, transportation of material may continue throughout the decommissioning process. Contaminated materials for off-site disposal must be packaged in accordance with Department of Transportation regulations published in 40CFR Parts 171-178 and NJ DEP

regulations published in N.J.A.C. 7:28-61.1. NRC Regulatory Guide 7.1 provides guidance for packaging and transporting radioactive materials. Verify that the licensee is in compliance with the Waste Acceptance Criteria for the specific disposal facility that will be used.

6. Restoration of Site: Verify that the licensee has restored the site to meet license conditions and specifications in NJDEP-approved plans.

7. Activities Identified during Review of Decommissioning Plan: Plan to inspect any other significant activities or conditions that may have been specified in the licensee's DP or license.

c. Inspections after Remediation

1. Certification of Waste Disposal: Verify that the licensee has submitted NJDEP Form 314 (Disposition of Materials) or equivalent information regarding the disposition of all licensed material in accordance with NJAC 7:28-51, 7:28-58 and 7:28-60.

2. Licensee Final Survey Program: There are many elements of the licensee's final survey program that need to be inspected. This inspection should occur while the licensee is in the process of performing the final survey program. The purpose of the "in-process" final survey inspection is to provide confidence that the licensee's survey results are accurate and representative of the conditions at the facility. See Appendix B, "Final Survey Program Inspection Field Notes," for a detailed checklist of inspection items for the licensee's final survey program. See IP 83890, "Closeout Inspection and Survey," for closeout procedures.

3. Confirmatory Survey: It may be necessary for NJDEP, or contractor, to conduct confirmatory measurements to provide supplemental information, in addition to the findings of the in-process inspection, to ensure that the survey results reported by the licensee are accurate and representative of the conditions at the facility. However, comprehensive confirmatory surveys should only be necessary if there is significant doubt regarding the licensee's final survey results. For example, a confirmatory survey would be needed if an in-process inspection of the licensee's final survey program identifies multiple weaknesses or if licensee has a history of violations that reduces the NJDEP's confidence in the survey results. The inspector may perform limited measurements (split samples, "side-by-side" direct measurements, etc.) as a part of the in-process inspection of a licensee's ongoing final survey program. The scope and number of these measurements should be significantly less than that performed during a "traditional" confirmatory survey performed after the licensee has completed the final survey. In-process inspections will be most effective for medium to large sites. For small sites, it may not be practical to

perform an in-process inspection, because the final survey will likely be relatively informal and may only take a few days to complete. In this case, the inspector's close-out inspection would be performed after the licensee has completed the survey and submitted the final survey report. However, the inspection of small sites should still include a review of the licensee's program to the extent practical, augmented by a limited confirmatory survey by NJDEP staff.

4. Site Maintenance for Restricted Use: If the site is to be released for restricted use, verify that all conditions limiting use of the site conform to license conditions and NJDEP-approved plans and are in place and functional. Ensure any required deed notices are in force.

5. Conditions for Release for Unrestricted Use: Verify that the licensee has met all applicable conditions for release of the site for unrestricted use in N.J.A.C. 7:28-12.

87104-04 INSPECTION RESOURCES

The direct on-site inspection hours required to complete this inspection are dependent upon: (1) the licensee's decommissioning activities being inspected; (2) the standard materials health and safety inspection areas covered in the inspection; (3) the overall complexity of decommissioning the facility; and (4) the duration of the licensee's decommissioning program. For facilities needing a significant decommissioning effort, it is estimated that approximately 10 to 40 inspection hours will be needed to complete each inspection of a key decommissioning activity or standard health and safety area from the operational program.

Appendices:

A. "Materials Decommissioning Inspection Field Notes for Facilities Needing Significant Decommissioning Effort"

B. "Final Survey Program Inspection Field Notes"

APPENDIX A

MATERIALS DECOMMISSIONING INSPECTION FIELD NOTES
FOR FACILITIES NEEDING SIGNIFICANT DECOMMISSIONING EFFORT

Inspection Report No._____ License No._____

Licensee (Name & Address)_____

Licensee Contact_____

Telephone No._____

Last Amendment No._____ Date of Amendment_____

Program Code_____

Date of Last Inspection_____

Date of This Inspection_____

Date of Next Inspection_____

Type of Inspection: ( ) Announced ( ) Unannounced
( ) Routine ( ) Special ( ) Initial Decomm. ( ) Reinspection of Decomm.

Level of Inspection: ( ) Normal ( ) Reduced ( ) Extended

Brief Description of Inspection Activities:

Brief Description of Findings and Action:

Summary of Findings and Action:

( ) No violations cited
( ) Violation(s)
( ) Violation(s)
( ) Followup on previous violations

Inspector:_____

Date_____
(Signature)

Approved:_____

Date_____

[Field notes are to be used by the inspector to assist with the performance of the inspection. Note that all areas indicated in the field notes are not required to be addressed during each inspection. However, for those areas not covered during the inspection, annotation ("Not Reviewed") should be made in each section where applicable. Additionally, all areas covered during the inspection should be documented in sufficient detail to describe what activities and/or records the inspector observed. The field notes to the "Decommissioning Inspection Procedure for Materials Licensees" should be supplemented with: (1) the applicable inspection procedures for operating facilities provided in the Inspection Procedure (IP) 87100 series; and (2) other written documentation of the inspection, as necessary.]

"Materials Decommissioning Inspection Field Notes for Facilities Needing Significant Decommissioning Effort" (Continued)

1. SUMMARY OF DECOMMISSIONING STATUS

The checklist below is intended to provide, in a written outline format, summary documentation of the status of the licensee's facility in the decommissioning process. This documentation will be filed as part of the inspection report. The inspector should use this information to develop each inspection plan(s) for the various stages of decommissioning, namely, before dismantlement, during dismantlement and site remediation, and after site remediation.

A. Licensee ceased operational program. ( ) Y ( ) N

B. Required decommissioning financial assurance mechanisms in place. ( ) Y ( ) N

C. Decommissioning Plan (DP) required. ( ) Y ( ) N

D. Licensee final survey required. ( ) Y ( ) N

E. NJDEP confirmatory survey required. ( ) Y ( ) N

F. NJDEP closeout inspection required. ( ) Y ( ) N

G. Licensee doing decommissioning planning and preparation before dismantlement. ( ) Y ( ) N

H. Licensee actively remediating site. ( ) Y ( ) N

I. Licensee completed site remediation. ( ) Y ( ) N

Description of Facility Status:

2. INSPECTION OF KEY DECOMMISSIONING ACTIVITIES

The following is a generic checklist of major licensee activities occurring at various stages of decommissioning. From this generic checklist and from facility-specific activities you identify, develop the set of licensee activities to be inspected - for each individual inspection throughout the decommissioning process. Plan to inspect licensee activities that present potential high-risk conditions. Then apply the standard health and safety inspection areas in Section 3 of these field notes (taken from the applicable 87100 series IP for the licensee's operational program) to the specific licensee decommissioning activities that are being inspected.

To complete the licensee activities checklist, the inspector will need to obtain information from the Licensing Project Manager, review the DP, make observations at the licensee's facility, review licensee records, take measurements and samples of contaminants, and undertake other investigative measures, to determine whether the licensee is meeting all regulatory and DP commitments for each decommissioning activity the licensee is performing.

A. LICENSEE ACTIVITIES INSPECTED BEFORE DISMANTLEMENT

1. SNM inventory cleanout/off-site removal of licensed material used in operations has been performed by licensee. ( )Y ( )N

2. Facility license conditions are in place and met by licensee. ( )Y ( )N

3. Site security and control of contaminated material being maintained in compliance with N.J.A.C. 7:28-6.1.( )Y ( )N

4. Support systems and services (e.g., lighting, water supply) are in place. ( )Y ( )N

5. Decommissioning schedules are consistent with timeliness requirements in N.J.A.C. 7:28 51.1, 7:28-58.1 and 7:28-60.1. ( )Y ( )N

6. Licensee's recordkeeping is consistent with N.J.A.C. 7:28 51.1, 7:28-58.1 and 7:28-60.1.
( )Y ( )N

7. Financial assurance requirements are being maintained in accordance with N.J.A.C. 7:28-4, 7:28-51.1, 7:28-58.1 and 7:28-60.1. ( )Y ( )N

8. Licensee is conducting site characterization in accordance with applicable radiation protection procedures. ( )Y ( )N

9. Construction of new site features (e.g., roads, rail spurs, staging areas, sediment control ponds) conforms to DP and does not compromise health and safety of workers and public. ( )Y ( )N

10. Licensee activities conform to specific license conditions and licensee programs and procedures. ( )Y ( )N

11. Other licensee activities: ( )Y ( )N

Basis for Findings:

B. LICENSEE ACTIVITIES INSPECTED DURING DECONTAMINATION, DISMANTLEMENT AND SITE REMEDIATION

1. Site security and control of contaminated material being maintained in compliance with N.J.A.C. 7:28-6.1. ( )Y ( )N

2. Decontamination and dismantlement of structures are being performed consistent with DP and sound industry practice (structures include buildings, utilities, treatment lagoons, etc.). ( )Y ( )N

3. Decontamination and remediation of the following are being performed consistent with DP and sound industry practice:

a. Soil. ( )Y ( )N

b. Sediment. ( )Y ( )N

c. Surface waters. ( )Y ( )N

d. Groundwater. ( )Y ( )N

e. Other mediums: ( )Y ( )N

4. Licensee release and disposal of decommissioning wastes are consistent with DP and approved by NJDEP for:

a. Liquid wastes (e.g., groundwater, surface water, liquid from treatment ponds, process liquids). ( )Y ( )N
b. Solid wastes (e.g., building materials, process and other facility equipment, concrete rubble, soil). ( )Y ( )N

c. Other wastes: ( )Y ( )N

5. Temporary, onsite storage of low-level radioactive wastes from decommissioning meets license conditions and guidance in IP 84890. ( )Y ( )N

6. Packaging and shipment of radioactive waste materials
meet requirements in (40 CFR Parts 171-178 and N.J.A.C. 7:28-61.1. ( )Y ( )N

7. Restoration of Site - Licensee has restored site to meet
license conditions and NJDEP-approved plans. ( )Y ( )N

8. Licensee survey of material and equipment for free release
sufficient to demonstrate compliance with release criteria. ( )Y ( )N

9. Other licensee activities: ( )Y ( )N

Basis for Findings:

C. LICENSEE ACTIVITIES INSPECTED AFTER COMPLETION OF SITE REMEDIATION

1. Licensee has submitted NJ DEP Form 314 for disposition of licensed material in accordance with N.J.A.C. 7:28-51.1, 7:28-58.1 and 7:28-60.1. ( ) Y ( ) N

2. Licensee's final survey program is acceptable (see Appendix B for inspection items for final surveys). ( ) Y ( ) N

3. NJDEP confirmatory survey performed. ( ) Y ( ) N

4. Site maintenance activities (if any, for restricted use) conform to license conditions and NJDEP-approved plans and are in place and functional. ( ) Y ( ) N

5. Other licensee activities: ( ) Y ( ) N

Basis for Findings:

3. INSPECTION OF STANDARD HEALTH AND SAFETY AREAS FROM THE OPERATIONAL INSPECTION PROGRAM

Identify the standard inspection areas (from the inspection program of the licensee's operational program) to be covered during each decommissioning inspection. [Inspection areas A through L below correspond to the typical inspection areas in the 87100 series IPs that are applicable to decommissioning.] Then identify the new activities within the standard inspection areas undertaken by the licensee during decommissioning. Some of the new activities given below, as well as any other activities the inspector identifies, should be considered inspection items under the general set of health and safety inspection areas used in the applicable 87100 series IP.

Minimum inspection areas for the initial decommissioning inspection: decommissioning organization; decommissioning activities in compliance with NJDEP-approved DP; licensee procedures for implementing the DP; Radiation Safety Committee(RSC) and Radiation Safety Officer (RSO) responsibilities; and the licensee's decommissioning training program.

A. GENERAL OVERVIEW

1. Describe the licensee's decommissioning organizational structure:

a. Licensee is performing decommissioning activities incompliance with its approved decommissioning plan. ( ) Y ( ) N

b. Licensee has implementing procedures for the decommissioning activities identified in the DP. ( ) Y ( ) N

c. The RSC and RSO fulfill license requirements to deal with all decommissioning activities. ( ) Y ( ) N

Basis for Findings:

B. FACILITIES

1. Describe, from field observation, the licensee-identified facilities and outdoor areas to be decommissioned:

2. The licensee's remediation plan includes all the contaminated facilities and areas on-site and off-site. ( ) Y ( ) N

3. All essential systems and services (e.g., electrical power, water supply, communications systems) are in place and functional for the planned decommissioning activities. ( ) Y ( ) N

4. Licensee's emergency plan is in place and operative for the duration of decommissioning. ( ) Y ( ) N

5. For complex sites needing site characterization, describe the key site characterization activities to be performed by the licensee to determine the nature and extent of contamination:

6. Licensee's characterization activities performed in conformance with good industry practice. ( ) Y ( ) N

Basis for Findings:

C. EQUIPMENT AND INSTRUMENTATION

1. Survey instruments are applicable to contaminants of interest.( ) Y ( ) N

2. Use of survey instruments appropriate for site. ( ) Y ( ) N

Basis for Findings:

D. MATERIALS

1. Radioactive materials licensed during operations have been removed offsite; residual quantities conform to license conditions.( )Y ( )N

2. Security and control of licensed materials, including contaminated areas, is being maintained. ( ) Y ( ) N

Basis for Findings:

E. TRAINING

1. Licensee has developed training program for new decommissioning activities (e.g., demolition of structures, excavation of soil); program is adequate. ( ) Y ( ) N

2. Training program being effectively implemented. ( ) Y ( ) N

Basis for Findings:

F. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL
1. Area surveys are being performed in areas being decommissioned. ( ) Y ( ) N

2. Where active remediation (e.g., demolition of structures, excavation of soil) is being performed, radiation levels in unrestricted areas do not exceed 2 mrem in any one hour. ( ) Y ( ) N

Basis for Findings:

G. RADIATION PROTECTION

1. The licensee's approved health physics program is being implemented in the field for new decommissioning activities. ( ) Y ( ) N

2. Site security and control of contaminated material are incompliance with NJAC 7:28-6.1. ( ) Y ( ) N

Basis for Findings:

H. RADIOACTIVE WASTE
MANAGEMENT/EFFLUENTS/ENVIRONMENTALMONITORING

1. Offsite disposal of decommissioning wastes conforms to free release criteria and disposal site requirements. ( ) Y ( ) N

2. All new effluent releases conform to DP and applicable regulations. ( ) Y ( ) N

3. The licensee's environmental monitoring program is being implemented in conformance with the DP and all applicable limits are being met. ( ) Y ( ) N

4. Temporary storage/staging areas for radioactive wastes
from building demolition, equipment dismantlement, soil excavation, etc., are adequately posted and protected. ( ) Y ( ) N

Basis for Findings:

I. RECORDKEEPING FOR DECOMMISSIONING

1. Copies of the licensee's decommissioning cost estimates and funding methods are on file. ( ) Y ( ) N

2. Licensee has adequate records for decommissioning activities performed (e.g., for decontamination and dismantlement of structures; decontamination and remediation of soil, sediment, surface waters, groundwater; surveys of remediated facilities). ( ) Y ( ) N

3. Licensee's financial assurance conforms to the financial assurance requirements of NJDEP-approved possession limits and NJDEP regulations. ( ) Y ( ) N

Basis for Findings:

J. TRANSPORTATION

1. Describe the licensee's program to package and ship decommissioning waste materials:

2. Licensee meets WAC for the disposal facility? ( ) Y ( ) N

3. Licensee's program meets all applicable requirements for marking labeling, placarding, and shipping paper requirements for radioactive waste shipments. ( ) Y ( ) N

Basis for Findings:

K. POSTING AND LABELING

1. All contaminated areas, waste processing areas, and waste handling areas are posted in conformance with regulations. ( ) Y ( ) N

2. Packaged radioactive waste materials are labeled in accordance with regulations. ( ) Y ( ) N

Basis for Findings:

L. OCCUPATIONAL HEALTH AND SAFETY

1. Describe the occupational health and safety observations made at the licensee's facilities:

2. Licensee and Occupational Safety and Health Administration were informed of occupational health and safety issues observed during the inspection. ( ) Y ( ) N

Basis for Findings:

4. VIOLATIONS, NON-CITED VIOLATIONS, FOLLOWUP ITEMS, AND OTHERISSUES

Briefly state (1) the requirements and (2) how and when the licensee violated the requirement. For non-cited violations, indicate why the violation was not cited. Briefly describe followup items and other issues.

APPENDIX B

FINAL SURVEY PROGRAM INSPECTION FIELD NOTES

1. STATUS OF LICENSEE FINAL SURVEY

A. Final survey report submitted to the NJDEP. ( ) Y ( ) N

B. Previous inspection(s) of licensee final survey program conducted. ( ) Y ( ) N

C. Final survey report not submitted, licensee final survey in progress. ( ) Y ( ) N

D. Final survey plan submitted and approved by NJDEP license reviewer. ( ) Y ( ) N

Basis for Findings:

2. INSPECTION AREAS FOR LICENSEE FINAL SURVEYS
Notes:

(1) For facilities where an approved decommissioning plan (DP) is required, inspections should be made against commitments in the DP and the licensee's final survey plan (which would have been approved by the NJDEP license reviewer during license review). For facilities where a DP is not required, inspections should be made against NJDEP regulations, and license conditions.

(2) For facilities that require a significant decommissioning effort, all the inspection areas listed below should be inspected while the licensee's final survey program is in progress. For small, licensed facilities that do not require a significant decommissioning effort, only some of the inspection areas below may apply, and it may not be practicable to inspect these areas until after the licensee's final survey is completed and the licensee's final survey report has been submitted to NJDEP.

(3) Inspection of a licensee's final survey may include independent confirmatory measurements by the inspector or NJDEP contractor. The extent of the confirmatory measurements, and whether the use of an NJDEP contractor is warranted, depends on a number of factors that are discussed in Section 2.C. In most cases, minimal confirmatory surveys should be sufficient.

(4) The inspector should identify which inspection areas listed below are performed during each inspection.

A. SITE CONDITIONS AT TIME OF LICENSEE FINAL SURVEY

1. Site has been decontaminated/remediated in accordance with DP or site procedures.
( ) Y ( ) N

Basis for Findings:

B. LICENSEE FINAL SURVEY PLANS AND PROCEDURES

1. Contaminants:

a. Licensee has identified all potential contaminants. ( ) Y ( ) N

b. Licensee has specified acceptable release criteria. ( ) Y ( ) N

c. Licensee has clearly documented the basis for any alternate criteria, if applicable. ( ) Y ( ) N

2. Organization and Responsibilities:

a. Survey program documented. ( ) Y ( ) N

b. Survey staff responsibilities and qualifications documented.( )Y ( )N

3. Quality Assurance/Quality Control:

a. Organization ( ) Y ( ) N

b. QA Program ( ) Y ( ) N

c. Operational Procedures ( ) Y ( ) N

d. Document Control/Records Management ( ) Y ( ) N

e. Equipment Maintenance and Control ( ) Y ( ) N

f. Audits and Corrective Action ( ) Y ( ) N

g. Independent third party measurement QC ( ) Y ( ) N

4. Laboratory analytical procedures, including QA/QC, acceptable, and results adequately documented. ( ) Y ( ) N

5. Laboratory certified by OQA ( ) Y ( ) N

6. Field Survey Instrumentation:
a. Survey instrumentation is appropriate for contaminants of interest and site conditions. ( ) Y ( ) N

b. Licensee has properly calibrated survey instrumentation.( ) Y ( ) N

c. Instrument operational procedures adequate ( ) Y ( ) N
Basis for Findings:

7. Licensee is performing the survey in conformance with the approved survey plan :

a. All potentially contaminated locations on-site and off-site have been properly classified as "impacted" or "non-impacted" areas. ( ) Y ( ) N

b. "Survey Units" have been properly selected. ( ) Y ( ) N

c. Background determination acceptable. ( ) Y ( ) N

d. Number and location of measurements and samples in each "survey unit" is acceptable. ( ) Y ( ) N

e. Surface scan procedures and percent coverage acceptable. ( )Y ( )N

f. Surface activity measurement procedures acceptable.

(1) Direct. ( ) Y ( ) N

(2) Removable. ( ) Y ( ) N

g. Exposure rate measurement procedures acceptable. ( ) Y ( ) N

h. Surveying and sampling of the following media conducted as appropriate:

(1) Soil and sediment, surface and subsurface. ( ) Y ( ) N

(2) Groundwater. ( ) Y ( ) N

(3) Surface water. ( ) Y ( ) N

(4) Buildings, interiors and exteriors. ( ) Y ( ) N

(5) Equipment and systems. ( ) Y ( ) N

(6) Grounds. ( ) Y ( ) N

(7) Other media: ( ) Y ( ) N

Basis for Findings:

8. Licensee's Final status Survey report sufficient to demonstrate that release criteria have been met.

Note: The final status survey report will, in general, not be available for review at the time of an "in-process" inspection of a final survey program. However, at the end of the survey project, after the final survey report has been submitted, the inspector should ensure that these areas have been reviewed by either the license reviewer or project manager. If questions remain as to whether these areas have been satisfied by the licensee, or the final status survey report has not been reviewed, the areas listed below should be addressed during the inspection.

a. Survey results demonstrate, with 95% confidence, that average residual contamination in each "survey unit" is less than release criteria. ( ) Y ( ) N

b. Survey results demonstrate that the Elevated Measurement criteria in NUREG-1575, Rev. 1 have been satisfied. ( ) Y ( ) N

c. Elevated survey results investigated by licensee. ( ) Y ( ) N Section 8.5.2 of MARSSIM addressed? ( )Y ( )N

d. "Survey Units" reclassified, as necessary, based on survey results. ( ) Y ( ) N

e. Reclassified "survey units" surveyed with proper number and location of samples and proper percentage of the surface scanned ( ) Y ( ) N

f. Survey report provides sufficient documentation of procedures and QA/QC. ( ) Y ( ) N

g. Survey report provides diagrams or other documentation identifying survey locations. ( ) Y ( ) N

Basis for Findings:

NOTE: If a licensee is performing their final survey using NUREG/CR-5849, NUREG-1575 Rev. 1 should not be applied.

C. NJDEP CONFIRMATORY SURVEY

1. Evaluate whether a confirmatory survey is justified.

a. Significant, unresolved, weaknesses identified during the inspection of the licensee's final survey program. ( ) Y ( ) N

b. Repetitive violations. ( ) Y ( ) N

c. Significant public or Congressional interest. ( ) Y ( ) N

d. Small site where an in-process inspection not practical. ( ) Y ( ) N

2. If a confirmatory survey is justified, determine if an NJDEP contractor should be used. Meeting one or more of the three criteria listed below will, in general, justify the use of a contractor.

a. Licensee's final survey involves unique or complex technical issues. ( ) Y ( ) N

b. Confirmatory survey is expected to require more than a man-week effort to complete field surveys and sampling.( ) Y ( ) N

c. Confirmatory survey is very high priority that cannot be completed by NJDEP staff in a timely manner. ( ) Y ( ) N

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87121

INDUSTRIAL RADIOGRAPHY PROGRAMS

87121-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

87121-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NJDEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective industrial radiography radiation safety program:

02.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR 20) limits.

02.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 FE-6 The licensee should ensure that workers are:

a. Knowledgeable of radiation uses and safety practices;

b. Skilled in radiation safety practices under normal and accident conditions; and,

c. Empowered to implement the radiation safety program.

02.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure:

a. Awareness of the radiation protection program;

b. That audits for ALARA practices are performed; and,

c. That assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

Usually the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, repetitive violations, or high radiation exposures.

87121-03 INSPECTION GUIDANCE

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection.

Common elements to all inspections include entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys, and the evaluation of program scope and any special license conditions.

03.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR 20) limits.

Security:
Through direct observation and licensee staff interviews, determine that all entrances to radiographic facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to radiographic storage facilities, etc.

If any entrance or area is found to be unsecured, determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

If entrances or other areas are found to be unsecured, examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be under constant surveillance or physically secured.

Facilities:
Through direct observation and licensee staff interviews, verify that any permanent radiographic installation is configured in accordance with the design and performance requirements found in N.J.A.C. 7:28-63.1 (see 10 CFR Part 34). Specifically, verify that the facility has an operable independent entrance control or visible-audible alarm system pursuant to N.J.A.C. 7:28-63.1 (see 10 CFR 34.33). Observe staff tests of the entrance controls and/or radiation warning signals, to confirm operability during the inspection. Verify that permanent radiographic facilities are shielded so that the radiation levels in adjacent areas, including the roof, do not exceed 0.02 millisievert (mSv) (2 millirem [mrem]) in any 1 hour. This evaluation should consider the maximum allowable source quantity and any other limitations on positioning within the facility.

Receipt and Transfer of Licensed Material:
Through observation and interviews, verify that the licensee receives packages and makes transfers of licensed material in accordance with NJDEP and applicable U.S. Department of Transportation (DOT) regulations and license conditions. Through discussions with licensee personnel, determine how the licensee ensures that transfers are made to authorized recipients. Focus on how the licensee receives packages, opens packages, and how and when package radiation surveys are performed (including wipe tests). Also determine what actions the licensee takes (or should take) when surveys reveal packages that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should, when practical, observe personnel performing the package receipt surveys.

Physical Inventory:
Through interviews and review of records, verify that, as required by NJAC 7:28-63.1 (see 10 CFR 34.29(a)), the licensee conducts semi-annual physical inventories to account for all licensed material received and possessed under the license. Verify that inventory records are maintained in accordance with NJAC 7:28-63.1 (see 10 CFR 34.69). Verify that sealed sources, and radiographic exposure devices used by the licensee are in accordance with sealed source and device (SS&D) registrations sheets. In order to make an assessment in this area, the inspector may ask the licensee how they ensure that they only use registered sources and devices. If practical, the inspector should verify that the inventory includes all radiographic exposure devices and storage containers containing depleted uranium and calibrators used for calibrating survey instruments.

