

NRC INSPECTION MANUAL

NMSS/MSIB |

INSPECTION PROCEDURE 87111

MATERIALS PROCESSOR/MANUFACTURER PROGRAMS

PROGRAM APPLICABILITY: 2800

87111-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission requirements.

01.03 To determine if the licensee is manufacturing sources or devices in accordance with statements made to NRC.

87111-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspections of materials processor/manufacturers. For the purpose of this IP, materials processor/manufacturers are those licensees that process raw material and/or sources and distribute those processed materials and sources to users as finished products. Examples are major radiopharmaceutical processor/manufacturers (not radiopharmacies), sealed source fabricators, device manufacturers, and other manufacturing licensees that use irradiated bulk quantities of raw materials or sources. This IP does not apply to inspection of distributors that are not involved in the processing of raw materials or sources, nor manufacturing of devices.

A review of the licensed activities will be commensurate with the scope of the licensee's program. Inspections should be conducted of licensee operations that are a potentially significant contributor to dose, regardless of shift on which they occurred. A determination regarding safety and compliance with NRC requirements should be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. All of these elements should be documented. See Appendix A, Part II, "Inspection Documentation." |

In reviewing the licensee's performance, the inspector should cover the period from the last to the current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

Some of the following areas may not be applicable to all large materials processor/manufacturers.

02.01 Preparation. Preparation will include reviewing documents, making travel arrangements, coordinating with appropriate staff, verifying that appropriate State agencies are notified, and selecting necessary equipment. In particular, the inspector shall identify whether any license amendments have been issued since the last inspection, or whether the licensee has informed NRC of any major program changes since the last inspection. The inspector shall also review: 1) the Nuclear Materials Events Database (NMED) and regional event logs and files, to determine if the licensee had any incidents or events since the last inspection; 2) the license file for notification(s) to NRC under the decommissioning timeliness requirements of § 30.36(d); and 3) the previous inspection history, including the last notice of violation (NOV) and response, if applicable.

02.02 Entrance Briefing. When the inspector arrives at the licensee's facility, he/she will inform an available senior management representative of the purpose and scope of the inspection.

02.03 Follow up on Previous Items

- a. Determine whether the licensee followed up on cited violations identified during the previous inspection.
- b. Determine whether the licensee took the corrective actions as described in its response to the NOV and followed-up on recommendations, outstanding safety items, and unresolved issues identified during the previous inspection .

02.04 General Overview

- a. 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).
- b. Scope of Program. Interview cognizant personnel to determine the types, quantities, and use of byproduct material, frequency of use, staff size, etc.
- c. Management Oversight. In the course of interviewing cognizant personnel, determine if management oversight is sufficient to provide the licensee staff with adequate resources and authority to administer the licensed program.
 - 1. RSC - If the licensee is required to have an RSC, review the committee meeting minutes for topics of discussion, membership, frequency, and attendance. The inspector should interview some members of the RSC to determine their involvement in the radiation safety program.
 - 2. RSO - Determine whether the RSO has been appointed and is named on the license; has sufficient authority, staff, and equipment; and fulfills the appropriate duties commensurate with the size and scope of licensed activities.
 - 3. Audits - Verify that audits are performed as required. Verify that the results of the audits are reviewed and addressed.

- d. Authorized Users. Determine that only authorized individuals perform and/or supervise licensed activities. Verify that users appointed by the licensee are qualified. Also verify that authorized users perform an appropriate level of supervision, as required by the license.
- e. ALARA (As Low As Is Reasonably Achievable). Determine that the licensee has ALARA practices in place and in use. Verify that the ALARA practices are effective. Determine management's and workers' commitment to the ALARA concept.
- f. Safety Significant Human Performance Issues. Conduct interviews with several workers to assess the existence of safety issues concerning work place design, production pressure, staffing hours, etc. Verify management's awareness of issues and measures taken to ensure that worker performance and safety are not being compromised due to these conditions.

02.05 Observation of Actual Facilities and Licensed Activities

- a. Perform a walk-through tour of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed.
- b. Conduct inspections of licensed operations that are a potentially significant contributor to dose, regardless of shift.
- c. Perform routine inspections, when applicable, during first run operations.
- d. Make direct observations of radiation safety systems and practices in use. Document these observations in the inspection record.
- e. The tour 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.

02.06 Facilities

- a. Verify that the facility conforms to that described in the license application; that material receipt, use, and storage areas are secured; and that the licensee uses processes or other engineering controls to maintain doses ALARA.
- b. Verify that the licensee is complying with license requirements for facilities and systems (e.g., sewerage, power supply, waste release, ventilation).
- c. Verify that unauthorized personnel will be prevented from entering high radiation areas and receiving high doses.
- d. Determine whether the licensee has evaluated air-flow patterns. (This is a fundamental activity for demonstrating the adequacy of ventilation design and functioning, from an ALARA practices perspective.)

02.07 Equipment and Instrumentation

- a. Verify that portable radiation detection and sampling equipment is appropriate, operable, calibrated, adequately maintained, and conforms to that described/referenced in the license.
- b. Determine whether the licensee has and is using safety devices and equipment in processing and storing licensed materials.

- c. Determine whether the licensee has and is using appropriate shielding during licensed activities to maintain doses ALARA.
- d. Determine whether the licensee has and is using calibrated laboratory radiation detection instrumentation that is appropriate for the licensee's program.
- e. Determine whether the licensee has air-handling equipment as described in the license document.
- f. Verify that the licensee has established and implemented procedures to identify and report safety component defects per the requirements of 10 CFR Part 21.

02.08 Materials

- a. Receipt and Transfer of Licensed Material. Verify that the licensee is receiving packages and making transfers of licensed material in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license conditions.
- b. Authorized Uses. Determine from observing the use of licensed material, discussing the activities with licensee personnel, and reviewing records, that the type, quantity, and use of licensed material at the licensee's facility are authorized by the license. Verify that the licensee has procedures to assure that it possesses only the quantities of materials authorized by the limits on the license. To the extent practical, assure by physical confirmation that the licensee's inventory is complete and accurate.
- c. Material Security and Control. Verify that the licensee has established procedures for maintaining security and control of licensed material, and that these procedures are understood and implemented by appropriate personnel. Verify that licensed material, in storage, in controlled or unrestricted areas, is secure from unauthorized removal or access. Verify that licensed material, not in storage, in controlled or unrestricted areas, is controlled and under constant surveillance. Verify that access to restricted areas is controlled by the licensee.
- d. Incidents and Unusual Occurrences. Evaluate any incidents or unusual occurrences since the last inspection, and evaluate the licensee's response.

