
INSPECTION PROCEDURE 87126

INDUSTRIAL/ACADEMIC/RESEARCH PROGRAMS

PROGRAM APPLICABILITY: 2800

87126-01 INSPECTION OBJECTIVES

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

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

87126-02 INSPECTION REQUIREMENTS

This inspection procedure (IP) contains the standard requirements and guidance for inspections of licensees authorized for academic, research and development, and industrial uses of limited scope (ARDL) and for non-medical broad scope licenses. IP 87125 should be followed for inspection of materials processors/manufacturers and IP 87127 should be followed for radiopharmacies.

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records.

The structure and the emphasis of the inspection will be on the following Focus Elements (FE) that describe the outcomes of an effective materials radiation safety program:

02.01 The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits.

02.02 The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 The licensee should ensure that workers are:

- a. knowledgeable of radiation uses and safety practices;
- b. skilled in radiation safety practices under normal and accident conditions; and,
- c. empowered to implement the radiation safety program.

02.07 The licensee's management system should be appropriate for the scope of use and should ensure:

- a. awareness of the radiation protection program;
- b. that audits for ALARA practices are performed; and,
- c. that assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

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

87126-03 INSPECTION GUIDANCE

General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual focus elements described above. The timing and sequence of inspection activities are left to the inspector's discretion based on the circumstances and conditions at the time of the actual inspection. Furthermore, inspectors should not feel constrained by the guidance in this procedure. If an inspector obtains information that indicates that a problem may exist in an area within the NRC's jurisdiction that is not specifically addressed in this procedure, the inspector should redirect, or otherwise expend, inspection effort to address that problem.

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

An examination of the licensee's records should not be considered the primary part of the inspection program. Rather, observations of activities in progress, equipment, facilities and use areas, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records, alone.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of licensed materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail.

Common elements to all inspections include entrance and exit meetings with appropriate licensee management, including the radiation safety officer (RSO), observations of facilities and work in progress, independent and confirmatory surveys, and the evaluation of program scope and any special license conditions. Specific guidance regarding these common elements can be found in IMC 2800.

Each of the following focus elements should be reviewed as appropriate, during each inspection of an ARDL-licensee or broad-scope licensee.

Specific Guidance

03.01 FE-1: The licensee should control access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below 10 CFR Part 20 limits

Facilities

- a. Through direct observation, determine that all entrances to licensee facilities are normally closed, locked or otherwise secured to prevent unauthorized entry. This should include main facility gates, main building entrances, doors to waste storage facilities, etc.
 1. If the inspector finds any entrance or area to be unsecured, the inspector should determine, through questioning of licensee staff, the reason for the area or entrance being unsecured. The inspector should determine if the licensee failed to follow established procedures in securing the area or if additional training of staff is needed. The inspector should determine if the licensee's facility is configured to separate working areas from unrestricted areas.
 2. If the inspector finds entrances or other areas unsecured, the inspector should examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be under constant surveillance or physically secured.

- b. Through observations, verify that use and storage areas are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas should be physically secured when unattended.
- c. Evaluate licensee practices regarding access controls including control of keys and access codes to ensure only currently authorized individuals have access to licensed materials.
- d. Ensure licensee practices include testing of interlock systems, as applicable. (such as for hot cells)
- e. Examine air flow patterns and building air intakes for potential of spreading contamination, and for releases or doses in excess of regulatory limits.

Receipt and Transfer of Licensed Materials

- a. Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and receiving areas; 2) inspects packages for damage; 3) performs appropriate package receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If the inspector is unable to observe the receipt of packages, the inspector should request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.
 - 1. If packages are left unattended, the inspector should assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).
 - 2. If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, the inspector should interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth in Focus Element 5 (Section 03.05, below).
- b. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive the forms and quantities of such materials.

Inventory Control

- a. Through observation, the inspector should physically examine the inventory of radioactive material on hand and selected records of receipt and transfer to determine that quantities and forms are as authorized on the license. The

inspector should compare the possession of selected sealed sources with inventory records. The inspector should verify that the licensee is limiting its possession and use of licensed materials to the isotopes, forms and quantities specified in the license. Examine the adequacy of methods used by the licensee to demonstrate compliance with license possession limits.