Material Security and Control:
Examine areas where radioactive materials are stored. Storage areas should be locked and have limited and controlled access. Radiographic exposure devices and storage containers must be physically secured to prevent access or removal by unauthorized personnel. Transport packages (including overpacks) containing licensed material must be locked and physically secure in the

transport vehicle. The inspector should make every reasonable effort to perform a "field inspection" at a temporary job site of the licensee. This inspection should be unannounced. If possible, make some of the observations of the licensee's operations before announcing your presence. During the field inspection, verify that the boundaries of the restricted area are controlled and posted; the radiation levels at the boundary of the restricted area do not exceed 0.02 mSv (2 mrem) in any 1 hour; and that the operations are conducted by at least two qualified individuals. Ask the licensee how they ensure that the radiation level limits (2 mrem in any 1 hour) are complied with, and make an assessment of the adequacy of the methods. Verify that the high radiation area is under constant surveillance, as required by NJAC 7:28-63.1 (see 10 CFR 34.51). At job sites where other workers are present, interview them to determine their understanding of the licensee's access control. Although these workers may not have or need any knowledge of the licensee's operations, if they were informed of the licensee's operations, this would be an indication of the licensee's good safety practices. Inspectors should keep in mind that, as non-licensees, such persons have no obligation to cooperate with the NJDEP.

Area Surveys:
The inspector should verify that radiation levels at the boundary of the restricted area do not exceed 0.02 mSv (2 mrem) in any one hour. This will require the inspector to determine the instantaneous exposure rate and the number of radiographic exposures performed by the licensee. The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation. However, the inspector should use NJDEP's instruments for independent verification of the licensee's measurements. The inspector should use a survey instrument that has been calibrated within the last 6 months. This will enhance the credibility of the inspector's survey results if there is any disagreement between the readings obtained from the licensee's instruments and the inspector's (NJDEP's). Ensure that the licensee's survey meters are operational and have been calibrated within the last 6 months. The inspector should verify that the radiographer or radiographer's assistant performs a survey of the exposure device and guide tube after each exposure of the source. The survey must be sufficient to confirm that the source has returned to its shielded position. If practical, observe how licensee conducts surveys, to determine the adequacy of surveys (See FE-5).

Leak Tests:
Through interviews with licensee staff and review of records, verify that required leak tests are performed at the required interval. Determine if the licensee exchanges or returns their iridium-192 sources to the vendor less than six months from the date that they were received, negating the need to perform periodic (six months) leak tests.

> If the licensee performs leak tests, verify that the wipe of a sealed source is taken from the nearest accessible surface to the sealed source where contamination might accumulate (i.e., the point on the camera or source exchanger where the guide tube or transfer tube connects) and at intervals not to exceed 6 months.
>
> Verify that devices containing depleted uranium are leak tested annually, to verify the integrity of the "s" tube.

The licensee should verify that the licensee's leak test analyses (or that of it's leak test services vendor) has sufficient sensitivity to measure 183 Becquerels (0.005 microcurie) for each type of isotope present on its license. Through discussions with licensee personnel and/or review of pertinent records, determine if the licensee had a leaking source or indication that the integrity of any "s" tubes was compromised. If leak test results show contamination in excess of the regulatory limits, verify that the licensee made appropriate notifications, evaluations, and removed the source from service.

Waste Storage and Disposal:
Determine if the licensee possesses any industrial radiographic sources or other licensed sources that have been removed from service. Verify that the sources are stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed the limits of N.J.A.C. 7:28-6.1 (see 10 CFR 20.1301), "Dose Limits for Individual Members of the Public." In the rare case where a licensee may have transferred a source to a burial site for offsite disposal, review the licensee's procedures and records to verify that each shipment is accompanied by a shipment manifest that includes all the required information. Also review the licensee's procedures and records to verify that each package intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of N.J.A.C. 7:28-59.1 (see 10 CFR 61.55 [subsection III.A.2. of Appendix G to Part 20].

Incidents and Unusual Occurrences:
Review and evaluate any incident or unusual occurrence that took place since the last inspection. Verify if incidents were required to be reported, and, if so, that proper reporting procedures were followed. For incidents or unusual occurrences not required to be reported, determine that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

Equipment:
Through interviews with key licensee personnel, verify that the types and quantities possessed by the licensee are within any applicable license limits (including SS&D registry limits) and that the licensee is using approved combinations of sources and devices. Verify that all sealed sources (source assemblies), radiography devices (cameras), and source changers used by the licensee (unless specifically exempted) meet N.J.A.C. 7:28-63.1 (see 10 CFR 34.20) requirements. Confirm that licensees are aware that associated equipment needs to comply with N.J.A.C. 7:28-63.1 (see 10 CFR 34.20). Refer to Regulatory Issue Summary 2005-10, "Performance–Based Approach for Associated Equipment in 10 CFR 34.20," (ML051590049) for additional information about acceptable methods to demonstrate that associated equipment complies with N.J.A.C. 7:28-63.1.

If the associated equipment appears to be modified or defective (defective equipment may be an indication of a modification), the inspector should verify whether or not the licensee had

developed and implemented a testing program to demonstrate that modified components meet the performance criteria in N.J.A.C. 7:28-63.1 (see 10 CFR 34.20). The inspector should alert the inspection supervisor who may extend the inspection and request an SS&D reviewer to evaluate the licensee's modification of the equipment. The expectation is that the design safety features of the industrial radiography system were not compromised by a replacement component of associated equipment that was modified by the licensee. Before using a modified system, the licensee is required to demonstrate that the replacement component meets the performance criteria in N.J.A.C. 7:28-63.1 (see 10 CFR 34.20(a)(1) and (2), (b)(3), (c)(5) and (8), and (e)).

Routine and Non-Routine Maintenance:
Through direct examination, assess the condition of licensee equipment, i.e. cameras, drive cables, source changers, etc. The examination should be sufficiently thorough to detect any of the following conditions: excessive or uneven wearing, fraying, unraveling, nicks, kinks or bends, loss of flexibility (abnormal stiffness), excessive grit or dirt, and stretching.

Should a defect, such as a damaged cable, be found in use, notify an appropriate licensee representative and then expand the scope of the examination. Monitor actions, if any, taken by the licensee in response to this discovery. Should the licensee elect to not take action, the inspector should consult with NJDEP management.

Verify that the licensee has an inspection and maintenance program that complies with N.J.A.C. 7:28-63.1 (see 10 CFR 34.31(a)) and provides for visual and operability checks of radiographic equipment, survey meters, transport containers, associated equipment, and source changers before use and quarterly to ensure that the equipment is in good working condition.

Verify that the licensee's inspection and maintenance program ensures that the sources are adequately shielded, and that the required labeling is present. The inspector should verify that the licensee is aware of the requirements contained in 10 CFR Part 21 and N.J.A.C. 7:28-63.1 (see 10 CFR 34.101(a)) and has procedures in place for reporting defects and certain equipment failures.

03.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

Operational Limits:
Verify that industrial radiography devices (and sources) are used in accordance with any operational limits described in the applicable SS&D sheet. Through observation and discussions with the licensee, assess that:

a. storage conditions for the devices protects from fire and the elements,

b. package integrity is appropriately maintained, and that

c. controls are in effect to minimize the risk from other hazardous materials.

Temporary Job Site Hazards:
During inspections of licensed activities at temporary job sites, verify that licensee personnel ensure that devices are protected from heavy construction equipment, welding equipment, high voltage lines, and other industrial hazards.

Fire Protection:
Materials licensees are not required by NJDEP regulations to implement a fire protection program. However, in many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. Determine if licensees have a plan in place for preventing fires and combating fires that might occur. Any perceived problems/deficiencies (i.e., improper storage of combustible or flammable material, fire extinguishers out of service, lack of fire alarm or detection system, lack of fire suppression system) noted by the inspector should be brought to the licensee's attention and discussed with NJDEP Radioactive Materials Section. Proper fire protection systems can be evidenced by the licensee's involvement with the local fire department.

Transportation:
Through direct observation, verify that the licensee properly transports radiographic devices. Examine packages (including overpacks) for proper labeling, review associated certification documentation. Examine vehicles for proper blocking and bracing of shipping containers. Verify that shipping papers are complete and available. Survey packages and vehicles to verify compliance with N.J.A.C. 7:28-61.1 (see 10 CFR 71) and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials. Through interviews of licensee staff, determine if there were any incidents required to be reported to the DOT.

03.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

Through observation:
Verify that personnel dosimetry devices (film badges, TLDs, or OSDs) are worn by appropriate licensee personnel, including all radiographers and radiographer's assistants. Also verify that direct reading dosimeters and alarm rate meters are also worn by appropriate personnel. Note that alarm rate meters are not required to be worn when radiography is being performed at permanent radiographic installations. Dosimetry devices appropriate to the type, energy of

emitted radiation, and the anticipated radiation fields, must be issued to licensee personnel. Verify that any dosimeters, that require processing to determine the radiation dose, are processed by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited processor.

Verify that, pursuant to N.J.A.C. 7:28-50.1 (see 10 CFR 19.13(b)), the licensee advises each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to the provisions of N.J.A.C. 7:28-6.1 (see 10 CFR 20.2106, "Records of individual monitoring results.)" Verify that this has been done by asking workers and management if the written report requiring this information has been provided to each of them within the last year. The report must include external doses from routine operations, accidents, and emergencies. The report to the individual must contain all of the information required in N.J.A.C. 7:28-50.1 (see 10 CFR 19.13(a)).

Verify that an evaluation has been performed that demonstrates that the use and storage of sealed sources will not likely result in exposures to members of the public or radiation levels in unrestricted areas that are in excess of the regulatory limits. For storage areas that are located adjacent to unrestricted areas, licensees must ensure (through measurement or calculation) that doses in the unrestricted areas do not exceed 2 millirem (mrem) in any one hour or 100 mrem in a year to the maximally exposed member of the public.

03.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

Through observation, verify that survey instrumentation has the appropriate range of use. Also verify that the survey instruments are properly calibrated at 6-month intervals. Verify that all survey instruments, pocket dosimeters, and alarming rate meters, in use, have current calibrations. The technical adequacy of calibration procedures at facilities that perform their own calibrations should be examined. Verify that the licensee performs an appropriate operability check before use on each day the equipment is used.

If the licensee is authorized to both collect and analyze leak test samples, determine if the type of counting equipment is appropriate for the samples being analyzed and the sensitivity required. Also determine if the laboratory instrumentation is calibrated for the appropriate geometries of the samples to be analyzed and is routinely checked for proper operation. The licensee should maintain calibration records, control charts, and maintenance and repair records, to demonstrate proper operation of laboratory instrumentation.

03.06 FE-6 The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

Certification:
Through review of records, verify that radiographers are certified by a recognized certifying entity. Ask to see the radiographer's certificate, or verify through other appropriate means that all radiographers, observed performing in that role are, in fact, certified.

General Training:
Interview one or more radiographers and/or radiographers' assistants to determine that they possess the adequate knowledge and understanding of the licensee's operating and emergency procedures. The interviews should include discussions about actual or hypothetical emergency conditions in order to assess the worker's response to such conditions. Whenever practical, observe licensed activities in progress to assess the worker's understanding of the radiation protection requirements associated with their assigned activities. Verify that all industrial radiography personnel understand the mechanism for raising safety concerns and the proper response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and radioactive material. The workers should also be informed of the pertinent provisions of NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP requirements.

If the licensee provides their own training, determine that instructors who provide classroom training to individuals in the principles of radiation and radiation safety have knowledge and understanding of the principles beyond those obtainable in a course similar to the one given to prospective radiographers.

Individuals who provide instruction in the hands-on use of radiography equipment should be qualified radiographers with at least 1 year of experience in performing radiography or possess a thorough understanding of the operation of radiographic equipment (e.g., manufacturers' service representatives).

Observe related activities (i.e., transportation of licensed materials, surveys and equipment checks, and maintenance activities) and interview personnel to assure that appropriate training was actually received by these individuals. Note that if a radiographer or radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months, they must demonstrate knowledge of training requirements by a practical examination, before these individuals can participate in a radiographic operation. Verify that radiographers understand that they must directly supervise radiographic operations and that radiographers' assistants are aware that they can operate radiographic equipment only under the direct supervision (direct observation) of radiographers. Verify that licensees are performing refresher training, for radiographers and radiographers' assistants, at least every 12 months.

Operating and Emergency Procedures:
Verify that licensee personnel are knowledgeable of the operational procedures by observing the performance of tasks at selected work stations and by a comparison of their performance with established procedures. Also examine the licensee's emergency procedures to determine that these procedures are as approved by or described to NJDEP. Through discussions with workers, verify that licensee personnel understand and implement the established procedures and are aware of procedural revisions. Some licensees may have agreements with other agencies (i.e., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

Posting and Labeling:
Verify that proper caution signs are being used at access points to areas containing licensed materials, radiation areas, and high radiation areas. (Note: The exemptions under N.J.A.C. 7:28-6.1(see 10 CFR 20.1903) do not apply to radiographic operations.)Also spot-check labeling on packages or other containers to determine that proper information (e.g., radionuclide, quantity, and date of measurement) is recorded. Verify that storage areas, radiation areas, and high radiation areas at temporary job sites are conspicuously posted as required. Depending on the associated hazard and licensing requirements, controls may include tape, rope, or structural barriers to prevent access into the restricted area. Examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

The NJDEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NJDEP regulations and license provisions and to terminate unsafe activities involving byproduct material. Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

• Maintaining awareness of significant events such as the loss or theft of licensed materials.

• Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.

• Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.

• Obtaining the NJDEP's prior written consent before transferring control of the license.

• Notifying NJDEP Radioactive Materials Section in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (N.J.A.C. 7:28-51.1. (see 10 CFR 30.34(h)).

• Assuring the appropriate response, when applicable, to generic communications from the NJDEP.

• Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities (N.J.A.C. 7:28-51.1 (see 10 CFR 30.35)).

• Notifying the NJDEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (N.J.A.C. 7:28-51.1 (see 10 CFR 30.36).

• Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

- Notifying the NRC of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR Part 21.

Radiation Safety Committee (RSC) (if applicable):
Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

Radiation Safety Officer (RSO):
Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety. Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

a. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

b. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of NJDEP management.

Audits:
Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

a. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

b. Determine if the lack of corrective actions caused the licensee to be in noncompliance with regulatory requirements.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87122

IRRADIATOR PROGRAMS

87122-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

87122-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NJDEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective irradiator radiation safety program:

02.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR 20) limits.

02.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 FE-6 The licensee should ensure that workers are:

a. Knowledgeable of radiation uses and safety practices;

b. Skilled in radiation safety practices under normal and accident conditions; and,

c. Empowered to implement the radiation safety program.

02.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure:

a. Awareness of the radiation protection program;

b. That audits for ALARA practices are performed; and,

c. That assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

Usually the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, repetitive violations, or high radiation exposures.

87122-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. Each of the following elements should be reviewed as appropriate, during each irradiator inspection. If the inspector identifies a concern while reviewing any of the following elements, they should closely examine the licensee's actual implementation of that respective portion of the radiation safety program to identify any potential violations or other regulatory concerns. If the inspector has not identified any concerns relating to the items described in the following sub-elements, the inspector may conclude that the licensee's performance is adequate for that particular element. The inspector has the flexibility, and is expected to, examine other related aspects of the licensee's program if during the examination of these elements, the inspector develops an additional radiation safety concern. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection.

Common elements to all inspections include inspection preparation, entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys, and the evaluation of program scope and any special license conditions.

Some of the following areas may not be applicable to all irradiator licensees. In particular, many of the following elements and requirements will not be applicable to self-contained dry-source-storage irradiator licensees. Also, references to N.J.A.C. 7:28-56.1 (see 10 CFR 36) requirements only apply to irradiators for which the dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources.

Specific Guidance

03.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C.7.:28-6.1 (see 10 CFR 20) limits.

Security:
Through direct observation and licensee staff interviews, determine that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

If any entrance or area is found to be unsecured, determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

If entrances or other areas are found to be unsecured, examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be under constant surveillance or physically secured.

Facilities:
Through direct observation and licensee staff interviews, verify that the irradiator facility is configured in accordance with the design and performance requirements found in N.J.A.C. 7:28-56.1 (see Subpart C of 10 CFR 36). Specifically, verify by the performance of interlock checks that access to the irradiator is controlled pursuant to N.J.A.C. 7:28-56.1 (see 10 CFR 36.23).

NOTE: Some irradiator licensees, in particular those using converted teletherapy units, have received exemptions from some of the safety systems described in N.J.A.C. 7:28-56.1 (see Subpart C of 10 CFR 36). Usually these exemptions are granted based on administrative procedures committed to by the licensee. Inspectors should check the license to ensure that the administrative commitments on which these exemptions were granted are actually implemented by the licensee and are effective.

Verify that the mechanisms to control source movement meet each of the requirements of N.J.A.C. 7:28-56.1 (see 10 CFR 36.31). If the product moves on a conveyor system, verify that the source rack and movement mechanism are protected by a barrier or guide, as required by N.J.A.C. 7:28-56.1 (see 10 CFR 36.35).

Receipt and Transfer of Licensed Material:
Through direct observation and licensee staff interviews, assess the adequacy of the licensee's package receipt practices implemented in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1906(e)). Irradiator facilities do not receive or transfer licensed material on a routine basis. Such activities are usually limited to source loadings or exchanges.

If the inspector is present at the time of the receipt of sources:

a. Determine that packages received at the licensee's facility are properly secured at all times in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1801 and 1802).

b. Assess, through observation of actual or simulated surveys, the adequacy of the licensee's performance of radiation measurements, that required wipe tests are properly evaluated and that the licensee has procedures for handling packages where survey results are above regulatory limits.

c. Determine that the incoming packages are checked for damage, and that the licensee has appropriate procedures for the handling of damaged packages.

d. Verify that the licensee is receiving packages and making transfers of licensed material in accordance with NJDEP and applicable U.S. Department of Transportation (DOT) regulations and license conditions.

Authorized Uses:
Through the observation of licensed activities, verify that the licensee's use of byproduct material is limited to that which is authorized in the license.

Physically examine the inventory of radioactive material on hand (e.g., check for any sources that may have fallen off the source rack). To the extent practical, ensure by physical confirmation that the licensee's inventory is complete and accurate.

If the inspector believes that there is reason to suspect that all irradiator sources have not been accounted for, perform a more detailed assessment of the licensee's accounting system. For example, a beam-type facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a facility with a pool irradiator with multiple sources will need a sophisticated accounting system, for all licensed material, that provides accurate information on the receipt, location, the quantity used and disposed of, and the amount transferred to other laboratories operating under the same license. In both types of accounting systems, the licensee should perform routine physical audits to ensure the accuracy of the system.

Loading, Unloading, and Repositioning of Sources:
Verify that loading, unloading, and repositioning the sources are performed by either the licensee or an organization specifically authorized by the NJDEP, USNRC or other Agreement State to perform these operations, per the requirements in N.J.A.C. 7:28-56.1 (see 10 CFR 36.13(g)). If the licensee performs these operations, the procedures used must be authorized in the license. If the licensee loads, unloads, or repositions sources, interview personnel who are authorized to perform the operations, to determine that contamination surveys of the shipping cask, radiation monitoring during operations, and (not a N.J.A.C. 7:28-56.1 requirement) recording of the location of each individual source placed in the source rack are performed. Review the survey records to confirm that the surveys were performed.

Leak Tests:
Verify that tests for leaking sources are performed in accordance with the manufacturer's recommendations, the requirements of N.J.A.C. 7:28-56.1 (see 10 CFR 36.59) , and/or the license. Verify that the leak test is analyzed in accordance with the license.

If there has been any indication of a leaking source, verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination, in accordance with N.J.A.C. 7:28-56.1 (see 10 CFR 36.59(c)). Consider taking confirmatory pool-water samples.

Ensure that the licensee has performed the following:

a. cleanup and cooling system operated as required by license;

b. demineralizers are operated and maintained in accordance with license conditions;

c. pool-water level and quality are maintained in accordance with license conditions; and

d. radiation monitor activates alarm N.J.A.C. 7:28-56.1 (see 10 CFR 36.59(d)).

03.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment

Shielding:
Verify that the shielding meets the requirements of N.J.A.C. 7:28-56.1 (see 10 CFR 36.25). Several independent measurements to confirm the licensee's survey data are acceptable verifications. Special emphasis should be given to areas where ducting or wire ways pass through shielding, edges of walls and doors where shielding overlaps, and where visible defects/cracks appear in the walls. Shield surveys should be completed before initial operation, after source exchange or modification, and at intervals not to exceed 3 years N.J.A.C. 7:28-56.1 (see 10 CFR 36.57(a))Verify that dose rates conform to the requirements specified in N.J.A.C. 7:28-56.1 (see 10 CFR 36.25 (a) and (b)).

Verify that the licensee has established and implemented procedures to identify and report safety component defects per the requirements of 10 CFR Part 21.

Area Surveys:
Verify, during observations and by direct measurements, that the radiation dose rates around the facility are within the limits of N.J.A.C. 7:28-6.1 (see 10 CFR 20) and N.J.A.C. 7:28-56.1 (see 10 CFR 36.25). The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation. However, the inspector must use NJDEP's instruments for independent verification of the licensee's measurements. If practical, observe how licensees conduct surveys, to determine the adequacy of surveys. Also, note the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured. The survey activities should be at a specified frequency in accordance with the related licensee procedures.

Equipment:

Verify that equipment and procedures comply with the requirements in N.J.A.C. 7:28-56.1 (see 10 CFR 36.23, 36.31 and 36.37). Verify that equipment and instrumentation are appropriate, operable, calibrated, adequately maintained, and conform to those described in the license.

If it is determined that equipment is not operable or appears to be inadequately maintained, verify that the licensee has established procedures to perform the inspection and maintenance requirements of N.J.A.C. 7:28-56.1 (see 10 CFR 36.61). Verify that non-routine operations (e.g. repairs) are performed by authorized personnel (licensee or others). Procedures and their implementation (practices) must be consistent with license commitments.

Equipment and instrumentation should be appropriate to the scope of the licensed program. All sampling and monitoring instruments should have current calibrations appropriate to the types and energies of radiation to be detected. The technical adequacy of calibration procedures at facilities that perform their own calibrations should be examined. Processing equipment, ventilation, and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use. An operable, calibrated, conductivity meter should be available.

Verify that the licensee has procedures to perform the inspection and maintenance requirements of N.J.A.C. 7:28-56.1 (see 10 CFR 36.61). The licensee should have a procedures manual for performing the inspections, as well as a log book, of the outcomes of the inspections, that can be reviewed. Procedures, as well as practices (as determined by review of records and interviews of staff), for maintenance, repair, modification, or replacement of equipment affecting safe operation of the facility must be consistent with licensee commitments regarding what will be done by licensee personnel (and the training to be provided for such activities) and what functions will be conducted by outside personnel (equipment manufacturers or others).

03.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

Fire Protection:
Verify that the fire protection requirements of N.J.A.C. 7:28-56.1 (see 10 CFR 36.27) are met. Discussions with the operators regarding the systems and procedures in the event of fire, and observations of the detectors, alarms, and fire extinguishing systems are acceptable verifications.

Ozone:
The inspector should be aware of the potential health hazard of ozone within the radiation facility. Irradiators with large sources are typically equipped with ventilation systems to exhaust ozone (and nitrogen oxides), produced by irradiation of air. Such facilities could be expected to also have operative ozone monitors as well as procedures to restrict access of personnel to areas when ozone concentrations exceed limits established by the Occupational Safety and Health Administration (OSHA). Also, note that ozone can be detected by odor at a concentration which is 15% of the

OSHA concentration limit; ozone odor does not necessarily indicate that an air concentration of ozone warranting concern is present. Concerns in this area should be referred to OSHA.

Transportation:
The inspector should review: the licensee's hazardous material training; packages and associated documentation; vehicles (including placarding, cargo blocking, and bracing, etc.); shipping papers; and any incidents reported to Department of Transportation (DOT). Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with N.J.A.C. 7:28-61.1 (see 10 CFR 71) and DOT regulations for transportation of radioactive materials.

03.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

Personnel Dosimeters:
Through observation, verify that personnel dosimetry devices are worn by appropriate licensee personnel in accordance with N.J.A.C. 7:28-56.1 (see 10 CFR 36.55). Dosimetry devices appropriate to the type, energy, and the anticipated radiation fields must be issued to licensee personnel. Verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited processor. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

Radiation Doses:
Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

> If any such incident or unusual occurrence took place, review and evaluate the licensee's actions. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NJDEP.
>
> For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed a sufficient investigation to identify the cause of the incident, and took appropriate corrective actions to prevent recurrence of the situation leading to the incident or unusual occurrence.

Reports:
N.J.A.C. 7:28-50.1 (see 10 CFR 19.13(b)) requires that each licensee shall advise each worker annually of the worker's dose as shown in dose records maintained by the licensee. Verify, through

discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all the information required in N.J.A.C. 7:28-50.1 (see 10 CFR 19.13(a)).

Public Doses:
Examine the licensee's evaluation or documentation to demonstrate compliance with dose limits for individual members of the public N.J.A.C. 7:28-6.1 (see 10 CFR 20.1302).

03.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

Instruments:
Radiation protection instrumentation should be appropriate to the scope of the licensed program. Verify that portable survey instruments are available, have the appropriate range of use and are used in accordance with the requirements. Verify that area radiation monitors required by N.J.A.C. 7:28-56.1 (see 10 CFR 36.23 (c), 36.29, 36.39 (e), 36.41 (e), and 36.59 (b)) are appropriate, operable; have the proper alarm settings (if applicable), are adequately maintained and conform to the requirements.

