SUPPLEMENTAL MATERIAL IN SUPPORT OF NEW JERSEY AGREEMENT APPLICATION

SUPPLEMENTAL INFORMATION SUBMITTED BY NEW JERSEY

NJDEP RESPONSES TO NRC COMMENTS
3/13/2009

#	APPLICATION SECTION	NRC COMMENT (February 27 and March 3, 2009	STATE RESPONSE	LEAD
1	**Inspection Elements** Section 4.4.1	"NJ Manual Chapter 2800, Materials Inspection Program, does not describe the inspection program for licensees with permanent field offices. New Jersey must submit for review a description of this inspection program. Section 07.04.b.1-b.3 of NRC Manual Chapter 2800 contains a description of an inspection program for licensees with permanent field offices which may be helpful in your response."	Added section to Manual Chapter 2800 section 07.04.	CB
2	**Inspection Elements** Section 4.4.1	"Section 03.01.b.1 of NJDEP IP 87132 references 10CFR 643, 647, and 657, which appear to be typographical errors. The correct references should be 10 CFR 35.643, 35.647, and 35.657."	Corrected	JG
3	**Licensing Elements** Section 4.3.1 Instructions for Completing Initial Application NJDEP Matrix #14	"It is still unclear whether licensees are to follow the instructions in this document or the NUREG-1556 guidance, or both. In some cases the instructions conflict with the NUREG-1556 guidance. Will NJDEP accept use of the checklists in the NUREG-1556 volumes? (These are designed for use by both licensees and license reviewers"	The state's checklist (i.e. Attachment 1 of BER SOP 3.01) has been deleted. The checklists from the NUREG-1556 series will be used by license reviewers.	WPC
4	**Licensing Elements** Section 4.3.1 NJDEP Matrix #21	"NJ response states that NJDEP views all information concerning radioactive material licensees' activities as a domestic security issue, therefore it is exempted from OPRA requirements to provide information to the public and there is no need for a procedure regarding withholding of information. The response does not address whether NJ will mark outgoing documents, such as licenses and correspondence, to indicate that they are security-related and not to be released to the public"	Security related documents sent to IC facilities will be marked to indicate that these items are security related and are not to be released to the public. No other documents will be marked.	WPC
5	**Licensing Elements** Section 4.3.1 NJDEP Matrix #27	"References to NRC regulations in the "State Response" for this item are not fully correct, but appear to be corrected in the "Instructions for Completing Initial Application." (Note the typo in the first NJAC reference in this section of the "Instructions …" should be N.J.A.C. 7.28-52.1)"	Typo corrected.	WPC
6	**Licensing Elements**	"In addition, NUREG-1556, Vol 9, Rev. 1 has been superseded by Rev. 2; the reference and the link to the NRC website should be updated."	Link is revised to direct applicants to the NUREG-1556 series volume of interest. Specific revisions will not be mentioned.	WPC
7	**Licensing Elements**	"Will NJDEP accept use of the Form 313A series and guidance, for medical use licensees to submit qualifications for proposed authorized individuals? If so, it might be helpful to state this and provide the link(s) to the NRC website."	NJDEP will accept Form 313A series and guidance as a method of submitting qualifications for requested authorized individuals. Link has been placed in Instructions for Completing Initial Application.	WPC
8	**Licensing Elements**	"Also, NUREG-1556, Vol. 13 has been superseded by Rev. 1: the reference and link to the NRC website should be updated"	See response to item #6.	WPC
9	**Licensing Elements**	"Page 2 instructs applicants not to submit copies of NRC or NJDEP licenses. While NJDEP will certainly have access to copies of its own licenses, there are likely to be many situations in which it is most expeditious for applicants to include copies of NRC licenses in order to verify previous authorization of authorized individuals"	Page is revised to state that NRC and State licenses may be submitted in support of an individual's credentials, but not in lieu of Form 313A or other acceptable training and experience documentation.	WPC
10	**Licensing Elements BER 3.04 and 3.07**	"Time frames for completion of review of licensing actions appear to differ in BER 3.04 section 3.1 (90 days for completion of licensing	The correct timeframes are 90 days for completing licensing action, with deficiencies issued by day 45. BER 3.07, section 3.0C is revised.	WPC

	Time Frames for completion of review of licensing actions	action, with deficiencies issued by day 45) and BER 3.07, section 3.0C, which says the objective is to issue licensing actions within 45 days and deficiency letters within 30 days (with clock re-starting after receipt of response). The time frames need to be clarified."		
11	**Licensing Elements** Exemptions NJDEP Matrix #16	"Comment is that we usually see this with medical only and don't use temporary exemptions routinely. He didn't see anything in the application that changed or expanded" A method for determining the acceptability and granting of exemptions is not included.	According to NUREG-1556, volume 20, temporary exemptions may be granted for humanitarian or emergency reasons. Such exemptions would be used on a case-by-case basis and would be approved by the Commission on Radiation Protection as per N.J.A.C. 7:28-2.8, which includes the method for determining the acceptability and granting of a temporary exemption. Review of an Application for License Termination 3.5.1.5 states "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".	WPC
12	**Licensing Elements** NJDEP Matrix #27	"We had a question regarding references to 10 CFR 31 and 31.32 and what portable gauges may be exempt from licensing requirements. Reviewer still has question on this. NJ answer was to say certain portable gauges may be exempt – Section 52 or 10 CFR 30 provides a listing of exempt devices for further clarification. Reviewer cannot find this information"	References to portable gauges exempt from licensing requirements is deleted.	WPC
13	**Licensing Elements** NJDEP Matrix #33	"NJ response limited this to PET radioactive materials. Vol. 21 was not limited to PET – dealt with production of radioactive materials using an accelerator. Reviewer had a question as to why limited to PET"	The wording is revised to say "byproduct material," rather than "PET" material.	WPC
14	**Licensing Elements** NJDEP Matrix # 34	"reviewer could not find what they referenced in response – 7:28-51, BER 2.02, page 15, item 3.14. Related to statement about continued operation under the authority of any license for which renewal application was submitted after expiration date"	The correct reference is BER Procedure 3.02, page 2, item 3.1.4. Legal authority for continued licensee operation under a license for which the application was submitted after the expiration date of a license is granted under N.J.A.C. 7:28-1.1 through 1.2. If public health and safety would be compromised by ceasing licensee activities (e.g. hospital therapy), the Department would allow operations for a limited amount of time.	WPC
15	**Event and Allegation Response Elements** Section 4.7.1.2	"The following event response procedures appear to be missing from the application: notifications of licensing staff and notifications to other affected licensees of generic problems"	Notifications of licensing staff and notifications ot othere affected licensees of generic problems are included in BER SOP 7.05 Guidance on Reactive or Special Inspections	PG
16	**Event and Allegation Response Elements**	"The following guidance should be added to the application; 1. Response to radioactive material incidents that do not require activation of the incident response plan. Specifically guidance regarding the need for a reactive/special inspection should be developed, 2. Follow-up actions and action levels for radiation exposures associated with materials incidents involving members of the public, 3. Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE), and 4. While NJ has procedures on responding to transportation incidents, the reviewer could not find anything regarding notifying DOT"	1. Guidance regarding the need for a reactive/special inspection is provided in new BER 7.05. 2. Guidance is included regarding follow-up actions and action levels for radiation exposures from materials incidents involving members of the public is included in BER 7.06. 3. Added SOP BER 7.04 Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy. 4. It is the carrier's responsibility to notify the DOT for transportation incidents. The Department staff would verify that this was done.	PG
17	**Technical Staffing and Training Qualification Plan**	"Medical Qualification Journal references to program code 2100 should be corrected to 2110 for medical institution, broad"	Corrected	JG
18	**Program**	The organizational charts for the Bureau of Environmental Radiation in	Corrected	PG

