
INSPECTION PROCEDURE 87125

MATERIALS PROCESSOR/MANUFACTURER PROGRAMS

Effective Date: January 29, 2024

PROGRAM APPLICABILITY: IMC 2800

87125-01 INSPECTION OBJECTIVES

- 01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.
- 01.02 To determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements using a risk-informed, performance-based regulatory approach.
- 01.03 To determine if the licensee is manufacturing sources or devices in accordance with statements made to NRC.

87125-02 INSPECTION REQUIREMENTS

The review of the licensed activities will be commensurate with the scope of the licensee's program. The inspector's evaluation of a licensee's program will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. Additionally, the inspector should use a risk-informed approach to perform the inspection, such as choosing the activities that carry the highest risk to inspect first. This can help ensure that in cases of limited time with the licensee due to varying circumstances, the most risk-significant licensee activities are reviewed for each inspection. If issues are identified, the inspector may refer to appendix A of this procedure for additional areas that may merit inspection.

For the purpose of this inspection procedure (IP), materials processor/manufacturers are those licensees that process raw material and/or sources and/or distribute those processed materials and sources to users as finished products. Examples are major radiochemical and radiopharmaceutical processor/manufacturers, including particle accelerators used to produce radionuclides for positron emission tomography (PET) and other uses; sealed source fabricators; device manufacturers; and other manufacturing licensees that use bulk quantities of raw radioactive materials or sources. This procedure also is applicable, in part, to manufacturer/distributors who assemble products containing licensed materials from parts received from other manufacturers, and those manufacturers/distributors who import products containing licensed materials for distribution in the United States.

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

ensure that licensees have procedures in place to ensure that the products are manufactured and distributed using good manufacturing practices, including the implementation of a quality assurance program. For sources and devices, the processor/manufacture must ensure that the products conform to the provisions of the registration certificate and the commitments made in the application at the time the source or device was registered (by NRC or an Agreement State). Licensees who assemble products containing licensed materials from parts obtained from other manufacturers, and those who import products are not involved in the processing of raw materials or sources in the manufacturing of materials or devices, require a manufacturing and distribution license to enable the products to be possessed and distributed in the United States and its territories. All such manufacturers/distributors are responsible to ensure that the finished products and imported products meet NRC requirements. They may be required to hold sealed source and device registrations and ensure that the provisions of the registration certificate and the commitments made in the application at the time the source or device was registered (by NRC or an Agreement State).

If the processor/manufacture is authorized by a license of broad scope, then IP 87126, "Broad Scope Academic and Research & Development Programs," should be used in addition to this procedure. Applicable sections of this procedure should be used for inspection of such manufacturer/distributors who import materials and devices and distribute them to persons who are authorized to possess material under a specific or general license.

Radiopharmacy is a special case of manufacturing which should be inspected using IP 87127, "Radiopharmacy Programs." Manufacturers/distributors of products that are distributed to persons who are exempt from the requirement of a license are inspected using IP 87128, "Manufacturing and Distribution of Exempt Products."

The structure and the emphasis of the inspection should be on the following risk modules that describe the outcomes of an effective radiation protection program at a processor/manufacture facility. Risk modules (RMs) are defined as components in the inspection procedures used to focus the inspection effort on: (1) licensed activities that present higher risk for a particular licensee type, and/or (2) radiation safety program areas that are expected to effectively reduce the risk associated with the use of radioactive material. To consider an inspection complete, the inspector should review applicable RMs based on ongoing activities at the time of the inspection. The RMs that carry the highest risk components should always be completed to the best of the inspector's ability. Additional inspection elements that carry less risk can be found as appendix A to this inspection procedure. These additional elements are not required to be reviewed as part of a risk-informed inspection approach but may be reviewed if the inspector has additional time, if the additional elements are related to safety issues identified in the RMs, or if multiple violations were identified through review of the following RMs.

02.01 RM-1: Observation of Activities

The inspector should observe a representative sample of the range of licensed activities authorized by the processor/manufacture license that may be ongoing during the inspection. This should include activities from receipt of raw materials, through the manufacturing process, to disposal of waste materials, and distribution of products. The inspector should observe activities performed by the radiation safety staff, as well as activities performed by authorized users and other radiation workers.