Calibrations:
Verify that the survey instruments are calibrated at least annually and in accordance with the requirements in N.J.A.C. 7:28-56.1 (see 10 CFR 36.57(c)). All survey, sampling, and monitoring instruments should have current calibrations appropriate to the types and energies of radiation to be detected. Survey instruments must be calibrated and checked for appropriate response in accordance with N.J.A.C. 7:28-56.1 (see 10 CFR 36.55(b) and 36.57(c)) and licensee procedures. The inspector may choose to examine the instrument calibration records (efficiency checks, lower-limit-of-detection calculations, etc.); physical location of counting instruments; methods of detection; and pool-water-sample locations.

Inspection and maintenance:
Verify that the licensee has established procedures to perform the inspection and maintenance requirements of N.J.A.C. 7:28-56.1 (see 10 CFR 36.61) with regard to radiation monitors. Verify that non-routine operations (e.g. repairs) are performed by authorized personnel (licensee or others). Procedures and their implementation (practices) must be consistent with license commitments.

03.06 FE-6 The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

Authorized Operators:

Verify through observations and interviews that the operators have knowledge commensurate with operational duties. (An example of an activity to observe is entering and leaving the radiation room, with requirements of this activity listed in N.J.A.C. 7:28-56.1 (see 10 CFR 36.67)). Authorized operators should be trained in accordance with the approved license criteria. The instruction, testing, training, periodic safety reviews and safety performance evaluations required for individuals operating an irradiator without a supervisor present are listed in N.J.A.C. 7:28-56.1 (see 10 CFR 36.51). Also listed in that section are training requirements for individuals permitted unescorted access to irradiators and for individuals who must be prepared to respond to alarms. If, during the course of observations or interviews, a situation develops that causes the inspector to question the quality the staff's knowledge, verify that appropriate training and initial instructions have been accomplished as specified in the license and/or regulations.

Review examples of tests and scoring to determine that relevant topics of NJAC 7:28-56 are effectively covered in the training program. Ascertain the licensee's method of reinstructing and retesting those operators who do not initially pass the testing.

Also, verify that the licensee is conducting operator safety reviews and safety performance evaluations at least annually as required by N.J.A.C. 7:28-56.1 (see 10 CFR 36.51(d) and 36.51(e). Non-authorized operators may only operate the irradiator in the presence of a supervisor who is an experienced authorized user. Determine that the authorized operators are personally performing or, if permitted in the license, supervising the work of non-authorized operators.

General Training:
Also interview workers other than operators to verify that, pursuant to N.J.A.C. 7:28-50.1 (see 10 CFR 19.12), instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Individuals should understand the radiation protection requirements associated with their assigned activities. Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NJDEP regulations and the license and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns. If any concerns are identified regarding the level of knowledge of staff, examine records of training and attendant examinations or tests (if applicable) to the extent that the inspector is satisfied that the training program is being implemented as required. Where examinations are required, read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities.

Operating and Emergency Procedures:
Verify that operational procedures are being followed by observing licensee personnel perform tasks at selected work stations and by a comparison of their activities with established procedures.

If concerns are identified regarding a specific procedure or task, examine the licensee's written procedures to determine that these procedures are as approved by NJDEP.

With regard to emergency procedures, verify that licensee personnel understand and implement the established procedures and are aware of any procedural revisions. When applicable, discuss with the licensee's representatives, or observe, the conduct of periodic tests and drills, especially for scenarios involving fires and large releases of radioactive material. Some licensees may have agreements with other agencies (i.e., fire, law enforcement, and medical organizations) regarding response to emergencies,. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

Posting and Labeling:
Verify that proper caution signs are being used at access points to areas containing licensed materials and radiation areas as required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902). Also randomly examine signals and alarms to determine operability and audibility at occupied locations, per N.J.A.C. 7:28-56.1 (see 10 CFR 36.23(b).

[Note: Do not perform tests of systems that may result in unnecessary radiation exposure to NJDEP or licensee personnel. Instead of actual tests, look for evidence of radiation effects damage to wiring and warning lights.]

Also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded. Examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

The NJDEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NJDEP regulations and license provisions and to terminate unsafe activities involving byproduct material.

Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

• Maintaining awareness of significant events such as the loss or theft of licensed materials.

• Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.

• Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.

• Obtaining the NJDEP's prior written consent before transferring control of the license;

• Notifying the NJDEP Radioactive Materials Section in writing, immediately following filing of petition for voluntary or involuntary bankruptcy N.J.A..C. 7:28-51.1 (see 10 CFR 30.34(h)).

• Assuring the appropriate response, when applicable, to generic communications from the NJDEP.

• Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities N.J.A.C. 7:28-51.1 (see 10 CFR 30.35).

• Notifying the NJDEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place N.J.A.C. 7:28-51.1 (see 10 CFR 30.36).

• Notifying the NRC of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21.

• Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

Radiation Safety Committee (RSC) (if applicable):
Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

Radiation Safety Officer (RSO):
Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is

knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety. Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

a. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

b. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of NJDEP Radioactive Materials Section.

Audits:
Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.2102(a)(2)). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

a. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

b. Determine if the lack of corrective actions caused the licensee to be in noncompliance with regulatory requirements.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87123

WELL LOGGING PROGRAMS

87123-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

87123-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NJDEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective well logging radiation safety program:

02.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (10 CFR 20) limits.

02.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 FE-6 The licensee should ensure that workers are:

a. Knowledgeable of radiation uses and safety practices;

b. Skilled in radiation safety practices under normal and accident conditions; and,

c. Empowered to implement the radiation safety program.

02.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;

b. That audits for ALARA practices are performed; and,

c. That assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

Usually the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, repetitive violations, or high radiation exposures.

87123-03 INSPECTION GUIDANCE:

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual Focus Elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the NJDEP's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem. An examination of the licensee's records should not be considered the primary part of the inspection program. In the records reviewed, look for trends such as increasing doses. Records such as surveys, waste disposal, receipt and transfer of licensed materials, training, and utilization logs, may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail.

Common elements to all inspections include preparation, entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys, and the evaluation of program scope and any special license conditions. Each of the following Focus Elements should be reviewed during each inspection of all well logging licensees. Inspectors should select sub-elements for review that are representative of the licensee's scope of use. If the licensee is using byproduct material at a temporary job site, then the inspector should consider those activities for the review of each Focus Element.

Specific Guidance

03.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR 20) limits.

Facilities:
Through direct observation, verify that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities (if the licensee has used unsealed materials for subsurface tracer studies), etc.

a. If any entrance or area is unsecured, determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

b. If entrances or other areas are unsecured, examine areas where radioactive materials are used and stored. Storage areas must be locked and have limited and controlled access. Radioactive material use areas must be under constant surveillance or physically secured.

Through observations, verify that use and storage areas, including radioactive waste storage facilities (if the licensee has used unsealed materials for subsurface tracer studies), are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas must be physically secured when unattended.

Observe the licensee's operation at a temporary job site. This inspection should be unannounced. If possible, make arrangements with licensee management or the licensee's client to observe the licensee's field operations before announcing your presence. Through interviews of other workers who are present at the field site, determine their understanding of the licensee's access control. Although these workers may not have or need any knowledge of the licensee's operations, if they were informed of the licensee's operations, i.e., to maintain a practical safe distance from licensed operations, this would be an indication of the licensee's good safety practices. As non-licensees, such persons have no obligation to cooperate with the NJDEP.

a. If other workers are unaware of basic radiation safety practices, determine if the licensee failed to provide instructions. Assess the role of other workers at the field site and the potential for radiation exposures of unacceptable consequence to other workers.

Receipt and Transfer of Licensed Materials:
Through observations and interviews of licensee personnel, verify that the licensee:

a. properly secures package receipt areas, such as loading docks or other shipping and receiving areas;

b. inspects packages for damage;

c. performs appropriate package receipt surveys;

d. opens packages in a safe manner;

e. assures that packages are properly prepared for transport; and

f. controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If unable to observe the receipt of packages, request that personnel who normally receive packages for the licensee to demonstrate package receipt processes and surveys.

If packages are left unattended, assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in FE-5.

Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Physical Inventory:
Through observation, physically examine the inventory of radioactive material on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license, including Sealed Source and Device (SS&D) registry limits.

a. Assess how the licensee ensures that only registered SS&D combinations are used.

b. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license. For example, a licensee may not use sealed sources in a well without a surface casing or inject licensed material into a fresh water aquifer except as specifically authorized by the NJDEP.

c. Verify that the inventory, including radioactive markers N.J.A.C. 7:28-57.1 (see 10 CFR 39.37, 39.47) is complete.

Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.

a. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NJDEP.

b. For incidents or unusual occurrences that were not required to be reported, determine that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

c. Verify that the licensee has adequate procedures in place for the abandonment of irretrievable sources. Verify that the licensee has a written agreement with the well owner/operator for recovery or abandonment of sources N.J.A.C. 7:28-57.1 (see 10 CFR 39.15).

03.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

Routine and Non-Routine Maintenance
Through interviews of licensee staff and observation of the licensee's equipment, verify that the licensee has inspection and maintenance programs required under N.J.A.C. 7:28-57.1 (see 10 CFR 39.43) and that associated records of defects are available. The equipment items involved in the program should include source holders, logging tools, uranium sinker bars, source-handling tools, storage containers, and transport containers. The program should ensure that no physical damage is visible and that the required labeling is legible. Physically examine a representative sample of source handling tools to determine their condition and their ability to adequately secure a source during transfer to and from its source storage container. Physically examine source storage containers to ensure that they are in good condition and that design safety features function as intended.

If licensee staff did not check well logging equipment each day before use and semiannually or if physical damage is evident or illegible labels are apparent, assess the licensee's process for completing the checks. Determine how the licensee failed to implement the written procedure.

If unauthorized individuals removed sealed sources from source holders or logging tools, assess the licensee's process for dismantling well logging equipment and the potential for radiation exposures. Determine how the licensee failed to implement the written procedure.

If individuals were not specifically approved by NJDEP, USNRC, or other Agreement State to open, remove, or modify a sealed source or to remove (e.g., chisel, drill, or cut) a stuck sealed source from the source holder, assess the licensee's process for performing the operation and the

potential for radiation exposures. Determine how the licensee failed to obtain approval from NJDEP.

Area Radiation Surveys:
Through interviews of selected licensee personnel, including the RSO, verify specifically that schedule and procedural requirements for surveys are adequate to demonstrate compliance with the regulations and with pertinent license requirements. Determine whether due consideration is given to gamma and neutron emissions from the radionuclides involved, and to total body exposure and extremity exposure. Verify that the licensee has established schedules for periodic surveys of work and storage areas of the facility site. Observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys. Review a random selection of survey records to verify that surveys are performed according to schedules; assess that the survey results are reviewed by an appropriate supervisor and that corrective actions have been taken, as appropriate. Request that licensee personnel spot-check radiation levels in selected areas using the licensee's instrumentation. Compare the results with those obtained using the NJDEP's instruments.

03.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

The inspector should be attentive to potential industrial safety hazards for referral to the U.S. Department of Labor's Occupational Safety and Health Administration (see Manual Chapter 1007). The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

Operational Limits:
Verify that well logging sources are used in accordance with any operational limits described in the applicable SS&D sheet. Sources have limits for temperature, pressure, corrosive chemical exposure, etc. Also, inspectors should assess that sources in storage are protected from fire (see "Fire Protection" below) and the elements, that package integrity is appropriately maintained, and that controls are in effect to minimize the risk from other hazardous materials.

Temporary Job Site Hazards:
During inspections of licensed activities at temporary job sites, verify that licensee personnel ensure that sources are protected from heavy equipment; such as cranes, drill pipe, etc.; welding equipment; high voltage lines; and other industrial hazards.

Fire Protection:
In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensees facilities, be alert to potential fire hazards. An effective licensee fire protection program should:

1) prevent fires from starting,

2) rapidly detect, control, and extinguish those fires that do occur, and

3) provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public. Through observation and discussion with the licensee, while touring the facilities, assess fire safe conditions and equipment, i.e., that:

a. work areas are generally uncluttered and free of combustible debris,

b. incompatible materials (i.e., materials labeled as "corrosive", "flammable", or "oxidizer") are isolated from each other and enclosed by fire resistant barriers,

c. fire detection systems are operable,

d. fire suppression systems are operable,

e. portable fire extinguishers are unexpired (check maintenance tags),

f. electric switches and electric motors are explosion-proof, arc welders or open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive chemicals, and that

g. the local fire department is involved with the licensee's fire protection program.

Through observations and discussions with licensee staff, assess that:

1) radioactive waste is protected from fire and the elements,

2) package integrity is appropriately maintained,

3) the storage area is ventilated, and

4) controls are in effect to minimize the risk from other hazardous materials.

Any problems/deficiencies noted should be promptly brought to the licensee's attention and discussed with NJDEP Radioactive Materials Section. Licensees should be practical in approaching the safety of the device in the event of fire. They should not endanger themselves to protect the source, but should be able to provide radiological hazard information to emergency medical and fire personnel who respond to the fire.

Transportation:

Verify that licensed material is packaged and transported (or offered for transport) in accordance with N.J.A.C. 7:28-61.1 (see 10 CFR 71) and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.

Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers.

If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs) issued by the NRC. The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

If the licensee reported any transportation incidents, review the licensee's actions in response to the incidents.

In the case where a licensee may have transferred a source to a burial site for offsite disposal, review the licensee's procedures and records to verify that each shipment is accompanied by a shipment manifest that includes all the required information. Also review the licensee's procedures and records to verify that each package intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of N.J.A.C. 7:28-59.1 (10 CFR 61.55 [Subsection III.A.2 of Appendix G to Part 20]. Verify that records are maintained that demonstrate compliance with the requirements for the disposal of licensed materials.

03.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

Personnel Dosimetry:

Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes.

If the licensee monitors worker exposures (internal and external), notwithstanding a prospective analysis indicating that monitoring was not required, review selected reports of monitoring results. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

a. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one worker consistently receives significantly more exposure than all other workers each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.

b. Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.

Through interviews of workers and observations of activities in progress, verify that radiation monitors are worn appropriately and are recording the highest dose for which they are intended.

a. If monitors are not (or cannot be) worn in the most appropriate location to record the highest dose received by the individual(s), through interviews of the RSO, verify that the licensee has performed assessments (through surveys, calculation, or both) of occupational exposures received and adjusted the dose of record for the worker(s).

b. Review the results of the licensee's assessment and verify the assumptions and outcomes. Verify that the dose of record for the affected worker(s) has been adjusted and that the adjusted dose is within the applicable regulatory limit and ALARA.

Through interviews of the RSO and review of records of external monitoring results, determine whether processing (collection, process, and assessment) of monitoring devices is being performed in a timely manner.

Through interviews of the RSO and workers who handle volatile radionuclides (i.e., radioiodine), verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies. [Note–the unsealed radionuclides used for subsurface tracer studies are generally non-volatile.]

Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

a. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NJDEP.

b. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

Contamination Control:

Through interviews of selected licensee staff, including the RSO, the inspector should verify that personnel have an adequate understanding of the procedures to be followed in the event that the licensee's sources are ruptured or licensed materials have caused contamination. Occasionally, well logging tools containing sources become lodged, or otherwise immobilized in the well. When this happens, operations are initiated to retrieve the tools from the well. The inspector should verify that the drilling fluids (mud) are monitored for radioactive materials whenever retrieval operations are ongoing.

Note that, the licensee is required to make radiation surveys of each area where licensed materials are used and stored. In particular, the licensee is required to perform a radiation survey at temporary job sites before and after each subsurface tracer study, to confirm the absence of contamination. Licensees must be authorized to knowingly inject radioactive materials into fresh water aquifers. If practical, observe how licensees conduct surveys to determine the adequacy of such surveys. Also, note the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

The inspector should determine if workers take smears or instrument readings in areas that are potentially contaminated and accessible to facility personnel. Particular attention should be given to well heads and storage areas. The inspector should also perform independent measurements, as needed, to verify licensee assumptions or measurements.

Leak Tests:

Through discussions with licensee personnel and/or by demonstration of leak test procedures, verify that leak tests are performed in accordance with the manufacturer's recommendations and/or license. In accordance with N.J.A.C. 7:28-57.1 (see 10 CFR 39.35), verify that the wipe of a sealed source is taken from the nearest accessible point to the sealed source where contamination might accumulate, at intervals not to exceed 6 months (or other frequencies in accordance with the sealed source and device evaluation certificate).

Verify that the licensee's leak test analyses (or that of its leak test services vendor) has sufficient sensitivity to measure 185 Becquerels (0.005 microcurie) for each type of isotope present on its license. Through discussions with licensee staff and/or review of pertinent records, determine if the licensee had a leaking source. If leak test results show contamination in excess of the regulatory limits, verify that the licensee made appropriate notifications, evaluations, and removed the source from service.

03.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (i.e., area and transportation surveys; bioassay and leak test analyses) have been routinely calibrated and maintained.

Survey Instruments:

Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to the NJDEP instrument. Verify that licensee's instrument response is comparable to the NJDEP instrument (+20%).

Through interviews of the RSO and workers, and by observation, determine whether the licensee has a system for tagging out inoperable and out-of-service survey instruments.

Instrument Calibration and Maintenance:

If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the NJDEP to perform that service.

Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Assess that calibrations include a determination of "as found" condition before adjustments are made. Assess that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.

If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."

Bioassay Instruments:

Through observations and interviews of the RSO and workers, verify that the licensee's instrumentation for performing in vivo bioassay measurements is adequate for those measurements. Determine that bioassay probes and scalers are compatible. Determine that licensee staff perform a response check using appropriate sources (such as a barium133 source to simulate iodine-131) and a suitable background measurement before taking bioassay measurements.

Leak Test Analysis:

If the licensee is authorized to both collect and analyze leak test samples, the inspector should determine if the type of counting equipment is appropriate for the samples being analyzed and the sensitivity required. The inspector should determine if the laboratory instrumentation is calibrated for the appropriate geometries of the samples to be analyzed and is routinely checked for proper operation. The licensee should maintain calibration records, control charts, and maintenance and repair records, to demonstrate proper operation of laboratory instrumentation.

03.06 FE-6 The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

Authorized Users:

Authorized users (logging supervisors and logging assistants) may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties.

Through observations and interviews of logging supervisors and logging assistants, assess implementation of radiation safety practices for well logging activities (i.e., loading of sources into tools, leak-testing procedures, maintenance activities). Verify their ability to recognize unsafe radiological conditions and to respond appropriately to emergency situations. Also verify that logging supervisors and logging assistants understand the mechanism for raising safety concerns to licensee managers.

Review selected training records to determine that examinations or tests (if applicable) have been implemented and are appropriate. Read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities. Note that, at a minimum, the licensee is required to provide safety reviews, as defined in N.J.A.C. 7:28-57.1 (see 10 CFR 39.2), for logging supervisors and logging assistants at least once during each calendar year.

General Training:

Verify, pursuant to N.J.A.C. 7:28-50.1 (see 10 CFR 19.12), that initial instructions have been given to workers who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of the storage, transfer, or use of radiation and/or radioactive material; health protection problems associated with exposure to radiation; precautions or procedures to minimize exposure; and the purposes and functions of protective devices employed. The workers should also be informed of the pertinent provisions of NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP requirements.

Operating and Emergency Procedures:

Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures. The emergency procedures will be approved by the NJDEP, and reviewed and updated by the licensee. Any revision requires an amendment to the license. Some licensees may have agreements with other agencies (i.e., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses. Verify that licensee personnel are knowledgeable of the operational procedures by observing the performance of tasks at selected work stations and by a comparison of their performance with established procedures. Determine that the licensee's emergency procedures have been approved by or described to NJDEP. Through discussions with workers, assess that licensee personnel understand and implement the established procedures and are aware of procedural revisions.

Determine the licensee has adequate procedures in place for handling irretrievable, abandoned sources. Through discussions with licensee staff, assess the licensee's handling of tracer materials. Verify, when practical (and when required), that well logging personnel wear appropriate protective clothing during their work activities. Requirements for protective clothing may be found in the licensee's procedures. Assess that all waste items (i.e., empty vials, gloves, napkins, cans, etc.) are appropriately packaged, labeled, and transported from the job site to the licensee's waste storage location, and that the licensee has appropriate methods to track the items in storage.

Posting and Labeling:

Determine that proper caution signs are being used at access points to areas containing licensed materials and radiation areas. The inspector should also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded. Observe locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit

individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

The NJDEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NJDEP regulations and license provisions and to terminate unsafe activities involving byproduct material. Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining the NJDEP's prior written consent before transferring control of the license;
- Notifying the NJDEP Radioactive Materials Section in writing, immediately following filing of petition for voluntary or involuntary bankruptcy N.J.A.C. 7:28-51.1 (see 10 CFR 30.34(h)).
- Assuring the appropriate response, when applicable, to generic communications from the NJDEP.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities N.J.A.C. 7:28-51.1 (see 30.35).
- Notifying the NJDEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place N.J.A.C. 7:28-51.1 (see 10 CFR 30.36).
- Notifying the NJDEP of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR 21.
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

Radiation Safety Committee (RSC) (if applicable):
Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required

frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc. Determine if the committee has been effective in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

Radiation Safety Officer (RSO): Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety. Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

a. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

b. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of NJDEP Radioactive Materials Section.

Audits:

Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with NJAC 7:28-8.2. Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

a. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

b. Determine if the lack of corrective actions caused the licensee to be in noncompliance with regulatory requirements.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87124

FIXED AND PORTABLE GAUGE PROGRAMS

87124-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

87124-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NJDEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

The inspector should determine if the licensee possesses licensed material as authorized by a general license. If so, the inspector should assess the adequacy of licensee's program for management and oversight of the generally licensed material.

The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective fixed or portable gauge radiation safety program:

02.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR 20) limits.

02.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 FE-6 The licensee should ensure that workers are:

a. Knowledgeable of radiation uses and safety practices;

b. Skilled in radiation safety practices under normal and accident conditions;

c. And, empowered to implement the radiation safety program.

02.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure:

a. Awareness of the radiation protection program;

b. That audits for ALARA practices are performed; and,

c. That assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

87124-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the NJDEP's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem.

An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records alone.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of licensed materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail. Common elements to all inspections include entrance and

exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent confirmatory surveys, and the evaluation of program scope and any special license conditions.

Each of the following elements should be reviewed as appropriate during each inspection of a fixed and portable gauge licensee.

Specific Guidance

03.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR 20) limits.

Facilities:
Through direct observation, verify that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

> If any entrance or area is unsecured, determine, through interviews of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.
>
> If entrances or other areas are unsecured, observe other areas where radioactive materials are used and stored and verify that they are locked and have limited and controlled access. Radioactive material use areas must be under constant surveillance or physically secured.

Through observations, verify that use and storage areas are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas should be physically secured when unattended.

Evaluate licensee practices regarding access controls including control of keys and access codes to ensure only currently authorized individuals have access to licensed materials.

Licensed material in use must be controlled and under constant surveillance. Portable gauges must be under constant surveillance when at a temporary job site. For fixed gauges in use, constant surveillance is not required, provided that the licensee has adequate facility security and effective procedures for ensuring that gauges are not removed by unauthorized personnel.

Determine the adequacy of the licensee's procedures for securing licensed materials at temporary job sites. Evaluate licensee's procedures for securing gauges that are not in use at temporary job sites. Evaluate how the licensee secures gauges that are in transport, including securing gauges in

a licensee vehicle when that vehicle is parked in a restaurant, hotel, or similar facility. Verify that either the gauge's transport case or operating handle is locked when the device is packaged for transport.

Receipt and Transfer of Licensed Materials:
Through observations and interviews of licensee personnel, verify that the licensee:

a. properly secures package receipt areas, such as loading docks or other shipping and receiving areas;

b. inspects gauge shipping containers for damage;

c. performs appropriate receipt surveys;

d. opens packages in a safe manner;

e. assures that packages are properly prepared for transport; and

f. controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If possible, observe the receipt of packages. Otherwise, request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

If packages are left unattended, then assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, then interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in FE-5. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Inventory Control:
Through observation, physically examine the inventory of gauges on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license. Compare the possession of gauges with inventory records. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license. Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.

a. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview

of the RSO and review of event reports that a complete and timely report was made to the NJDEP.

b. For incidents or unusual occurrences that were not required to be reported, determine whether the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

Equipment:
The SS&D sheet specifies the type of safety features installed on the device and specifies the frequency at which these features should be inspected for proper operation. Fixed gauges operated in high temperature environments may require supplemental cooling systems that have inspection and maintenance requirements. Ensure devices are used in accordance with any operating limits (such as temperature and vibration limits) described on the applicable SS&D sheet. Verify that engineered safety features (such as shutters, locking mechanisms, or interlocks) are appropriate, operable, calibrated, adequately maintained, and conform to the description in the applicable SS&D sheet. Ensure that the facility provides protection of shield integrity, including fire protection. Licensees should have copies of, or access to, these SS&D Certificates, in addition to the manufacturers' manuals for operation and maintenance.

Process or Other Engineering Controls:
Verify that, where applicable, that the licensee uses processes or other engineering controls to maintain doses as low as is reasonably achievable (ALARA). For example, fixed gauge licensees may install protective cages around the area where a gauge is mounted to prevent inadvertent access to the radiation beam.

Routine and Non-Routine Maintenance:
Confirm that any maintenance of gauges is performed in accordance with the applicable manufacturer's maintenance procedures. Maintenance procedures must include ALARA provisions, and ensure that the gauge functions as designed and the source integrity is not compromised. For portable gauges, routine maintenance may include the cleaning and lubrication of the source rod and shutter mechanism (e.g., to remove caked dirt, mud, asphalt, or residues from the source rod; lubricate the shutter mechanism). For fixed gauges, routine maintenance is normally limited to cleaning of the gauge housings to ensure that required labels remain legible. More extensive maintenance or servicing (beyond routine cleaning and lubrication) that involves detaching the source or source rod from portable gauges must be performed by the gauge manufacturer or a person specifically authorized by the NJDEP. Persons performing installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed source, and non-routine maintenance or repair of components related to the radiological safety of fixed gauges (i.e., the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, shielding) must be authorized by the NJDEP, USNRC or other Agreement State. The license will contain a condition if the licensee is authorized to perform these activities.