	Organization	section 4.1.2 should be updated to reflect the organizational changes in section 4.6.3.1.		
19	**Program Organization**	Clarify the differences in the current title designations and the Agreement State title designations.	Clarified in the introduction to 4.6.1	PG
20	**Licensing Elements** NJDEP Matrix #31	"In "Licensing Guidance" on page 17, the last two paragraphs of section R refer to general licensees. This document provides guidance for specific licensees and so this language should not be included here"	Wording was revised to indicate instructions for filling out the Registration form.	WPC
21	**Licensing Elements** NJDEP Matrix #32	"The New Jersey submission needs to include technical licensing procedures for 10 CFR Part 40, Domestic Licensing of Source Material," which are not addressed in the NUREG-1556 series) including standard review plans, checklists and licensing guides"	New Jersey discussed this item with FSME staff and this comment has been addressed.	JG
22	**Licensing Elements** NJDEP Matrix #34	"Please explain what New Jersey proposes (e.g. enforcement discretion) and what legal mechanism would be used to implement a legally binding requirement on the expired license holder"	See response to item 14.	WPC
23	**Licensing Elements** NJDEP Matrix #34	"On page 29 under Review of an Application for License Termination, item 3.5.1.5, the NRC is not aware of a similar NRC policy and having the Section Supervisor grant this authorization seems somewhat contradictory to the policy stated for expired licenses on page 15"	See response to item 14. Letter was revised for Commissioner's signature.	WPC
24	Radioactive Material License Application Instructions	"In the heading – 2nd and 3rd sentences indicate that regulations for licensing diffuse naturally occurring or accelerator produced radioactive material are in subchapter 4 while regulations for licensing of byproduct and source materials are found in other subchapters. This separation seems unclear given that the EPAct of 2005 resulted in certain accelerator produced materials to now be byproduct material"	N.J.A.C. 7:28-4 applies to diffuse naturally occurring or diffuse accelerator produced radioactive materials as the title indicates. The sentence is revised to insert "diffuse" before accelerator. N.J.A.C. 7:28-4.1(b) lists the exceptions to subchapter 4, namely byproduct, source, and special nuclear material. Byproduct, source, and special nuclear material are all defined by the NRC and adopted by reference in N.J.A.C. 7:28-6.1. Diffuse is defined in N.J.A.C. 7:28-1.4(a)2. Diffuse accelerator produced radioactive material, produced by activation of certain parts of the accelerator or surrounding building materials, still requires regulation and is not covered under the NRC's definition of byproduct material.	JG
25	Radioactive Material License Application Instructions	"Under item D, self-shielded irradiators are regulated pursuant to 10 CFR Part 30, not Part 36"	Citation is revised.	WPC
26	Radioactive Material License Application Instructions	"On page 9 under item F, it suggests that definitions and requirements for an academic, research and development, and other limited scope license may be found in 10 CFR 33. Limited scope licenses fall under Part 30. Only broad scope licenses fall under Part 33"	Citation is revised.	WPC
27	Radioactive Material License Application Instructions	"On page 9 under item G, refers to 10 CFR 31. This is the wrong reference. It should be subpart A of 10 CFR 32. I would also suggest that NJ add a sentence noting that only the NRC issues exempt distribution licenses in the 2nd paragraph when referring readers to NUREG-1556, Vol. 8."	Citation is revised, with recommended sentence added.	WPC
28	Radioactive Material License Application Instructions	"On page 11 under item J, the first sentence refers to 10 CFR 32. However, possession to possess for M&D is subject to Part 30"	Citation is revised. Sentence added that only NRC may authorize exempt distribution.	WPC
29	Radioactive Material License Application	"On page 12 under item R, the list should include Ra-226 at 3.7 MBq"	Radium-226 was added to Item R.	WPC

	Instructions			
30	Reciprocity Application Form	"Under item 19, sentence a. includes "(see 10 CFR 31)," however NRC reciprocity requirements are located at 10 CFR 150.20" "This reference also appears in the instructions for "Reprot of Proposed Activities within New Jersey Jurisdiction Boundaries …," 2nd paragraph, 2nd sentence and under item 17 in the note"	Citations revised.	WPC
31	Notice to Employees	"NJs form does not contain the same (or all) information found on NRC's Form 3"	Essential information from NRC's Form 3 is included in New Jersey's form. Detailed information would be provided to an employee once they notify the State of alleged violations/discriminatory actions.	WPC
32	BER Section 4.3.1 Appendix B	"A sample letter appears on page 3. Should it cite a regulatory basis or provide for hearing rights when denying an application as similar to 10 CFR 2.108"	Letter revised to cite NJ regulations.	WPC
33	Section 4.3.1	"Change provide to provided in 3rd paragraph, 4th sentence"	Revised	WPC
34	Procedure 3.01	"Add a space after the ")" in item 2.2, 2nd sentence"	Revised	WPC
35	Procedure 3.01	"Delete space after "determines" in item 3.2.7"	Revised	WPC
36	Security Related Checklist	"Starting on page 4 and on a number of following pages, it refers to FSME/DMSSA/SSSB when it should now be SMPB"	Revised	WPC
37	Radioactive Material License Application Instructions	"On page 12 in the heading, section L is underlined while the other sections are bolded and not underlined"	Revised	WPC
38	Section 4.3.1	"Remove "??" on the Appendix B Sample Letters on page 12"	Revised	WPC
39	Procedure 3.06	"Correct the word "notifying" in the first sentence and remove a duplicated "if" in the 2nd paragraph on page 2 under section 2.0"	Revised	WPC

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. 7:28-62.1 (See 10 CFR 150)

☐ 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. 7:28-62.1 (see 10 CFR 150) 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. 7:28-62.1 (see 10 CFR 150) 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. 7:28-62.1 (see 10 CFR 150) 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. 7:28-62.1 (see 10 CFR 150). 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. 7:28-62.1 (see 10 CFR 150) 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.

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 provided 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 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

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 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 1.

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 2 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
Pre-licensing Guidance/Checklist for Risk-Significant Radioactive Materials

Official Use Only
Not for distribution outside
Bureau of Environmental Radiation

BER 3.01 Attachment 1

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)**

BER 3.01 Attachment 2

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. 7:28-1.1 through N.J.A.C. 7:28-1.2.

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

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 diffuse 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.
- Copies of NRC or NJDEP licenses may be submitted in support of an individual's credentials, but not in lieu of Form 313A or other acceptable training and experience documentation.
- 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. NRC Form 313A series and guidance, for medical use licensees, may be helpful in submitting qualifications for proposed authorized individuals. Applicants are encourage to go to the NRC public web site for the most recent versions of the NRC Form 313A series of forms and guidance at http://www.nrc.gov/materials/miau/med-use-toolkit.html

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:

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 NUREG 1556 series: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556 . The portable gauge 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 NUREG 1556 series: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556 . 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 1556 series:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556. 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. 7:28-51.1 (see 10 CFR 30). 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 NUREG 1556 series:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556

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 NUREG 1556 series:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556 . The irradiator 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. 7:28-51.1 (see 10 CFR 30). 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 . The academic, research and development and other programs of limited scope including gas chromatographs and X-ray flourescence analyzers 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. 7:28-53.1,(see Subpart A of 10 CFR 32) "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. Only the NRC issues exempt distribution licenses.