02.02 RM-2: Safety and Security of Licensed Materials

The inspector should observe a representative sample of facilities authorized under the license to determine if licensed materials are appropriately attended when in use or secured when in storage, with particular attention to control of the material throughout the manufacturing process. The inspector should observe if licensed materials are used or stored in the vicinity of other hazards or hazardous materials which could increase the risk of release of licensed materials. The inspector should verify that the licensee has adequate inventory controls in place to ensure that all licensed materials are accounted for.

02.03 RM-3: Surveys for Contamination and Exposure Control

The inspector should observe licensee staff perform surveys for contamination and exposure to ensure that 1) the licensee has the necessary variety and availability of instrumentation needed to perform surveys of the range of radioactive materials authorized on the license, and 2) the licensee staff performs adequate surveys. Surveys may be performed using fixed or portable radiation survey instruments and monitors; equipment for sample collection; and instrumentation for analyses of samples.

02.04 RM-4: Assessment of Dose to Workers and the Public

The inspector should review the results of dose assessment for all activities under the manufacturing/distribution license for which monitoring of radiation workers is required. Particular attention should be paid to verifying assessments of internal dose to ensure that appropriate procedures are implemented, and results are accurate. The inspector should also review results of assessments of public dose due to use of licensed materials and releases of effluents.

02.05 RM-5: Assessment of Quality Assurance of Product(s)

The inspector should observe performance of quality assurance activities that ensure the licensees manufacture and distribute products in accordance with the requirements of NRC regulations, the license, and the sealed source and device registration where applicable.

02.06 RM-6: Management Oversight

The inspector should determine the effectiveness of the management of the manufacturing and distribution radiation protection program to determine that it is appropriate for the scope of the licensed materials used in the manufacturing process(es) and the products that are distributed. The inspector should verify that licensee staff is aware of the radiation protection program, and appropriately trained. The inspector should review the processor/manufacturer assessments of past performance, present conditions and future needs, including that annual radiation program review; and confirm that appropriate action is taken when needed.

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 risk modules described above; however, this does not mean that the risk modules should be reviewed in this specific order. Instead, the inspector should use a risk-informed approach to decide which of the risk modules to inspect first. This is likely going to be predicated upon what licensed activities are ongoing when the inspector arrives at the licensed facility. 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.

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 be aware that some information, such as dose to workers, can be reviewed only through records. All inspections require some review of records which supplement the direct observations and discussions.

- Priority should be given to examination of records that are closely related to health and safety, such as personnel dose-monitoring records, incident reports, and surveys. Look for trends such as increasing doses or releases; look for unusual doses or survey results; and look for licensee identification of issues and resulting corrective actions taken.
- Priority should be given to review of the Radiation Safety Committee (RSC) meeting minutes, where applicable. The annual program review or audits of the licensed program also may be useful. It may be helpful to review such documents prior to review of other records, because often the RSC minutes contain other records, and the annual program review may contain a summary of issues. Inspectors should focus on response to incidents and events; and other activities related to management and oversight the radiation protection program implemented by the RSO and radiation safety staff.
- Other records which support the radiation protection program, such as receipt and transfer of licensed materials, inventory, leak tests, calibration of analytical or portable instruments used to make quantitative measurements, training, audits and radiation protection program reviews, may be reviewed by selective sampling and cross-checking until the inspector is satisfied that the records are being maintained and are correct. The inspector may examine records more thoroughly if necessary to determine the extent of a suspected problem.

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

Each of the following risk modules should be reviewed, as appropriate, during each inspection of a processor/manufacturer.