03.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health administration. The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

Operational Limits:
Verify that gauges are operated in accordance with any operating limits (i.e., heat, vibration, corrosive materials, or other industrial or environmental hazards) described on the applicable SS&D sheet. Determine whether fixed gauges are installed in accordance with the limiting conditions described in the sealed source and device catalog certificate and by the device manufacturer (i.e.: temperature, vibration, etc.). Verify that gauges in storage are protected from fire and the elements and that adequate controls are in effect to minimize the risk from other hazardous materials. Verify that radiological labeling is clearly visible and legible.

Temporary Job Site Hazards:
During inspections of licensed activities at temporary job sites, verify that licensee personnel ensure that devices are protected from heavy construction equipment, welding equipment, high voltage lines, and other industrial hazards.

Fire Protection:
Materials licensees are not required by NJDEP regulations to implement a fire protection program. However, in many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. Determine if licensees have a plan in place for preventing fires and combating fires that might occur. Any perceived problems/deficiencies (i.e., improper storage of combustible or flammable material, fire extinguishers out of service, lack of fire alarm or detection system, lack of fire suppression system) noted by the inspector should be brought to the licensee's attention and discussed with NJDEP Radioactive Materials Section. Proper fire protection systems can be evidenced by the licensee's involvement with the local fire department.

Transportation:
Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with N.J.A.C. 7:28-61.1 (see 10 CFR 71) and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials. Examine: packages and the associated certification documentation; vehicles (including cargo blocking and bracing, and gauge security); and, shipping papers. Review any incidents required to be reported to the DOT.

03.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities.
These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams. Verify that the licensee has performed adequate surveys to show compliance with public dose limits and that conditions in controlled areas and unrestricted areas meet the requirements specified for these areas.

For most fixed and portable gauge licensees, occupationally exposed workers are not likely to receive annual doses in excess of ten percent of the applicable limit in N.J.A.C. 7:28-6.1 (see 10 CFR 20). Therefore, these licensees are not normally required to implement a radiation dosimetry program. In these instances, evaluate the licensee's demonstration that personnel are not likely to receive in excess of ten percent of the N.J.A.C. 7:28-6.1 (see 10 CFR 20) occupational dose limit. In all cases, if a licensee does not provide personnel monitoring devices, it must have a documented prospective evaluation of occupational exposure that demonstrates that monitoring is not required. Dosimetry devices must be appropriate to the type, energy, and the anticipated radiation fields must be issued to licensee personnel when monitoring is required. Verify that any dosimeters that require processing to determine the radiation dose, are processed by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited processor.

Verify that the licensee annually advises each worker, who is required to be monitored, of the worker's dose as shown in records maintained by the licensee.

For most fixed and portable gauge licensees, extensive evaluations of doses received by members of the public from licensed activities may not be necessary. Verify that the use and storage of gauges will not likely result in exposures to members of the public or radiation levels in unrestricted areas that are in excess of the regulatory limits. For storage areas that located adjacent to unrestricted areas, licensees must ensure (through measurement or calculation) that doses in the unrestricted areas do not exceed 2 millirem (mrem) in any one hour or 100 mrem in a year the maximally exposed member of the public.

Area Surveys:
Most fixed and portable gauge licensees are not required to perform routine surveys. Surveys of fixed gauges are required when the licensee (or its licensed contractor) installs, removes, or relocates a gauge. Generally, portable gauge licensees are only required to perform surveys if they are authorized to perform maintenance involving the removal of the source rod, or the device's shielding. If practical, observe how licensees conduct any required surveys to determine the adequacy of such surveys. Note the types of any instruments used, and whether they are designed and calibrated for the type of radiation being measured. (See FE-5)

Leak Tests:
Verify that leak tests of sealed sources are performed at the required frequency. Also verify that leak test samples are analyzed in accordance with the license requirements. If records of leak test results show contamination in excess of the regulatory requirements, then verify that the licensee made appropriate notifications and removed the source from service.

Storage and Disposal of Gauges Removed From Service:
Determine if the licensee has gauges that have been removed from service. Verify that the gauges are stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed the limits of N.J.A.C. 7:28-6.1 (see 10 CFR 20.1301, "Dose Limits for Individual Members of the Public.") Licensee personnel should be aware of the presence of the device and the need to prevent unauthorized disposal or abandonment. Typically, gauge licensees dispose of devices either by returning the device to the manufacturer or by transfer to another appropriately licensed person. Verify that any person that the licensee has transferred gauges to was properly licensed to receive them. Also assess the licensee's procedures and records to verify that each package intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of N.J.A.C. 7:28-59.1 (see10 CFR 61.55 [Subsection III.A.2 of Appendix G to Part 20].

03.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

Gauge licensees should either possess, or have access to radiation survey equipment. Equipment and instrumentation should be appropriate to the scope of the licensed program.

Verify that the instrumentation has the appropriate range of use. Also verify that the survey instruments are calibrated at the appropriate frequency and checked for operability before use. Survey and monitoring instruments must be appropriately calibrated for the types and energies of radiation to be detected.

03.06 FE-6 The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

Authorized Users:
Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties. Typically, successful completion of one of the following is considered as evidence of adequate training and experience for operating gauging devices:

a. Gauge manufacturer's course for users; or

b. Equivalent course that meets Appendix D criteria in either NUREG 1556, volume 1, Program-Specific Guidance About Portable Gauge Licenses" or NUREG 1556, volume 4, Program-Specific Guidance About Fixed Gauge Licenses"

Authorized users are required to either be physically present or to otherwise supervise the use of gauges. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as " . . . used by or under the supervision of . . . " For some licenses that have the condition " . . . under the direct supervision of . . . ," the authorized user must be physically present at the facility for easy contact or to observe the individual(s) working. Another phrase used is " . . . may only be used by . . . " Finally, " . . . under the direct supervision and physical presence of . . . " means the authorized user must directly supervise and be present at the work station. Considering the many license condition phrases, the inspector must exercise judgment to interpret the role of the authorized users.

When the wording of the license condition is " . . . used by or under the supervision of . . . ," an authorized user named on the license is considered to be supervising the use of licensed materials when he or she directs personnel in the conduct of operations involving the licensed material. This does not imply that the authorized user must be present at all times during the use of such materials. The authorized user is responsible for assuring that personnel under his/her supervision have been properly trained and instructed and is responsible for the supervision of operations involving the use of licensed materials, whether he or she is present or absent.

General Training:
Determine that appropriate training and initial instructions are being accomplished as specified in the license and/or regulations. The inspector must verify that appropriate training is provided to authorized users (including the RSO), other persons using licensed materials, and other licensee employees who may have unescorted access to licensed materials or to restricted areas. The requirements for certain kinds of training and instruction are found in the regulations, while the procedures for their implementation are generally found in the procedures included in the license's "tie-down" condition.

Discuss with the licensee how, and by whom, training is conducted, and the content of the training provided to workers (generally found in the license application). Generally, most gauge licensee employees are not likely to receive an occupational dose of more than 1 mSv (100 mrem) in a year. The only exception would likely be a licensee that performs an extensive amount of maintenance on it's own gauges. Verify that initial instructions have been given to workers, if any, who are likely to receive more than 1 mSv (100 mrem) in a year. For this kind of training, it is the licensee management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

Through interview of one or more users of radioactive materials (other than the RSO) determine that they possess the adequate knowledge and understanding of the licensee's operating and emergency procedures. The interviews should include discussions about actual or hypothetical emergency conditions in order to assess the worker's response to such conditions. Observe

licensed activities in progress or a demonstration of activities to assess the worker's understanding of the radiation protection requirements associated with their assigned activities.

Operating and Emergency Procedures:
Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for lower-inspection-priority licenses. The emergency procedures will be approved by the NJDEP, and reviewed and updated by the licensee. Any revision requires an amendment to the license. Verify that licensee personnel are knowledgeable of the operational procedures by observing the performance of tasks at selected work stations and by a comparison of their performance with established procedures. Assess the licensee's emergency procedures to determine that these procedures are as approved by or described to NJDEP. Through interview of workers, verify that licensee personnel understand and implement the established procedures and are aware of procedural revisions.

Licensees should be aware of relative radiological risks and not try to protect the device to the extent that they would be subjected to fire or other life-threatening situations (e.g., attempting to rescue a portable gauge from the path of approaching soil compacting equipment.)

Some licensees may have agreements with other agencies (i.e., fire, law enforcement, and medical organizations) regarding response to emergencies. Through interviews of licensee officials, determine what actions the licensee has taken to ensure that such agencies (involved in such agreements) understand their roles in emergency responses.

Posting and Labeling:
Through observation, verify that proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. Through observation of labeling on packages or other containers, verify that the proper information (e.g., isotope, quantity, and date of measurement) is recorded. Areas with radiation hazards should be conspicuously posted, as required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902). Through observation, verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

The NJDEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NJDEP regulations and license provisions and to terminate unsafe activities involving byproduct material. Through observations, interviews and the review of selected records,

determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

• Maintaining awareness of significant events such as the loss or theft of licensed materials.

• Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.

• Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.

• Obtaining the NJDEP's prior written consent before transferring control of the license;

• Notifying the NJDEP Radioactive Materials Section in writing, immediately following filing of petition for voluntary or involuntary bankruptcy N.J.A.C. 7:28-51.1 (see 10 CFR 30.34(h).

• Assuring the appropriate response, when applicable, to generic communications from the NJDEP.

• Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities N.J.A.C. 7:28-51.1 (see 10 CFR 30.35).

• Notifying the NJDEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place N.J.A.C. 7:28-51.1 (see 10 CFR 30.36).

• Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

Radiation Safety Committee (RSC) (if applicable):
Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness

of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

Radiation Safety Officer:
Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety. Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

a. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

b. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of NJDEP Radioactive Materials Section.

Audits:
Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.2102(a)(2)). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

a. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

b. Determine if the lack of corrective actions caused the licensee to be in noncompliance with regulatory requirements.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87125

MATERIALS PROCESSOR/MANUFACTURER PROGRAMS

87125-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

01.03 To determine if the licensee is manufacturing sources or devices in accordance with statements made to NJDEP.

87125-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspections of materials processor/manufacturers. For the purpose of this IP, materials processor/manufacturers are those licensees that process raw material and/or sources and distribute those processed materials and sources to users as finished products. Examples are major radiopharmaceutical processor/manufacturers (not radiopharmacies), sealed source fabricators, device manufacturers, and other manufacturing licensees that use irradiated bulk quantities of raw materials or sources. This IP does not apply to inspection of distributors that are not involved in the processing of raw materials or sources, or manufacturing of devices.

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NJDEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. Inspections of materials processors/manufacturers differ from other materials inspections in a significant manner. In addition to the routine objectives of an inspection, these inspections also ensure that sources and devices manufactured by the licensee conform to the provisions of the registration certificate and the commitments made in the application at the time the source or device was registered by NJDEP. The inspection is the main source of information to NJDEP that the manufacturer is still making sources and devices as authorized in the license and registration certificate. The inspection should determine whether the licensee is deviating from the provisions of the registration certificate and the processes and procedures, as described in the references listed in the source or device registration certificates. The manufacturer must have copies of the registration certificate as well as the references available in order to be able to meet the provisions of the certificate and the commitments that the licensee made in the application. The inspector should use these documents to supplement the directions in the Inspection Procedure with product specific information.

The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective materials processor/manufacturer radiation safety program:

02.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR 20) limits.

02.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 FE-6 The licensee should ensure that workers are:

a. Knowledgeable of radiation uses and safety practices;

b. Skilled in radiation safety practices under normal and accident conditions; and,

c. Empowered to implement the radiation safety program.

02.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure:

a. Awareness of the radiation protection program;

b. That audits for ALARA practices are performed; and,

c. That assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

Usually the inspector's evaluation will examine licensee activities back to the date of the previous inspection. However, issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, repetitive violations, or high radiation exposures.

87125-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection.

Common elements to all inspections include preparation, entrance and exit meetings with appropriate licensee management, including radiation safety committee (RSC) members and the radiation safety officer (RSO), observations of facilities and work in progress, independent and confirmatory surveys, and the evaluation of program scope and any special license conditions.

Each of the following areas should be reviewed during each inspection of all large materials processor/manufacturers.

Specific Guidance:

03.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR 20) limits.

Facilities:
Through direct observation:
Verify that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

> If any entrance or area is unsecured, determine, through interviews of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.
>
> If entrances or other areas are unsecured, observe other areas where radioactive materials are used and stored and verify that they are locked and have limited and controlled access. Radioactive material use areas must be under constant surveillance or physically secured.

Through observations:
Verify that use and storage areas are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas should be physically secured when unattended.

Receipt and Transfer of Licensed Materials:
Through observations and interviews of licensee personnel, verify that the licensee:

1) Properly secures package receipt areas, such as loading docks or other shipping and receiving areas;
2) Inspects packages for damage;

3) Performs appropriate package receipt surveys;

4) Opens packages in a safe manner;

5) Assures that packages are properly prepared for transport; and

6) Controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If possible, observe the receipt of packages. Otherwise, request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys:

a. If packages are left unattended, assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

b. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in FE-5 below).

Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Inventory Control:
Through observation, physically examine the inventory of radioactive material on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license. Compare the possession of selected sealed sources with inventory records. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license.
Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.

a. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports that a complete and timely report was made to the NJDEP.

b. For incidents or unusual occurrences that were not required to be reported, determine whether the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

Process and Engineering Controls:
Through observations, interviews of licensee personnel, and independent and confirmatory surveys, assess the adequacy of glove boxes, hot cells, remote-handling devices, shields and shielding devices, and other engineered safeguards to assure that they are adequate for the purposes for which they are intended. Specifically:

For Hot Cells:
Determine that the licensee controls the entry of personnel to hot cells, the removal of material from process enclosures, and contamination originating within the hot cells.

a. If any weaknesses in hot cell operations are identified, review the records of radiation surveys and/or air monitoring around the hot cell area.

b. If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of FE-4.

For Glove Boxes:
Determine that the licensee periodically checks the integrity of gloves and replaces gloves as necessary; controls the removal of material from process enclosures; and controls contamination originating within the glove boxes.

a. If any weaknesses in glove box operations are identified, review the records of surveys around the glove box area and extremity monitoring records of individuals who work in the area.

b. If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of FE 4.

For temporary or portable shielding verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.

For all processes where shielding is used, assess the adequacy of shielding during maximum loading of hot cells and glove boxes. Determine, by surveying the areas near manufacturing processes, the continued adequacy of shielding. If the licensee initiates new processes in existing hot cells or glove boxes, determine whether the licensee has evaluated the adequacy of existing shielding before beginning the new process.

Product Shielding:

Ambient radiation levels should be determined for areas normally occupied by workers. If higher than expected readings are found, determine the source of the higher dose rates.

Through direct observations, interviews of licensee personnel and independent measurements, verify that large quantities of stock or bulk radioactive materials are adequately shielded. Verify that such shielding cannot be easily removed or opened. Determine whether the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads.

Through direct observations and interviews of licensee personnel, verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials, such as individual vials and manufactured sealed sources, and that licensee personnel use the shields when handling the containers/sources. Verify that unit shields are adequate for the quantities of radioactive materials typically contained in them.

Randomly select a number of finished products/devices that are ready for distribution and verify that the external radiation levels are consistent with expected values.

a. If higher than expected levels are noted, verify that the shielding included in prepared, distributed products conforms to that described in the license documents, as appropriate.

b. Verify that the licensee has not made changes to the size, shape, or contents (i.e., lead versus stainless steel) of the shielding materials without prior approval of the NJDEP.

Routine and Non-Routine Maintenance:
By interviewing selected maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine that maintenance personnel verify, either through their own or health physics staff surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from process equipment, entering rooms or areas (such as bunkers or hot cells) normally posted as high radiation or very high radiation areas, or entering tanks or vessels that normally contain or have contained radioactive materials. Verify that shielding removed for maintenance and opened man ways are properly replaced prior to lifting of maintenance holds when equipment is returned to service.

For maintenance activities that include potentially significant radiological conditions, such as high dose rates (>100 millirem per hour general area or > 1 rem per hour contact) or contamination levels (>100,000 disintegrations per minute per 100 square centimeters), determine whether the licensee has established more stringent requirements, such as more detailed pre-job briefing of personnel, additional protective clothing, and/or constant job coverage by a health physics technician.

Area Radiation Surveys:
Through interviews of selected licensee personnel, including the RSO, verify that the licensee has established schedules for periodic surveys of work and storage areas of the facility site; verify that surveys are conducted using approved procedures; review a random selection of survey records to verify that surveys are performed according to schedules; verify that the survey results are reviewed by appropriate supervision; and verify that corrective actions have been taken, as appropriate. Attempt to observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys. Verify specifically that schedule and procedural requirements for surveys are adequate to demonstrate compliance with the regulations and with pertinent license requirements. Determine whether due consideration is given to energy, beta exposure, and extremity exposure, and whether neutron surveys are performed if appropriate.

Request that licensee personnel spot-check radiation levels in selected areas using the licensee's instrumentation. Compare the results with those obtained using the NJDEP's instruments.

03.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration: The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

Fire Protection:
In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensees facilities, be alert to potential fire hazards. An effective licensee fire protection program should:

a. Prevent fires from starting,

b. Rapidly detect, control, and extinguish those fires that do occur, and

c. Provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public.

Through observation and discussion with the licensee, while touring the facilities, assess fire safe conditions and equipment, i.e., that:

a. Work areas are generally uncluttered and free of combustible debris,

b. Incompatible materials (i.e., materials labeled as "corrosive", "flammable", or "oxidizer") are isolated from each other and enclosed by fire resistant barriers,

c. Fire detection systems are operable,

d. Fire suppression systems are operable,

e. Portable fire extinguishers are unexpired (check maintenance tags),

f. Electric switches and electric motors are explosion-proof, arc welders or open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive chemicals, and that

g. The local fire department is involved with the licensee's fire protection program.
Any problems/deficiencies noted should be promptly brought to the licensee's attention and discussed with NJDEP Radioactive Materials Section.

Transportation:
Verify that licensed material is packaged and transported (or offered for transport) in accordance with N.J.A.C. 7:28-61.1 (see 10 CFR 71) and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.

Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers.

If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs) issued by the NRC. The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

If the licensee reported any transportation incidents, review the licensee's actions in response to the incidents.

Operational Limits:
Verify that the licensee operates process equipment within the equipment manufacturer's or industry consensus operational limits. Such limits may include temperature, humidity, vibration, or radiological considerations. In addition, such equipment may be subject to periodic preventative maintenance requirements/recommendations. If so, verify that such maintenance is performed.

03.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

a. Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes.

b. If the licensee monitors worker exposures (internal and external), notwithstanding a prospective analysis indicating that monitoring was not required, review selected reports of monitoring results. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one worker consistently receives significantly more exposure than all other workers each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.

Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.

Through interviews of workers and observations of activities in progress, verify that radiation monitors are worn appropriately and are recording the highest dose for which they are intended.

a. If monitors are not (or cannot be) worn in the most appropriate location to record the highest dose received by the individual(s), through interviews of the RSO, verify that the licensee has performed assessments (through surveys, calculation, or both) of occupational exposures received and adjusted the dose of record for the worker(s).

b. Review the results of the licensee's assessment and verify the assumptions and outcomes. Verify that the dose of record for the affected worker(s) has been adjusted and that the adjusted dose is within the applicable regulatory limit and ALARA.

Through interviews of the RSO and review of records of external monitoring results, determine whether processing (collection, process, and assessment) of monitoring devices is being performed in a timely manner.

Through interviews of the RSO and workers who handle volatile radionuclides (i.e., radioiodine), verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are

exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies.

Through observations of facilities and activities in progress, interviews of the RSO and workers, independent and confirmatory measurements, and reviews of records of licensee evaluations, verify that the licensee effectively uses procedures and engineering controls to maintain doses to members of the public and radiation levels in unrestricted areas within regulatory limits and ALARA.

Through observations of facilities and activities in progress, interviews of the RSO and workers, and reviews of records of air monitoring results and licensee evaluations, verify that licensee releases of gaseous radioactive effluents to unrestricted areas are within the constraint value. Verify that air sampling equipment is calibrated and operational, and that sampling lines are intact and draw from their intended collection points.

Through observations, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors in-line ventilation filtration systems for saturation. Determine whether filter systems are monitored for differential pressure to ensure that there is no bypass of the filters, including perforations/channels and worn or degraded seals.

Through observations, independent measurements, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors the flow rates of fume and laminar flow hoods used to process licensed materials. Verify that licensee staff use calibrated instruments to measure flow rates. Verify that hood flow rates are adequate to prevent outflow of volatile, gaseous, and particulate materials into work areas, including the prevention of high eddy currents originating from excessive hood flow rates.

Through observations, verify that respiratory protection equipment is certified by NIOSH/MSHA. Determine that the licensee has selected the proper equipment for its licensed operations. Through interviews of the RSO, determine that the licensee has established a maintenance and training program for the use of respiratory protection equipment.

Through interviews of selected workers who have used, or are designated/approved to use, respiratory protection equipment, determine that they are individually fitted for the type of respirators that they are expected to use and that respiratory equipment is operationally tested immediately prior to each use.

Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

a. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NJDEP.

b. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated.

If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the NJDEP, USNRC or other Agreement State to perform that service.

Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Verify that calibrations include a determination of "as found" condition before adjustments are made. Verify that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.

If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."

Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to NJDEP instrument. Verify that licensee's instrument response is comparable to NJDEP instrument (+20%).

Through interviews of the RSO and workers, and by observation, determine that licensee has a system for tagging out inoperable and out-of-service survey instruments.

Through observations and interviews of the RSO and workers, verify that the licensee's instrumentation for performing in vivo bioassay measurements is adequate for those measurements. Determine that bioassay probes and scalers are compatible. Determine that licensee staff performs a response check using appropriate sources (such as a barium-133 source to simulate iodine-131) and a suitable background measurement before taking bioassay measurements.

Through observations and interviews of selected licensee personnel, determine the type and quantity of radiation laboratory instrumentation used by the licensee, such as liquid scintillation counters, alpha/beta counters, and gamma counting systems. Determine if the types of laboratory

equipment are appropriate for the samples being analyzed and the sensitivity required. Determine if the laboratory instrumentation is calibrated for the appropriate geometries of the samples to be analyzed and is routinely checked for proper operation. Determine whether the licensee maintains calibration records, control charts, and maintenance and repair records to demonstrate proper operation of laboratory instrumentation.

03.06 FE-6 The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

Authorized Users:
Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify through interviews that the authorized user has knowledge commensurate with operational duties. In cases where users are specified by license condition, determine that the licensed materials they use conform to the license condition. Determine that the authorized users are personally performing or, if permitted in the license, supervising, the authorized work, rather than someone else not named in the license. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of ...." For other types of licensees, supervision is defined in the regulations. For some licenses that have the condition "... under the direct supervision of ..," the authorized user must be physically present at the facility, for easy contact or to observe the individual(s) working. Another phrase used is "... may only be used by ...." Finally, "... under the direct supervision and physical presence of...." means the authorized user must directly supervise and be present at the work station. CAUTION: Considering the many license condition phrases and regulations, exercise judgment when assessing the role of the authorized users. When the wording of the license condition is "... used by or under the supervision of ...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

General Training:
Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).

N.J.A.C. 7:28-50.1 (see 10 CFR Part 19) Required Training:
Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NJDEP

regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

Training Required by License Commitments:
Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. Through interviews of one or more users of radioactive materials, assess their understanding of the training that they have received, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities. Through observation of related activities and discussions with selected licensee personnel, verify that they actually received radiation safety training. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee.

Determine, by observing and interviewing workers, if training and experience are adequate to enable users to safely undertake activities authorized by the license and whether they are aware of the risks involved. Examine the licensee's program for on-the-job training of new workers.

Determine if there is adequate retraining for workers to cover regulation changes and/or radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

Operating and Emergency Procedures:
Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures may be approved by NJDEP and reviewed and updated by the licensee.

Review and assess the licensee's process for controlling documents (procedures) and making revisions to procedures. Revisions to operating procedures should be reviewed by licensee health physics staff to ensure that the revisions do not adversely affect radiological safety. Select a sample of operating or process areas and determine that pertinent procedures are available to personnel, are current, and are in use in those selected areas. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities. Determine whether process activities use procedures for reference or are required to be used "in-hand."

During interviews of selected licensee personnel, assess the worker's knowledge and understanding of the licensee's emergency procedures, through proposed hypothetical emergency scenarios (i.e., "what if" questions). The scenarios should include those types of accidents appropriate to the licensee's program (i.e., contaminated packages identified during receipt surveys, fires, contamination events involving large quantities (100 millicuries of iodine-131 or 1 curie of technetium-99m)).

If the licensee is required to have and implement an emergency plan, assess in-plant procedures for handling accidents including evacuation, prevention of spread of contamination, securing sources, handling accident victims, and any other major portions of the emergency plan. Verify, by discussions with workers, and review of procedures, that the emergency plan has been implemented and is being maintained. Verify that lines of communication with outside organizations that may be called on to assist in an emergency are current and tested. Ensure that biennial emergency plan drills and/or exercises include notification of NJDEP staff.

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies.

Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

Posting and Labeling:
Determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. N.J.A.C. 7:28-6.1 provides exceptions to posting caution signs (see 10 CFR 20.1903.). When applicable, randomly examine signals and alarms to determine proper operation. Observe labeling on randomly selected packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

Areas with radiation hazards should be conspicuously posted, as required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902.) Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile radioactive materials are used in an area, such an area should be controlled for airborne contamination. High radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program. Examine locations where notices to workers are posted. Applicable documents, notices, or forms must be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

The NJDEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NJDEP regulations and license provisions and to terminate unsafe activities involving byproduct material.

Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

• Maintaining awareness of significant events such as the loss or theft of licensed materials.

• Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.

• Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.

• Obtaining the NJDEP's prior written consent before transferring control of the license.

• Notifying the NJDEP Radioactive Materials Section in writing, immediately following filing of petition for voluntary or involuntary bankruptcy as per N.J.A.C. 7:28-51.1 (see 10 CFR 30.34(h)).

• Assuring the appropriate response, when applicable, to generic communications from the NJDEP.

• Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities as per N.J.A.C. 7:28-51.1 (see 10 CFR 30.35).

• Notifying the NJDEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place as per N.J.A.C. 7:28-51.1 (see 10 CFR 30.36).

• Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

Radiation Safety Committee (RSC) (if applicable):
Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics

of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

Radiation Safety Officer (RSO):
Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety. Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

a. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

b. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of NJDEP Radioactive Materials Section.

Audits:
Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.2102(a)(2)). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

a. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

b. Determine if the lack of corrective actions caused the licensee to be in noncompliance with regulatory requirements.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87126

INDUSTRIAL/ACADEMIC/RESEARCH PROGRAMS

87126-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

87126-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspections of licensees authorized for academic, research and development, and industrial uses of limited scope (ARDL) and for non-medical broad scope licenses. IP 87125 should be followed for inspection of materials processors/manufacturers and IP 87127 should be followed for radiopharmacies.

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NJDEP, and independent measurements of radiation conditions at the facility and a review of selected records, rather than exclusive reliance on a review of records.

The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective materials radiation safety program:

02.01 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below New Jersey Administrative Code (N.J.A.C.) 7:28-6.1 (see 10 CFR Part 20) limits.

02.02 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 The licensee should ensure that workers are:

a. knowledgeable of radiation uses and safety practices;
b. skilled in radiation safety practices under normal and accident conditions; and,
c. empowered to implement the radiation safety program.

02.07 The licensee's management system should be appropriate for the scope of use and should ensure:

a. awareness of the radiation protection program;
b. that audits for ALARA practices are performed; and,
c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

87126-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the NJDEP's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem.

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, observations, and demonstrations.

An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, a combination of a review of selected records and observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records, alone.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of licensed materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that

are more closely related to health and safety (such as personnel dose monitoring records and incident reports) should be examined in detail. Common elements to all inspections include entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent and confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800. Each of the following focus elements should be reviewed as appropriate, during each inspection of an ARDL-licensee or broad-scope licensee.

Specific Guidance

03.01 FE-1: The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 (see 10 CFR Part 20) limits.

Facilities

a. Through direct observation, determine that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

1. If the inspector finds any entrance or area to be unsecured, the inspector should determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. The inspector should determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. The inspector should determine if the licensee's facility is configured to separate working areas from unrestricted areas.
2. If the inspector finds entrances or other areas unsecured, the inspector should examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be under constant surveillance or physically secured.

b. Through observations, verify that use and storage areas are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas should be physically secured when unattended.

c. Evaluate licensee practices regarding access controls including control of keys and access codes to ensure only currently authorized individuals have access to licensed materials.

d. Ensure licensee practices include testing of interlock systems, as applicable (such as for hot cells).

e. Examine air flow patterns and building intakes for potential of spreading contamination and for releases or doses in excess of regulatory limits.

Receipt and Transfer of Licensed Materials

a. Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and receiving areas; 2) inspects packages for damage; 3) performs appropriate package receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If the inspector is unable to observe the receipt of packages, the inspector should request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

1. If packages are left unattended, the inspector should assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).
2. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, the inspector should interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in Focus Element 5 (Section 03.05, below).

b. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive the forms and quantities of such materials.

Inventory Control

a. Through observation, the inspector should physically examine the inventory of radioactive material on hand and selected records of receipt and transfer to determine that quantities and forms are as authorized on the license. The inspector should compare the possession of selected sealed sources with inventory records. The inspector should verify that the licensee is limiting its possession and use of licensed materials to the isotopes, forms and quantities specified in the license. Examine the adequacy of methods used by the licensee to demonstrate compliance with license possession limits.

(Note: The licensee should have an accounting system that suits the type of licensed program. For example, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility will need a sophisticated accounting system for all licensed material that provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other facilities operating under the same license, and the amount remaining after decay. The accounting systems should also

consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees.)

b. Through interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving lost, missing, or stolen licensed materials.

1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NJDEP.

2. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment

a. Process and Engineering Controls
Through observations, interviews of licensee personnel, records review and independent and confirmatory surveys, assess the adequacy of glove boxes, hot cells, remote handling devices, shields and shielding devices, ventilation systems and other engineered safeguards to assure that they are adequate for the purposes for which they are intended. Specifically:

1. Hot Cells. Verify that the licensee controls: the entry of personnel into hot cells; the removal of material from process enclosures; and contamination originating within the hot cells.
(a) If any weaknesses are identified in hot cell operations, then review the records of radiation surveys and/or air monitoring around the hot cell area.
(b) If records indicate elevated radiation or airborne contamination levels, then review the personnel monitoring records of individuals who worked in the area. For all processes where shielding is used, assess the adequacy of shielding during maximum loading of hot cells and ensure the licensee verified the adequacy of shielding before beginning new processes.

2. Glove Boxes. Verify that the licensee: periodically checks the integrity of gloves and replaces gloves as necessary; controls the removal of material from process enclosures; and controls contamination originating within the glove boxes.
(a) If any weaknesses are identified in glove box operations, then review the records of surveys around the glove box area and extremity monitoring records of individuals who work in the area. For all processes where shielding is used, assess

the adequacy of shielding during maximum loading of glove boxes and ensure the licensee verified the adequacy of shielding before beginning new processes.

b. Shielding

1. Temporary or Portable Shielding. Verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.

2. Bulk Product Shielding. Verify that the licensee maintains large quantities of stock or bulk radioactive materials in adequate shielding. Verify that such shielding cannot be easily removed or opened. Verify that the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads. Ensure that licensee personnel are aware of lifting equipment load limitations and that the limitations are not exceeded.

3. Unit Shielding. Verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials (i.e., vials, syringes, individual sources, etc.) and that licensee personnel use the shields when handling the containers. Unshielded containers of hard-beta- and gamma emitting radionuclides should not be directly handled by personnel.

4. Shipped Product Shielding. Verify that the shielding included in packaging of materials that are transferred to a carrier for transport/transfer to an off site location conforms to that described in the SSD registry or license documents, as appropriate. The licensee may not make changes to the size, shape, or contents (i.e., lead versus stainless steel) of the shielding materials without prior approval of the NRC, NJDEP, or another 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.

c. 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 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

a. Operational Limits.
Through observation, discussions with licensee staff and review of product specification information, verify that the licensee operates process equipment within the equipment manufacturer's or industry consensus operational limits. Such limits may include temperature, humidity, vibration, or radiological considerations. In addition, such equipment may be subject to periodic preventative maintenance requirements/recommendations. If so, verify that such maintenance is performed.

b. Fire Protection.
In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensees facilities, the inspector should be alert to potential fire hazards. An effective licensee fire protection program should (1) prevent fires from starting, (2) rapidly detect, control, and extinguish those fires that do occur, and (3) provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public.

Through observation and discussion with the licensee, while touring the facilities, assess fire-safe conditions. Problems/deficiencies noted by the inspector should be promptly brought to the licensee's attention and discussed with management.

c. Natural Hazards.
Depending on the licensee's geographic location, it could be susceptible to natural hazards, such as tornadoes, flooding, and earthquakes. Verify that those licensee's have considered the impact of such hazards in the design and modification of areas critical to safety; the selection and location of facilities for the storage of large quantities of radioactive materials, including
radioactive waste storage facilities; and in the development of emergency procedures and contingency plans, when applicable.

d. Transportation.
Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is packaged and transported (or offered for transport) in accordance with N.J.A.C. 7:28-61.1 (see 10 CFR Part 71) and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials. Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are

prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers. Examine any incidents that were required to be reported to the DOT. If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs). The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

For further inspection guidance refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer to "Hazard Communications for Class 7 (Radioactive) Materials." These field reference charts, related to hazard communications for transportation of radioactive materials, are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings. They also contain references to the DOT regulatory requirements.

03.04 FE-4: The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

Verify that the licensee has performed adequate surveys to show compliance with public dose limits and that conditions in controlled areas and unrestricted areas meet the requirements specified for these areas.

a. Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

1. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one worker consistently receives significantly more exposure than all other workers each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.
2. Through interviews of workers and observations of activities in progress,

determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.

b. External Exposure Controls

Examine any changes made for control and use of personnel monitoring equipment; verify that limits, precautions, controls, etc., established by the licensee are consistent requirements. Examine the type of monitoring devices used, the period of use or exchange period, and the number used to determine if these aspects seem consistent with the monitoring program. Determine who the supplier is, and if the service has been changed since the last inspection, determine the reasons for the change. Verify that the personnel dosimetry processor is accredited by National Voluntary Laboratory Accreditation Program (NVLAP). NOTE: If the licensee operates its own dosimetry program, ensure that it has received the appropriate NVLAP accreditation and that the accreditation includes the type, energy, and intensity of radiations applicable to the licensee's operations.

For pocket dosimeters or pocket chambers, determine when they are read and recharged, the number used, and review the calibration procedure or charge leakage test procedure.

For electronic dosimeters, determine that the energy response and alarm set points are appropriate for the radiological conditions present during licensee operations. Verify that the licensee has established a calibration procedure and frequency for the dosimeters. Examine a random sample of electronic dosimeters that are available for use and verify that they have been calibrated in accordance with the procedures and stated frequency.

For all personnel monitoring devices used (whole body and extremity monitors, pocket chambers, electronic dosimeters), verify that the licensee has provided appropriate guidance to personnel regarding the wearing and placement of monitors. During observations of activities in progress, verify that dosimeters are properly worn, paying particular attention to physical manipulations of containers of radioactive materials (i.e., vials, syringes, etc.), whether or not they are shielded, and verify that extremity monitors are located so that they record the maximum dose.

Evaluate the adequacy of the licensee's procedures or system for evaluating and using personnel monitoring data to control and minimize exposures. The licensee should account for occupational radiation doses to personnel resulting from exposures to licensed material and other radiation sources not licensed by the NJDEP.

Review reports of exposure summaries generated since the last inspection to determine that licensee's performance is in accordance with regulatory requirements.

Determine, through discussion with authorized users and the RSO, if minors have been permitted to work in restricted areas and, if so, determine that licensee's

performance is in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.1207) by review of exposure records.
For licensees who are not required to monitor, due to the lack of a likelihood that any worker would receive more than 5 millisievert (500 millirem) in a year, a sampling of voluntary monitoring may be appropriate. If a licensee is not required to monitor and chooses not to monitor worker exposures, the inspector need only review the licensee's presumptive analysis of exposures and verify the assumptions used in that analysis.

c. Internal Exposure
During review of exposure evaluations, verify that the licensee's performance is in accordance with internal exposure limits.

Review randomly selected air sampling and bioassay records. Determine if the licensee has established appropriate action levels and verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies.

By observation, discussion, and review of documentation, verify that engineering controls are considered and used to the extent practicable. Evaluate process and engineering controls incorporated as part of the facility or equipment.

Review documentation of evaluations performed as the result of unplanned exposures. Discuss these intakes with exposed personnel and licensee health physics staff and evaluate the circumstances of the incidents. Verify the appropriateness of preventive measures instituted following an unplanned exposure.

d. Area Radiation and Contamination Control

1. Area Surveys
Through direct observation of surveys and interviews of licensee personnel, evaluate the licensee's area radiation survey program. The inspector should:

- Determine if the licensee's schedule for performing periodic surveys of work areas and unrestricted areas complies with license requirements.
- Determine surveys are conducted using approved procedures.
- Review a random sample of survey records and determine whether surveys are being performed according to schedules.
- Verify that survey results are reviewed by appropriate supervision.
- Verify that corrective actions have been taken, as appropriate.
- Determine whether survey is adequate for type (α, β, γ, or neutron) and energy of radiation to be detected and measured.

• Determine whether both particulate, non-noble gases and vapors are considered, if appropriate.
• Determine if workers take smears or instrument readings in areas that are readily accessible to facility personnel such as bench tops, sinks used for disposal, and storage areas.
• Ask licensee to spot-check radiation levels in selected areas using the licensee's own instrumentation. Compare measurements with an NJDEP instrument.

Note: The inspector must use NJDEP's instruments for independent verification of the licensee's measurements. NJDEP instruments should also be used to make measurements in support of violations to be cited.

e. Leak Tests and Sealed Source Inventories
Through direct observation and licensee staff interviews, assess the adequacy of the licensee's implementation of its leak test and inventory procedures. The inspector should:

• Verify that leak tests are performed at the frequency specified in the license.
• Verify that leak test samples are collected in accordance with either licensee or leak test vendor procedures.
• If the licensee analyzes leak tests on sealed sources as a service to other licensees, it is important that the licensee demonstrate to the inspector an adequate method of performing and analyzing leak tests.
• Determine if sealed source inventories are performed at the required frequency.
• Evaluate the licensee's inventory methods to ensure that they could detect missing
Licensing requirements for sealed source inventories should also be considered.
Review selected records to verify integrity of sources.

f. Contamination Control
Verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination. When appropriate, consider taking confirmatory wipe samples. Review a random sample of wipe test records and determine whether wipe tests are being performed according to schedule. If any results are discovered that are greater than the licensee's internal trigger levels, discuss cause and any corrective action taken with the RSO.

g. Protective Clothing
If practical, observe the use of protective clothing worn by research lab personnel or other applicable staff during their work activities. Should provide the inspector with an acceptable means of reviewing this requirement. Requirements for protective clothing may be found in the licensee's procedures or as posted by the licensee.

h. Process Controls
By observation, determine compliance with license requirements for repair, tagging, opening, modification, and replacement of sealed sources and devices. Ensure that the licensee has methods or procedures to minimize exposure during maintenance on devices. Verify through discussions with workers and by reviewing procedures that, when maintenance or

modification is performed, controls are in place and are effective to warn workers of radiological hazards, prevent unnecessary exposure, and prevent the spread of contamination.

i. Waste Management

1. Waste Storage and Disposal

Verify that the waste is protected from fire and the elements, that package integrity is adequately maintained, that the storage area is properly ventilated, and that adequate controls are in effect to minimize the risk from other hazardous materials. Verify that the licensee has appropriate methods to track the items in storage.

Inspection effort should be directed at verifying that written procedures have been established in a manner approved by management. The procedures should be readily available to any persons having responsibility for low-level waste classification and preparation for transfer of such wastes to land disposal facilities.

Verify that storage for decay is not causing elevated radiation doses to waste processing workers. If applicable, confirm that the resident time of waste at the facility does not exceed the time limit authorized in the license. For licensees who have implemented an interim waste storage program, verify that the program is consistent with the license. For further guidance on interim waste storage, see Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees."

Examine monitoring systems. Review and evaluate a sample of the procedures and other administrative and physical controls for the release and disposal of radioactive waste.

The inspector should determine whether radioactive material labels have been removed or defaced from discarded materials, being careful to not endanger him or herself to biological, chemical, or physically hazardous waste (e.g., sharp objects). Ensure that wastes prepared for shipment to a disposal site comply with applicable standards and regulations regarding chemical and physical form, stability, type of container, and labeling. Also ensure that the licensee implements an adequate QC program as required by N.J.A.C. 7:28-6.1 (see Appendix F of 10 CFR Part 20) to ensure compliance with applicable regulations.

For further inspection guidance, refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of N.J.A.C. 7:28-6 and 7:28-59."

2. Effluents

Examine the waste release records generated since the last inspection, all annual or semiannual reports, all pertinent non-routine event reports, and a random selection of liquid and airborne waste release records. Randomly select procedures for both liquid and airborne systems and verify that the licensee's procedures are being followed. The verification can be made by observations of an operation, a review of selected records, interviews with workers, etc.

For liquid wastes, determine if the licensee has: identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complied with the regulatory requirements for disposal in the publicly-owned sanitary sewerage system. If the licensee disposes of liquid wastes to surface waters, ground waters, or a private sanitary sewerage treatment system, determine whether the licensee is in compliance with the regulations and all applicable license restrictions.

For airborne radioactivity, determine if the licensee has identified all routes of airborne releases to the environment and complies with the regulations and all applicable license restrictions. For a licensee authorized to dispose of radioactive material by incineration, determine compliance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.2004) and license requirements, and discuss with the licensee its methods for evaluating concentrations in the ash.

Determine compliance with license conditions relating to environmental monitoring. If applicable, observe sampling stations and equipment for adequacy. Review a sample of procedures, records, and reports to verify that the licensee has established and is maintaining an environmental monitoring program, if required in the license.

Review the licensee's ALARA goals, where applicable, and determine if the licensee has implemented these goals. Determine if the licensee has calculated annual doses resulting from air effluents and if the doses: (1) are within the licensee's ALARA goals (as described in its radiation protection program); (2) exceed the licensee's ALARA goals; or (3) are uncertain because there is insufficient information or basis for determination. Review the licensee's history in meeting ALARA goals, and its corrective actions when the goals were not met.

Verify that the licensee's air effluents, excluding Radon-222 and its daughters, have not exceeded the constraint limit in N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101). Information on evaluating air effluents is available in Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors." If the licensee estimated or measured a dose greater than 0.1 millisievert (10 mrem) per year, from air emissions, to the nearest individual member of the public, the licensee should have notified NJDEP as per N.J.A.C. 7:28-6.1 (see 10 CFR 20.2203(a)(2)(vi.). If the licensee has notified NJDEP that its air effluents have exceeded the constraint level, the inspector should review the effectiveness and timeliness of the licensee's corrective actions. Records of the results of measurements and calculations needed to evaluate the release of radioactive effluents to the environment are required pursuant to N.J.A.C. 7:28-6.1 (see 10 CFR 20.2103(b)(4.)

For further inspection guidance, refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Reasonably Achievable (ALARA)."

j. Respiratory Protection

Through observations, verify that respiratory protection equipment is certified by NIOSH/MSHA. Determine that the licensee has selected the proper equipment for its licensed operations. Through interviews of the RSO, determine that the licensee has established a maintenance and training program for the use of respiratory protection equipment. Through interviews of selected workers who have used, or are designated/approved to use, respiratory protection equipment, determine that they are individually fitted for the type of respirators that they are expected to use and that respiratory equipment is operationally tested immediately prior to each use.

In taking credit for the protection provided by the use of respiratory protective equipment, N.J.A.C. 7:28-6.1 (see 10 CFR 20.1703) requires that the protection factor be greater than the multiple by which peak concentrations are expected to exceed the values of N.J.A.C. 7:28-6.1 (see Table 1, Appendix B, Column 3 of 10 CFR Part 20), unless ALARA considerations indicate otherwise. Verify that this criterion is considered in selecting respirators.

k. Reports to Workers.

N.J.A.C. 7:28-50.1 (see 10 CFR 19.13(b)) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all the information required in N.J.A.C. 7:28-50.1 (see 10 CFR 19.13(a.)).

l. ALARA

The licensee should, in addition to complying with regulatory requirements and license conditions, make reasonable efforts to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas ALARA. This can be accomplished by the implementation of good radiation planning and practices, and by the commitment, from management and workers, to policies that prevent departure from ALARA practices. Also, licensees are required to keep occupational doses and doses to members of the public ALARA as required in N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101(b)).

Assess the licensee's ALARA practices, and verify implementation of any ALARA commitments in licensing documents, by reviewing:

1. A written commitment by high-level management to minimize worker exposure by the implementation of clearly defined procedures and policies;

2. That licensee personnel are made aware of management's commitment to keep occupational exposures ALARA;

3. That the radiation safety staff have been given authority to assure ALARA procedures and policies are carried out;

4. That workers are adequately trained, not only in the radiation safety procedures, but also in the ALARA philosophy;

5. That management and its designees perform periodic audits to find out how exposures and effluent releases might be lowered;

6. That modifications to procedures, equipment, and facilities have been made to reduce exposures at reasonable costs, where possible;

7. That the licensee has QA and QC programs, where applicable; and

8. That the licensee has a functioning and effective preventive maintenance program, where applicable.

Review and evaluate engineering controls to assure that, for example, exhausts from ventilated enclosures are adequately treated to reduce emissions to the out-of- plant environs to the lowest reasonably achievable levels within regulatory limits. Evaluate ventilated enclosures to assure that they are adequate to minimize internal exposures. Review shielding and the use of remote handling tools to assure that facilities and equipment are adequate to reduce exposure (both internal and external) to the lowest reasonably achievable levels within regulatory limits.

m. Event Evaluation

Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

• Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NJDEP.

• For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored

a. Through observations of portable radiation detection and measurement equipment

in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated at the required frequency.

b. If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by NRC, NJDEP, or another Agreement State to perform that service.

c. Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Verify that calibrations include a determination of "as found" condition before adjustments are made. Verify that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.

d. If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."

e. Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to NJDEP instrument. Verify that licensee's instrument response is comparable to NJDEP instrument (+/- 20%).

f. Through interviews of the RSO and workers, and by observation, verify that licensee has a system for tagging out inoperable and out-of-service survey instruments.

g. Through observations and interviews of the RSO and workers, determine whether the licensee's instrumentation for performing bioassay measurements is adequate for those measurements. Verify that bioassay probes and scalers are compatible. Verify that licensee staff perform a response check using appropriate sources and a suitable background measurement before taking bioassay measurements.
h. Through observations and interviews of the RSO and workers, assess the procedures and methods, and equipment used by the licensee to assure compliance with air-monitoring and air-handling commitments requirements (such as flow rates into hoods, air flows in ventilation systems, differential pressures in cells, in glove boxes, and across filter systems).

i. Assess the equipment used by the licensee to satisfy these measurements. If appropriate, verify that air measurement equipment is functional and calibrated at the required frequency.

03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program

a. Authorized Users
Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify through interviews that the authorized user has knowledge commensurate with operational duties. In cases where users are specified by license condition, determine that the licensed materials they use conform to the license condition.

Determine that the authorized users are personally performing or, if permitted in the license, supervising, the authorized work, rather than someone else not named in the license. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of ...." For other types of licensees, supervision is defined in the regulations. For some licenses that have the condition "... under the direct supervision of ..," the authorized user must be physically present at the facility, for easy contact or to observe the individual(s) working. Another phrase used is "... may only be used by ...." Finally, "... under the direct supervision and physical presence of ..." means the authorized user must directly supervise and be present at the work station. Considering the many license condition phrases and regulations, the inspector must exercise judgment when assessing the role of the authorized users.

When the wording of the license condition is "... used by or under the supervision of ...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

b. General Training
Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).

1. N.J.A.C. 7:28-50.1 (see 10 CFR Part 19) Required Training
Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the

pertinent provisions of NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

2. Training Required by License Commitments.
Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. One or more users of radioactive materials should be interviewed to determine their understanding of the training that they have received, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

The inspector should also observe related activities and discuss the radiation safety training received by selected individuals to assure that appropriate training was actually received by these individuals. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee. Determine, by observing and interviewing workers, if training and experience are adequate to enable users to safely undertake activities authorized by the license and whether they are aware of the risks involved. Examine the licensee's program for on-the-job training of new workers. Determine if there is adequate retraining for workers to cover regulation changes and/or radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

c. Operating and Emergency Procedures
Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures may be approved by NJDEP and reviewed and updated by the licensee. However, licensees who follow the guidance in the appropriate NUREG 1556 series will likely develop procedures, including emergency procedures that have not received specific NJDEP review and approval. Review and evaluate the licensee's process for controlling documents (procedures) and making revisions to procedures. Revisions to operating procedures should be reviewed by licensee health physics staff to ensure that the revisions do not adversely affect radiological safety. Select a sample of operating or process areas and verify that pertinent procedures are available to personnel, are current, and are in use in those selected areas. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities. Determine whether process activities use procedures for reference or are required to be used "in-hand."

During interviews of selected licensee personnel, propose hypothetical emergency scenarios (i.e., "what if" questions) to assess the worker's knowledge and understanding of the licensee's emergency procedures. The scenarios should include those types of accidents appropriate to the licensee's program (i.e., contaminated packages identified during receipt surveys, fires, contamination events involving large quantities of licensed materials).

If the licensee is required to have and implement an emergency plan, evaluate in-plant procedures for handling accidents including evacuation, prevention of spread of contamination, securing sources, handling accident victims, and any other major portions of the emergency plan. Verify, by discussions with workers, and review of procedures, that the emergency plan has been implemented and is being maintained. Verify that lines of communication with outside organizations that may be called on to assist in an emergency are current and tested. Ensure that biennial emergency plan drills and/or exercises include notification to NJDEP staff.

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

d. Posting and Labeling.

The inspector should determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. N.J.A.C.7:28-6.1 (see 10 CFR 20.1903) provides exceptions to posting caution signs. When applicable, the inspector should also randomly examine signals and alarms to determine proper operation. The inspector should also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded. Areas with radiation hazards should be conspicuously posted, as required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902.)

Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile radioactive materials are used in an area, such an area should be controlled for airborne contamination. High-radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

The inspector should also examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

The NJDEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NJDEP regulations and license provisions and to terminate unsafe activities involving byproduct material.

Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
- Obtaining the NJDEP's prior written consent before transferring control of the license;
- Notifying the appropriate NJDEP regional administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy as per N.J.A.C. 7:28-51.1 (see 10 CFR 30.34(h.)
- Assuring the appropriate response, when applicable, to generic communications from the NJDEP.
- Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities as per N.J.A.C. 7:28-51.1 (see 10 CFR 30.35.)
- Notifying the NJDEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place as per N.J.A.C. 7:28-51.1 (see 10 CFR 30.36.)
- Notifying the NRC of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21. *(Regulatory authority for 10 CFR Part 21 is being retained by the NRC)*
- Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

a. RSC (where required or used)

Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

b. RSO

Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

- If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.
- If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of NJDEP management.

c. Audits

Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.2102(a)(2.) Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

• If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

• Determine if the lack of corrective actions caused the licensee to be in noncompliance with regulatory requirements.