The NUREG 1556 series provides assistance in preparing license applications for distribution of exempt products:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556 .

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 NUREG 1556 series provides assistance in preparing license applications for medical use of radioactive materials:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556

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 NUREG 1556 series:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556 . The broad scope 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. 7:28-51.1 (see 10 CFR 30). 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 NUREG 1556 series: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556 . The Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution 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. Exempt distribution is authorized only be the NRC.

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 . Within the commercial radiopharmacy 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 the NUREG 1556 series: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556.

L. Non-Commercial Production/Distribution

Applicants applying for authorization for the production and noncommercial distribution of byproduct material drugs to medical use licensees in a consortium, should refer to the NUREG-1556 series http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556.

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 the NUREG 1556 series: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556.

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 the NUREG 1556 series: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556. The NUREG on changes of control and bankruptcy involving byproduct, source or special nuclear materials 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.")

The NUREG 1556 series 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 .

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.

The NUREG 1556 series 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 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 NUREG 1556 series:
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556. 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." Registration of 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, 3.7 Mbq (0.1 mCi) of radium-226, 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.

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.

APPENDIX B
Sample Letters

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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, in accordance with N.J.A.C. 7:28-1 et seq., the New Jersey Radiation Protection code, 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

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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], based on the recommendation of the Commission on Radiation Protection, I am granting your petition for exemption as described below as per N.J.A.C. 7:28-2.8 :

[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], Commissioner
Department of Environmental Protection

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

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 90 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 45 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 90-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 7.04

REQUESTING EMERGENCY ACCEPTANCE OF RADIOACTIVE MATERIAL BY THE U.S. DEPARTMENT OF ENERGY (DOE)

01 PURPOSE
To establish procedures for requesting emergency assistance from the U.S. Department of Energy (DOE) in retrieving and storing inadequately-controlled, radioactive material licensed by NRC or an Agreement State.

02 OBJECTIVE
To ensure adequate protection of the public health and safety from radiation hazards arising from situations in which (1) radioactive material licensed by NRC or an Agreement State is discovered to be inadequately controlled; and (2) appropriate governmental actions are needed because of the lack of a capable licensee.

03 APPLICABILITY
This applies to the NJDEP's Bureau of Environmental Radiation.

04 DEFINITIONS
04.01 Inadequately-Controlled Radioactive Material. Byproduct, source or special nuclear material, licensed by NRC or an Agreement State, that is (1) in the possession of an unlicensed party, (2) in the possession of a licensee not authorized to possess the material, or (3) in the possession of a licensee authorized to possess the material, but for which there is little confidence that the licensee will be able to continue to maintain appropriate security of the material.
Examples of such situations are abandoned sources or devices containing sources that are traceable to a licensee that cannot take control of the material; unauthorized transfer of licensed material by or to licensees; and licensed material in the possession of licensees or former licensees who are unable to adequately control the material.

04.02 Emergency Situation. For the purpose of requesting emergency acceptance by DOE, an emergency situation is a situation that is causing, or has high potential to cause, a significant health and safety risk to members of the general public.

05 RESPONSIBILITIES AND AUTHORITIES
Manager, Bureau of Environmental Radiation (BER)
a. Determines when a situation involves licensed material lacking a capable licensee to control it, and requests DOE emergency acceptance in accordance with this manual chapter.
b. Assign a point-of-contact to coordinate DOE retrieval of licensed material (normally, this would be the Supervisor of the Radioactive Materials Section or designee).

06 BASIC REQUIREMENTS
06.01 General Guidance
a. Guidance for immediate response actions is contained in the Radioactive Material and Radiological Assessment Team manual and the New Jersey Radiation Response Protocol. This procedure contains the steps to be followed after any immediate actions to secure inadequately controlled material have been taken, and it has been determined that emergency acceptance by DOE is required to eliminate a significant threat to public health and safety because all other available options for disposing of the material have been exhausted.

b. In general, this procedure is intended for situations involving discrete sources at a single location, or locations that are closely related geographically or functionally. Other situations shall be evaluated on a case-by-case basis.
c. DOE will retrieve inadequately-controlled radioactive material that has been traced to a DOE facility or prime contractor. For material licensed by NRC or an Agreement State, DOE has agreed to accept the material only when it is clear that the material is causing, or has high potential to cause, a significant threat to public health and safety; and the responsible licensee is not available, or not capable of adequately controlling it.
d. NRC shall always make the initial request to DOE for emergency acceptance of material licensed by NRC or an Agreement State. Agreement States should not contact DOE directly.

06.02 Requesting Emergency Acceptance by DOE
a. Agreement States requesting emergency acceptance of State-licensed material shall contact the NRC. The Agreement State should recount and document a chronology of events, discuss results of actions taken to identify a responsible licensee and dispose of the material, provide a description of the material, and designate a point-of-contact (POC). The information required to request emergency acceptance by DOE is outlined in Exhibit 1.
b. If all the above information is received by the NRC and determined to be sufficient to request DOE assistance, NRC personnel shall prepare a letter to the Deputy Assistant Secretary for Waste Management, DOE, Washington DC 20545, requesting that DOE accept management of the material, and forwarding a summary of the information listed above.
c. The state point of contact will follow the requirements in the NRC's Manual Chapter 1303.

EXHIBIT 1
INFORMATION FOR DOE REQUESTS

General:

Office/Division, Region (RI, RII, RIII, RIV), or State initiating request:

Point-of-Contact:

Phone/Fax/Email:

Possessor's Name (Company or Individual):

Contact Name (possessor):

Phone/Fax/Email:

Possessor's Address:

Exact location of material (address, if different than above, and location within facility):

Describe the current security of the material (e.g., in a locked room, file cabinet, etc.):

Additional Notes:

State Reviewer:_____ Date:_____

IMPORTANT: IF THE MATERIAL IS POSSESSED BY A LICENSEE NO LONGER ABLE TO ADEQUATELY CONTROL IT, YOU MUST ATTACH A COPY OF THE LICENSE LISTING THE MATERIAL.

Device and Source Details:

Include as much information as possible for each discrete source or device. Attach additional sheets as necessary.

Source List:

	Form of Material (ceramic matrix, pellets, etc.)	Nuclide	Activity	Assay Date
1				
2				
3				

Provide the waste classification of the material in accordance with 10 CFR 61.55:
[The Branch Technical Position (BTP) on Waste Concentration Averaging should be considered when determining the waste classification (ML033630732)]

For devices, provide the total weight (in pounds or kilograms) of any depleted uranium used as shielding:

For Neutron Sources, provide Target Element [e.g., Beryllium (Be)]:

If the material is possessed by a licensee that will provide for the transport of the material to DOE, provide a description of the approved transportation package and any special handling tools necessary to remove the material from the transport package:

A. Device Containing a Sealed Source: Information must be provided for each device. Attach engineering drawings, photographs, specifications, descriptions, etc., as available. Complete Section B for the sealed source. If more than one device, attach additional sheets or repeat Section A block as necessary.