- This guidance is focused on the processors/manufacturers who perform processing and/or manufacturing. The scope of the inspection will vary according to the type(s) of product(s) that are manufactured by the licensee. This is related to the type(s) of: raw material(s), manufacturing process(es), and radiation safety concerns throughout the process. The inspector should review each risk module to determine areas applicable to the activities authorized by the license.
- This guidance is applicable to the manufacturers/distributors who perform assembly of finished products, using licensed materials manufactured by another licensee. The scope of the inspection will vary according to the type, form, and quantity of licensed material in the parts to be assembled, and the scope of the required assembly. The inspector should review each of the risk modules to determine applicable areas for inspection. In all cases, the licensee is responsible for assessment of doses to workers and the public from any activities with receipt, handling, and distribution of the product. The licensee also is responsible for quality assurance of the finished product; if applicable, this includes commitments in the sealed source and device registration for the product.
- This guidance is applicable to manufacturer/distributors who import finished products for distribution in the United States. Most of these licensees import the products to a central location specified on the license and distribute the products from that location. A few licensees may have the product shipped directly to the final customer. The scope of this inspection will vary according to the radiation safety concerns of the finished product, and the amount of handling of that product by workers. The inspector should review the risk modules to determine applicable areas for inspection. In all cases, the licensee is responsible for assessment of doses to workers and the public from any activities with receipt, handling, and distribution of the product. The licensee also is responsible for quality assurance of the finished product; if applicable, this includes commitments in the sealed source and device registration for the product.

Specific Guidance

03.01 RM-1: Observation of Activities

The inspector should observe a representative sample of the range of licensed activities authorized by the processor/manufacturer license that may be ongoing during the inspection. This should include activities performed by the radiation safety staff, as well as activities performed by authorized users and other radiation workers. This should include activities that span receiving raw materials, through the manufacturing process, to disposal of waste materials, and distribution of products.

The primary inspection activity for unsealed materials should be the observation of activities in progress. If manufacturing occurs over multiple work shifts or alternate work times than the usual daytime work hours, such as at accelerator facilities (typically cyclotrons, but other types of particle accelerators may be used) producing radionuclides for medical and other uses, observations during those hours may be required. Observation begins as soon as the inspector arrives at the licensee site. The inspector

should be alert for postings or other indications that licensed materials may be in use as the inspector walks to the safety office to meet with the RSO and radiation safety staff.

Most processor/manufacturers produce a limited number of products that contain licensed materials. However, the types, form, and quantities will vary according to, and may change during the various stages of, the process(es) for manufacturing of the products. Processor/manufacturer programs may require specialized facilities such as hot cells, may release a variety of effluents, may process their own radioactive wastes, and may be authorized for additional activities that are described in other inspection procedures. If uranium and/or thorium (source material) compounds or special nuclear materials or other alpha emitters are used, IP 87140, "Source, Special Nuclear Material and Other Alpha Emitter Use Programs," may be helpful.

Note: The inspector should be aware that licensed materials used at processor/manufacturer programs may be used with, or in the vicinity of biological hazards; chemical hazards; other ionizing and non-ionizing radiation hazards; electrical, physical and other industrial hazards. The inspector should be aware of areas with moving equipment, moving product lines, automated equipment, and similar potential hazards found in manufacturing facilities. The inspector should follow the licensee's safety requirements when in such areas.

Additionally, 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 IMC 1007). The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

Some areas may require special training or protective equipment prior to entry, such as clean rooms and areas where product sterility is of concern. The inspector should be prepared to take the training, wear the required protective equipment, or to conduct the inspection through alternate means. In rare instances, due to the nature of the associated hazards, the inspector may be prohibited from entry and must conduct the inspection through alternate means than direct, in-person observation.

The activities to be observed should be selected based on the types, forms and quantities of materials being used; 2) the activities being performed; and 3) the size of the program. The inspector should have an initial plan of the activities to be observed. This plan may change as a result of new information gathered at the entrance meeting, such as changes in the activities since the last inspection, and the availability of activities which may be observed during the inspection. The inspector should use this information, along with the guidance in appendix B to this IP to make risk-informed changes to the inspection plan developed during inspection preparation.

The inspector should observe a reasonable sample of each type of product that is manufactured (such as synthesis of radiochemical or radiopharmaceuticals; manufacture of radioisotope generators for medical use; manufacture of sealed and/or plated sources; manufacture of devices) through the stages of manufacturing. Sampling should be risk-informed by the type of activity and the number of facilities performing that activity, using information from the entrance meeting and the guidance in appendix B to IP 87125. If the inspector identifies a suspected problem, the sample size may be increased to determine the scope of the problem.