02.09 Training

- a. General Training. Verify that appropriate training and initial instructions are being accomplished as specified in the license and/or regulations. Verify that workers are knowledgeable of the risks associated with the licensed activities (including e.g., typical dose rates, contamination, ALI's, steps to take if the individual chooses to declare pregnancy status, etc.).
- b. Operating and Emergency Procedures. Verify that operational procedures are being followed by observing licensee personnel perform tasks at selected work stations and by a comparison of their activities with established procedures. Also examine the licensee's emergency procedures to determine that these procedures are as approved by NRC. Through discussions with workers, verify that licensee personnel understand and implement the established procedures and are aware of procedural revisions. Document in the inspection record what activities the inspector observed.

When applicable, discuss with the licensee's representatives, or observe (for the higher-priority licensees), the conduct of periodic tests and drills, especially for scenarios involving fires and large releases of radioactive material.

02.10 Area Radiation and Contamination Control

- a. Area Surveys. Verify, during observations and by direct measurements, that the radiation levels are within the limits of 10 CFR Part 20, and that these areas are properly posted.
- b. Leak Tests and Sealed Source Inventories. Verify that leak tests of sealed sources are performed at the required frequency. Also verify that leak tests are analyzed in accordance with the license. If records of leak test results show contamination in excess of the regulatory requirements, verify that the licensee made appropriate notifications and removed the source from service. QA for leak tests should also be reviewed. Verify that license-condition-required sealed source inventories are performed.
- c. Contamination Control. Verify that, if applicable, the licensee performs surveys for removable contamination at the required frequencies. If the licensee has had spills or other incidents of contamination exceeding the licensee's action levels, verify that the licensee has taken appropriate actions.
- d. Protective Clothing. Verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed.
- e. Process Controls. Verify that the licensee has established process controls for maintenance on processing lines, sealed sources, and devices.

02.11 Radiation Protection

- a. Radiation Protection Program. Verify that a radiation protection program commensurate with the licensee's activities is being implemented and documented, and that the program is being reviewed at least annually, both for content and implementation.
- b. Radiation Protection Procedures. Verify that changes in the radiological protection procedures made since the last inspection are consistent with regulations and license requirements. [Note that some procedures may require prior NRC approval before the licensee can make changes.]
- c. Instruments and Equipment. Verify that radiation protection instruments and equipment have the proper alarm settings (if applicable) and are checked for appropriate response, in accordance with license requirements and licensee procedures. Verify that laboratory instrumentation and equipment used for analysis of samples (leak tests, wipes, bioassays, etc.) are operable, and are appropriately calibrated and maintained for the samples to be analyzed.
- d. Personnel Dosimeters. Verify that personnel dosimetry devices are worn by appropriate licensee personnel. Dosimetry devices appropriate to the type, energy, or emitted radiation, and the anticipated radiation fields, should have been issued to facility personnel. Verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program-approved and-accredited processor/manufacture.

Verify that pursuant to 10 CFR 19.13(b) the licensee advises each worker annually of the worker's dose, as shown in records maintained by the licensee, pursuant to the provisions of 10 CFR 20.2106, "Records of individual monitoring results."

02.12 Waste Management

- a. Waste Storage and Disposal. Verify that the waste is stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed the limits of 10 CFR 20.1301, "Dose limits for individual members of the public." Also, verify that any radiation areas or high radiation areas surrounding the storage area have been identified and properly posted. Verify that disposals of decay-in-storage waste are performed in accordance with the regulations and license conditions. (Note that licensees, other than medical, must be specifically authorized in the license to dispose of waste by decay-in-storage.) Verify that the licensee is conducting appropriate surveys and defacing radioactive material labels before disposing of the waste.

Review the licensee's procedures and records to verify that each shipment of radwaste intended for offsite disposal is accompanied by a shipment manifest that includes all the required information.

Review the licensee's procedures and records to verify that each package of radwaste intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with the classification criteria of 10 CFR 61.55 [Subsection III.A.2 of Appendix F to 10 CFR 20.1001-20.2401].

- b. Effluents. Review and verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within the limits established by the license and other regulatory requirements and ALARA.

Determine the quality of the relevant procedures and the degree to which ALARA techniques are incorporated into them. Determine the extent to which process and engineering controls are used to minimize effluents.

Determine whether effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with manufacturer's recommendations and good health physics practices.

Determine if all significant release pathways are monitored, all un-monitored pathways have been characterized, and all surveillance procedures for effluents are being implemented.

Additional inspection requirements are specified in IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)."

- c. Transfer. Verify that wastes are transferred to an authorized recipient specifically licensed to receive radioactive waste.
- d. Records. Verify that records of waste storage, transfer, and disposal are maintained in accordance with the requirements of Part 20 and the license.
- e. Financial Assurance and Decommissioning. For all licensees, including sealed source licensees, review the licensee's records of information important to the safe and effective decommissioning of the facility. Verify that the records are complete,

updated, and assembled appropriately, in accordance with the requirements in 10 CFR 30.35(g).

Review the licensee's list of restricted areas required under 10 CFR 30.35(g)(3) and determine whether laboratories or other rooms have been released since the last inspection. If areas have been released, verify that the licensee has adequately decontaminated each room and documented the basis for releasing each room. Document the location of the released rooms in the inspection record, and document your findings regarding the adequacy of the licensee's decontamination.

Verify whether radiological conditions at the facility have changed since the financial assurance instrument and/or decommissioning plan was submitted such that either document needs to be changed to address the new radiological conditions. Examples of changes are radiological incidents such as spills or process upsets. Unauthorized changes by the licensee to processes, types of licensed materials, possession limits, or chemical or physical forms of licensed materials may also prompt a reevaluation of whether the financial assurance instrument and/or decommissioning plan remains sufficient. If the inspector identifies changes that may affect the financial assurance instrument or decommissioning plan, he/she should immediately notify regional management.

If a parent-company guarantee or a self-guarantee is used to assure decommissioning financial assurance, review the licensee's financial assurance file to ensure that 10 CFR Part 30, Appendix A or Appendix C requirements are met.

- f. Decommissioning Timeliness. Review compliance with the Decommissioning Timeliness Rule requirements in 10 CFR 30.36(d) through (h). This is one area of the inspection record that should be completed on all inspections. If the license to conduct principal activities has expired or been revoked; if the licensee has made a decision to permanently cease principal activities at the site, in any separate building, or at any outdoor area; or if there has been a 24-month duration when no principal activities were conducted at the site, in any separate building, or at any outdoor area, then the decommissioning timeliness requirements in 10 CFR 30.36, 10 CFR 40.42, 10 CFR 70.38, or 10 CFR Part 72 apply. If this is the case, complete in full the "Decommissioning Timeliness Inspection" Attachment, Attachment B to Appendix A.

02.13 Transportation. Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with 10 CFR Part 71 and DOT regulations for transportation of radioactive materials.

02.14 Posting and Labeling. Verify that the licensee has posted the appropriate documents, notices, forms, and caution signs as required. Also verify that containers of licensed material are labeled appropriately.

02.15 Generic Communications of Information. Confirm that the licensee is receiving the applicable bulletins, information notices, NMSS Licensee Newsletter, etc. Verify that the licensee has taken appropriate action in response to these notices.