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

- b. Through interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving lost, missing, or stolen licensed materials.
 - 1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NRC.
 - 2. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

NOTE: Item c. below only applies to those licensees authorized to possess sufficient quantities of source or special nuclear materials that the licensee is required to report the receipt, transfer or disposal of these materials to the Nuclear Materials Management and Safeguards System (NMMSS). IMC 2800, Enclosure 7 contains specific guidance.

- c. Through interviews of the RSO or other responsible licensee personnel, along with the review of relevant records, verify that the licensee has fulfilled the applicable reporting requirements relating to the NMMSS.
 - 1. Discuss the location of all subject material possessed by the licensee. Compare the licensee's most recent record of physical inventory performed with the information documented in the licensee's NMMSS account on the DOE/NRC Form 742, "Material Balance Report."
 - 2. Review the licensee's records documenting the receipt, transfer or disposal of NMMSS-reportable materials. Compare these records to the NMMSS TJ-45 report. Verify that each set of records properly documents and accounts for any receipt, transfer or disposal of NMMSS-reportable materials that may

2 have occurred subsequently to the most recent filing of the DOE/NRC Form
2 742 by the licensee.

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2 3. Verify the information listed on the licensee’s inventory record by walking
2 down the licensee’s facility and (if practicable) visually identifying, at a
2 minimum, a representative sample of the materials that the licensee reports
2 possession of to NMMSS. If appropriate, verify the presence of the subject
2 material with a radiation survey instrument.

NOTE: The inspector should not ask licensee personnel to open
any container or otherwise change the container’s
shielding to facilitate this survey.

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2 4. Review administrative information listed in the NMMSS Report D-3 with
2 licensee personnel to ensure that the information is up to date. Verify that
2 licensee personnel are cognizant of the need to make any required changes
2 and the processes available for making any needed corrections.

2 03.02 FE-2: The licensee should maintain shielding of licensed materials in a manner
consistent with operating procedures and design and performance criteria for devices and
equipment

a. Process and Engineering Controls

Through observations, interviews of licensee personnel, and independent and confirmatory surveys, assess the adequacy of glove boxes, hot cells, remote-handling devices, shields and shielding devices, ventilation systems and other engineered safeguards to assure that they are adequate for the purposes for which they are intended. Specifically:

1. Hot Cells. Verify that the licensee controls: the entry of personnel into hot cells; the removal of material from process enclosures; and contamination originating within the hot cells.
- (a) If any weaknesses are identified in hot cell operations, then review the records of radiation surveys and/or air monitoring around the hot cell area.
 - (b) If records indicate elevated radiation or airborne contamination levels, then review the personnel monitoring records of individuals who worked in the area.

For all processes where shielding is used, assess the adequacy of shielding during maximum loading of hot cells and ensure the licensee verified the adequacy of shielding before beginning new processes.

2. Glove Boxes. Verify that the licensee: periodically checks the integrity of gloves and replaces gloves as necessary; controls the removal of material

from process enclosures; and controls contamination originating within the glove boxes.

- (a) If any weaknesses are identified in glove box operations, then review the records of surveys around the glove box area and extremity monitoring records of individuals who work in the area.

For all processes where shielding is used, assess the adequacy of shielding during maximum loading of glove boxes and ensure the licensee verified the adequacy of shielding before beginning new processes.

b. Shielding

1. Temporary or Portable Shielding. Verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.
2. Bulk Product Shielding. Verify that the licensee maintains large quantities of stock or bulk radioactive materials in adequate shielding. Verify that such shielding cannot be easily removed or opened. Verify that the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads. Ensure that licensee personnel are aware of lifting equipment load limitations and that the limitations are not exceeded.
3. Unit Shielding. Verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials (i.e., vials, syringes, individual sources, etc.) and that licensee personnel use the shields when handling the containers. Unshielded containers of hard-beta- and gamma-emitting radionuclides should not be directly handled by personnel. Verify that unit shields are adequate for the quantities of radioactive materials typically contained therein.
4. Shipped Product Shielding. Verify that the shielding included in packaging of materials that are transferred to a carrier for transport/transfer to an off site location conforms to that described in the SSD registry or license documents, as appropriate. The licensee may not make changes to the size, shape, or contents (i.e., lead versus stainless steel) of the shielding materials without prior approval of the NRC or the Agreement State that approved the registry, as applicable. Observe SSD that are ready for shipment and verify that the external radiation levels are consistent with the registry sheet/license document. Otherwise, determine that DOT requirements for shielding are met.