Device Manufacturer:
Device Model Number:
Device Serial Number:
SSD Device Registration Certificate Number (if known):
Date of manufacture or age of device (if known):
Weight of device (including any DU shielding):
Physical dimensions of device:
Device condition: Damaged: ____ Intact: ____ Contaminated (isotope):

B. Sealed Source: Information must be provided for each source. Attach engineering drawings, photographs, specifications, descriptions, etc., as available. If more than one source, attach additional sheets or repeat Section A block as necessary.

Is this sealed source associated with the device above (specify device if more than one)? Sealed Source Manufacturer:

Sealed Source Model Number:
Sealed Source Serial Number:
SSD Source Registration Certificate Number (if known):
Is the source special form (if known)?
Physical Dimensions of source/source holder:
Date of manufacture or age of source (if known):
Isotope:
Assay Date:
Activity:
IAEA Source Categorization (at time of request):
Source condition: Leaking: ____ Damaged: ____ Intact:
Attach most recent leak test results (within last 6 months), if available:

IMPORTANT: The owner of the material should make in a letter, or be prepared to make upon DOE receipt, the following certification (including the warning statement).

I, the undersigned, certify the transfer of ownership to the U.S. Department of Energy (DOE) of [clearly identify material], and assert that the radioactive material has not been acquired solely to make it eligible for acceptance by the DOE.

I certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts [list applicable parts, i.e., 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70] and that all information, contained herein, is true and correct to the best of my knowledge and belief.

SIGNATURE OF CERTIFYING OFFICER:
DATE:
NAME (TYPE OR PRINT):
TITLE (TYPE OR PRINT):

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat.749 makes it a criminal offense to make a willfully false statement or representation to any Department or Agency of the United States as to any matter within its jurisdiction.

NJDEP – BER Procedure No. 7.05
Guidance on Reactive or Special Inspections

The NJ Department of Environmental Protection State's "Radioactive Materials and Radiological Assessment Team" manual includes the necessary steps that will be taken to respond to, assess and mitigate any material event that occurs within the State. If the event occurred due to the actions of a licensee, staff and management will decide if a reactive inspection is warranted. Steps the licensee took to minimize the likelihood of a recurrence will be reviewed during this followup inspection. Reach-back capabilities to Federal agencies are included for events that exceed the capabilities of the State. The Bureau of Environmental Radiation, in conjunction with the New Jersey State Police and the New Jersey Office of Counter-Terrorism, also utilizes the "New Jersey Radiological Response Protocol" as a template for the use of radiation detection and isotope identification equipment to classify radioactive substances and ascertain their legitimacy.

Criteria for Evaluating Special Inspections

1. Examples that normally require consideration of immediate dispatch (typically within 2 days) of one or more inspectors, for follow-up action, are listed below. These reactive inspections are carried out at the discretion of the Radioactive Materials Supervisor, depending on the information available and the immediate implications of the accident.

(a) Single exposure of an occupational worker in excess of the dose limits in 10 CFR 20.1201.

(b) Loss of control of radioactive material that caused a member of the public to receive an exposure in excess of the limits in 10 CFR 20.1301.

(c) Discovery of State -licensed material in an unrestricted area.

(d) An unplanned contamination event that requires a 24-hour report to the State, as per 10 CFR 30.50(b), 40.60(b), or 70.50(b), as applicable.

(e) An intake of radioactive material in excess of an annual limit on intake.

Examples that normally require consideration of a special inspection before the next routine inspection (typically within a few weeks) may include the following:

(a) Medical misadministrations that meet the abnormal occurrence threshold. See MD 8.1, "Abnormal Occurrence Reporting Procedure," and MD 8.10, "NRC Medical Event Assessment Program."

(b) Release of radioactive material to an unrestricted area in excess of 2 times the concentration limits in 10 CFR 20.1302.

(c) Disposal of license material in quantities or concentrations in excess of the limits in 10 CFR 20.2003, 2004, or 2005.

(d) Loss of control of radioactive material that could have caused a member of the public to receive an exposure in excess of the limits in 10 CFR 20.1301.

Criteria for Conducting Special Inspections

During a special inspection, the RMS Supervisor should make an initial determination of the hazard, the need for further action, and should proceed as follows:

1. Discuss the current status of the incident with the licensee, or if not a licensee, the individual(s) who found the radioactive material.
2. Collect details about the cause of the incident and the incident chronology.
3. Review licensee follow-up actions for consistency with the regulations, license requirements, approved procedures, and the nature of the incident.
4. Evaluate the potential radiological consequences and personnel exposure, using all available.
5. Evaluate the need for a medical consultant, based on the potential radiological consequences and personnel exposure.
6. Determine if proposed licensee actions and plans will provide a safe recovery from the incident and help prevent a recurrence.

Follow-up Actions
The Team Lead is responsible for the screening, evaluation, follow-up, and closeout of reports of all types of incidents reported by licensees under their cognizance. The regional offices should:
a. Use the Nuclear Medical Event Database (NMED) system to track, review, and follow up written reports of incidents. Initial input of entries is handled by central office.
b. Document all types of reports of incidents in an inspection report or other type of record. Corrective actions should be tracked to completion.

Documentation Guidance
Any follow-up actions that the staff takes on a reported incident should be summarized in writing and maintained in an official file.

Examine Regulatory Significance of Incident
Examine regulatory significance of the incident and close out the DEP response, considering the following factors:
a. Possibility of generic implications.
b. Value of documented case study.
C. Need to prevent recurrence.
d. Possible need for new rulemaking.

NJDEP-BER Procedure No. 7.06

FOLLOW-UP ACTIONS AND ACTION LEVELS FOR RADIATION EXPOSURES ASSOCIATED WITH INCIDENTS INVOLVING MEMBERS OF THE PUBLIC

01 PURPOSE

To provide advice and guidance on a course of action to follow in case of incidents involving radiation exposure to members of the public. The guidance provided in this document is for Bureau of Environmental Radiation (BER) staff to use in responding to incidents that do not -require activation of the Department's Nuclear Power Station Emergency Response Plan. It is specifically for use after actions have been taken to prevent the source of exposure from further affecting the public, and it is intended for use as initial guidance, when situations arise.

02 OBJECTIVES

To ensure that correct follow-up action is taken when there is an incident involving radiation exposure to members of the public.

03 DEFINITIONS

03.01 Agreement State. A state that has signed an agreement with the NRC under which the State regulates the use of by-product, source and small quantities of special nuclear material and NARM within that state.

03.02 Member of the Public. Any individual except when that individual is receiving an occupational dose

03.03 Radioactive Material in the Public Domain. Any radioactive material, subject to NRC or Agreement State jurisdiction, for which control in accordance with NRC or Agreement State regulations or with applicable license conditions is not being implemented, and which may, or have already resulted in, radiation exposures to members of the public.

04 APPLICABILITY

This procedure applies to BER staff.

05 RESPONSIBILITY

The Incident Team Leader shall have the lead responsibility for follow-up actions for incidents involving radiation exposure to members of the public, unless directed otherwise.