02.16 Notifications and Reports

- a. Determine compliance with the regulations and license requirements for notification and reports to NRC.

- b. Gather information on events reported to NRC. Follow up on site with the licensee to obtain information and verify the licensee's event response that could not have been performed from the regional office.
- c. Verify that the licensee's event report is accurate and timely.
- d. Verify that appropriate corrective action was taken in response to the event.

02.17 Source or Device Review. Determine compliance with the device registration certificate (registered by NRC or an Agreement State). Determine whether the licensee registrant has deviated from the process described in the source or device registration certificate, including modification to the source or device design, without approval from the registering agency (NRC or the appropriate Agreement State).

02.18 Quality Assurance (QA) and Quality Control (QC)

- a. Verify that the licensee is implementing QA and QC programs for products manufactured, processed, or distributed.
- b. Review the adequacy of the procedures and instructions of the QA/QC program.
- c. Review a sample of QA/QC audit or inspection reports and, if applicable, determine if follow up and corrective action were taken for deficiencies.

02.19 Special License Conditions. If applicable, review the licensee's compliance with any special license conditions.

02.20 Independent and Confirmatory Measurements. Compare and verify, on a sampling basis, survey results or data that are used by the licensee to show compliance with the regulations or license conditions. Conduct independent measurements to ascertain the radiological conditions of the facility. Conduct these independent measurements on all inspections under this inspection procedure, unless warranted by special circumstances. If independent measurements were not made, provide a justification in the inspection record explaining why independent measurements were not performed. The inspector shall use radiation detection instruments that are calibrated, at a minimum, on an annual basis.

- | 02.21 Exit Meeting. The inspector will conduct an exit meeting with the most senior licensee management representative and the RSO to discuss the preliminary inspection findings, including any apparent violations, safety-related concerns, and any unresolved items identified during the inspection. Discuss any negative Performance Evaluation Factors (PEFs) and encourage the licensee to respond to the PEFs of concern. For further guidance, refer to IP 87107, "Performance Evaluation Factors."
- | 02.22 Post-Inspection Actions. After an inspection, the inspector shall summarize the findings with his/her appropriate NRC supervisor. This is especially important if there are, or are expected to be, controversial issues arising from the findings.

Inspectors shall also meet with the appropriate licensing staff member or supervisor when any pertinent licensing issues are raised during the inspection, when inspection findings impact on any licensing actions, to discuss licensee PEF results which indicate potential problems that should be addressed during licensing, or to give feedback on how the licensee has addressed recent licensing actions. This meeting shall be documented in the inspection record.

Occasionally, inspection findings will warrant communication with Enforcement staff, Office of Investigations staff, State liaison staff, or Federal agencies with whom NRC has Memoranda of Understanding (MOUs).

The inspector will ensure that inspection findings are clearly documented, and reported to the licensee as appropriate. The inspector shall also follow the requirements of Inspection Manual Chapter (IMC) 0620, "Inspection Documents and Records," regarding notifying the licensee that retained information is subject to public disclosure and giving the licensee the opportunity to request withholding it (see IMC 0620, Section 04.06.b).

87111-03 INSPECTION GUIDANCE

General. The inspection of a materials processor/manufacture serves several functions, described in the objectives of this IP. Inspections of materials processors/manufacturers differ from other materials inspections in a significant manner. In addition to the routine objectives of an inspection, these inspections also ensure that sources and devices manufactured by the licensee conform to the standards at the time the source or device was registered (by NRC or an Agreement State). The inspection is the main source of information to NRC that the manufacturer is still making sources and devices as authorized in the license and registration certificate. The inspection should determine whether the licensee is deviating from the processes, procedures and/or devices, as described in the source or device registration certificates.

An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records alone. Inspectors should review worker knowledge of the risks associated with licensed activities (e.g., typical dose rates, contamination, ALI's, etc.). Also, this can serve as a measure to evaluate the effectiveness of the radiation safety training.

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, observations, and demonstrations.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of radioactive materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail. The type of records that were reviewed and the time periods covered by these records should be noted in the appropriate "Basis for Findings" section(s) of the inspection record.

When an inspector identifies an apparent violation, he/she should gather copies from the licensee, while on site, of each pertinent record that is needed to substantiate the finding. 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 file more complete. In all cases where licensee documents are retained beyond the inspection, the inspector must follow the requirements of IMC 0620 to ensure that the licensee understands that the retained record will become publicly available, and to give the licensee the opportunity to request withholding of the information pursuant to the requirements of 10 CFR 2.790(b)(1). Any copies of records retained for the file should be attached to the inspection record. If copies of licensee documents cannot be collected, the inspector should make certain that he/she

has retained in the inspection record, for future reference, the pertinent information to support the inspection findings.

The inspector should look for evidence of safety significant human performance issues (e.g., work place design, production pressure, staffing hours, etc.) that may have a possible adverse impact on worker safety and safe work practices. Care should be exercised in accessing safety significant human performance measures because of the lack of regulatory requirements in this area. Issues identified must have a negative safety consequence.

The inspector should keep the licensee apprised of the inspection findings throughout the course of the inspection and not wait until the exit meeting.

The inspector should inform NRC management as soon as possible of significant findings identified during the course of the inspection that may require immediate corrective actions or further NRC investigation, such as unsafe radiological conditions at the facility, willful violations, or other potential escalated enforcement issues.

03.01 Preparation. Before the inspection, the inspector should do the following:

- Review the licensee's previous inspection history (at a minimum review the past two inspections), the license (including Financial Assurance requirements and instruments), and the status of any allegations or incidents. Note the licensee's commitments in response to previous violations for follow-up during the inspection
- Review the Nuclear Materials Events Database (NMED) and regional event/incident logs, event/incident files, and the docket file to determine whether the licensee was involved in any incidents or events. If NRC did receive notification of an incident, review that incident during the inspection and document the licensee's follow up in the inspection record
- In the inspection record, complete the administrative information, the inspection compliance history, the listing of any license amendments or program changes since the last inspection, and the description of any incidents or events that have occurred since the last inspection
- Determine the dates that the licensee submitted the most recent financial assurance instrument and decommissioning plan (if applicable)
- Discuss the licensee's program with previous inspector(s) and/or license reviewer(s) as necessary
- Be sure that appropriate State radiation control program personnel have been notified of the upcoming inspection
- Review pending licensing actions
- Obtain a map of the area and/or directions
- Make travel arrangements and prepare itinerary
- Select calibrated instruments and perform source check
- Select appropriate documents
- Select appropriate equipment to take

In selecting the appropriate documents, the inspector should consider taking the applicable regulations, inspection record, generic communications, license, NRC forms, etc. The inspector should also consider taking any guidance documents (such as regulatory guides and information notices) that may be helpful to the licensee.

In selecting the appropriate equipment the inspector should consider the type of licensee to be inspected. The equipment may include safety glasses and safety shoes, sample vials, wipes, pocket dosimeters, alarming rate meters, etc.