c. Sealed Sources and Devices

Through discussions with licensee management and workers, and by observing licensee practices, determine whether the licensee is manufacturing any different sources or devices since the product was registered with NRC or an Agreement

State. In particular, ask whether recent models of a device have been changed from previous versions (includes any changes, whether or not they affect safety), and, if so, whether the new models were registered with NRC or an Agreement State. Verify that the devices being manufactured conform to the registration certificate. Check to see whether the devices are entered into the sealed source and device registry. If the inspector finds any devices that: 1) do not have a registration certificate; 2) have been changed since the device was registered, with no update on the registration certificate; or 3) are not entered in the sealed source and device registry, immediately contact the inspection supervisor. The region should then contact the Materials Safety and Inspection Branch (MSIB) of the Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS), for further guidance. If possible, the region should make the contact with IMNS while the inspector is still on site, so that he/she may follow up during the remaining course of the inspection.

- d. Routine and Non-Routine Maintenance. By interviewing selected maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine that maintenance personnel verify, either through their own or health physics staff surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from equipment, entering rooms or areas (such as bunkers or hot cells) normally posted as high radiation or very high radiation areas, or entering tanks or vessels that normally contain or have contained radioactive materials. Verify that shielding removed for maintenance and opened access panels are properly replaced prior to lifting of maintenance holds when equipment is returned to service.

For maintenance activities that include potentially significant radiological conditions, such as high dose rates (>100 millirem per hour general area or > 1 rem per hour contact) or contamination levels (>100,000 disintegrations per minute per 100 square centimeters), determine whether the licensee has established more stringent radiation work permit (RWP) requirements, such as more detailed pre-job briefing of personnel, appropriate protective clothing, and/or constant job coverage by a health physics technician.

03.03 FE-3: The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration (see Manual Chapter 1007). The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

- a. Operational Limits. Through observation, discussions with licensee staff and review of product specification information, verify that the licensee operates process equipment within the equipment manufacturer's or industry consensus operational limits. Such limits may include temperature, humidity, vibration, or radiological considerations. In addition, such equipment may be subject to periodic

preventative maintenance requirements/recommendations. If so, verify that such maintenance is performed.

- b. Industrial/Chemical Hazards. Verify that the licensee controls the use/storage of hazardous (corrosive or combustible) chemicals near process equipment which could degrade their performance or render safety features inoperable. If the licensee is required to implement an emergency plan, verify that the plan includes these hazards, as appropriate, as initiating events.
- c. Fire Protection. In many cases, the risk posed to radiological safety by fires is comparable to or exceeds the risk from other events involving licensed activities. During the course of inspection of the licensee's facilities, the inspector should be alert to potential fire hazards. An effective licensee fire protection program should (1) prevent fires from starting, (2) rapidly detect, control, and extinguish those fires that do occur, and (3) provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by fire suppression activities will not prevent the licensee from taking actions to safely control licensed material and prevent the spread of contamination and unnecessary exposures to workers or the public.

Through observation and discussion with the licensee, while touring the facilities, assess firesafe conditions and equipment, i.e., that: (1) work areas are generally uncluttered and free of combustible debris, (2) incompatible materials (i.e., materials labeled as "corrosive", "flammable", or "oxidizer") are isolated from each other and enclosed by fire resistant barriers, (3) fire detection systems are operable, (4) fire suppression systems are operable, (5) portable fire extinguishers are unexpired (check maintenance tags), (6) electric switches and electric motors are explosion-proof, arc welders or open flames are administratively controlled in work areas that also contain flammable or combustible liquids or gases or highly reactive chemicals, and that (7) the local fire department is involved with the licensee's fire protection program.

Problems/deficiencies noted by the inspector should be promptly brought to the licensee's attention and discussed with Regional management.

- d. Natural Hazards. Depending on the licensee's geographic location, it could be susceptible to natural hazards, such as tornadoes, flooding, and earthquakes. Verify that those licensee's have considered the impact of such hazards in the design and modification of areas critical to safety; the selection and location of facilities for the storage of large quantities of radioactive materials, including radioactive waste storage facilities; and in the development of emergency procedures and contingency plans, when applicable.
- e. Transportation. Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is packaged and transported (or offered for transport) in accordance with 10 CFR Part 71 and U. S. Department of Transportation (DOT) regulations for transportation of radioactive materials.