87126-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87127

RADIOPHARMACY PROGRAMS

87127-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

87127-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NJDEP, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective radiopharmacy radiation safety program:

02.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 limits (see 10 CFR Part 20.)

02.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 FE-3 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 FE-5 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 FE-6 The licensee should ensure that workers are:

a. Knowledgeable of radiation uses and safety practices;

b. Skilled in radiation safety practices under normal and accident conditions; and,

c. Empowered to implement the radiation safety program.

02.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure:

a. Awareness of the radiation protection program;

b. That audits for ALARA practices are performed; and,

c. That assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

87127-03 INSPECTION GUIDANCE:

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual Focus Elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the NJDEP's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expand, inspection effort to address that problem. Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, observations, and demonstrations.

An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records alone.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of licensed materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail. Common elements to all inspections include

preparation, entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent and confirmatory surveys, and the evaluation of program scope and any special license conditions.

Specific Guidance

Each of the following areas should be reviewed during each inspection of a radiopharmacy:

03.01 FE-1 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below N.J.A.C. 7:28-6.1 limits (see 10 CFR part 20).

Facilities:
Through direct observation, verify that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.

a. If any entrance or area is unsecured, determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. Determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. Determine if the licensee's facility is configured to separate working areas from unrestricted areas.

b. If entrances or other areas are unsecured, examine areas where radioactive materials are used and stored. Storage areas must be locked and have limited and controlled access. Radioactive material use areas must be under constant surveillance or physically secured.

Through observations, verify that use and storage areas, including radioactive waste storage facilities, are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas must be physically secured when unattended.

Receipt and Transfer of Licensed Materials:
Through observations and interviews of licensee personnel, verify that the licensee:

1) Properly secures package receipt areas, such as loading docks or other shipping and receiving areas;

2) Inspects packages for damage;

3) Performs appropriate package receipt surveys;

4) Opens packages in a safe manner;

5) Assures that packages are properly prepared for transport; and

6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If unable to observe the receipt of packages, request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

a. If packages are left unattended, assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).

b. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in FE-5 below.

Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Inventory Control:
Through observation, physically examine the inventory of radioactive material on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license. Compare the possession of selected sealed sources with inventory records. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license.

Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.

a. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports that a complete and timely report was made to the NJDEP.

b. For incidents or unusual occurrences that were not required to be reported, determine that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.02 FE-2 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

Process and Engineering Controls:
Through observations, interviews of licensee personnel, and independent and confirmatory surveys, assess the adequacy of glove boxes, hot cells, remote-handling devices, shields and

shielding devices, and other engineered safeguards to assure that they are adequate for the purposes for which they are intended. Specifically:

For hot cells: Determine that the licensee controls the entry of personnel to hot cells, the removal of material from process enclosures, and contamination originating within the hot cells.

a. If any weaknesses in hot cell operations are identified, review the records of radiation surveys and/or air monitoring around the hot cell area.

b. If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of FE-4.

For glove boxes: Determine that the licensee, periodically checks the integrity of gloves and replaces gloves as necessary; controls the removal of material from process enclosures; and controls contamination originating within the glove boxes.

a. If any weaknesses in glove box operations are identified, review the records of surveys around the glove box area and extremity monitoring records of individuals who work in the area.

b. If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of FE-4

For temporary or portable shielding, verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.

For all processes where shielding is used, assess the adequacy of shielding during maximum loading of hot cells and glove boxes. Determine, by surveying the areas near manufacturing processes to ensure the continued adequacy of shielding. If the licensee initiates new processes in existing hot cells or glove boxes, determine whether the licensee has evaluated the adequacy of existing shielding before beginning the new process.

Product Shielding:

Ambient radiation levels should be determined for areas normally occupied by workers. If higher than expected readings are found, the inspector should determine the source of the higher dose rates.

Through direct observations, interviews of licensee personnel, and independent measurements, verify that large quantities of stock or bulk radioactive materials are adequately shielded. Verify that such shielding cannot be easily removed or opened. Determine whether the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads.

Through direct observations and interviews of licensee personnel, verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials, such as unit dose vials and syringes, and that licensee personnel use the shields when handling the containers. Verify that unit shields are adequate for the quantities of radioactive materials typically obtained in them.

Randomly select a number of finished products that are ready for distribution and verify that the external radiation levels are consistent with expected values.

a. If higher than expected levels are noted, verify that the shielding included in prepared, distrributed products conforms to that described in the license documents, as appropriate.
b. Verify that the licensee has not made changes to the size, shape, or contents (i.e., lead versus stainless steel) of the shielding materials without prior approval of the NJDEP.

Routine and Non-Routine Maintenance:
By interviewing selected maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine that maintenance personnel verify, either through their own or health physics staff surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from process equipment, entering rooms or areas (such as bunkers or hot cells) normally posted as high radiation or very high radiation areas, or entering tanks or vessels that normally contain or have contained radioactive materials. Verify that shielding removed for maintenance and opened man ways are properly replaced prior to lifting of maintenance holds when equipment is returned to service.

For maintenance activities that include potentially significant radiological conditions, such as high dose rates (>100 millirem per hour general area or > 1 rem per hour contact) or contamination levels (>100,000 disintegrations per minute per 100 square centimeters), determine whether the licensee has established more stringent requirements, such as more detailed pre-job briefing of personnel, additional protective clothing, and/or constant job coverage by a health physics technician.

Area Radiation Surveys:
Through interviews of selected licensee personnel, including the RSO, verify that the licensee has established schedules for periodic surveys of work and storage areas of the facility site; verify that surveys are conducted using approved procedures; review a random selection of survey records to verify that surveys are performed according to schedules; verify that the survey results are reviewed by appropriate supervision; and verify that corrective actions have been taken, as appropriate. Attempt to observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys. Verify specifically that schedule and procedural requirements for surveys are adequate to demonstrate compliance with the regulations and with pertinent license requirements. Determine whether due consideration is given to energy, beta exposure, and extremity exposure.

Request that licensee personnel spot-check radiation levels in selected areas using the licensee's instrumentation. Compare the results with those obtained using the NJDEP's instruments.

03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration (see Manual Chapter 1007). The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

Fire Protection: In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensee's facilities, be alert to potential fire hazards. An effective licensee fire protection program should:

a. Prevent fires from starting,

b. Rapidly detect, control, and extinguish those fires that do occur, and

c. Provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public.

Through observation and discussion with the licensee, while touring the facilities, assess fire safe conditions and equipment, i.e., that:

a. Work areas are generally uncluttered and free of combustible debris,

b. Incompatible materials (i.e., materials labeled as "corrosive", "flammable", or "oxidizer") are isolated from each other and enclosed by fire resistant barriers,

c. Fire detection systems are operable,

d. Fire suppression systems are operable,

e. Portable fire extinguishers are unexpired (check maintenance tags),

f. Electric switches and electric motors are explosion-proof and open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive chemicals, and that

g. The local fire department is involved with the licensee's fire protection program. Any problems/deficiencies noted should be promptly brought to the licensee's attention and discussed with NJDEP Radioactive Materials Section.

Transportation:
Verify that licensed material is packaged and transported (or offered for transport) in accordance with N.J.A.C. 7:28-61.1 (see 10 CFR Part 71) and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.

Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers.

If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs) issued by the NRC. The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

If the licensee reported any transportation incidents, review the licensee's actions in response to the incidents.

03.04 FE-4 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

Through interviews of the RSO, determine whether the licensee has made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes.

If the licensee monitors worker exposures (internal and external), notwithstanding a prospective analysis indicating that monitoring was not required, review selected reports of monitoring results. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

a. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one pharmacist consistently receives significantly more exposure than all other pharmacists each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.

b. Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.

Through interviews of workers and observations of activities in progress, verify that radiation monitors are worn appropriately and are recording the highest dose for which they are intended.

a. If monitors are not (or cannot be) worn in the most appropriate location to record the highest dose received by the individual(s), through interviews of the RSO, verify that the licensee has performed assessments (through surveys, calculation, or both) of occupational exposures received and adjusted the dose of record for the worker(s).

b. Review the results of the licensee's assessment and verify the assumptions and outcomes. Verify that the dose of record for the affected worker(s) has been adjusted and that the adjusted dose is within the applicable regulatory limit and ALARA.

Through interviews of the RSO and review of records of external monitoring results, determine whether processing (collection, process, and assessment) of monitoring devices is being performed in a timely manner.

Through interviews of the RSO and workers who handle volatile radionuclides (i.e., radioiodine), verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies.

Through observations of facilities and activities in progress, interviews of the RSO and workers, independent and confirmatory measurements, and reviews of records of licensee evaluations, verify that the licensee effectively uses procedures and engineering controls to maintain doses to members of the public and radiation levels in unrestricted areas within regulatory limits and ALARA.

Through observations of facilities and activities in progress, interviews of the RSO and workers, and reviews of records of air monitoring results and licensee evaluations, verify that licensee releases of gaseous radioactive effluents to unrestricted areas are within the constraint value. Verify that air sampling equipment is calibrated and operational, and that sampling lines are intact and draw from their intended collection points.

Through observations, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors in-line ventilation filtration systems for saturation. Determine whether filter systems are monitored for differential pressure to ensure that there is no bypass of the filters, including perforations/channels and worn or degraded seals.

Through observations, independent measurements, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors the flow rates of fume and laminar flow hoods used to process licensed materials. Verify that licensee staff uses calibrated instruments to measure flow rates. Verify that hood flow rates are adequate to prevent outflow of volatile, gaseous, and particulate materials into work areas, including the prevention of high eddy currents originating from excessive hood flow rates.

Through observations verify that respiratory protection equipment is certified by NIOSH/MSHA. Determine that the licensee has selected the proper equipment for its licensed operations. Through interviews of the RSO, determine that the licensee has established a maintenance and training program for the use of respiratory protection equipment.

Through interviews of selected workers who have used, or are designated/approved to use, respiratory protection equipment, determine that they are individually fitted for the type of respirators that they are expected to use and that respiratory equipment is operationally tested immediately prior to each use.

Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.

a. Review and evaluate any such incidents or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NJDEP.

b. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

<u>03.05 FE-5</u> The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated.

If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the NJDEP , USNRC or other Agreement State to perform that service.

Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Verify that calibrations include a determination of "as found" condition before adjustments are made. Verify that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.

If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."

Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to NJDEP instrument. Verify that licensee's instrument response is comparable to NJDEP instrument (±20%).

Through interviews of the RSO and workers, and by observation, determine whether the licensee has a system for tagging out inoperable and out-of-service survey instruments.

Through observations and interviews of the RSO and workers, verify that the licensee's instrumentation for performing in vivo bioassay measurements is adequate for those measurements. Determine that bioassay probes and scalers are compatible. Determine that licensee staff performs a response check using appropriate sources (such as a barium-133 source to simulate iodine-131) and a suitable background measurement before taking bioassay measurements.

Through interviews of pharmacy staff and review of selected records, verify that the licensee performs appropriate checks and tests on each dose calibrator used to dispense dosages for distribution. Such checks and tests include constancy (to verify reproducible instrument response), linearity (to verify instrument response over the range of activities dispensed), accuracy (to verify appropriate energy response), and geometry dependence (to verify instrument response over the range of volumes and containers used to dispense radioactive materials). Verify that the licensee has established acceptance levels for each dose calibrator check and test, and that personnel performing the checks and tests are aware of them and understand the appropriate response if acceptance levels are not met. Determine whether any dose calibrators have been identified that failed a check or test and verify that licensee's response was appropriate. The inspector should request that licensee personnel demonstrate a dose calibrator constancy check.

For each dose calibrator used to measure and dispense beta-emitters, verify through observations, interviews, and reviews of selected records, that the licensee has performed geometry

dependence testing for each source/container configuration used and that the licensee has established appropriate calibration factors for each configuration used.

03.06 FE-6 The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

Authorized Users:
Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify through interviews that the authorized user has knowledge commensurate with operational duties. In cases where users are specified by license condition, determine that the licensed materials they use conform to the license condition. Determine that the authorized users are personally performing or, if permitted in the license, supervising, the authorized work, rather than someone else not named in the license. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of ...." For other types of licensees, supervision is defined in the regulations. For some licenses that have the condition "... under the direct supervision of ..," the authorized user must be physically present at the facility, for easy contact or to observe the individual(s) working. Another phrase used is "... may only be used by ...." Finally, "... under the direct supervision and physical presence of ..." means the authorized user must directly supervise and be present at the work station. CAUTION: Considering the many license condition phrases and regulations, exercise judgment when assessing the role of the authorized users. When the wording of the license condition is "... used by or under the supervision of ...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

Authorized Nuclear Pharmacists (ANPs):

ANPs may either be named on the license or appointed by the licensee. For those appointed by the licensee, verify that these individuals are qualified as ANPs in accordance with N.J.A.C. 7:28-53.1 (see 10 CFR 32.72(b)) and have knowledge commensurate with their operational duties. The regulations in N.J.A.C. 7:28-53.1 (see 10 CFR 32.72(b)(1)) permit the nuclear pharmacy licensee to have an individual "under the supervision of" an authorized nuclear pharmacist prepare radioactive drugs for medical use. These regulations do not specifically require that the authorized user be present at all times during the use of such materials. However, the authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to N.J.A.C. 7.28-55.1 (see 10 CFR 35.27(b)), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

General Training:

Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).

N.J.A.C. 7:28-50.1 (see 10 CFR Part 19)-Required Training:

Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

Training Required by License Commitments:

Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary materials, assess their understanding of the training that they have received, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's initial performance of licensed activities. Through observation of related activities and discussions with selected licensee personnel, verify that they actually received radiation safety training. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations. Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee. Determine, by observing and interviewing workers, if training and experience are adequate to enable users to safely undertake activities authorized by the license and whether they are aware of the risks involved. Examine the licensee's program for on-the-job training of new workers. Determine if there is adequate retraining for workers to cover regulation changes and/or radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

Operating and Emergency Procedures:
Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures will be approved by NJDEP and reviewed and updated by the licensee.

Review and evaluate the licensee's process for controlling documents (procedures) and making revisions to procedures. Revisions to operating procedures should be reviewed by licensee health physics staff to ensure that the revisions do not adversely affect radiological safety. Select a sample of operating or process areas and verify that pertinent procedures are available to personnel, are current, and are in use in those selected areas. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities. Determine whether process activities use procedures for reference or are required to be used "in-hand."

During interviews of selected licensee personnel, assess the worker's knowledge and understanding of the licensee's emergency procedures, through proposed hypothetical emergency scenarios (i.e., "what if" questions). The scenarios should include those types of accidents appropriate to the licensee's program (i.e., contaminated packages identified during receipt surveys, fires, contamination events involving large quantities (100 millicuries of iodine-131 or 1 curie of technetium-99m)).

If the licensee is required to have and implement an emergency plan, assess procedures for handling accidents including evacuation, prevention of spread of contamination, securing sources, handling accident victims, and any other major portions of the emergency plan. Verify, by discussions with workers, and review of procedures, that the emergency plan has been implemented and is being maintained. Verify that lines of communication with outside organizations that may be called on to assist in an emergency are current and tested. Ensure that biennial emergency plan drills and/or exercises include notification of NJDEP staff.

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies.

Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

Posting and Labeling:
Determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. N.J.A.C. 7:28-6.1 (see 10 CFR 20.1903) provides exceptions to posting caution signs. When applicable, randomly examine signals and alarms to determine proper operation. Observe labeling on randomly selected packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

Areas with radiation hazards should be conspicuously posted, as required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902.) Depending on the associated hazard, controls may include tape, rope, or

structural barriers to prevent access. If volatile radioactive materials are used in an area, such an area should be controlled for airborne contamination. High radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program. Examine locations where notices to workers are posted. Applicable documents, notices, or forms must be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.07 FE-7 The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; that assessment of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed.

The NJDEP holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NJDEP regulations and license provisions and to terminate unsafe activities involving byproduct material. Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

• Maintaining awareness of significant events such as the loss or theft of licensed materials.

• Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.

• Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.

• Obtaining the NJDEP's prior written consent before transferring control of the license.

• Notifying the NJDEP Radioactive Materials Section, immediately following filing of petition for voluntary or involuntary bankruptcy N.J.A.C. 7:28-51.1 (see 10 CFR 30.34(h).

• Assuring the appropriate response, when applicable, to generic communications from the NJDEP.

• Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities N.J.A.C. 7:28-51.1 (see 10 CFR 30.35).

• Notifying the NJDEP of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place N.J.A.C. 7:28-51.1 (see 10 CFR 30.36).

• Notifying the NJDEP of defects or other radiation safety equipment malfunctions.

• Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.

Radiation Safety Committee(RSC)(if applicable):
Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

Determine if the committee has been assertive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

Radiation Safety Office (RSO):
Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety. Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

a. If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.

b. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of NJDEP Radioactive Materials Section.

Audits:
Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with N.J.A.C. 7:28-6.1 (see 10 CFR 20.2102(a)(2).

Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.

a. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.

b. Determine if the lack of corrective actions caused the licensee to be in noncompliance with regulatory requirements.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87130

NUCLEAR MEDICINE PROGRAMS, WRITTEN DIRECTIVE NOT REQUIRED

87130-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with NJDEP requirements.

87130-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; 7) Dose administration and 8) 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 NJDEP 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 NJDEP 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 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 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 Dose Administration. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records that doses administered to patients have been measured in the licensee's dose calibrator; that the nuclear medicine technologist is aware of the acceptable range of dosage for each study; that procedures are in place to address a dosage that falls outside of an acceptable range; that the amount of material administered, time of administration and identity of the person that administered the dosage are retained by the licensee and that constancy, linearity, accuracy and geometry testing are conducted on the dose calibrator at the appropriate intervals. The instrument's response should fall within the acceptable range per test or the actions taken by the licensee to address a failed test should be recorded.

02.08 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.

02.09 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 NJDEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in N.J.A.C. 7:28-55.1 (see Subparts D through H of 10 CFR Part 35), if the licensee has submitted the information required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.12(b) through (d), and the licensee has received written approval from the NJDEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NJDEP 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 NJDEP management as soon as practicable to independently verify that such use is authorized under NJDEP regulatory requirements.

87130-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with NJDEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NJDEP, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A combination of direct examination of these licensed activities, discussions with cognizant workers and a review of selected records should be a good indicator of the performance of a licensee's overall radiation safety program.

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 NJDEP 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. Especially 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 NJDEP 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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.13.) Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

b. Adequate Equipment and Instrumentation

1. Through discussion with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee is appropriate to the scope of the licensed program. The inspector should independently verify through direct observations that survey instruments have been calibrated in accordance with N.J.A.C. 7:28-55.1 (see 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 the survey and monitoring instruments available for use have current calibrations and are appropriate to the types and energies of radiation to be detected.

2. If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects in accordance with 10 CFR 21 (the NRC has retained regulatory authority of Subchapter 21.)

c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with NJDEP and applicable U.S. Department of Transportation (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 relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-

term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with NJDEP 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 to DOT and NJDEP. 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," NUREG 1556, vol. 7 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. 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 N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-50.1 and 6.1 (see 10 CFR 19.11 and 20.1902.)

g. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.67(b.) If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

h. Waste Storage and Disposal. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that radioactive waste is stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed NJDEP regulatory limits. Through further discussions, observations, and reviews, if necessary, the inspector should verify that disposals of decay-in-storage waste are performed in accordance with NJDEP regulatory requirements. The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less and can be decayed in storage until surveys are indistinguishable from background, then be disposed of as nonradioactive 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-6 and N.J.A.C. 7:28-59" and the U.S. NRC's Information Notice (IN) 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20."

i. Effluents. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that releases into a public sanitary

sewerage system and septic tanks , if any, are consistent with the form and quantity restrictions of NJDEP 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 NJDEP regulatory requirements and are ALARA (This should include xenon or other gas waste, also). In addition, from those discussions, observations and reviews, if necessary, the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with the manufacturer's recommendations. Furthermore, from those discussions, observations and reviews, if necessary, the inspector should verify that all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented by the licensee. For further inspection guidance, the inspector should refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)."

03.02 Shielding of Licensed Material

In the application for the license, the licensee committed to develop and implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101 and 20.1301.) Through observations and interviews, the inspector should assess the actual implementation of ALARA procedures which include shielding of licensed material.

a. Syringe and Vial Shields. Determine a sufficient number, type, and condition of syringe and vial shields are being used to protect workers and members of the public from unnecessary radiation. Verify labeling of syringe and vial shields required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.69.)
b. Other Shielding. Determine use of shielding for waste receptacles, storage containers, and work areas to protect workers in the hot lab. If shielding is not evident, then the inspector should assess the licensee's evaluation of radiation doses to workers and members of the public respectively under N.J.A.C. 7:28-6.1 (see 10 CFR 20.1201 and 20.1301.) The licensee may have determined that shielding was not needed. The inspector should verify that the licensee instructed workers under N.J.A.C. 7:28-50.1 (see 10 CFR 19.12) about shielding.

03.03 Comprehensive Safety Measures

During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration.

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 N.J.A.C. 7:28-6.1 (see 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 NJDEP regulatory limits as per N.J.A.C. 7:28-6.1 (see 10 CFR 20.1201, 1202, 1207 and 1208.) If from those reviews and discussions the inspector determines that a worker had exceeded an NJDEP regulatory limit, the inspector should immediately contact NJDEP management to discuss the matter and determine what steps need to be taken in following up on this matter. N.J.A.C. 7:28-50.1 (see 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 N.J.A.C. 7:28-50.1 (see 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 shallow dose equivalent 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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1501.)

03.05 Radiation Instrumentation, Surveys, and Leak Tests

a. Equipment and Instrumentation

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with NJDEP regulatory requirements and the manufacturer's recommendations. The inspector should verify that: (a) the radiation survey instruments have been calibrated in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.61); (b) the instruments used to measure the activity of unsealed byproduct material meet the requirements of N.J.A.C. 7:28-55.1 (see 10 CFR 35.60); (c) licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 the survey and monitoring instruments available for use are 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.

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 NJDEP 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 NJDEP 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 NJDEP.) 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-50.1 (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 NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP 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, and "dry runs" for more complex or hazardous operations.

b. Operating and Emergency Procedures. During the conduct of the inspection, the inspector should verify through direct observations of licensed activities, if practical, licensee personnel perform tasks at selected work stations to verify that such licensed activities are performed in accordance with the licensee's operating procedures. Through discussions with cognizant licensee staff, the inspector should verify that those individuals interviewed understand and implement procedures establish by the licensee and are aware of procedural revisions. If appropriate, the inspector should review the licensee's emergency procedures to determine that these procedures are adequate to ensure compliance with NJDEP regulatory requirements. 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 NJDEP under N.J.A.C. 7:28-6.1 (see 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. Protective Clothing. Through direct observations of licensed activities and discussions with cognizant licensee representatives, the inspector should verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed. The observation of the protective clothing that licensee staff wears during their work activities should provide the inspector with an acceptable means of reviewing this requirement. If the inspector identifies a concern with this practice, the inspector should discuss this practice with appropriate licensee representatives to ensure that licensee staff are following licensee procedures for wearing adequate protective clothing.

03.07 Management Oversight

The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management and the RSO. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to NJDEP. 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 the NJDEP supervisor 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.

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 N.J.A.C. 7:28-55.1 (see 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 NJDEP 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 lab personnel, locations of use, human research and medical use activities, mobile nuclear medicine services, distribution of pharmaceuticals under N.J.A.C. 7:28-55.1 (see 10 CFR Part 35) license, and the principal types and quantities of licensed materials used.

c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify that, when deficiencies are identified, the RSO

has sufficient authority to implement corrective actions, including termination of operations that pose a threat to health and safety.

2. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Authorized Users. Authorized users (physicians, nuclear pharmacists, and medical physicists) are named on the license. The inspector should note that the regulations in N.J.A.C. 7:28-55.1 (see 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, as long as there are personnel present who have been properly trained and instructed pursuant to N.J.A.C. 7:28-55.1 (see 10 CFR 35.27(a). However, the authorized user is ultimately responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

e. Authorized Uses. The inspector should determine from observing the use of licensed material, discussing the activities with cognizant licensee personnel, and if necessary, from a review of selected records, that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license. From those observations, discussions, and reviews, if necessary, the inspector should verify that the total activity of licensed material does not exceed the maximum activity authorized either in the license or in the design specifications of the device's sealed source device registration certificate.

f. Financial Assurance and Decommissioning. The decommissioning record keeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in N.J.A.C. 7:28-51.1 (see 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 N.J.A.C. 7:28-51.1 (see 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, provided a license amendment has been submitted to and approved by the NJDEP. 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 NJDEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NJDEP regulatory limits, the inspector should immediately contact NJDEP 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 NJDEP. 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 NJDEP. 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 NJDEP. 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 N.J.A.C. 7:28-51.1 (see Section II, Appendix A and C of 10 CFR 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 N.J.A.C. 7:28-51.1, 58.1, and 60.1 (see 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 NJDEP 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 NJDEP, 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 be classified as a Severity Level III violation and 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 NJDEP management as soon as practicable for further guidance. For the Department conducting inspections of licensees undergoing decommissioning, the inspector should refer to NRC MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees;" and IP 87104, "Decommissioning Inspection Procedure for Materials Licensees."

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these NJDEP 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 theNJDEP. 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 NJDEP 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 NJDEP 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 NJDEP 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 a Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" as per N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see Subparts D through H of 10 CFR 35.1000), the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in this subchapter if the licensee has submitted the information required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.12 (b) through (d); and the licensee has received written approval from the NJDEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NJDEP 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 NJDEP management as soon as practicable to independently verify that such use is authorized under the regulations. For further inspection guidance, refer to MC 2800.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87131

NUCLEAR MEDICINE PROGRAMS
WRITTEN DIRECTIVE REQUIRED

87131-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with New Jersey Department of Environmental Protection (NJDEP) requirements.