During any walk through the licensee's facilities, the inspector should:

- Keep the inspector's survey meter on (but with the audible response turned off if walking through public areas where persons unfamiliar with radiation detection may become concerned) and observe if radiation levels are as expected. If unusual or unexpected radiation levels are detected, discuss them with the RSO and staff.
- Verify that the licensee's use of licensed material is limited to that which is authorized in the license.
- Conduct surveys and make comparative measurements with licensee staff where appropriate.
- Observe if facilities for use and storage of licensed materials are appropriately secured or attended, and if postings are appropriate.
- Observe radiation workers working with licensed materials through the manufacturing process. If there is no use at the time of the inspection, a demonstration of selected activities may be requested. Watch for use of appropriate protective equipment, dosimetry, survey, and monitoring techniques.
- Observe radiation safety staff performing surveys, collecting and analyzing samples, collecting and processing wastes, and other activities with licensed materials. Watch for use of appropriate protective equipment, dosimetry, survey, and monitoring techniques.
- Interview radiation safety staff, radiation workers, and selected ancillary persons working in the vicinity of licensed materials. Ask questions to determine their understanding of radiation safety practices applicable to their tasks.
- Watch for radiological postings on doors or equipment other than your destination. If the reason for the posting is not apparent, ask about it in order to determine if additional inspection should be done.
- Be aware that some records of interest will be maintained in work areas and may be reviewed while at those locations. Typical records in work areas are:
 - "use logs" for specialized facilities such as hot cells or "Hot Labs";
 - postings of maintenance checks of the flow rate and operation of hoods or other air handling systems;
 - inventory of stock material from receipt to disposal;
 - area surveys by staff;
 - calibration stickers on survey instruments;
 - calibration records of analytical instruments;
 - waste processing records;

- sewer disposal records; and
- decay-in-storage records.

Inspectors have identified workers who received doses in excess of limits after making adjustments to product lines without adequate safety precautions, and without discussion with the radiation safety staff, in order to keep production going. Inspectors have identified workers who were unaware of appropriate handling procedures, which changed in the different stages of manufacturing; in some of these cases, workers received doses in excess of regulatory limits, and damage and/or contamination of equipment occurred.

03.02 RM-2: Safety and Security of Licensed Materials

The inspector should observe a representative sample of facilities authorized under the manufacturing/distribution license to determine if licensed materials are appropriately attended when in use or secured when in storage. The inspector should observe if licensed materials are used or stored in the vicinity of other hazards or hazardous materials which could increase the risk of release of licensed materials. The inspector should verify that the licensee has adequate inventory controls in place to ensure that all licensed materials are accounted for. Through observations and discussions with licensee staff, the inspector should determine if the facilities used during the various stages of manufacturing are appropriately designed to protect workers and members of the public from direct radiation and indirect radiation (shine and other). The inspector should determine if:

- Appropriate shielding is available and providing adequate protection through surveys and discussions with staff.
- Appropriate engineered controls are used throughout the manufacturing process to contain radioactive material, any radioactive effluents, and wastes containing licensed materials.
- Appropriate administrative controls are in place to protect workers and members of the public, where engineered controls are not practicable.
- Adequate protective equipment is available and used by licensee staff, including adequate radiation survey and monitoring equipment for the types, forms, and quantities of licensed materials in the manufacturing process.

a. Security

- Through direct observation, the inspector should determine how the licensee ensures that material is secured to prevent unauthorized access from receipt of raw materials, through the manufacturing and distribution process, to disposal of wastes. The inspector should verify that storage areas are physically secured when unattended and that radioactive material use areas are under constant surveillance when licensee personnel are present or physically secured against unauthorized access. If quantities of materials in use require implementation of security pursuant

to 10 CFR Part 37, the inspector should refer to IP 87137 for the inspection of that area. [10 CFR Part 20.1801, 20.1802, Part 37]

- The inspector should determine if the licensee's facility is configured such that working areas are restricted or controlled and are separate from unrestricted areas of the facility. [10 CFR Part 20.1003]