Observe the preparation of radioactive materials for shipment. Verify that the proper packaging is used for the type of materials/devices shipped. Verify that the licensee properly marks and labels packages in accordance with DOT requirements. Verify that the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. Verify that proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers. Examine any incidents that were required to be reported to the DOT.

If the licensee tests and certifies its own DOT Type A packaging materials, review test procedures and required certification documentation for selected packages. Verify that the packaging materials are used in the same or similar configurations as in their certification testing.

Verify that any DOT Type B containers are used in accordance with their Certificates of Compliance (COCs) issued by the NRC. The licensee must maintain copies of the COCs for the packages that it has used and ensure that it follows the instructions and limitations of the COCs when preparing the packages for shipment.

For further inspection guidance refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer to "Hazard Communications for Class 7 (Radioactive) Materials." These field reference charts, related to hazard communications for transportation of radioactive materials, are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings. They also contain references to the DOT regulatory requirements.

03.04 FE-4: The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations

A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.

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

- a. Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes. Verify, based on the review of reports of monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities.

1. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one worker consistently receives significantly more exposure than all other workers each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.
 2. Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.
- b. External Exposure Controls. Examine any changes made for control and use of personnel monitoring equipment; verify that limits, precautions, controls, etc., established by the licensee are consistent with regulations and license requirements.

Examine the type of monitoring devices used, the period of use or exchange period, and the number used to determine if these aspects seem consistent with the monitoring program. Determine who the supplier is, and if the service has been changed since the last inspection, determine the reasons for the change. Verify that the personnel dosimetry processor is accredited by National Voluntary Laboratory Accreditation Program (NVLAP). NOTE: If the licensee operates its own dosimetry program, ensure that it has received the appropriate NVLAP accreditation and that the accreditation includes the type, energy, and intensity of radiations applicable to the licensee's operations.

For pocket dosimeters or pocket chambers, determine when they are read and recharged, the number used, and review the calibration procedure or charge leakage test procedure.

For electronic dosimeters, determine that the energy response and alarm set points are appropriate for the radiological conditions present during licensee operations. Verify that the licensee has established a calibration procedure and frequency for the dosimeters. Examine a random sample of electronic dosimeters that are available for use and verify that they have been calibrated in accordance with the procedures and stated frequency.

For all personnel monitoring devices used (whole body and extremity monitors, pocket chambers, electronic dosimeters), verify that the licensee has provided appropriate guidance to personnel regarding the wearing and placement of monitors. During observations of activities in progress, verify that dosimeters are properly worn, paying particular attention to physical manipulations of containers of radioactive materials (i.e., vials, syringes, etc.), whether or not they are shielded, and verify that extremity monitors are located so that they record the maximum dose.

Evaluate the adequacy of the licensee's procedures or system for evaluating and using personnel monitoring data to control and minimize exposures. The licensee should account for occupational radiation doses to personnel resulting from

exposures to licensed material and other radiation sources (e.g. accelerators) not licensed by the NRC.

Review reports of exposure summaries generated since the last inspection to determine that licensee's performance is in accordance with regulatory requirements.

Determine, through discussion with authorized users and the RSO, if minors have been permitted to work in restricted areas and, if so, determine that licensee's performance is in accordance with 10 CFR 20.1207 by review of exposure records.

For licensees who are not required to monitor, due to the lack of a likelihood that any worker would receive more than 5 millisievert (500 millirem) in a year, a sampling of NRC Forms 5 generated as a result of voluntary monitoring may be appropriate. If a licensee is not required to monitor and chooses not to monitor worker exposures, the inspector need only review the licensee's presumptive analysis of exposures and verify the assumptions used in that analysis.

- c. Internal Exposure. During review of exposure evaluations, verify that the licensee's performance is in accordance with internal exposure limits.

Review randomly selected air sampling and bioassay records. Determine if the licensee has established appropriate action levels and verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies.

By observation, discussion, and review of documentation, verify that engineering controls are considered and used to the extent practicable. Evaluate process and engineering controls incorporated as part of the facility or equipment.

Review documentation of evaluations performed as the result of unplanned exposures. Discuss these intakes with exposed personnel and licensee health physics staff and evaluate the circumstances of the incidents. Verify the appropriateness of preventive measures instituted following an unplanned exposure.