During the inspection, focus (among other areas) on whether the licensee is in compliance with any license amendments issued since the last inspection or with any program changes described by the licensee since the last inspection. This requires review of documentation submitted in support of the licensing action, before the inspection. The inspection represents NRC's first opportunity to verify whether the licensee has enacted the most recent changes to the license.

03.02 Entrance Briefing. 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/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 NRC's presence on site, and apprise management that an exit briefing will be conducted, at the end of the inspection, that will 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.

Certain inspection items involving visual observations and/or records review are better performed unannounced; therefore, these types of items should not be discussed during the entrance briefing.

The licensee representative should be asked to identify any recent problems related to the licensed program, such as equipment failures and unusual radiological problems (e.g., excessive personnel exposures, unexpected releases to the environment, QA problems, etc.).

03.03 Follow-up on Previous Items

- a. Through observations and discussions with licensee personnel, determine the following information relating to corrective action on previous violations:
 1. the licensee responded in a timely manner;
 2. corrective actions were taken for each of the violations and the results of the corrective actions were as described in the licensee's reply to NRC;
 3. corrective actions were made within the time period described in the licensee's reply to NRC;
 4. corrective actions were successful in preventing recurrence of the previous violation;
 5. other licensee commitments discussed in the reply were also completed; and

6. the licensee posted copies of the enforcement correspondence as required by 10 CFR 19.11(a)(4).

- b. Through observations and discussions with licensee personnel, determine what action the licensee has made regarding outstanding safety items and unresolved issues identified during the last inspection. If applicable, close out these items.

03.04 General Overview. The inspector will interview the cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

- a. Organization. Determine the reporting structure between executive management, the RSO, the Chairperson, and other members of the RSC, if applicable to the licensee being inspected. Determine whether the RSO has sufficient access to licensee management.

Through discussions with licensee staff, the inspector should determine if changes in ownership or staffing have occurred. If the owner has changed, determine whether the licensee notified the NRC and requested approval of the change of ownership as required by 10 CFR 30.34(b), and has received approval from the NRC. If the name of the licensee, or the individuals named in the license have changed, determine whether the licensee has submitted to the NRC, as appropriate, a notification or request to amend the license. This information must be provided whenever changes in ownership or personnel are made (except for some licenses where only responsibilities are defined). Ask licensee management 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.

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 ask licensee management and the RSO about the RSO's authority and about any changes that may impact the RSO's duties, responsibilities, or effectiveness. The inspector should also review the size and capability of the radiation safety staff which provides support to the RSO in implementing the radiation safety program.

- b. Scope of Program. Through discussions with licensee personnel, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc., which can not always be gained by reviewing records alone. This is also an opportunity for the inspector to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection, including implementation of any license amendments. The inspector should determine if the licensee is authorized for multiple permanent field office locations and /or temporary job sites. Document any inspections conducted at these locations.

- c. Management Oversight. The inspection is a verification of the licensee's implementation of the required program. In the review to verify implementation, the inspector should pay particular attention to the scope of the program; frequency of licensee audits and the use of qualified auditors; procedures for recording and reporting deficiencies to management; and methods and completion of follow up actions by management.

1. RSC (where required or used) - Topics of discussion should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc. The committee should be made up of a representative from each type of program area, the RSO, and a representative from management. The inspector should review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. The required frequency that the RSC must meet will be identified in the license application or other commitment documents.

Determine if the committee has been aggressive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trend analyses to appropriate personnel performing licensed activities.

2. 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 verify 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, to implement corrective actions, including termination of operations that pose a threat to health and safety.

The radiation safety staff are comprised of the individuals that report directly to the RSO and assist the RSO in implementing the radiation safety program. The radiation safety staff may include health physicists, technicians, and other support personnel who are needed to perform radiation-related oversight of the manufacturing or processing activities. The knowledge and training of the radiation safety staff should be commensurate with their assigned duties.

3. Audits - The frequency and scope of audits of the licensed program will vary. However, note that at a minimum, licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. 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, 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.

Determine compliance with license conditions relating to implementation of a system of internal inspections by the licensee or other management control systems (such as external audits by a consultant) that are described in the license. Examine, in particular, the scope of the audit program, frequency of audits, procedures for recording and reporting deficiencies to management, methods and completion of follow up actions taken by management, and policy regarding announced and unannounced audits.

- d. Authorized Users. Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties. In cases where users are specified by license condition, determine that the licensed materials they use conform to the license condition.

Determine that the authorized users are personally performing or, if permitted in the license, supervising, the authorized work, rather than someone else not named in the license. The level of supervision will depend on the wording in the license conditions or regulations. Some licenses have conditions such as "... used by or under the supervision of" For other types of licensees, supervision is defined in the regulations. For some licenses that have the condition "... under the direct supervision of ...," the authorized user must be physically present at the facility, for easy contact or to observe the individual(s) working. Another phrase used is "... may only be used by" Finally, "... under the direct supervision and physical presence of ..." means the authorized user must directly supervise and be present at the work station. Considering the many license condition phrases and regulations, the inspector must exercise judgment to interpret the role of the authorized users.

When the wording of the license condition is "... used by or under the supervision of ...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized user/supervisor are responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

e. ALARA

1. The licensee should, in addition to complying with regulatory requirements and license conditions, make reasonable efforts to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas ALARA. This can be accomplished by the implementation of good radiation planning and practices, and by the commitment, from management and workers, to policies that prevent departure from ALARA practices. Also, licensees are required to keep occupational doses and doses to members of the public ALARA, in 10 CFR 20.1101(b).
2. The inspector should review ALARA practices, and verify implementation of any ALARA commitments in licensing documents, by reviewing:
 - (a) A written commitment by high-level management to minimize worker exposure by the implementation of clearly defined procedures and policies;
 - (b) That licensee personnel are made aware of management's commitment to keep occupational exposures ALARA;
 - (c) That the radiation safety staff have been given authority to assure ALARA procedures and policies are carried out;

- (d) That workers are adequately trained, not only in the radiation safety procedures, but also in the ALARA philosophy;
 - (e) That management and its designees perform periodic audits to find out how exposures and effluent releases might be lowered;
 - (f) That modifications to procedures, equipment, and facilities have been made to reduce exposures at reasonable costs, where possible;
 - (g) That the licensee has QA and QC programs, where applicable; and
 - (h) That the licensee has a functioning and effective preventive maintenance program, where applicable.
3. Review and evaluate engineering controls to assure that, for example, exhausts from ventilated enclosures are adequately treated to reduce emissions to the out-of-plant environs to the lowest reasonably achievable levels within regulatory limits. Evaluate ventilated enclosures to assure that they are adequate to minimize internal exposures. Review shielding and the use of remote handling tools to assure that facilities and equipment are adequate to reduce exposure (both internal and external) to the lowest reasonably achievable levels within regulatory limits.