b. Process and Engineering Controls

- Through observations, interviews of licensee personnel, and independent and confirmatory surveys, assess the adequacy of glove boxes, hot cells, remote-handling devices, shields and shielding devices, and other engineered safeguards to assure that they are adequate for the purposes for which they are intended. The inspector should observe if the facilities used during the various stages of manufacturing are appropriately designed to protect workers and members of the public from radioactive materials due to effluent releases and/or contamination or other release of radioactive materials. [10 CFR Part 20.1003, 20.1406, 20.1601, 20.1602, 20.1902, 20.1903]
- For hot cells, determine that the licensee controls: the entry of personnel to hot cells; the removal of material from process enclosures; and contamination originating within the hot cells.
 - If any weaknesses in hot cell operations are identified, review the records of radiation surveys and/or air monitoring around the hot cell area.
 - If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow-up during evaluation of RM-2 and RM-3.
- For glove boxes, determine that the licensee: periodically checks the integrity of gloves and replaces gloves as necessary; controls the removal of material from process enclosures; and controls contamination originating within the glove boxes.
 - If any weaknesses in glove box operations are identified, review the records of surveys around the glove box area and extremity monitoring records of individuals who work in the area.
 - If records indicate elevated radiation or airborne contamination levels, review the personnel monitoring records of individuals who worked in the area and verify that doses are within regulatory limits and ALARA. Continue follow up during evaluation of RM-2 and RM-3.
 - For other areas where materials are handled which could cause potential contamination or releases, determine if the licensee has:
 - appropriate engineered controls throughout the manufacturing process to contain radioactive material, any radioactive effluents, and wastes containing licensed materials.

- appropriate administrative controls to protect workers and members of the public, where engineered controls are not practicable
- adequate protective equipment is available and used by licensee staff, including adequate radiation survey and monitoring equipment for the types, forms, and quantities of licensed materials in the manufacturing process

If a sampling of records indicates weaknesses in the control of contamination or effluent releases, continue follow up during evaluation of RM-2 and RM-3.

Inspectors have identified hot cells with measurable 'streaming' radiation from locations where cracks had developed in the access ports for the remote manipulators or wiring conduits or similar equipment, leading to unexpected (or unknown) radiation fields.

Inspectors have identified glove boxes with cracks and tears in the gloves, leading to extremity doses and/or contamination. Inspectors have identified hot cells and glove boxes with malfunctioning air handling systems (loss of negative pressure, leakage from air ducts into work areas) leading to releases of radioactive material into work areas or in effluents, and/or intakes by licensee personnel.

Inspectors have identified air monitoring systems not properly calibrated, and monitoring system readouts that provided incorrect monitoring information. Many of these issues resulted in violations for failure to survey.

c. Shielding

The licensee should maintain shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for equipment and devices. [10 CFR Part 20.1003, 20.1406, 20.1601, 20.1602, 20.1902, 20.1903]

The inspector should:

- determine if shielding is appropriate, available, and providing adequate protection through surveys and discussions with licensee staff;
- verify if appropriate administrative controls are in place to protect workers and members of the public, where shielding is not practicable.
- for temporary or portable shielding - verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.
- for all processes where shielding is used - assess the adequacy of shielding during maximum loading of hot cells and glove boxes. Determine, by surveying the areas near manufacturing processes, the continued adequacy of shielding. If the licensee initiates new processes in existing hot cells or glove boxes, determine whether the licensee has evaluated the adequacy of existing shielding before beginning the new process.

Product shielding should result in ambient radiation levels for areas normally occupied by workers. If higher than expected readings are found, determine the source of the higher dose rates.

- Through direct observations, interviews of licensee personnel, and independent measurements, verify that large quantities of stock or bulk radioactive materials are adequately shielded. Verify that such shielding cannot be easily removed or opened. Determine whether the licensee maintains adequate lifting equipment for such shields and that the equipment includes adequate safeguards to prevent dropped loads.
- Through direct observations and interviews of licensee personnel, verify that the licensee maintains an adequate supply of shields for unit quantities of radioactive materials, such as individual vials and manufactured sealed sources, and that licensee personnel use the shields when handling the containers/sources. Verify that unit shields are adequate for the quantities of radioactive materials typically contained in them.
- Select a number of finished products/devices that are ready for distribution and verify that the external radiation levels are consistent with expected values. If higher than expected levels are noted, verify that the shielding included in prepared, distributed products conforms to that described in the license documents, as appropriate. Verify that the licensee has not made changes to the size, shape, or contents (i.e., lead versus stainless steel) of the shielding materials without prior approval of the NRC or an Agreement State.

Inspectors have identified inadequate shielding of back walls of specialized facilities that are adjacent to office or other public areas, with dose rates that exceeded public dose limits, although adequate shielding was available to radiation workers in front of specialized facilities.