87131-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas:

1) Security and control of licensed material;

2) Shielding of licensed material;

3) Comprehensive safety measures;

4) Radiation dosimetry program;

5) Radiation instrumentation and surveys;

6) Radiation safety training and practices;

7) Dose Administration; and

8) Management oversight;

9) Other Medical Uses of Byproduct Material or Radiation from Byproduct Material.

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 NJDEP 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 the 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 NJDEP 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 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 Dose Administration. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records that doses administered to patients have been measured in the licensee's dose calibrator; that the nuclear medicine technologist is aware of the acceptable range of dosage for each study; that procedures are in place to address a dosage that falls outside of an acceptable range; that the amount of material administered, time of administration and identity of the person that administered the dosage are retained by the licensee and that constancy, linearity, accuracy and geometry testing are conducted on the dose calibrator at the appropriate intervals. The instrument's response should fall within the acceptable range per test or the actions taken by the licensee to address a failed test should be recorded. Additionally, the inspector should verify, through discussions with staff and a review of selected records, that procedures are in place and are used to ensure the dosage administered to a patient is what was prescribed by the written directive.

02.08 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.

02.09 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 NJDEP regulations, the licensee may use byproduct material or a radiation

source approved for medical use which is not specifically addressed in N.J.A.C. 7:28-55.1 (see Subparts D through H of 10 CFR Part 35), if the licensee has submitted the information required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.12(b) through (d)), and the licensee has received written approval from the NJDEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NJDEP 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 NJDEP Radioactive Materials Section Supervisor as soon as practicable to independently verify that such use is authorized under NJDEP regulatory requirements.

87131-03 INSPECTION GUIDANCE

General Guidance:

A determination regarding safety and compliance with NJDEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NJDEP, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A combination of direct examination of these licensed activities, discussions with cognizant workers and a review of selected records should be a good indicator of the performance of a licensee's overall radiation safety program.

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 NJDEP 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. Especially 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 NJDEP 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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.13). Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

b. Adequate Equipment and Instrumentation:

1. Through discussion with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee is appropriate to the scope of the licensed program. The inspector should independently verify through direct observations that survey instruments have been calibrated in accordance with N.J.A.C. 7:28-55.1 (see 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 those survey and

monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected.

2. If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects in accordance with 10 CFR 21 (the NRC has retained regulatory authority of Subchapter 21.)

c. Receipt and Transfer of Licensed Materials: Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with NJDEP and applicable U.S. Department of Transportation (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 relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation: Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's

hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with NJDEP 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 to DOT and NJDEP. 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," NUREG 1556, vol. 7 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 the radioactive material will be administered as directed by the authorized user in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.41.) The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.2040)

g. Patient Release: Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected records, the inspector should determine if a licensee is knowledgeable about patient release criteria and that a process exists to establish that a patient administered radiopharmaceuticals or therapeutic quantities of radioactive material is releasable from control in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.75.)

1. The inspector should note that the patient release criteria permit licensees to release individuals from control if the TEDE for any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.75.)

2. Through further discussions the inspector should verify that the licensee is familiar with the requirements in N.J.A.C. 7:28-55.1 (see 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. The inspector should 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 N.J.A.C. 7:28-55.1 (see 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 NJDEP 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 N.J.A.C. 7:28-55.1 (10 CFR 35.3045), "Report and Notification of a Medical Event; and

2) follow the procedure for reactive inspections and the guidance provided in Management Directive 8.10, "NRC Medical Event Assessment Program." Upon identification of such an event, the inspector should notify NJDEP 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 N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-50.1 and 6.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.67(g)). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

k. Waste Storage and Disposal: Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that radioactive waste is stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed NJDEP regulatory limits. Through further discussions, observations, and reviews, if necessary, the inspector should verify that disposals of decay-in-storage waste are performed in accordance with NJDEP regulatory requirements. The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902 and 20.1904); and

4. Waste was returned from a landfill due to radioactive contamination.

a. Effluents: Through discussions with cognizant licensee representatives and 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 NJDEP regulatory requirements. 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. The inspector should examine the waste release records generated since the last inspection, annual or semiannual reports, pertinent non routine 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 NJDEP regulatory requirements and are ALARA (This should include xenon or other gas waste, also). In addition, from those discussions, observations and reviews, if necessary, the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with the manufacturer's recommendations.

Furthermore, from those discussions, observations and reviews, if necessary, the inspector should verify that all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented by the licensee. For further inspection guidance, the inspector should refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low as Is Reasonably Achievable (ALARA)."

03.02 Shielding of Licensed Material: In an application for a license, a licensee must commit to develop, implement, and maintain procedures under N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101 and 20.1301). for safe use of unsealed byproduct material. Through observations and interviews, the inspector should assess the actual implementation of ALARA procedures which include shielding of licensed material.

a. Syringe and Vial Shields: Determine a sufficient number, type, and condition of syringe and vial shields are being used to protect workers and members of the public from unnecessary radiation. Verify labeling of syringe and vial shields required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.69.)

b. Shielding in the Hot Lab: Determine use of shielding for waste receptacles, storage containers, generator systems, and work areas to protect workers in the hot lab.

c. Shielding for Nuclear Medicine Therapy: Determine use of shielding for administration of therapeutic quantities of byproduct material to protect workers and family members of the patient who may be present. To limit doses to workers and individual members of the public, a licensee may use portable shielding in patient rooms or the licensee may have installed permanent shielding in certain patient rooms designated for patients that cannot be released under N.J.A.C. 7:28-55.1 (see 10 CFR 35.75.) In an application for a license, the applicant would have described the shielding along with calculations to estimate dose levels. For portable shields, an applicant would also commit to develop administrative procedures for proper use and placement of the shields within a patient room. If shielding is not evident, then the inspector should assess the licensee's procedure and further evaluation of radiation doses to workers and members of the public respectively under N.J.A.C. 7:28-6.1 (see 10 CFR 20.1201, 1301 and 1302). The inspector should verify that the licensee instructed workers under N.J.A.C. 7:28-50.1 (see 10 CFR 19.12) about shielding. The licensee may have determined that shielding was not indicated under certain conditions to protect the patient or human research subject from a non-radiological hazard which has significant health and safety consequences to the patient or human research subject.

03.03 Comprehensive Safety Measures: During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration. 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 N.J.A.C. 7:28-6.1 (see 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 NJDEP regulatory limits as per N.J.A.C. 7:28-6.1 (see 10 CFR 20.1201, 1202, 1207 and

1208). If from those reviews and discussions the inspector determines that a worker had exceeded an NJDEP regulatory limit, the inspector should immediately contact NJDEP management to discuss the matter and determine what steps need to be taken in following up on this matter. N.J.A.C. 7:28-50.1 (see 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 N.J.A.C. 7:28-50.1 (see 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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1502).

03.05 Radiation Instrumentation and Surveys:

a. Equipment and Instrumentation:

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with NJDEP

regulatory requirements and the manufacturer's recommendations. The inspector should verify that:

(a) The radiation survey instruments have been calibrated in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.61).

(b) The instruments used to measure the activity of unsealed byproduct material meet the requirements of N.J.A.C. 7:28-55.1 (see 10 CFR 35.60).

(c) Licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 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.

b. Area Radiation Surveys: During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that radiation levels are within NJDEP 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 NJDEP 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 NJDEP office.). 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-50.1 (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 NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP 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 authorized nuclear pharmacists instruction in the preparation of drugs.

b. Operating and Emergency Procedures: During the conduct of the inspection, the inspector should verify through direct observations of licensed activities, if practical, licensee personnel perform tasks at selected work stations to verify that such licensed activities are performed in accordance with the licensee's operating procedures. Through

discussions with cognizant licensee staff, the inspector should verify that those individuals interviewed understand and implement procedures establish by the licensee and are aware of procedural revisions. If appropriate, the inspector should review the licensee's emergency procedures to determine that these procedures are adequate to ensure compliance to NJDEP regulatory requirements. 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 NJDEP under N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.75), in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.310). The inspector should note that radiation safety instruction must be conducted initially and at least annually and be commensurate with the duties of the personnel.

d. Protective Clothing: Through direct observations of licensed activities and discussions with cognizant licensee representatives, the inspector should verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed. The observation of the protective clothing that licensee staff wear during their work activities should provide the inspector with an acceptable means of reviewing this requirement. If the inspector identifies a concern with this practice, the inspector should discuss this practice with appropriate licensee representatives to ensure that licensee staff are following licensee procedures for wearing adequate protective clothing.

03.07 Management Oversight: The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization: During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management and the RSO. Through discussions with cognizant licensee staff, the inspector should determine

whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to NJDEP. 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 NJDEP staff 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. 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 N.J.A.C. 7:28-55.1 (see 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 NJDEP 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 lab personnel, locations of use, human research and medical use activities, mobile nuclear medicine services, distribution of pharmaceuticals under N.J.A.C. 7:28-55.1 see 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. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101(c)) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Authorized Users: Authorized users (physicians, nuclear pharmacists, and medical physicists) are named on the license. The inspector should note that the regulations in N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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: The inspector should determine from observing the use of licensed material, discussing the activities with cognizant licensee personnel, and if necessary, from a review of selected records, that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license. From those observations,

discussions, and reviews, if necessary, the inspector should verify that the total activity of licensed material does not exceed the maximum activity authorized either in the license or in the design specifications of the device's sealed source device registration certificate.

f. Financial Assurance and Decommissioning: The decommissioning record keeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in N.J.A.C. 7:28-51.1 (see 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 N.J.A.C. 7:28-51.1 (see 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 NJDEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NJDEP regulatory limits, the inspector should immediately contact NJDEP management for further guidance. Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions.

Occasionally, those conditions may change overtime and the licensee may not notify NJDEP. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, which 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 NJDEP. 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 NJDEP. 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 N.J.A.C. 7:28-51.1 (see Section II, Appendix A and C of 10 CFR 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 N.J.A.C. 7:28-51.1, 58.1, and 60.1 (see 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 NJDEP 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 NJDEP, 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 be a violation and 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 NJDEP management as soon as practicable for further guidance. For the Department conducting inspections of licensees undergoing decommissioning, the inspector should refer to NRC MC 2602, "Decommissioning Inspection Program for Materials Licensees;" IP 87104, and "Decommissioning Inspection Procedure for Materials Licensees."

h. Generic Communications of Information: Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, etc., and that the information contained in these documents is

disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these NJDEP 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 NJDEP 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 NJDEP 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 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 NJDEP requirement.

k. Research Involving Human Subjects: If applicable, the inspector must verify that this type of research satisfies 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" as per N.J.A.C. 7:28-55.1 (see 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 radioactive material or radiation from radioactive 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 N.J.A.C. 7:28-55.1 (see Subparts D through H of 10 CFR 35.1000), the licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed if the licensee has submitted the information required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.12 (b) through (d));; and the licensee has received written approval from the NJDEP in a license or license amendment and uses the material in accordance with the

regulations and specific conditions the NJDEP 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 radioactive material or radiation from radioactive 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 NJDEP management as soon as practicable to independently verify that such use is authorized under the regulations. For further inspection guidance, refer to MC 2800.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87132

BRACHYTHERAPY PROGRAMS

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 New Jersey Department of Environmental Protection (NJDEP) 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 licensees 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 NJDEP 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 the 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 after loaders, 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 prevented loss of licensed material so as to limit radiation exposure to workers and members of the public to values below NJDEP 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 NJDEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in New Jersey Administrative Code (N.J.A.C.) 7:28-55.1 (see Subparts D through H of 10 CFR Part 35) if the licensee has submitted the information required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.12(b) through (d)), and the licensee has received written approval from the NJDEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NJDEP 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 NJDEP management as soon as practicable to independently verify that such use is authorized under NJDEP regulatory requirements.

87132-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with NJDEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NJDEP, 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 NJDEP 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. Especially 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 NJDEP 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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 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 After loaders. 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 not 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.61, 615, 633 and 643).

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 NJDEP 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 NJDEP.

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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 643). Also, the inspector should verify that additional technical requirements are conducted on the unit at the required frequency as required by N.J.A.C. 7:28-55.1 (see 10 CFR 647). Furthermore, the inspector should verify that the licensee has performed acceptance testing on the treatment planning system in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 657).

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 NJDEP 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 ophthalmic 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

ophthalmic 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.

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 NJDEP and applicable U.S. Department of Transportation (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 NJDEP 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 to DOT and NJDEP.

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 NJDEP 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 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.41). The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.2040).

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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.75).

2. Through further discussions the inspector should verify that the licensee is familiar with the requirements in N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 NJDEP 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 in N.J.A.C. 7:28-55.1 (see 10 CFR 35.3045), "Report and Notification of a Medical Event;" and 2) follow the procedure for reactive inspections and the guidance provided in NRC's Management Directive 8.10, "NRC Medical Event Assessment Program" available on NRC's Electronic Reading Room. Upon identification of such an event, the inspector should notify NJDEP 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 N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-6.1 (see 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 are 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 N.J.A.C. 7:28-6.1 and 7:28-50.1 (see 10 CFR 19.11 and 10 CFR 20.1902).

During tours of the licensee's facility, the inspector should verify that emergency procedures are appropriately posted at the control console in accordance with N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-6 and N.J.A.C. 7:28-59".

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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1201, 1301 and 1302)). The inspector should verify that the licensee instructed workers under N.J.A.C. 7:28-50.1 (see 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.

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 N.J.A.C. 7:28-6.1 (see 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 NJDEP regulatory limits as per N.J.A.C. 7:28-6.1 (see 10 CFR 20.1201, 1202, 1207 and 1208)). If from those reviews and discussions the inspector

determines that a worker had exceeded an NJDEP regulatory limit, the inspector should immediately contact NJDEP management to discuss the matter and determine what steps need to be taken in following up on this matter. N.J.A.C. 7:28-50.1 (see 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 N.J.A.C. 7:28-50.1 (see 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 N.J.A.C. 7:28-6.1 (see 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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 in accordance with the requirements of N.J.A.C. 7:28-55.1 (see 10 CFR 35.633 and 643)). During the inspection, the inspector should review selected dosimetry worksheets from the previous full calibration measurements required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.633 and 643)). If the licensee participates in comparison 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.

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 NJDEP 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 N.J.A.C. 7:28-55-6.1 (see 10 CFR 20.1301) are met. However, the inspector must use NJDEP 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 NJDEP office.) The inspector should conduct such surveys as further discussed in Section 03.12.

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

The inspector should verify by independent measurement that shielding surveys of the unit head and treatment room are in compliance with the requirements of N.J.A.C. 7:28-55.1 (see 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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-50.1 (see 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 NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 misadministration 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 ophthalmic applicators. They are NIST, itself, and the University of Wisconsin Accredited Dosimetry Calibration Laboratory. The inspector should note that the applicator is required to be a N.J.A.C. 7:28-55.1 (see 10 CFR 35.49) source.

2. The inspector should also refer to USNRC IN 96-66, "Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators," available in the NRC's Electronic Reading Room, 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 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 N.J.A.C. 7:28-6.1 (see 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 ophthalmic 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 N.J.A.C. 7:28-61.1 (see 10 CFR 71.9), the transportation of eye applicators between license-authorized offices or hospitals is to be conducted by a physician licensed by the NRC or Agreement State to dispense drugs in the practice of medicine, and licensed under 10 CFR Part 35 or N.J.A.C. 7:28-55.1.

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 NJDEP. 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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 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 NJDEP regulatory requirements and the licensee's license. Also, the inspector should follow-up with this matter with appropriate NJDEP licensing staff to ensure that they are 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 N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.27), 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 in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.615(f)).

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 N.J.A.C. 7:28-56.1 (see 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 N.J.A.C. 7:28-51.1 (see 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 N.J.A.C. 7:28-51.1 (see 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 NJDEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NJDEP regulatory limits, the inspector should immediately contact NJDEP 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 NJDEP. 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 NJDEP. 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 NJDEP. 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 N.J.A.C. 7:28-51.1 (see Section II, Appendix A and Appendix C, respectively, to 10 CFR 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 N.J.A.C. 7:28-51.1, 58.1, and 60.1 (see 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 NJDEP 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 NJDEP, 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 be classified as a Severity Level III violation and 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 NJDEP regional 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 the NRC's NUREG/BR-0241. "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees."

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, NMSS Newsletter, 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 NJDEP 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 NJDEP 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 NJDEP 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 NJDEP 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 the New Jersey Commission on Radiation Protection.

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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.12(b) through (d); and the licensee has received written approval from the NJDEP in a license or license amendment and

uses the material in accordance with the regulations and specific conditions the NJDEP 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. For further inspection guidance, refer to MC 2800.

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

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87133

MEDICAL GAMMA STEREOTACTIC RADIOSURGERY AND TELETHERAPY PROGRAMS

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 New Jersey Department of Environmental Protection (NJDEP) 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 amore 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 NJDEP 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. 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 NJDEP 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 Radioactive Material or Radiation from Radioactive 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 NJDEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in N.J.A.C. 7:28-55.1 (see subparts D through H of 10 CFR Part 35, if the licensee has submitted the information required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.12(b) through (d), and the licensee has received written approval from the NJDEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NJDEP 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 NJDEP Radioactive Materials Section as soon as practicable to independently verify that such use is authorized under NJDEP regulatory requirements.

87133-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with NJDEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NJDEP, 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 NJDEP Radioactive Materials Section. 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. The NJDEP views all information concerning radioactive material licensees activities as a domestic security issue, and as such are exempted from the requirements of the Open Public Record Act (OPRA). Therefore, these records will not become publicly available. .

. 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 NJDEP Radioactive Materials Section 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 NJDEP guidance under such circumstances.

Specific Guidance

03.01 Security and Control of Licensed Material:

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 N.J.A.C. 7:28-55.1 (see 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).

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 N.J.A.C. 7:28-55.1 (10 CFR 35.61, 615, 632, 635, 642 and 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 NJDEP, USNRC or other Agreement State. The inspector should verify that the dosimetry system used to perform full calibration measurements is in accordance with NJDEP regulatory requirements; and that safety systems are checked as required by NJDEP 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 NJDEP

Radioactive Materials Section 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.

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 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 NJDEP Radioactive Materials Section 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 N.J.A.C. 7:28-55.1. (see 10 CFR 35.632 and 635). The inspector should verify that spot checks are conducted at the required frequency, and as required by N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.657).

Additional NJDEP 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 NRC Information Notice 99-27.

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 NJDEP is also aware of the report.

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

NJDEP and applicable U.S. Department of Transportation (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 NJDEP, USNRC or other Agreement State.

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 NJDEP 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 to DOT and NJDEP. 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.

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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.610).

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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.41). The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.2040).

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 NJDEP 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:

a. remind the licensee of the need to comply with the reporting requirements described in N.J.A.C. 7:28-55.1 (see 10 CFR 35.3045, "Report and Notification of a Medical Event;") ; and

b. follow the procedure for reactive inspections and the guidance provided in (Management Directive 8.10), "Medical Event Assessment Program." Upon identification of such an event, the inspector should notify NJDEP Radioactive Materials Section as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

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 N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-6.1 (see 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 radio surgery 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 N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-50.1 (see 10 CFR 19.11),, N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902) and 10 CFR 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.610).

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 N.J.A.C.7:28-55.1 (see 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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1201, 20.1301, and 20.1302). The inspector should verify that the licensee instructed workers under N.J.A.C. 7:28-50.1 (see 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. 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:

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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101).

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 NJDEP regulatory limits (N.J.A.C. 7:28-6.1). If from those reviews and discussions the inspector determines that a worker had exceeded an NJDEP regulatory limit, the inspector should immediately contact NJDEP Radioactive Materials Section to discuss the matter and determine what steps need to be taken in following up on this matter.

N.J.A.C. 7:28-50.1 (see 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 N.J.A.C. 7:28-50.1 (see 10 CFR 19.13(a)).

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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1501).

03.05 Radiation Instrumentation Surveys and Leak Tests:

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 to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with NJDEP 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 N.J.A.C. 7:28-55.1 (see 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.

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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.632 and 635). During the inspection, the inspector should review selected dosimetry worksheets from the previous full calibration measurements required by N.J.A.C. 7:28-55.1 (see 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 inter comparison of dosimetry measurements, the inspector should review the licensee's performance results to determine that systemic measurement errors are identified and corrected.

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.

When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects. This will vary dependent upon the scope of the licensee's program.

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 NJDEP 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 NJDEP 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 NJDEP office.)

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 N.J.A.C. 7:28-55.1 (see 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.

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 N.J.A.C. 7:28-55.1 (see 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 NJDEP 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.

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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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), the inspector should verify that the licensee made the appropriate notifications per N.J.A.C. 7:28-55.1 (see 10 CFR 35.67(e)) and removed the source from service.

03.06 Radiation Safety Training and Practices:

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 N.J.A.C. 7:28-50.1 (see 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 NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP 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.

Operating and Emergency Procedures:
Emergency procedures will be developed, implemented and maintained by the licensee in accordance with N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 NJDEP under N.J.A.C. 7:28-6.1 (see 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.

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 NJDEP. 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 NJDEP 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.

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 N.J.A.C. 7:28-55.1 (see 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 NJDEP regulatory requirements and the licensee's license.

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.

Radiation Safety Officer (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.

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 N.J.A.C. 7:28-6.1 (see 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.

Radiation Safety Committee (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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.24(f)). If applicable, through discussions with cognizant 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 N.J.A.C. 7:28-55.1 (see 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.

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 note that the regulations in N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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 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 radioactive 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 N.J.A.C. 7:28-56.1 (see 10 CFR 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:

a. 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.

b. License authorizes depleted uranium shielding if used in the shielding of the gamma stereotactic radiosurgery or teletherapy unit.

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 N.J.A.C. 7:28-51.1 (see 10 CFR 35.35(g)). These records should contain, among other information:

a. records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site;

b. 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

c. 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 N.J.A.C. 7:28-51.1 (see 10 CFR 35.35(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 betaken to address the matter, determine if members of the public have received radiation exposures that exceeded NJDEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NJDEP regulatory limits, the inspector should immediately contact NJDEP Radioactive Materials Section for further guidance.

Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change overtime and the licensee may not notify NJDEP. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, which 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 NJDEP.

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 NJDEP. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact NJDEP Radioactive Materials Section 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 N.J.A.C. 7:28-51.1 (see Section II, Appendix A and Appendix C, respectively, to 10 CFR 30).

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 N.J.A.C. 7:28-51.1, 58.1 and 60.1 (see 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 NJDEP 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 NJDEP, 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 be classified as a Severity Level III violation and 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 NJDEP Radioactive Materials Section 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;" and IP 87104, "Decommissioning Inspection Procedure for Materials Licensees."

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 NJDEP communications, when a response is required.

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 NJDEP. 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 NJDEP 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 NJDEP regulatory requirements.

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 NJDEP requirement.

Research Involving Human Subjects:
If applicable, the inspector must verify that this type of research satisfies the following conditions:

a. All research is conducted, supported, or regulated by a Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" N.J.A.C. 7:28-55.1 (see 10 CFR 35.6), or the licensee is authorized to conduct such research;

b. the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and

c. 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 Radioactive Material or Radiation from Radioactive Material:

Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from radioactive material are always on the fore front of providing optimal medical care to patients. Due to the increase in these various new medical uses of radioactive material or radiation from radioactive 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.1000), the licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in N.J.A.C. 7:28-55.1 (see subparts D through H of 10 CFR 35) above if the licensee has submitted the information required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.12(b) through (d)); and the licensee has received written approval from the NJDEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NJDEP 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 radioactive 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 NJDEP Radioactive Materials Section as soon as practicable to independently verify that such use is authorized under the regulations.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 87134

MEDICAL BROAD-SCOPE PROGRAMS

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 New Jersey Department of Environmental Protection (NJDEP) 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 amore 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 NJDEP 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 NJDEP 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 Radioactive Material or Radiation from Radioactive 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 NJDEP regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in N.J.A.C. 7:28-55.1 (see Subpart D through H of 10 CFR 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 NJDEP Radioactive Materials Section as soon as practicable.

87134-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with NJDEP requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NJDEP, 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 are a 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 NJDEP radioactive materials section supervisor. 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. The NJDEP views all information concerning radioactive material licensees activities as a domestic security issue, and as such are exempted from the requirements of the Open Public Record Act (OPRA). Therefore, these records will not become publicly available.

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 NJDEP 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 NJDEP guidance under such circumstances.

Specific Guidance:

03.01 Security and Control of Licensed Material

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 N.J.A.C. 7:28-55.1 (see 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).

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 N.J.A.C. 7:28-55.1 (see 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.

> 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 NJDEP is also aware of the report.

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 NJDEP and applicable U.S. Department of Transportation (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 those systems.

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).

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 NJDEP 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 to DOT and NJDEP.

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.

Written Directive:
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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.41). The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with N.J.A.C. 7:28-55 (see 10 CFR 35.2040).

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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.75)

a. The inspector should note that the patient release criteria permit 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.75).

b. Through further discussions the inspector should verify that the licensee is familiar with the requirements in N.J.A.C. 7:28-55.1 (see 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.

c. 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.75(d))..

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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.3045 "Report and Notification of a Medical Event"); and

Follow the procedure for reactive inspections and the guidance provided in Management Directive 8.10, "NJDEP Medical Event Assessment Program". Upon identification of such an event, the inspector should notify NJDEP Radioactive Materials Section as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

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 N.J.A.C. 7:28-6.1 (see 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 N.J.A.C. 7:28-50.1 (see 10 CFR 19.11) and N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902)..

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 N.J.A.C. 7:28 -55.1 (see 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.

Waste Storage and Disposal:
The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1902 and 1904); and

4. Waste was returned from a landfill due to radioactive contamination.

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 NJDEP 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 non routine 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 NJDEP regulatory requirements and are ALARA (This should include xenon or other gas waste, also).

<u>03.02</u> Shielding

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.

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 glove boxes. 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 glove boxes, verify that the licensee has evaluated the adequacy of shielding before beginning the new process.

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.

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. Verify that unit shields are adequate for the quantities of radioactive materials typically contained therein.

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 NJDEP 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.