03.05 Walk-Through Orientation Tour

- a. The inspector should make initial observations of licensed activities to determine that materials are being safely handled and that good health physics practices are followed. The inspector should look at areas of use, storage, and disposal to make an initial assessment of the licensee's ALARA practices with regard to facility design, engineering controls, house-keeping practices, etc. The inspector should ensure that observations of activities are documented in the inspection record.
- b. During the walk-through tour, the inspector should observe equipment, facilities, work in progress, posting of areas, restricting of areas, surveys, and security of devices and materials. To the extent possible, the inspector should verify by direct observation that work is performed only by authorized personnel and that workers are appropriately supervised in their work.

03.06 Facilities

- a. Descriptions of the facilities are generally found in the applications for a license and subsequent amendments that are usually tied down to a license condition. The actual or as-built facility should be configured to provide safe working areas separated from unrestricted areas and sufficient access controls to preclude unauthorized entry. The inspector should also be aware of potential industrial safety hazards for referral to the U.S. Department of Labor's Occupational Safety and Health Administration.
- b. Determine compliance with license conditions and descriptions in the license regarding: 1) utilities and services, such as the emergency electrical power supply, sewerage systems into which radioactive waste and effluents are released, and fire protection systems; 2) auxiliary facilities, such as laundry rooms, laboratories, storage rooms, warehouses, and waste holdup tanks; and 3) shielding and safety interlocks.
- c. Confirm that the licensee has procedures which properly identify radiation areas and high radiation areas. Verify the adequacy of procedures, methods, and

devices used to prevent unauthorized personnel from entering high-radiation areas, and ensure that provisions are made for proper posting of areas, functioning of interlock systems (such as for hot cells), and shielding of the processing areas where high-radiation levels may exist.

- d. Determine that air flow patterns and building air intakes are not causing the spread of contamination, nor releases or doses in excess of regulatory limits.

03.07 Equipment and Instrumentation

- a. Portable radiation detection and sampling equipment should be appropriate to the scope of the licensed program. The inspector should verify that survey instrumentation has the appropriate range of use, which for some licensees can be found in the regulations. Determine if the quantity and type appear adequate to meet the licensee's requirements. By spot-checking, compare the type and number of portable instruments against any description in the license. The inspector should also verify that the survey instruments are calibrated at the appropriate frequency and checked for proper operation before use. All survey, sampling, and monitoring instruments should have current calibrations appropriate to the types and energies of radiation to be detected (a commonly overlooked item is the expiration date of Liquid Scintillation Counting calibration sources). The technical adequacy of calibration procedures at facilities that perform their own calibrations should be examined. Calibrations should generally be made at two or more points on each scale, with the high and low points separated significantly.
- b. Processing equipment, ventilation, and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use. The inspector should evaluate whether the licensee is following license commitments for process and storage systems and equipment, such as hoods, glove boxes, hot cells, remote-handling devices, shields and shielding devices, ventilation systems, and retention tanks. For hot cells, the inspector should evaluate the control of entry and removal of material and decontamination procedures. For glove boxes, the inspector should evaluate the procedures for checking the integrity of gloves and replacing gloves. For shielding, the inspector should confirm that appropriate shielding is available and is being used to maintain doses ALARA.
- c. The inspector should evaluate whether the licensee is following license commitments for radiation laboratory instrumentation, such as liquid scintillation systems, alpha/beta counters, and gamma counting systems. Determine if the types of laboratory equipment are appropriate for the samples being analyzed and the sensitivity required. Determine if the laboratory instrumentation is calibrated for the appropriate geometries of the samples to be analyzed and is routinely checked for proper operation. The licensee should maintain calibration records, control charts, and maintenance and repair records to demonstrate proper operation of laboratory instrumentation.
- d. The inspector should evaluate procedures, methods, and equipment used by the licensee to assure compliance with air-monitoring and air-handling commitments in licensing documents regarding ventilation, such as flow rates into hoods, air flows in ventilation systems, differential pressures in cells, in glove boxes, and across filter systems. The inspector should check by sampling gauges and data recorders for parameters to verify conformance with license requirements. Using a hand-held anemometer, the inspector should spot-check the linear airflow rate at the face of several hoods to verify that it meets the commitments made in the license.

03.08 Materials. Determine compliance with license conditions relating to the authorized licensed material, in terms of the isotopes, forms, and quantities. Determine, and evaluate the adequacy of, the method used by the licensee to demonstrate compliance with license limits. Observe the primary activities and operations to determine compliance with license conditions that address the authorized uses of licensed materials.

- a. Receipt and Transfer of Licensed Materials. Depending on the size of the licensed program, the package receipt procedures (a few or many) will be found in the license application. These procedures should be carefully reviewed before an inspection is conducted. By discussions with the licensee, determine if the procedures have been changed or modified. Some changes will require a license amendment whereas other minor changes (updating telephone numbers, editing procedures for clarity, etc.) may not require NRC approval. Randomly examine procedures used by the licensee to determine if they are in accordance with those identified in the license application, and determine whether these changes warrant a license amendment.

The procedures for picking up, receiving, and opening packages should include how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). The procedures also should include what actions are to be taken if surveys reveal packages that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should observe, when practical, personnel perform the package receipt surveys. The inspector should randomly examine records of package surveys.

Determine that the licensee has verified client license authorizations to comply with transfer requirements. Through discussions with licensee personnel, determine how the licensee ensures that transfers are made to authorized recipients.

- b. Authorized Uses. Authorized uses of byproduct material will be found in the licenses and license applications. Licenses will list the isotopes, physical or chemical forms, and the maximum possession limits. The inspector should physically examine the inventory of radioactive material on hand or examine records of receipt and transfer to determine that quantities and forms are as authorized. Additionally, the inspector should verify that the licensee's use of byproduct material is limited to that which is authorized in the license.

The inspector should determine that inventories for each radionuclide are within the license limits. In this regard, records of inventories following receipt and transfer should indicate/demonstrate that the materials on hand at any one time are within the licensee's possession limit. When practical, the records examined should be compared with a physical inventory of materials possessed.

The licensee should have an accounting system that suits the type of licensed program. For example, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility will need a sophisticated accounting system for all licensed material that provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other facilities operating under the same license, and the amount remaining after decay. The accounting systems should also consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the licensee should perform routine physical audits to ensure the accuracy of the system.

- c. Material Security and Control. Examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be under constant surveillance or physically secured. The licensee should have procedures for access controls. Controls may include a utilization log to indicate when radioactive material is taken from and returned to storage areas. The inspector should verify that adequate controls are in place and working effectively.

Verify the adequacy of procedures, methods, and devices used to prevent unauthorized or accidental removal of radioactive materials from processing and storage areas.

- d. Incidents and Unusual Occurrences. Review and evaluate any incident or unusual occurrence that took place since the last inspection. Verify if incidents were required to be reported, and, if so, that proper reporting procedures were followed. For incidents or unusual occurrences not required to be reported, determine that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.09 Training

- a. General Training. Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).
 - 1. 10 CFR Part 19 Required Training- Verify, pursuant to 10 CFR 19.12, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.
 - 2. Training Required by License Commitments-Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. One or more users of radioactive materials should be interviewed to determine that they have received the required training, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

Randomly examine records of training of personnel and attendant examinations or tests (if applicable) to the extent that the inspector is satisfied that the training program is being implemented as required. Where examinations are required, read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities.