- d. Area Radiation and Contamination Control

1. Area Surveys. Through direct observation of surveys and interviews of licensee personnel, evaluate the licensee's area radiation survey program. The inspector should:

- Determine if the licensee's schedule for performing periodic surveys of work areas and unrestricted areas complies with license requirements.

- Determine surveys are conducted using approved procedures.
- Review a random sample of survey records and determine whether surveys are being performed according to schedules.
- Verify that survey results are reviewed by appropriate supervision.
- Verify that corrective actions have been taken, as appropriate.
- Determine whether survey is adequate for type (α , β , γ , or neutron) and energy of radiation to be detected and measured.
- Determine whether both particulate, non-noble gases and vapors are considered, if appropriate.
- Determine if workers take smears or instrument readings in areas that are readily accessible to facility personnel such as bench tops, sinks used for disposal, and storage areas.
- Ask licensee to spot-check radiation levels in selected areas using the licensee's own instrumentation. Compare measurements with an NRC instrument.

Note: The inspector must use NRC's instruments for independent verification of the licensee's measurements. NRC instruments should also be used to make measurements in support of violations to be cited.

- e. Leak Tests and Sealed Source Inventories. Through direct observation and licensee staff interviews, assess the adequacy of the licensee's implementation of its leak test and inventory procedures. The inspector should:
- Verify that leak tests are performed at the frequency specified in the license.
 - Verify that leak test samples are collected in accordance with either licensee or leak test vendor procedures.
 - If the licensee analyzes leak tests on sealed sources as a service to other licensees, it is important that the licensee demonstrate to the inspector an adequate method of performing and analyzing leak tests.
 - Determine if sealed source inventories are performed at the required frequency.
 - Evaluate the licensee's inventory methods to ensure that they could detect missing Licensing requirements for sealed source inventories should also be considered.

- f. Contamination Control. Verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination. When appropriate, consider taking confirmatory wipe samples.
- g. Protective Clothing. If practical, observe the use protective clothing worn by research lab personnel or other applicable staff during their work activities should provide the inspector with an acceptable means of reviewing this requirement. Requirements for protective clothing may be found in the licensee's procedures or as posted by the licensee.
- h. Process Controls. By observation, determine compliance with license requirements for repair, tagging, opening, modification, and replacement of sealed sources and devices. Ensure that the licensee has methods or procedures to minimize exposure during maintenance on devices. Verify through discussions with workers and by reviewing procedures that, when maintenance or modification is performed, controls are in place and are effective to warn workers of radiological hazards, prevent unnecessary exposure, and prevent the spread of contamination.
- i. Waste Management
 - 1. Waste Storage and Disposal. Verify that the waste is protected from fire and the elements, that package integrity is adequately maintained, that the storage area is properly ventilated, and that adequate controls are in effect to minimize the risk from other hazardous materials. Verify that the licensee has appropriate methods to track the items in storage.

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

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

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

The inspector should determine whether radioactive material labels have been removed or defaced from discarded materials, being careful to not endanger him or herself to biological, chemical, or physically hazardous waste (e.g., sharp objects). Ensure that wastes prepared for shipment to a

disposal site comply with applicable standards and regulations regarding chemical and physical form, stability, type of container, and labeling. Also ensure that the licensee implements an adequate QC program as required by Appendix F of 10 CFR Part 20 to ensure compliance with applicable regulations.

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

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

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

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

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

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

Verify that the licensee's air effluents, excluding Radon-222 and its daughters, have not exceeded the constraint limit in 10 CFR 20.1101. Information on evaluating air effluents is available in Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors." If the licensee estimated or measured a dose greater than 0.1 millisievert (10 mrem) per year, from air emissions, to the nearest individual member of the public, the licensee should have notified NRC [10 CFR 20.2203(a)(2)(vi)]. If the licensee has notified NRC that its air effluents have exceeded the constraint level, the inspector should review the effectiveness and timeliness of the licensee's corrective actions. Records of the results of measurements and calculations needed to evaluate the release of radioactive effluents to the environment are required pursuant to 10 CFR 20.2103(b)(4).

For further inspection guidance, refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Reasonably Achievable (ALARA).