06 GENERAL GUIDANCE

Incidents involving radiation sources are, by nature, event-specific. Because the conditions surrounding each incident are unique, follow-up action must be developed on a case-by-case basis. The information provided in this procedure is meant to be a guide, and should not be used in isolation of other guidance for incidents and basic radiation safety principles. Staff should use the other guidance as deemed appropriate for responding to radioactive source incidents, including incident assessment; dose assessment if individuals are exposed to radiation; need for medical consultants;

interaction with other Federal, State and local government agencies; types of inspections, etc.

Staff should use the guidance in BER 7.05 in conjunction with the guidance in this procedure to direct staff to: (1) evaluate the potential or actual exposure of a member of the public, (2) keep public exposures as low as possible, and (3) evaluate the potential radiological consequences and personnel exposures. With any incident, staff will be working closely with any known licensees involved with the incident. If a responsible licensee is not immediately known, general response procedures are outlined in RAMRAT manual and the Radiation Response Protocol which include descriptions of which Federal, State or local entity would be in charge under various circumstances. The purpose of BER 7.06 is to provide additional information and dose ranges/guidance if members of the public are exposed to radiation.

Some incidents may be considered abnormal occurrences. NRC submits an abnormal occurrence report to Congress annually. The report, NUREG-0090, "Report to Congress on Abnormal Occurrences," includes the criteria for abnormal occurrences. As part of an incident assessment involving radiation exposure to members of the public, Central Office should also provide appropriate information to the NRC State Liaison in accordance with current procedures for submitting incidents considered possible Abnormal Occurrences.

06.01 Specific Guidance

The guidance is intended for incidents involving radiation sources and not for routine, non-accident operations. The regulations have specific limits for exposures to members of the public. The dose limit for members of the public is given in Section 20.1301, "Dose limits for individual members of the public." Licensees are to conduct operations so that the limits in Section 20.1301 are not exceeded for members of the public. Currently, the public dose limit is 1 mSv (100 mrem). Section 20.1301 (c) allows a licensee to permit visitors to an individual who is undergoing medical treatment and cannot be released under Section 35.75 to receive a dose not to exceed 5 mSv (500 mrem). Note that any accidental exposures to members of the public may be investigated, depending on the nature of the exposure, regardless of the dose. However, exposures from routine operations, for example, when material is disposed or released via effluents in accordance with the regulations, would not be part of the scope of this.

If a licensee is required to report to the Department, under 10 CFR Section 20.2202, "Notification of incidents," and Section 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits, "the licensee is responsible, in accordance with Section 19.13(d), for notifying and providing an exposure report to any individuals that were exposed. Depending on the circumstances of the incident, BER may also notify the affected individuals. For example, BER might notify individual(s) if the staff believes that the licensee response is not adequate, a responsible licensee is not known at the time, or the staff wants to make sure the individual(s) are getting complete information.

The actual doses to members of the public are likely to be uncertain, especially during the initial follow-up after an incident. Doses will usually be estimated in a dose range or a maximum dose based on the circumstances of the incident. For this reason, it is important to talk with exposed individuals because this can help the staff in assessing the incident and in estimating the dose'.

Depending on the nature of the incident, further analysis of the estimated dose may be necessary, using techniques such as bioassays, whole body counting, and cytogenetic analysis, and should be considered as the estimated doses approach 10-20 rem and up. In evaluating the need for these types of analyses, staff should keep in mind that performing the study can help reassure an individual who was exposed to radiation, but it can also increase the anxiety about the exposure. Therefore, staff should be sensitive to this and use their best judgment in deciding when to recommend cytogenetic analysis.

Because people are often more anxious about radiation exposure than with other hazards and risks, staff should be especially sensitive when providing information about the incident and the estimated doses. Staff must be as factual as possible about characterizing the dose based on available information, without causing undue stress. Staff should not discuss medical issues or provide medical advice to exposed individuals. Instead, staff should refer individuals to their personal physicians.

06.02 Dose Ranges and Guidance

1. Dose Range from 0 to 1 mSv (100 mrem)

Exposures with estimated doses in this range are within the public dose limit in 10 CFR Part 20. There are no regulatory requirements requiring reporting and notifications. Typically, no further action is needed, but the need for additional action must be evaluated based on the specific incident.

2. Dose Range from 1 mSv (100 mrem) to 50 mSv (5 rem)

In cases when the estimated dose is between 1 and 50 mSv (100 mrem and 5 rem), staff will need to determine if a medical consultant is necessary. If a medical consultant is necessary, the medical consultant will determine whether or not a medical evaluation of exposed individuals is necessary. Staff should not discuss medical issues with an individual who was exposed, or provide medical advice. Instead, if an individual expresses concern or wishes additional information on possible medical affects, staff should refer the individual to his/her personal physician or to the department's medical consultant, if DEP has consulted with one to analyze the incident. If additional assistance is needed, BER staff can call the Radiation Emergency Assistance Center/Training Site (REAC/TS). Information on REAC/TS is provided below in Attachment 3, "Medical Assistance in Radiation Exposure Emergencies."

3. Dose Range Greater than 50 mSv (5 rem)

For estimated doses that appear to be over 50 mSv (5 rem), assess the incident following the guidance in 2. above. If the calculated effective dose equivalent is more than 100 mSv (10 rem), further medical evaluation should be considered. Depending on the circumstances of the incident, a medical consultant may be brought in, the exposed individual will be referred to his/her personal physician, and/or REAC/TS may be consulted for additional guidance. At dose estimates in this range, and approaching 200

mSv (20 rem), the need for further analysis of the dose, as discussed above, should be evaluated.

4. Members of the Public Who Are Pregnant

Information regarding the disclosure of pregnancy must be on a voluntary basis because of issues involving individual privacy, If, in the course of evaluating an incident involving exposures to members of the public, staff is informed by a female member of the public that she is pregnant, the follow-up action is essentially the same as in 1. through 3. above, extending the evaluation to look at the impact on the embryo/fetus. A medical consultant will probably be asked to evaluate the incident and the likely dose to the embryo/fetus. As stated previously, staff should not discuss medical issues or provide medical advice to the woman, but should refer her to her personal physician. Additional information on exposures to the embryo/fetus can be found in: 1) NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure," and 2) National Council on Radiation Protection and Measurements Report No. 128, "Radionuclide Exposure of the Embryo/Fetus." Additionally, staff may get additional guidance if needed from REAC/TS.

4.6.1 Technical Staff Organization

The Bureau of Environmental Radiation has conducted an analysis of the expected workload, and established an appropriate staffing plan. Included in this section are the number, distribution and types of radioactive materials licenses, organization charts and breakdown of the Radioactive Materials and Radiological Assessment Sections. The sections are organized into medical and non-medical/industrial and decommissioning areas. Staff will be responsible for both licensing and inspection responsibilities in the respective areas. There will be 13.25 FTE assigned to the Agreement State Program.

There are approximately 500 NRC specific licenses in New Jersey. The RMS conducts a licensing and inspection program for 504 NARM users. When the NRC and state licenses are combined it is estimated that there will be approximately 700 specific licenses in New Jersey. In addition, there are over 400 general license registrations.

New Jersey's Agreement State staffing plan allocates a total of 13.25 FTE for the agreement state materials program. Twelve staff members, including the RMS supervisor and two administrative support personnel will devote 100% of their time to Agreement State Program activities. An additional three staff members will provide 1.25 FTE towards agreement state program activities.