The inspector should also observe related activities and discuss the radiation safety training received by selected individuals to assure that appropriate training was actually received by these individuals. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

Determine if ancillary workers (such as janitorial or clerical staff), contract workers, and visitors are informed about basic radiation safety practices for the type of material used by the licensee.

Determine, by observing and interviewing workers, if training and experience are adequate to enable users to safely undertake activities authorized by the license and whether they are aware of the risks involved. Examine the licensee's program for on-the-job training of new workers. Determine if there is adequate retraining for workers to cover regulation changes and/or radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

- b. Operating and Emergency Procedures. Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures will be approved by NRC and reviewed and updated by the licensee. Any revision requires an amendment to the license (except for broad-scope licenses).

Review and evaluate a sample of operating and emergency procedures required by the license. Select a sample of operating or process areas and verify that pertinent procedures are available to personnel and in use in those selected areas. If no operations are being performed, ask workers to describe their work to determine compliance with approved written procedures.

Review and evaluate the adequacy of any changes in the operating and emergency procedures made since the last inspection, or since license issuance, if performing an initial inspection. The inspector should assure, through spot checks, that revisions and changes to procedures have been properly implemented.

If the licensee is required to have and implement an emergency plan, evaluate in-plant procedures for handling accidents including evacuation, prevention of spread of contamination, securing sources, handling accident victims, and any other major portions of the emergency plan. Verify, by discussions with workers, and review of procedures, that the emergency plan has been implemented and is being maintained. Verify that lines of communication with outside organizations that may be called on to assist in an emergency are current and tested.

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. Discuss with the licensee's representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

03.10 Area Radiation and Contamination Control

- a. Area Surveys. The inspector may ask the licensee to spot-check radiation levels in selected areas using the licensee's own instrumentation. However, the

inspector must use NRC's instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated within the required time period ["in calibration"], and should be checked with a radiation source ["source checked"] for proper operation prior to leaving the regional office.)

If practical, observe how licensees conduct surveys to determine the adequacy of surveys. Also, note the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

The inspector should determine if workers take smears or instrument readings in areas that are readily accessible to facility personnel. Particular attention should be given to bench tops, sinks used for disposal, and storage areas. The survey activities should be at a specified frequency in accordance with the related licensee procedures. The inspector should also perform independent measurements as needed to verify licensee assumptions or measurements.

- b. Leak Tests and Sealed Source Inventories. Through discussions with licensee personnel and/or by demonstration of leak test procedures, the inspector should verify that leak tests are performed in accordance with the license. If the licensee analyzes leak tests on its manufactured products as a service to other licensees, it is important that the licensee demonstrate to the inspector an adequate method of performing and analyzing leak tests. Licensing requirements for sealed source inventories should also be considered.
- c. Contamination Control. The inspector should verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination. The inspector may choose to examine the instrument calibration records (efficiency checks; lower-limit-of-detection calculations; geometry; linearity, etc.), physical location of counting instruments, methods of detection, and wipe-sample locations. Additionally, when appropriate, the inspector should consider taking confirmatory wipe samples.
- d. Protective Clothing. If practical, the observation of the protective clothing worn by research lab personnel or other applicable staff during their work activities should provide the inspector with an acceptable means of reviewing this requirement. Requirements for protective clothing may be found in the licensee's procedures or as posted.
- e. Process Controls. By observation, determine compliance with license requirements for repair, tagging, opening, modification, and replacement of sealed sources and devices. Ensure that the licensee has methods or procedures to minimize exposure during maintenance on processing lines or devices. Verify through discussions with workers and by reviewing procedures that, when maintenance or modification is performed, controls are in place and are effective to warn workers of radiological hazards, prevent unnecessary exposure, and prevent the spread of contamination.

03.11 Radiation Protection. Specific guidance is set forth in IP 83822, "Radiation Protection."

10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report

to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

Verify that the licensee has performed adequate surveys to show compliance with public dose limits and that conditions in controlled areas and unrestricted areas meet the requirements specified for these areas.

03.12 Waste Management

- a. Waste Storage and Disposal. Verify that the waste is protected from fire and the elements, that package integrity is adequately maintained, that the storage area is properly ventilated, and that adequate controls are in effect to minimize the risk from other hazardous materials. Verify that the licensee has appropriate methods to track the items in storage.

Inspection effort should be directed at verifying that written procedures have been established in a manner approved by management. The procedures should be readily available to any persons having responsibility for low-level waste classification and preparation for transfer of such wastes to land disposal facilities.

Verify that storage for decay is not causing elevated radiation doses to waste processing workers. If applicable, confirm that the resident time of waste at the facility does not exceed the time limit authorized in the license. For licensees who have implemented an interim waste storage program, verify that the program is consistent with the license. For further guidance on interim waste storage, see Information Notice 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees."

Examine monitoring systems. Review and evaluate a sample of the procedures and other administrative and physical controls for the release and disposal of radioactive waste.

The inspector should determine whether radioactive material labels have been removed or defaced from discarded materials, being careful to not endanger him or herself to biological, chemical, or physically hazardous waste (e.g., sharp objects). Ensure that wastes prepared for shipment to a disposal site comply with applicable standards and regulations regarding chemical and physical form, stability, type of container, and labeling. Also ensure that the licensee implements an adequate QC program as required by Appendix F of 10 CFR Part 20 to ensure compliance with applicable regulations.

For further inspection guidance, refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61."

- b. Effluents. Examine the waste release records generated since the last inspection, all annual or semiannual reports, all pertinent non-routine event reports, and a random selection of liquid and airborne waste release records. Randomly select procedures for both liquid and airborne systems and verify that the licensee's procedures are being followed. The verification can be made by observations of an operation, a review of selected records, interviews with workers, etc.

For liquid wastes, determine if the licensee has: identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complied with the regulatory requirements for disposal in the publicly-owned sanitary sewerage system. If the licensee disposes of liquid wastes to surface waters, ground waters, or a private sanitary sewerage treatment

system, determine whether the licensee is in compliance with the regulations and all applicable license restrictions.

For airborne radioactivity, determine if the licensee has identified all routes of airborne releases to the environment and complies with the regulations and all applicable license restrictions. For a licensee authorized to dispose of radioactive material by incineration, determine compliance with 10 CFR 20.2004 and license requirements, and discuss with the licensee its methods for evaluating concentrations in the ash.

Determine compliance with license conditions relating to environmental monitoring. If applicable, observe sampling stations and equipment for adequacy. Review a sample of procedures, records, and reports to verify that the licensee has established and is maintaining an environmental monitoring program, if required in the license.