- j. Respiratory Protection. Through observations, verify that respiratory protection equipment is certified by NIOSH/MSHA or otherwise approved by NRC. Determine that the licensee has selected the proper equipment for its licensed operations. Through interviews of the RSO, determine that the licensee has established a maintenance and training program for the use of respiratory protection equipment. Through interviews of selected workers who have used, or are designated/approved to use, respiratory protection equipment, determine that they are individually fitted for the type of respirators that they are expected to use and that respiratory equipment is operationally tested immediately prior to each use.

In taking credit for the protection provided by the use of respiratory protective equipment, 10 CFR 20.1703 requires that the protection factor be greater than the multiple by which peak concentrations are expected to exceed the values of Table 1, Appendix B, Column 3 of 10 CFR Part 20, unless ALARA considerations indicate otherwise. Verify that this criterion is considered in selecting respirators.

- k. Reports to Workers. 10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).
- l. ALARA. The licensee should, in addition to complying with regulatory requirements and license conditions, make reasonable efforts to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas

ALARA. This can be accomplished by the implementation of good radiation planning and practices, and by the commitment, from management and workers, to policies that prevent departure from ALARA practices. Also, licensees are required to keep occupational doses and doses to members of the public ALARA, in 10 CFR 20.1101(b).

Assess the licensee's ALARA practices, and verify implementation of any ALARA commitments in licensing documents, by reviewing:

1. A written commitment by high-level management to minimize worker exposure by the implementation of clearly defined procedures and policies;
2. That licensee personnel are made aware of management's commitment to keep occupational exposures ALARA;
3. That the radiation safety staff have been given authority to assure ALARA procedures and policies are carried out;
4. That workers are adequately trained, not only in the radiation safety procedures, but also in the ALARA philosophy;
5. That management and its designees perform periodic audits to find out how exposures and effluent releases might be lowered;
6. That modifications to procedures, equipment, and facilities have been made to reduce exposures at reasonable costs, where possible;
7. That the licensee has QA and QC programs, where applicable; and
8. That the licensee has a functioning and effective preventive maintenance program, where applicable.

Review and evaluate engineering controls to assure that, for example, exhausts from ventilated enclosures are adequately treated to reduce emissions to the out-of-plant environs to the lowest reasonably achievable levels within regulatory limits. Evaluate ventilated enclosures to assure that they are adequate to minimize internal exposures. Review shielding and the use of remote handling tools to assure that facilities and equipment are adequate to reduce exposure (both internal and external) to the lowest reasonably achievable levels within regulatory limits.

- m. Event Evaluation. Through reviews of dosimetry reports and annual licensee evaluations of public dose, and interviews of the RSO and selected licensee personnel, verify that the licensee has not experienced any events, since the last inspection, involving exposures to occupational workers or members of the public that were in excess of any regulatory limit.
- Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be

reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NRC.

- For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

03.05 FE-5: The licensee should provide radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored

- a. Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated at the required frequency.
- b. If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the NRC or an Agreement State to perform that service.
- c. Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Verify that calibrations include a determination of "as found" condition before adjustments are made. Verify that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.
- d. If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."
- e. Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to NRC instrument. Verify that licensee's instrument response is comparable to NRC instrument ($\pm 20\%$).
- f. Through interviews of the RSO and workers, and by observation, verify that licensee has a system for tagging out inoperable and out-of-service survey instruments.
- g. Through observations and interviews of the RSO and workers, determine whether the licensee's instrumentation for performing bioassay measurements is adequate for those measurements. Verify that bioassay probes and scalers are compatible.

Verify that licensee staff perform a response check using appropriate sources and a suitable background measurement before taking bioassay measurements.

- h. Through observations and interviews of the RSO and workers, assess the procedures and methods, and equipment used by the licensee to assure compliance with air-monitoring and air-handling commitments requirements (such as flow rates into hoods, air flows in ventilation systems, differential pressures in cells, in glove boxes, and across filter systems).
- i. Assess the equipment used by the licensee to satisfy these measurements. If appropriate, verify that air measurement equipment is functional and calibrated at the required frequency. Examine a representative sample of sampling gauges and data recorders and verify that it is operating within its design specifications. Using a properly calibrated hand-held anemometer, spot-check the linear airflow rate (corrected for altitude, when necessary) at the face of several hoods to verify that it meets the commitments made in the license. Using smoke tubes, visualize the airflow at the hood face to ensure that no excessive turbulence is present that may result in the spread of radioactive contamination.