The BER Bureau Chief plans on spending 35% of her time to the agreement state program, including management review of certain actions, personnel responsibilities, rule development and other management duties. The RMS Supervisor plans to devote 100% of his time to the agreement state program, including management review of licensing and inspection actions, personnel responsibilities, rule development, accompaniment of inspectors for annual management review, general supervision and other management duties. The RMS Supervisor will provide the day-to-day supervision of the agreement state program.

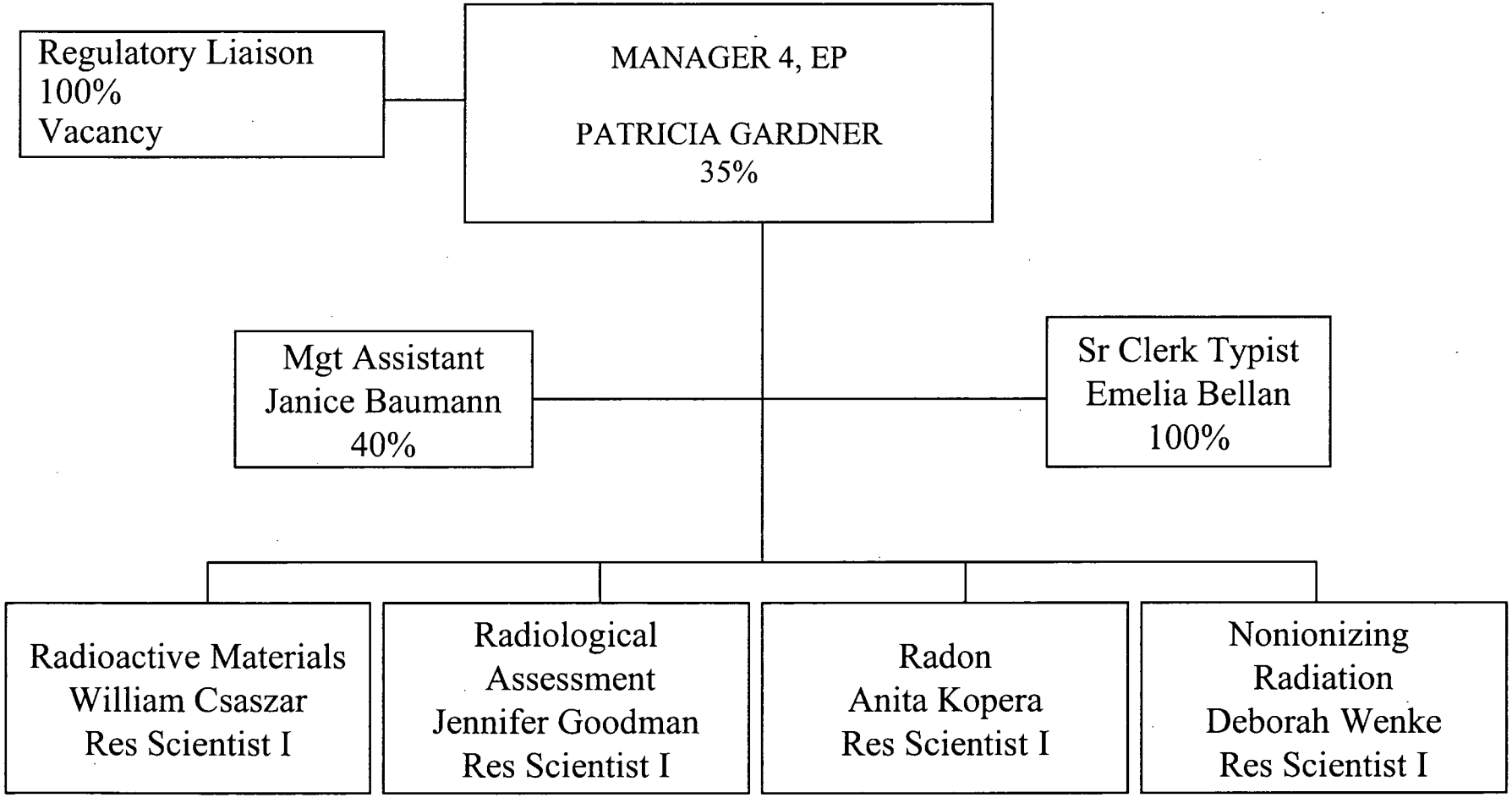
There are various official Civil Service title series used in the Bureau of Environmental Radiation. These include the Radiation Physicist, Research Scientist and Environmental Specialist series. These titles are used by a variety of programs within the Department of Environmental Protection. These series have similar education and experience requirements and track in similar progressions. The Research Scientist series has a minimum education requirement of a Master Degree, while the other series require a Bachelor Degree.

In addition to the Civil Service official titles, programs use working titles. The working title relates to the actual work performed by the individual. The working titles for staff working in the Agreement State Program regardless of their official civil service title are defined in the job specifications and performance evaluations listed in Section 4.6.1.3. Once New Jersey becomes an Agreement State, staff working in the program will get revised performance evaluations using the new Agreement State working title job specifications.

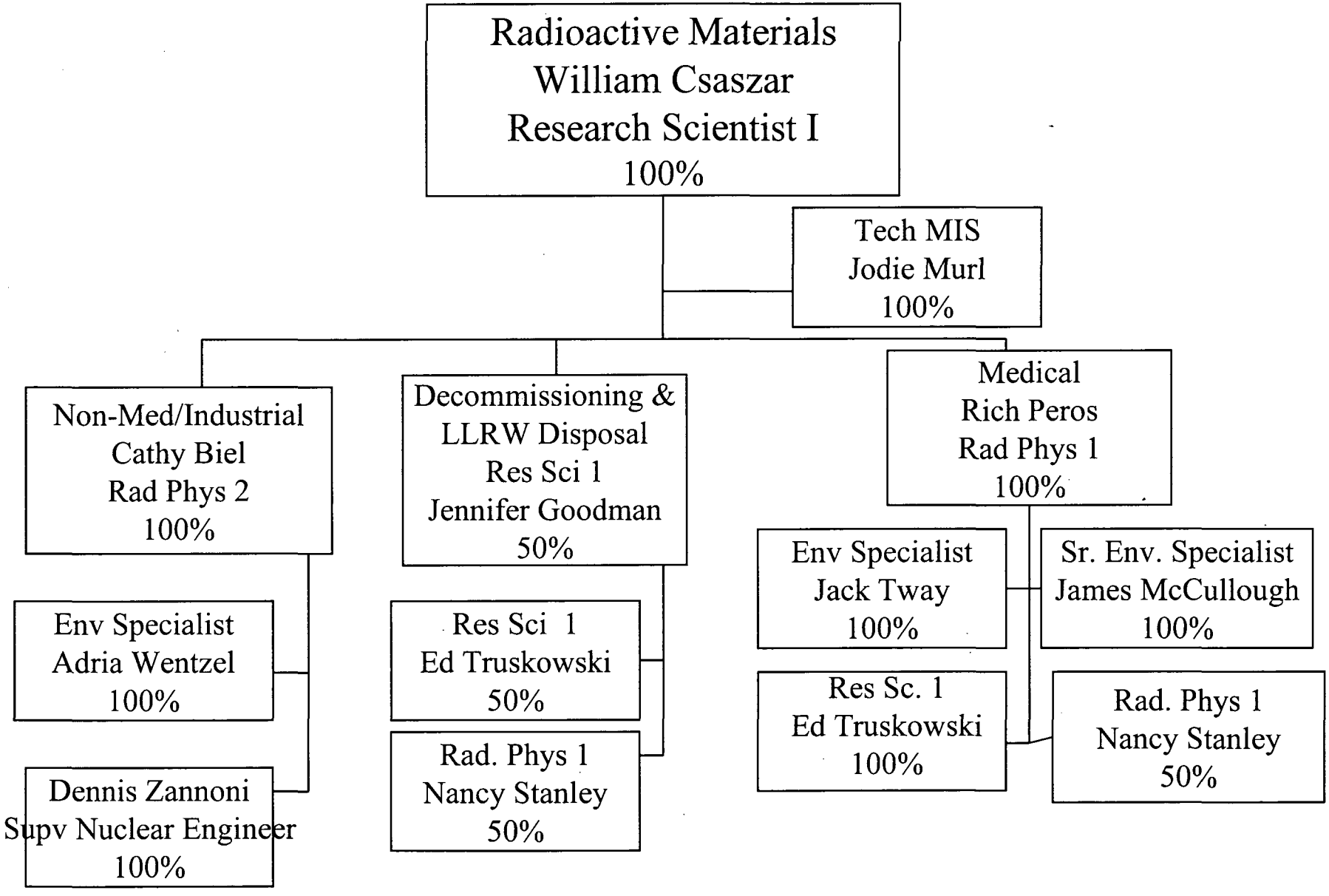
Included in Section 4.6.1 are:

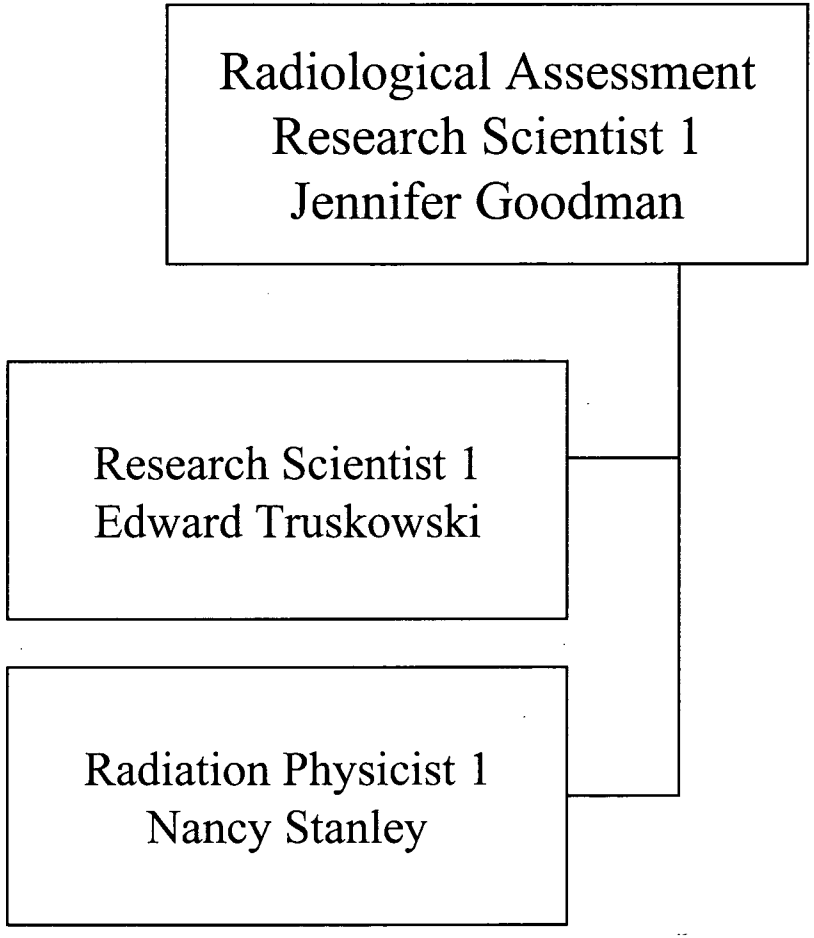
- Staffing Analysis
- Staffing Plan
- Example Job Specification
- Example Performance Evaluations

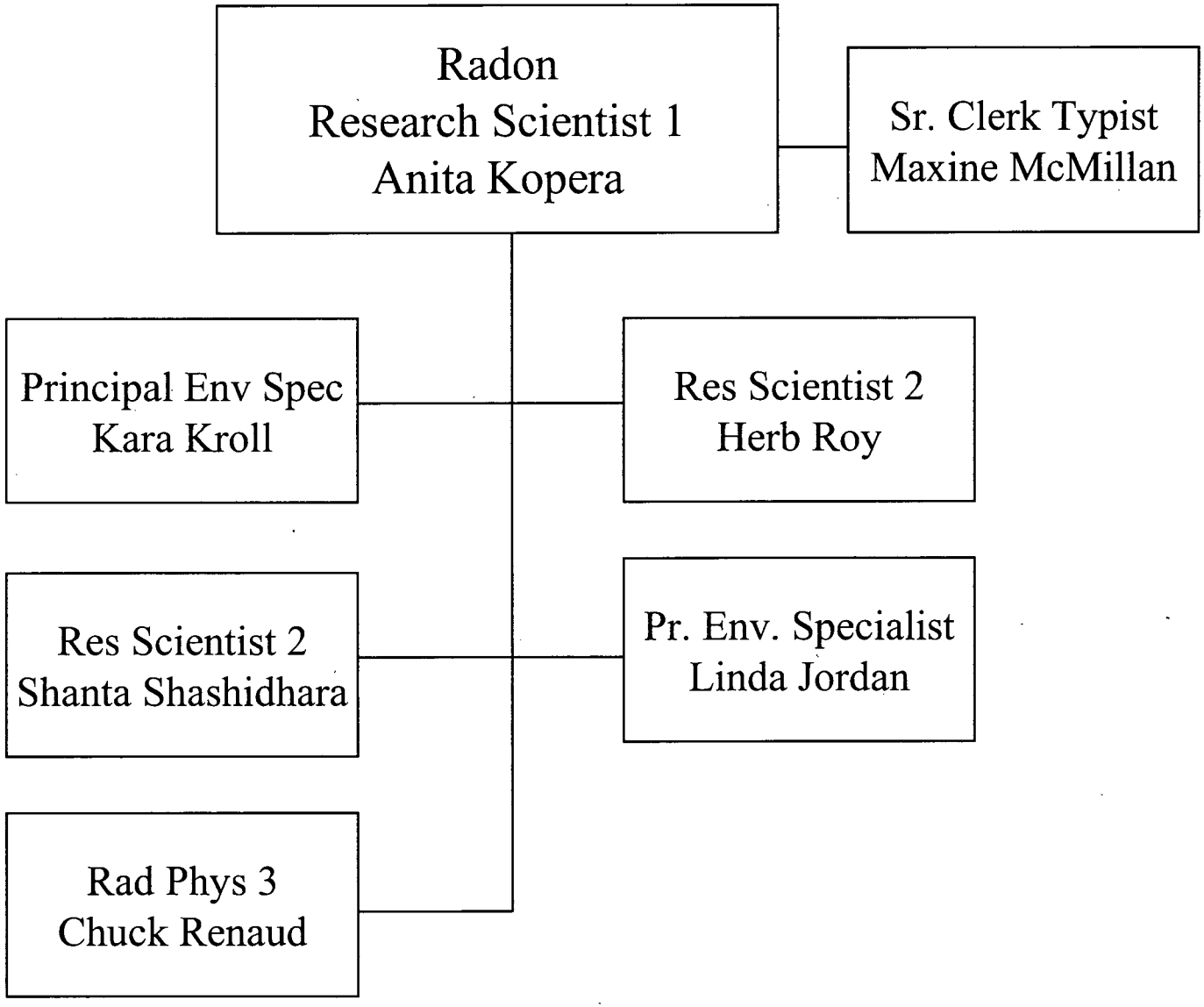
NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL REGULATION
DIVISION OF ENVIRONMENTAL SAFETY & HEALTH
RADIATION PROTECTION & RELEASE PREVENTION ELEMENT
BUREAU OF ENVIRONMENTAL RADIATION