Review the licensee's ALARA goals, where applicable, and determine if the licensee has implemented these goals. Determine if the licensee has calculated annual doses resulting from air effluents and if the doses: (1) are within the licensee's ALARA goals (as described in its radiation protection program); (2) exceed the licensee's ALARA goals; or (3) are uncertain because there is insufficient information or basis for determination. Review the licensee's history in meeting ALARA goals, and its corrective actions when the goals were not met.

For further inspection guidance, refer to IP 87102.

- c. Transfer. Ascertain if the licensee has an adequate method of determining that recipients of radioactive wastes are licensed to receive such waste (i.e., licensee obtains a copy of the waste recipient's current license before the transfer).
- d. Records. Each licensee is required to maintain records of the disposal of licensed material made under 10 CFR 20.2002-2005, 10 CFR Part 61, and disposal by burial in soil. These records must be retained until the Commission terminates each pertinent license requiring the record. The inspector should review these records to verify that disposals are made in accordance with the applicable regulations, and that records are complete and accurate for each type of disposal.

The records, procedures, and methods of control must provide sufficient assurance and evidence of compliance with disposed of or released quantities and concentrations, as limited by the license and regulations. The inspector should determine the adequacy of licensee records of waste disposal and effluent releases. As a general rule, the records should be sufficient to determine at some future time the types, quantities, and locations of disposal of licensed material.

- e. Financial Assurance and Decommissioning. The decommissioning record-keeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These documents should contain, among other information: (1) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site (when contamination remains after cleanup, or when contaminants may have spread to inaccessible areas, such as seepage into concrete); (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 (e.g., buried pipes); (3) except for areas with only non-leaking sealed sources or byproduct materials with half-lives of less than 65 days, a single record detailing restricted areas and formerly restricted areas, buried waste, areas requiring decontamination that are outside of restricted

areas, and areas outside of restricted areas that, if the license expired, would have to be decontaminated or approved for disposal; and (4) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). On all inspections, including inspections of sealed source licensees, 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 laboratories or other 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. Inspectors should identify the rooms that have been released since the last inspection and perform confirmatory measurements (on a spot-check sampling basis, including questionable areas) to confirm that radiation and contamination levels are below release limits. The inspector should review the licensee's survey procedures, equipment and results and determine if these are acceptable. If the inspector determines they are not acceptable, then another inspection for confirmatory measurements purposes should be scheduled.

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 NRC. 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 NRC. Then during the inspection, through observations, discussions with licensee personnel, and records review, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to NRC. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should immediately contact regional management from the licensee's site to discuss the situation.

Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent-company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent-company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

- f. Decommissioning Timeliness. Determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, determine if the licensee has made a decision to cease principal activities at the site or at any separate building or outdoor area, including burial grounds. Finally, 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 that 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,

and the inspector must complete the "Decommissioning Timeliness Inspection record," Attachment B to Appendix A.

The requirements of 10 CFR 30.36, 10 CFR 40.42, and 10 CFR 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. However, in those cases, the inspector should follow the guidance in 03.12.e. of this IP regarding confirmatory measurements of the released area. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The Decommissioning Timeliness Rule became effective on August 15, 1994. In completing the Attachment B inspection record, specific guidance is needed regarding the timing of the notification requirements. If the license has expired or been revoked, or if the licensee has made a decision to permanently cease principal activities, and the licensee provided NRC notification before August 15, 1994, then August 15, 1994, is considered to be the date for initiating the decommissioning calendar (i.e., date of notification). If there has been a 24-month duration in which no principal activities have been conducted at the location before the effective date of the rule, but the licensee did not notify NRC, then the 24-month time period of inactivity is considered to be initiated on August 15, 1994, and the licensee must provide notification to NRC, within either 30 or 60 days of August 15, 1996 (depending on whether the licensee requests a delay).

There is an exemption to the decommissioning timeliness requirements. The provisions in the Decommissioning Timeliness Rule: in 10 CFR 40.42(d)(4), for the 24-month period of inactivity; in 10 CFR 40.42(f), for the content of the decommissioning plan; and in 10 CFR 40.42(g), for the timing of completion of the plan, do not apply to the reclamation of waste disposal areas and/or tailings impoundments at uranium recovery facilities and thorium mills.

NRC has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failures to: (a) notify NRC; (b) meet decommissioning standards; (c) complete decommissioning activities, in accordance with regulation or license condition; or (d) 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 immediately contact regional management.

For planning and conducting inspections of licensees undergoing decommissioning, refer to IMC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and the draft Decommissioning Manual Chapter and Handbook.

03.13 Transportation. The inspector should review: the licensee's hazardous material training; packages and associated documentation; vehicles (including placarding, cargo blocking, and bracing, etc.); shipping papers; and any incidents reported to DOT. This is an ideal area for the inspector to make observations of licensee practices. The DOT and NRC regulations for transportation of radioactive materials were recently revised, and the revisions generally became effective April 1, 1996.

For further inspection guidance, refer to IP 86740, "Inspection of Transportation Activities." For large materials programs where the licensee ships licensed materials or devices, this is a critical area of the inspection. The inspector should complete IP 86740 in full, with the understanding that shipping and transportation are one of the licensee's major functions. Any problems in the licensee's shipment program have the potential to be systemic, and affect all the licensee's shipments.

Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the NRC field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

If any packages are on hand and awaiting shipment at the time of inspection, the inspector should observe the packages and determine whether the packages meet DOT requirements. If packages are not on hand or awaiting shipment at the time of the inspection, the inspector should discuss the licensee's transportation practices with workers. If any vehicles are about to be used at the time of the inspection for transport of licensed material, the inspector should use the opportunity to ensure that DOT requirements are met with respect to the vehicle.

The inspector should determine whether any shipping incidents have occurred and determine compliance with regulations for reporting incidents to appropriate authorities. The inspector should ask whether the shipper has received any reports of incidents involving shipments of licensed material, review the incident reports to ascertain the circumstances and causes of the incident, and determine if corrective actions were taken by the licensee.

03.14 Posting and Labeling. The inspector should determine whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. Section 1903 provides exceptions to posting caution signs. When applicable, the inspector should also randomly examine signals and alarms to determine proper operation. The inspector should also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile radioactive materials are used in an area, such as area should be controlled for airborne contamination. High-radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high-radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

The inspector should also examine locations where notices to workers are posted. Applicable documents, notices, or forms should be posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply.

03.15 Generic Communications of Information. Through discussions with licensee management and the RSO, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, NMSS Licensee Newsletter, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. Also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.