03.06 FE-6: The licensee should ensure that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program

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

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

When the wording of the license condition is "... used by or under the supervision of ...," an authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material. This does not mean that the authorized user must be present at all times during the use of such materials. The authorized

user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.

- b. General Training. Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).
 1. 10 CFR Part 19-Required Training. Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of 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 their understanding of the training that they have received, both in the basic instructions and that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use radioactive material in research studies or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

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

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

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

- c. Operating and Emergency Procedures. Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for licensees with lower inspection priority. The emergency procedures may be approved by NRC and reviewed and updated by the licensee. However, licensees who follow the guidance in the appropriate NUREG 1556 series will likely develop procedures, including emergency procedures that have not received specific NRC review and approval.

Review and evaluate the licensee's process for controlling documents (procedures) and making revisions to procedures. Revisions to operating procedures should be reviewed by licensee health physics staff to ensure that the revisions do not adversely affect radiological safety. Select a sample of operating or process areas and verify that pertinent procedures are available to personnel, are current, and are in use in those selected areas. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities. Determine whether process activities use procedures for reference or are required to be used "in-hand."

During interviews of selected licensee personnel, propose hypothetical emergency scenarios (i.e., "what if" questions) to assess the worker's knowledge and understanding of the licensee's emergency procedures. The scenarios should include those types of accidents appropriate to the licensee's program (i.e., contaminated packages identified during receipt surveys, fires, contamination events involving large quantities of licensed materials).

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

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

- d. Posting and Labeling. The inspector should determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials, radiation areas, and those areas containing airborne radioactive materials. Section 20.1903 provides exceptions to posting caution signs. When applicable, the inspector should also randomly examine signals and alarms to determine proper operation. The inspector should also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

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

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

03.07 FE-7: The licensee's management system should be appropriate for the scope of use and should ensure awareness of the radiation protection program; that audits for ALARA practices are performed; and that assessments of past performance, present conditions, and future needs are performed, and that appropriate action is taken when needed

The NRC holds the licensee responsible for the radiation protection program; therefore, it is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes under emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding NRC regulations and license provisions and to terminate unsafe activities involving byproduct material..

Through observations, interviews and the review of selected records, determine that senior licensee management is fulfilling its responsibility of ensuring the effective operation of the radiation safety program. Specific areas of management focus should include:

- Maintaining awareness of significant events such as the loss or theft of licensed materials.
- Maintaining radiation safety, security and control of radioactive materials, and compliance with regulations.

- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that members of the public and workers are adequately protected from radiation hazards and that compliance with regulations is maintained.
 - Obtaining the NRC's prior written consent before transferring control of the license;
 - Notifying the appropriate NRC regional administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)).
 - Assuring the appropriate response, when applicable, to generic communications from the NRC.
 - Assuring that adequate provisions have been made to fund the safe and effective decommissioning of licensee facilities. (10 CFR 30.35)
 - Notifying the NRC of the decision to discontinue licensed activities or to decommission a facility in which licensed activities took place. (10 CFR 30.36)
 - Notifying the NRC of defects or other radiation safety equipment malfunctions in accordance with the requirements of 10 CFR, Part 21.
 - Maintaining awareness of issues and measures to ensure worker performance and safety are not being compromised due to safety significant human performance issues.
- a. RSC (where required or used). Through the review of records, and interviews of the RSO and RSC members, determine that the committee is made up of a representative from each type of program area, the RSO, and a representative from management. If practical, attend and observe the conduct of an RSC meeting. Review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. Determine that the RSC meets at the required frequency as specified in the license application, other commitment documents, or in a specific license condition. Topics of discussion during committee meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, etc.

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

- b. RSO. Through the review of records, and interviews of the RSO and authorized users, verify that the RSO has been appointed by licensee management, identified on the license, and is responsible for implementing the radiation safety program. Determine, through interviews, that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. Determine that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC or licensee management, to implement corrective actions, including termination of operations that pose a threat to health and safety.

Determine that the knowledge and training of any radiation safety staff are commensurate with their assigned duties. Verify that the radiation safety staff levels, including numbers and types of positions, are as described in the license application.

- If the inspector identifies high staff turnover or prolonged shortfalls in staffing levels, through interviews and observation determine if these shortfalls have had a negative impact on licensee performance.
 - If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.
- c. Audits. Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.
- If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.
 - Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

87126-04 REFERENCES

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

END