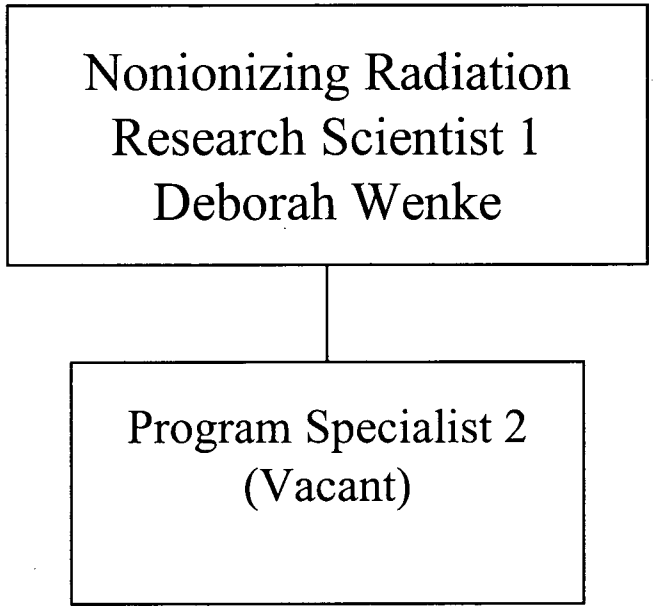


Proposed Agreement State Staffing and Organization




Radiological Assessment
Research Scientist 1
Jennifer Goodman
Research Scientist 1
Edward Truskowski
Radiation Physicist 1
Nancy Stanley


Radon
Research Scientist 1
Anita Kopera
Sr. Clerk Typist
Maxine McMillan
Principal Env Spec
Kara Kroll
Res Scientist 2
Herb Roy
Res Scientist 2
Shanta Shashidhara
Pr. Env. Specialist
Linda Jordan
Rad Phys 3
Chuck Renaud


Nonionizing Radiation
Research Scientist 1
Deborah Wenke
Program Specialist 2
(Vacant)

4.7.1 Procedures for Responding to Events and Allegations

The response to a materials event will be as per the procedures that are included in the State's "Radioactive Materials and Radiological Assessment Team" manual. This document includes the necessary steps that will be taken to respond to, assess and mitigate any material event that occurs within the State. Reach-back capabilities to Federal agencies are included for events that exceed the capabilities of the State. If the event occurred due to the actions of a licensee, staff and management will decide if a reactive inspection is warranted. Steps the licensee took to minimize the likelihood of a recurrence will be reviewed during this followup inspection. If a generic problem that could affect multiple licensees is discovered, information related to the particular issue will be made available to potentially impacted licensees. A list of radiological instrumentation is included as Attachment 8 to SOP RR-101.

The Bureau of Environmental Radiation maintains access to the services of the New Jersey Department of Health and Senior Services' (DHSS) Environmental and Chemical Laboratory Services (ECLS) for any radioanalytical services it may need as part of incident response efforts. Included is a parameter and method list for radioactive materials. Also included is the current price list for the specified methods.

As part of its response capabilities, the Bureau of Environmental Radiation also maintains procedures to issue United States Department of Transportation (DOT) exemptions for previously unrecognized radioactive material so it will be in compliance with DOT requirements.

The Bureau of Environmental Radiation, in conjunction with the New Jersey State Police and the New Jersey Office of Counter-Terrorism, utilizes the "New Jersey Radiological Response Protocol" as a template for the use of radiation detection and isotope identification equipment to classify radioactive substances and ascertain their legitimacy. **Because of the sensitive nature of this document, and its classification For Official Use Only, it is not for distribution to any other party.**

Included in the Application is the NJ Department of Environmental Protection State's "Radioactive Materials and Radiological Assessment Team" manual. This document includes the necessary steps that will be taken to respond to, assess and mitigate any material event that occurs within the State. If the event occurred due to the actions of a licensee, staff and management will decide if a reactive inspection is warranted. Steps the licensee took to minimize the likelihood of a recurrence will be reviewed during this followup inspection. Reach-back capabilities to Federal agencies are included for events that exceed the capabilities of the State.

New Jersey's Department of Environmental Protection's Radiation Protection and Release Prevention Element maintains an agreement with the Conference of Radiation Control Program Directors (CRCPD) to be a member of the National Orphan Radioactive Material Disposition Program, allowing the Bureau of Environmental Radiation to assist an individual or firm in the disposition of unwanted sources.

Allegations of improper activities will be investigated in a timely manner. If the allegation is confirmed, appropriate action will be taken to address the situation. Severe infractions can be discussed with, and potentially referred to, the State Office of the Attorney General, if so warranted.

Included in Section 4.7.1 are:

Radioactive Materials Radiological Assessment Team Manual

- SOP RR-101 Notification, Initial Response and Mobilization
- SOP RR-102 On-Scene Radiological Response
- SOP RR-103 Radiological Assessment and Protective Action Guidance

New Jersey Department of Health & Senior Services Radioanalytical Services Laboratory overview

- NJDHSS price list

SOP 7.01 Procedure for Issuance of US DOT Exemptions

Attachment 1 - U.S.D.O.T. Exemption E-10656 (Contaminated Metal or Recycling Material)

Attachment 2 - U.S.D.O.T. Exemption E-11406 (Contaminated Trash or Refuse Material)

Attachment 3 - Procedures for Notifications Made By Waste Facilities That Involve Trash Contaminated With Radioactive Material

SOP 7.02 Management of Allegations
SOP 7.03 Instrument Calibration and Quality Assurance Program
SOP 7.04 Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy
SOP 7.05 Guidance on Reactive or Special Inspections
SOP 7.06 BER – 7.06 Follow-up Actions and Action Levels for Radiation Exposures Associated with Incidents Involving Members of the Public

Introduction to CRCPD National Radioactive Material Disposition Program materials

- CRCPD National Radioactive Material Disposition Program

Inspection Procedure 92702 Followup on Enforcement Actions

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.

b. Permanent Field Offices

1. If the license authorizes licensed activities to be conducted from two or three permanent facilities (main office plus one or more field offices), only one location must be inspected at the inspection interval for the type of license. If the license authorizes licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified in this chapter for the type of license. If the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected. Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.

2. If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities.

3. If an inspection identifies significant program weaknesses (i.e., Severity Level III or above violation(s), multiple Severity Level IV violations indicative of poor program management/oversight), the inspector should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

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

ARE CONSIDERED SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION (SUNSI)

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-24 1/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.

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, 35.615, 35.633 and 35.643).

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