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 > 1rem 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 Safety Measures

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. 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

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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1101).

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 NJDEP regulatory limits in N.J.A.C. 7:28-6.1 (see 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 NJDEP regulatory limit, the inspector should immediately contact NJDEP Radioactive Materials Section to discuss the matter and determine what steps need to be taken in following up on this matter. N.J.A.C. 7:28-50.1 (see 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 N.J.A.C. 7:28-50.1 (see 10 CFR 19.13(a)).

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.

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 N.J.A.C. 7:28-6.1 (see 10 CFR 20.1501).

03.05 Radiation Instrumentation Surveys and Leak Tests

Equipment and Instrumentation:
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 NJDEP regulatory requirements and the manufacturer's recommendations. The inspector should verify that:

a. The radiation survey instruments have been calibrated in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 30.61).

b. The instruments used to measure the activity of unsealed byproduct material meet the requirements of N.J.A.C. 7:28-55.1 (see 10 CFR 35.60).

c. Licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 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.

Area Radiation Surveys:
During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements that radiation levels are within NJDEP 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 NJDEP 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 NJDEP office). 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.

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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.67(c)). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185becquerels) or approved level included in a license condition, the inspector should verify that the licensee made the appropriate notifications as per N.J.A.C. 7:28-55.1 (see 10 CFR 35.67(e) and removed the source from service.

03.06 Radiation Safety Training and Practices:

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 N.J.A.C. 7:28-50.1 (see 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 milli Sievert (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 NJDEP regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NJDEP 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 pharmacist's instruction in the preparation of radioactive drugs.

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 NJDEP under N.J.A.C. 7:28-6.1(see 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 response.

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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.75), in accordance with N.J.A.C. 7:28-55.1 (see 10 CFR 35.310). The inspector should note that radiation safety instruction must be conducted initially and at least annually and be commensurate with the duties of the personnel.

Specialized Training:
The inspector should note that specialized instruction required in N.J.A.C. 7:28-55.1 (see 10 CFR 35.27) was provided to supervise 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.

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:

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 NJDEP. 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 NJDEP 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.

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. 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 N.J.A.C. 7:28-55.1 (see 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 NJDEP 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35) license; and principal types and quantities of licensed materials used.

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.

Radiation Safety Officer (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.

Radiation Safety Committee (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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.24(f)). If applicable, through discussions with cognizant 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 N.J.A.C. 7:28-55.1 (see 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.6).

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 N.J.A.C. 7:28-6.1 (see 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.

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 N.J.A.C. 7:28-55.1 (see 10 CFR 35), are trained in accordance with the approved criteria, and have knowledge commensurate with operational duties. The inspector should note that the regulations in N.J.A.C. 7:28-55.1 (see 10 CFR 3511(b)) allow an individual to receive, possess, use, or transfer radioactive 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 N.J.A.C. 7:28-55.1 (see 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 in N.J.A.C. 7:28-55.1 (see 10 CFR 35) and has knowledge commensurate with operational duties.

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.

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 N.J.A.C. 7:28-51.1 (see 10 CFR 30.35(g)). These records should contain, among other information:

a. Records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site;

b. 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

c. 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 N.J.A.C. 7:28-51.1 (see 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 NJDEP regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NJDEP regulatory limits, the inspector should immediately contact NJDEP Radioactive Materials Section for further guidance. Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change overtime and the licensee may not notify NJDEP. The inspector should be aware of changes in radiological conditions, while inspecting a licensee's facility, which 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 NJDEP. 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 NJDEP. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact NJDEP Radioactive Materials Section 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.

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. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect. The inspector should note that the NJDEP 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 NJDEP, 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 be classified as a Severity Level III violation and 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 NJDEP Radioactive Materials Section as soon as practicable for further guidance.

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 NJDEP communications, when a response is required.

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 NJDEP 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 NJDEP regulatory requirements.

Special License Conditions:
Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of equipment for non-medical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license

conditions. The inspector should also note that some special license conditions may state an exemption to a particular NJDEP requirement.

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 satisfies the following conditions:

a. All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" N.J.A.C. 7:28-55.1 (see 10 CFR 35.6) or the licensee is authorized to conduct such research;

b. The licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and

c. 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 Radioactive Material or Radiation from Radioactive Material:

Due to the advancements of medical research and development, a variety of new medical uses of radioactive 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 radioactive material or radiation from radioactive 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 N.J.A.C. 7:28-55.1 (see 10 CFR 35.1000) the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in N.J..C. 7:28-55.1 (see subparts D through H of 10 CFR 35),if the licensee has submitted the information required by N.J.A.C. 7:28-55.1 (see 10 CFR 35.12 (b) through (d)) and the licensee has received written approval from the NJDEP in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NJDEP 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 radioactive 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 NJDEP management as soon as practicable to independently verify that such use is authorized under the regulations.

NJDEP INSPECTION MANUAL
INSPECTION PROCEDURE 92702

FOLLOWUP ON ENFORCEMENT ACTIONS

92702-01 INSPECTION OBJECTIVES

To determine that adequate corrective actions have been implemented for traditional enforcement actions. To verify that the root causes of these enforcement actions have been identified, that their generic implications have been addressed, and that the licensee's programs and practices have been appropriately enhanced to prevent recurrence.

Note that for construction inspection activities, licensee programs referenced throughout this procedure include the licensee Quality Assurance (QA) program.

92702-02 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance. This inspection procedure provides a mechanism to perform in-office and on-site follow-up inspection of traditional enforcement actions as deemed necessary by the Department.

Enforcement sanctions typically require written explanations and statements of reply concerning corrective actions, steps taken to prevent recurrence, and a schedule for completion of corrective and preventive actions. Specific responses or actions may be required in other enforcement sanctions. The inspector should carefully review the enforcement actions and inspection report transmittal letters which may contain NJDEP perceptions of, and concerns with, licensee performance. Such statements are valuable background information.

The NJDEP inspection program places strong emphasis on the inspection of licensee performance as the basis for determining the overall adequacy of the implementation of licensee programs. Thus, when a deficiency in the licensee performance is identified, and especially when repetitive conditions occur, a key element to be reviewed is the failure of the licensee program to identify and correct the deficiency. Where licensee corrective actions for NJDEP identified deficiencies are not adequate, additional inspections may be warranted to assess the adequacy of the licensee corrective actions for internally identified problems.

Enforcement actions that have been issued require a follow-up to ensure required actions are completed. Inspection follow-up should be completed as described below.

02.01 Documentation Review. Conduct a review of licensee responses to traditional enforcement actions to ascertain that the licensee responses and stated corrective and preventive actions were timely and appropriate. Evaluate whether the responses describe the conduct of a root cause analysis and implementation of any appropriate changes in training or procedures. Assess whether generic implications were addressed and whether the licensee programs and practices have been enhanced where appropriate to prevent recurrence.

Determine which responses are to receive onsite follow-up inspection based on their safety or security significance and complexity, inherent inadequacy, or apparent weaknesses in licensee administrative or management controls.

Guidance: The timing of NJDEP follow-up to a routine inspection would depend on the relative qualitative safety or security significance of a deficient licensee program in the area of the traditional enforcement action. Typically, the inspection staff will have information about the probable root cause of traditional enforcement actions as a result of their normal inspection activity. In addition, as part of the enforcement process, the licensee would make their own determination of their program adequacy. The available information can then be used to make a determination on the timing of NJEP follow-up, along with the scope and depth of follow-up that is warranted. The documentation review should include relevant inspection reports, inspection report transmittal letters, licensee response letters to enforcement correspondence, minutes of related enforcement meetings with the licensee, and any other agency records of communication on the issue with the licensee. Depending on the relative safety or security significance of the issue, the inspector and their management may conclude that an in-office review of the licensee docketed evaluation and corrective actions may suffice to close out the finding, rather than performing an onsite follow-up inspection. The review will initially take place in-office. The reviewer will determine any necessary on-site follow-up activity and coordinate on-site follow-up with the region. The reviewer will also provide a feeder inspection report input to document the results of their review.

02.02 Onsite Inspection. As necessary, conduct an onsite inspection of the selected traditional violations, with respect to timeliness, completeness, and adequacy of licensee actions in the following areas. Where appropriate, these inspections are to be actual physical verifications of equipment and processes.

a. Corrective Actions. Determine whether:

1. Licensee management has assigned responsibility for implementing corrective actions, including any necessary changes in procedures and practices.

2. Corrective actions have been fully implemented.

3. The licensee has posted copies of enforcement correspondence for radiological working conditions as required by NJDEP.

4. Follow-up actions were initiated for deviations noted in any recent Quality Assurance (QA) audits conducted by the licensee of the inspection area in which traditional enforcement actions were identified.

b. Root Cause Analysis. Review adequacy of licensee analysis.

c. Generic Implications Analysis. Review adequacy of licensee analysis.

d. QA Program Procedures and Practices Changes. For activities performed to satisfy a construction inspection program, determine that the licensee's review of the QA program evaluated the program's scope and effectiveness.

Guidance: The onsite inspection, if necessary, is to both determine the adequacy of the licensee actions to correct the deficiencies associated with the traditional enforcement action, and to examine whether the licensee evaluations included a review of items from their internal self-assessment activities when assessing the repetitive and generic nature of an NJDEP action and the effectiveness of the related licensee programs. Where an item is identified as repetitive in nature, the licensee should have conducted an in-depth analysis of the effectiveness of their management

control systems. This analysis entails the determination of the root cause(s) of deficient management controls and their potential generic implications. Confirm that the licensee has instituted appropriate corrective and preventive measures. The inspector should use their discretion to perform field verification activities to supplement their review of licensee programs to gain assurance that the corrective and preventive measures have been appropriately implemented in the field.

4.4.2 INSPECTIONS QUALITY ASSURANCE

SECTION 4.4.2
Technical Quality of Inspections and Inspection Reports

New Jersey's procedures addressing the methods used to assure the quality of inspections and inspection reports can be found in the following areas of this Agreement Application:

Section 4.4.1 Inspection Manual and Inspection Procedures

Section 4.4.3 Inspection Administrative Procedures

Section 4.5.1 Routine Enforcement Procedures

Section 4.6.2 Formal Qualification Plan

The quality assurance for inspection actions involves training of staff, use of appropriate procedures, supervisory accompaniment on selected inspections and supervisory review of work performed. All inspection activity and enforcement actions are subject to supervisory review. All inspectors are required to obtain the training necessary under the Qualification Plan.

New Jersey Department of Environmental Protection
Radioactive Materials Group

INSPECTOR FIELDWORK EVALUATION REPORT

Inspector: _____ Evaluator: _____

Licensee: _____ License Number: _____

Location: _____ ☐ Announced ☐ Unannounced

Date of Inspection: _____ Inspection Type: _____

I. **Preliminary Discussion with Inspector:** **Done**

1. Explain the extent of the reviewer's participation in the inspection ☐
2. Discuss the procedure for introducing the reviewer to the licensee and explaining his/her presence during the inspection ☐
3. Explain the method that will be used for evaluating the inspector's performance ☐

II. **Summary of Evaluation:**

1. Inspector's performance rating: ☐ Meets the Guidelines ☐ Needs Improvement
2. Comments:
3. The inspector would benefit from additional training in:
4. The evaluation was discussed with me.

_____ _____
Inspector's Signature Date

_____ _____
Qualified Inspector's Signature Date

III. Inspection Preparation

	YES	NO	N/A
1. Has the inspector reviewed the license and prior compliance history?			
2. Has the inspector planned the inspection?			
3. Does the inspector have the appropriate instruments?			
4. Are the instruments in calibration?			
5. Does the inspector have the necessary supplemental materials? (Regulations, inspection forms, personal dosimetry, ID, wipe materials, Smoke tubes, and bombs, thermal anemometer, dose calibrator sources, instrument check sources, etc.)			

Comments:

IV. Opening

	YES	NO	N/A
1. Was the opening interview conducted with management?			
2. Were incidents or overexposures discussed?			
3. Did licensee understand the purpose, scope and techniques?			

Comments:

V. Inspection

	YES	NO	N/A
1. Did the inspector use appropriate form or checklist?			
2. Did the inspector perform a "walk through" at the beginning of the inspection?			
3. Were licensee operations and use and handling of materials observed?			
4. Were the facilities checked for proper posting?			
5. Was security verified?			
6. Were workers checked for personal dosimetry?			
7. Were workers interviewed to verify their understanding of safety procedures?			
8. Were ancillary workers also interviewed?			
9. Were adequate wipes, surveys, and measurements taken?			
10. Did inspector check for adherence to ALARA?			
11. Were records verified against oral statements for a. procurement and inventory			
b. receipt and transfer of materials			
c. internal audits			
d. qualification and training of users			
e. emergency plan and procedures			
f. committee meetings and minutes			
g. authorized users			
h. instrument calibration			
i. dose calibrator tests			

j. surveys and monitoring			
k. personnel dosimetry and bioassay			
l. leak tests			
m. generator-assay, moly breakthrough and logs			
n. release of effluents, sewer and air			
o. management and disposal			
12. Did the inspector safely handle radioactive materials?			
13. Did the inspector address all necessary elements of the licensee's program?			
14. Were hazards or potential problems discovered and given follow-up? If not, explain:			

Comments:

VI. Closing

	YES	NO	N/A
1. Was there careful assembly of supporting information prior to the Exit interview?			
2. Did the inspector close with appropriate level of management or make every effort to do so?			
3. Were recommendations clearly distinguished from items of Noncompliance?			
4. Were items of noncompliance fully explained with regulation or license condition cited?			
5. Did the inspector explain what follow-up actions would occur?			
6. Was the licensee advised of any requirements?			
7. Did the inspector properly decide if certain practices or operations Should cease immediately?			
8. Were previous items of noncompliance discussed?			

Comments:

VII. Professionalism

	YES	NO	N/A
1. Did the inspector use proper judgment in evaluating radiation Safety?			
2. Did the inspector demonstrate an adequate knowledge of health Physics and regulations?			
3. Was the inspector's appearance appropriate for the type of licensee?			
4. Was rapport with management and workers sufficient for free exchange of information?			
5. Were the inspector's questions phrased appropriately?			

Comments:

VIII. Inspection Report

	YES	NO	N/A
1. Did the inspector document all items in the Inspection Report?			
2. Were all deficiencies addressed?			
3. Was the inspection report generated in a timely manner?			

Comments:

Reviewed:

_____ _____

Evaluator **Date**

_____ _____

Unit Supervisor **Date**

4.4.3 INSPECTION ADMINISTRATIVE PROCEDURES

4.4.3 Administrative Procedures for Inspections

The required procedures to generate an inspection report, have it reviewed and subsequently sent to a licensee are part of the Radioactive Materials Section's computerized New Jersey Environmental Management System (NJEMS) data tracking system. Everyone involved in the processing of an inspection report will be required to use this system. Turnovers in personnel will not be an issue, since any new personnel will learn and utilize the established system. Procedures that cover the administrative procedures related to the processing of an inspection report are included in this section of the application.

4.4.3
INSPECTION ADMINISTRATIVE PROCEDURES

All documents related to the licensing and inspection of radioactive material in New Jersey will be kept in filing cabinets in a secure area in the Bureau of Environmental Radiation. All electronic files are kept on the Department of Environmental Protection's password protected servers with restricted access.

Section 4.4 of this application, Inspection Program, provides the inspection staff and other appropriate staff members with basic administrative procedures for performing, managing, and tracking inspection actions from the time each action is received by the Radioactive Materials Section (RMS) until the action is completed.

The New Jersey Environmental Management System (NJEMS) is a database system used by the New Jersey Department of Environmental Protection to centrally locate information regarding licenses/permits, inspection information, and incidents. The system currently supports the Bureau of Environmental Radiation's inspection and enforcement records and documentation. Development of the portion of this system that will handle review, issuance and tracking of Licensing and Registration documentation to support the proposed Agreement State activities is continuing. Once in place, this one database will be the digital repository for licensing, inspection, enforcement, and incidents information and permit us to generate and track documents relating to these tasks. A licensing tracking system, part of the NJEMS, supports collection and review of license applications and enforcement actions. NJEMS also provides the capability to generate licenses, correspondence, and reports. By using NJEMS, the Bureau is able to create new licenses, modify existing licenses, and renew licenses.

This system supports a standardized review process and provides licensing and inspection management reports. NJEMS allows the RMS staff and management to provide timely responses to inquiries and specialized queries. Consequently, all incoming licensing documents will be entered into this license tracking system.

Record Retention

Paper and electronic records of inspection reports, enforcement actions, licensing documents, and routine correspondence are kept on the premises of the New Jersey Department of Environmental Protection, Bureau of Environmental Radiation. Paper documents are saved and filed according to license number and are stored in a secured entry resource room. Electronic files are kept as part of NJEMS on a network accessible to authorized Bureau staff. All records are periodically archived to effectively utilize space.

PROCEDURES FOR PROCESSING AND FILING INSPECTION REPORTS

This procedure describes the steps that Enforcement personnel must follow to prepare for and document standard compliance inspections in NJEMS by using the Compliance Evaluation screen. This SOP will cover the following scenarios:

A) Inspection Targeting

B) Preparing for Inspection/Creating the Compliance Evaluation Checklist

C) Documenting Inspection Results.

In addition to documenting inspections, the Compliance Evaluation screen shall be used to document compliance status of other enforcement functions such as incident investigations. There is a wide array of reports throughout the individual enforcement programs, therefore use of the Compliance Evaluation screen for documentation of these activities will be addressed in program specific procedures.

A) INSPECTION TARGETING (Programs with NJEMS inspection targeting capability)

1. The RMS supervisors will identify licensees for inspection utilizing the NJEMS Inspection Targeting and Batch processing features to create inspection targets.

2. These NJEMS features will create tasks ("Schedule Targeted Inspection") in the assigned inspectors To Do List based upon the Staff Pre-Assignment Screen. The inspector will utilize the Activity Tracking To Do List to receive the inspection assignments and plan inspection completion in accordance with the task default due dates. If the inspector is not able to meet the default due date, she or he should notify their supervisor who will assign a revised due date for the task(s).

3. Maintenance of the Activity Tracking and the To Do List is critical to data integrity, providing individual and program accountability, and to ensure that predecessor dependant workflow tasks are properly created in the system. Upon "scheduling" the inspection the task "Schedule Targeted Inspection" or "Conduct an Inspection" should be marked as completed by entering a completed date. Hours to complete are required for this task.

B) INSPECTION PREPARATION

1. As assigned, either via the inspector's To Do List or by direct assignment by a RMS supervisor, the inspector will create a new Standard Compliance Inspection activity within the Central File of the assigned licensee. From the Central File, select location based upon the assigned facility licensee. Click the *Create New Document* button, Activity Category – Enforcement; **Activity Class** – Standard Compliance Inspection;

Activity ID – New; Activity Type – Standard Compliance Inspection; Document Type – Form; Document Template – Compliance Evaluation; Title – "SCI on mm/dd/yyy. Click OK to create.

2. The inspector will review all relevant data for the licensee. This will include, but not be limited to, existing NJEMS permits, historic compliance evaluations, the **Violation List Screen** and historic enforcement actions. Because NJEMS is a relatively new system, some or all of the data pertaining to the facility/program interest may exist in paper files or preexisting computer systems that must also be accessed. The inspector should also note other programs' activities at that site.

3. The inspector will prepare an inspection checklist utilizing the Compliance Evaluation screen by including all appropriate Program Interests and Subject Items/Requirement Sets. Since subject items/requirement sets are specific to each type of licensee, inspectors must follow program policy as to what subject items/requirement sets are to be included in inspections. Inspectors are not authorized to omit individual requirements unless directed otherwise by their programs. The sets developed for inspection were meant to help the inspector to look at all applicable requirements deemed appropriate for the inspection.

4. The inspector will go to Activity Tracking and enter a completed date for the "prepare checklist" task and enter the hours to complete this task.

5. The inspector will print the inspection checklist and use that to perform the inspection in accordance with all Department policies and procedures. At this point the inspection will be performed as directed by program specific guidelines. All information obtained and observations made during the inspection shall be recorded on the checklist for input into NJEMS upon return to the office.

C) DOCUMENTING INSPECTION RESULTS

1. Upon return to the office from the inspection, the inspector will enter the date the inspection is completed as the completed date for the "site visit" task in Activity Tracking Number of hours to complete task should also be entered.

2. The inspector will document all observations in the Compliance Evaluation screen prepared for that inspection. For evidentiary purposes, the inspector must be sure to capture all of the data in the Compliance Evaluation screen. The data must be in sufficient detail to substantiate the case and enable you to remember and understand five years later what you observed during your visit in the event the case goes to litigation. Any information in NJEMS should be factual and relevant to the case. You should not be entering your opinion or non-relevant observations.

3. If the start date of the inspection is different than the intended date entered when creating the inspection checklist, change the date to reflect the actual date of inspection. Enter the correct start date and end date and time. One Compliance Evaluation screen is created for each separate and distinct inspection, not for every site visit. Therefore, if an inspection covers multiple days and multiple site visits but is considered all part of the

same inspection, it should be documented in only one Compliance Evaluation screen. The end date field on the Description Tab will reflect the last date that the inspector performed a site visit. In order to capture each site visit in NJEMS, the inspector must add the task **"Site visit"** to Activity Tracking for each individual site visit

4. Enter all appropriate data on the Description Tab (inspector names, person(s) interviewed, witnesses, attribute and substances and impacts). Note: only the inspectors listed in the compliance evaluation and supervisors will be able to edit that document.

5. The inspector will enter general inspection observations related to the licensee in the General Comment field. This field is intended to capture data related to the licensee and inspection as a whole, not to individual violations. Any supporting documentation or reports obtained during the inspection that are not stored in NJEMS should be referenced with its location in this field.

6. The inspector will enter subject items/requirement set and specific requirement compliance and violation information on the Checklist and Non-Checklist tabs. The inspector may have to modify his original inspection checklist to include subject items/requirement sets not originally included but which were observed during the inspection.

7. The inspector will record relevant observations made during the inspection as they relate to individual requirements as listed as individual rows in the Checklist or Non-Checklist tab.

8. The documentation will include completion of the individual requirement's Compliance Status field. Compliance status will be chosen from the drop-down list associated with the field. For individual requirements not inspected, the inspector will mark the compliance status as not inspected in accordance with the appropriate program policy. *Note:* compliance status – *Out of Compliance* or *OC* will refer the inspected requirement and associated data contained within the row as a violation to the *Violation List* when the screen is approved and locked by a program supervisor (see #22 to follow). See Enforcement Action SOP.

9. The Results or Comments field will be used to support the determination noted for compliance status. In the case of a complaint determination, relevant observations or supporting data should be noted in this field. For all requirements, which are marked out of compliance, the inspector must clearly document the findings in the requirement's results or comments field. The inspector must be very accurate and fully document each violation. This data will eventually become the Description of Noncompliance (DNC) which is used in the enforcement action to address the violation. A default description of noncompliance will default into this field, when the requirement is marked out of compliance, if it is available in the requirement library. This field is editable to allow for the addition of relevant information needed to fully describe the violation, but the default language is to remain unchanged so that violation wording is standardized.

10. The Non-Checklist tab is used to record individual violations that are not addressed in the Checklist. The Non-Checklist tab can be used along with the Checklist tab or instead of

the Checklist tab. This tab is used for permit violations where the permit requirements have not been entered into NJEMS. Violations which need to be addressed after the inspector has completed his checklist data entry will also be documented on the Non-Checklist (i.e. supervisor discovers a requirement not included in the Checklist which should have been and was determined out of compliance).

11. Completion of the Non-Checklist tab shall be consistent with completion of the Checklist tab.

12. The inspector should save all relevant supporting documentation and reports obtained during the course of the inspection in NJEMS when ever possible. This would include photographs taken, sketches drawn, reports collected, etc... Until such time that scanning capabilities are available, this will not be possible for much of the data collected. However it is currently possible to save digital photos and electronic documents to NJEMS, by adding to a "blank" word document.

13. Once the inspector has completed the Compliance Evaluation, the inspector will check in all documents related to this activity.

14. The inspector will enter today's date in the Completed Date column for the task, submit report, and enter the Hours to Complete field. The inspector should be sure that all relevant tasks have been completed and that the supervisor's name appears in the assigned to field for the review and approve task so that it appears on the supervisor's To Do List.

15. The supervisor will then review the Compliance Evaluation to make sure that all of the necessary data has been accurately captured, all supporting documentation saved to the correct activity in Central File, and all NJEMS SOPs and policies have been followed. The supervisor is responsible for making sure that the data captured in NJEMS is accurate. The supervisors have primary responsibility for data integrity.

16. If the Compliance Evaluation is incomplete, the supervisor will add the "correct and resubmit" task and enter the inspector's name in the Assigned-To field. The supervisor must also include comments for this task explaining why the compliance evaluation is being returned. If the due date must be revised, because the correction must be expedited, the supervisor will enter a revised due date. The supervisor may also send a system tickler to let the inspector know what PI and Activity number was returned. Note: The supervisor should evaluate whether or not it is necessary to revise the system due date for the "review and approval" task assigned to him or her.

17. The inspector will correct and resubmit to the supervisor by adding the "review and approve" task for reassignment to the supervisor. The process of resubmitting and reviewing will continue until the Compliance Evaluation is considered complete.

18. Once the Compliance Evaluation is complete and accurate, the supervisor will Refer and Lock the screen. This will forward any of the violations discovered to the Violation List for inclusion in an Enforcement Action. This will also set the activity's status to conducted. The supervisor will also lock any related documents for this activity. It's important not to refer and lock the compliance evaluation until the supervisor is sure

there will be no need for modification. Unlocking the document in the system, can only be done by the system administrator and under limited conditions.

19. The supervisor will enter today's date for the Completed Date for the task "review and approve" in Activity Tracking and enter the time taken in the Hours to Complete field.

    If no violations were identified, a compliance letter is issued to the licensee and no further action is needed. If violations were identified, refer to the Enforcement Action SOP for instruction on documenting the violations in an Enforcement Action.