03.16 Notifications and Reports

- a. The inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications, after loss or theft of material; over-exposures; incidents; high-radiation levels; safety-related equipment failure, etc. Additionally, some licensees are required to make annual reports to NRC. Licensees are also required to notify individuals of their occupational doses, if monitored, or members of the public, if public dose limits are exceeded. The licensee should also have ready access to the NRC Operations Center telephone number.
- b. Through observations and discussions with licensee personnel, the inspector should gather information concerning the events reported to NRC. The depth of on site follow up by the inspector should be proportional to the severity of the event. The guidance here is flexible, to the extent that the type of event may cause some of the guidance to be inapplicable. Follow-up involves on site verification that could not be done during the regional in-office review, and is in addition to the in-office review.
- c. Corrective Actions
 1. Determine that the corrective action stated in the report is appropriate to correct the stated cause.
 2. Verify that the corrective action stated in the report has been taken. Corrective action items of a long-term nature, such as a design change, should be tracked to completion by the inspector.
 3. For corrective actions not yet complete, verify that responsibility has been assigned for assuring completion. Formal requirements should be established to assure that corrective actions have been completed.
 4. Determine whether the corrective action is adequate to prevent recurrence. Corrective action should generally include: action taken at the time of the event, to eliminate the cause or to mitigate consequences; action taken to correct the specific fault or failure; and action taken to reduce the probability of, or to prevent, recurrence. The inspector should request that any changes in the licensee's corrective action from that stated in the report should be documented in an updated report to NRC.
- d. Inspectors should verify that licensees have procedures for reporting defects in accordance with Part 21. The complexity of the procedures will vary. Manufacturers should have detailed procedures to evaluate the safety significance of identified defects. Other licensees need only address identification and reporting requirements. Examples of commercial items for which reporting of defects would be required under Part 21, if associated with substantial safety hazards (e.g., a total effective dose equivalent of 25 rems [0.25 Sv] or more), and which might be found in laboratory-type facilities include radiation monitoring equipment, air sampling equipment, hoods, and computer software.

03.17 Source or Device Review. Through discussions with management and workers, and by observing licensee practices, determine whether the licensee is manufacturing any different sources or devices since the product was registered with NRC or an Agreement State. In particular, ask whether recent models of a device have been changed from previous versions, and, if so, whether the new models were registered with NRC or an Agreement State. Verify that the devices being manufactured conform to the registration certificate. Check to see whether the devices are entered into the sealed source and

device registry. If the inspector finds any devices that: 1) do not have a registration certificate; 2) have been changed since the device was registered, with no update on the registration certificate; or 3) are not entered in the sealed source and device registry, immediately contact the inspection supervisor. The region should then contact the Materials Safety Branch (MSB) of the Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS), for further guidance. If possible, the region should make the contact with IMNS while the inspector is still on site, so that he/she may follow up during the remaining course of the inspection.

03.18 Quality Assurance and Quality Control (QA and QC)

- a. If the licensee manufactures sources or devices using licensed material, the licensee will have committed to programs for QA and QC in either its license or in the device registration documentation. Verify that the licensee is using those QA and QC programs.
- b. Discuss the QA/QC program with members of the QA staff or management, to determine if they are familiar with their responsibilities. Determine whether the QA/QC program is being implemented.
- c. Most QA/QC programs will generate audit or inspection reports. On a sampling basis, spot-check some of these reports. If deficiencies in the licensed program (including the source or device manufacturing process) were noted, ask the licensee how they followed up and what corrective actions were taken to address the deficiencies. Determine whether the corrective actions were successful in addressing the deficiencies. Determine whether the licensee has an effective internal program for assuring quality in the final product and identifying problems in its own processes.

03.19 Special License Conditions. Some licenses will contain 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. The inspector should also note that some special license conditions will state an exemption to a particular NRC requirement.

03.20 Independent and Confirmatory Measurements. 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 (e.g., 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. 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. Confirmatory measurements are those whereby the inspector compares his/her measurements with those of the licensee's. Independent measurements are those performed by the inspector independently of the licensee's measurements. To perform the independent or confirmatory measurement, use NRC radiation detection equipment calibrated, at a minimum, on an annual basis.

03.21 Exit Meeting. When the inspection is over, there should be 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 may hold a preliminary exit meeting with appropriate staff on site. However, there must be a formal exit meeting with a senior management representative (and the licensee's RSO, if not present at the

preliminary exit meeting) as soon as practical after the inspection. This meeting will usually be held by telephone conference call.

During the exit meeting, the licensee representatives should be made aware of the preliminary inspection findings including any negative PEFs, apparent violations of regulatory requirements, safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations. Significant safety concerns must receive immediate attention from the licensee.

If safety concerns or violations of significant regulatory requirements are identified that affect safe operation of a licensee facility, prompt corrective action must be initiated by the licensee. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated. If the inspector and the licensee disagree on the magnitude of the concern regarding safe operation of the facility, regional management should be notified immediately.

Although deficiencies identified in some areas (e.g., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report or Notice of Violation.

03.22 Post-Inspection Actions. Regional office policy will dictate with whom the inspector will review his or her inspection findings (e.g., the inspector's supervisor), following the guidance in Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." The inspector should discuss the findings in detail that is commensurate with the scope of the licensee's program. Violations, items of concern (e.g., negative PEFs), and unresolved items should be discussed in sufficient depth for management to make appropriate decisions regarding enforcement actions, referral to other State and Federal agencies, and decisions on the scheduling of future inspections of the licensee's facility.

If appropriate, the inspector should also discuss inspection findings with licensing staff. This information exchange can be particularly useful if the licensee is having its license renewed or has recently submitted a license amendment request. The inspector should inform licensing staff about how the licensee has addressed (or failed to address) special license amendments or recent licensing actions. Licensing information requested by the licensee should also be discussed with the licensing staff.

Inspectors should be aware that NRC has entered into several MOUs, with other Federal agencies, that outline agreements on items such as exchange of information and evidence in criminal proceedings. The inspector should ensure that the exchange of information relevant to inspection activities is made in accordance with the appropriate MOU.

The inspector may report the results of inspections to the licensee either by issuing an NRC Form 591 or a regional office letter to the licensee, following the guidance in IMC 2800. The inspector must also ensure that the findings are documented in the inspection record and/or inspection report, in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement, and when it was violated. The inspection record should not be used as merely a checklist to note areas reviewed, but should be used to describe what procedures or activities were observed and/or demonstrated by the licensee during the inspection, and any items of concern identified that were not cited as a violation of regulatory requirements.

Inspectors may complete the inspection record either by hand or electronically. If the inspector is documenting the inspection record in electronic format, the sub-items under major sections that are not applicable or not reviewed may be deleted. However, the heading itself (e.g., "Radioactive Waste Management," or "Transportation") should remain

in the inspection record, and the inspector should enter appropriate remarks about why the section is not applicable or not reviewed.

For further inspection guidance, refer to Section 07.04 of IMC 2800.

87111-04 REFERENCES

A listing of IMCs and IPs, applicable to the inspection program for materials licensees, can be found in Section 2800-11 of IMC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

Specific references to regulatory requirements can be found in the "Materials Processor/Manufacturer Inspection References" Appendix, following this IP.

END

Appendices:

- A. "Materials Processor/Manufacturer Inspection Record"
- B. "Materials Processor/Manufacturer Inspection References"