Inspectors have identified individuals reaching behind shielded areas of product lines to repair the line or adjust product, resulting in higher doses than normal for the workers, and sometimes in excess of limits.

Inspectors have identified non-functioning process cells, requiring workers to change radioactive product in the remaining operable cells, without allowing for decay, resulting in doses that required some workers to cease activities with licensed materials in order to remain below regulatory limits.

d. Routine and Non-Routine Maintenance

- 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. Such equipment may be subject to periodic preventative maintenance requirements/recommendations. If so, verify that such maintenance is performed.

- By interviewing selected radiation staff and maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine if staff verify through surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from process equipment, entering rooms or areas (such as bunkers or hot cells) normally posted as high radiation or very high radiation areas, or entering tanks or vessels that normally contain or have contained radioactive materials. Verify that shielding removed for maintenance and opened manways are properly replaced prior to lifting of maintenance holds when equipment is returned to service.
- For maintenance activities that include potentially significant radiological conditions, such as high dose rates (>100 millirem per hour general area or > 1 rem per hour contact) or contamination levels (>100,000 disintegrations per minute per 100 square centimeters), determine whether the licensee has established more stringent requirements, such as more detailed pre-job briefing of personnel, additional protective clothing, and/or constant job coverage by a health physics technician.

Inspectors have identified failure to maintain equipment in operable condition as a contributing cause to exposures to licensee staff working in the manufacturing process, and workers repairing inoperable or damaged manufacturing process equipment.

e. Inventory Control

- Through observations and discussion with staff, the inspector should verify that the licensee has procedures in place for safely receiving and opening containers of raw materials used in the manufacturing process, and verifying the types, forms and quantities received. [10 CFR Part 20.1906]
- The inspector should request a current inventory to compare the actual inventory of radioactive material on hand by selecting a sample of licensed materials from the inventory and observing the materials at the licensee's facility where possible. Materials may include sealed and unsealed materials in the form of raw material, materials in the manufacturing process, finished products, returned products, and wastes.
 - The inspector should observe and discuss the methods the licensee uses to assess the quantities of unsealed materials for the inventory.
 - The inspector should observe and discuss the methods the licensee uses to assess the quantities of activated materials, if applicable (typically at accelerator production facilities), for the inventory. Activated materials may be part of facilities and equipment in use or in waste.

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

- The inspector should verify the method(s) the licensee uses to track the inventory of licensed material through the manufacturing process from receipt through distribution and/or disposal.

- If the licensee is 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), review that information in accordance with IMC 2800.
- If the licensee distributes products to specific licensees, through observations and discussions with staff, determine the process the licensee uses to determine that customers are authorized to receive the materials requested, and that material meets the applicable requirements for transfer. [10 CFR Part 30.41, 40.51 70.42; and 32.72, 32.74, 32.201, 32.210]
- If the licensee distributes products to persons who possess them under a general license, through observations and discussions with staff, determine the process the licensee uses to ensure that distributions are packaged, labeled, tracked, and reported to the NRC and Agreement State(s), as required. [Subpart B of 10 CFR Part 32]
- If the licensee distributes products to persons who are exempt from the requirement of a license, refer to IP 87128 “Manufacturing and Distribution of Exempt Products.”

Inspectors have responded to events involving the release of significant contamination during opening of a package of incoming raw material.

Inspectors have identified:

Manufacturer(s) not tracking inventory correctly, leading to a violation of license limits and failure to implement applicable security requirements.

Incomplete inventory or poor inventory of unsealed materials and activated materials, resulting in exceeding license limits or quantities for which financial assurance is required.

Distributor(s) not reporting transfers of inventory as required for tracking in the general license database (reports not submitted/not submitted on time, or incomplete).

f. Other safety concerns affecting licensed materials

- Through observations and discussions with licensee staff, the inspector should determine if the licensee implement comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material. The focus should be on potential non-radiological hazards that the inspector observes, or has brought to their attention by licensee staff, that could affect licensed material in the facility. The inspector should be aware of the presence of:
 - chemical hazards such as corrosive or combustible materials;
 - electrical hazards such as high voltage equipment;

- physical hazards such as handling of heavy items such as shielding containers; moving machinery and process lines; automated process lines; and manufacturing equipment; etc.
- adequate fire protection such as smoke/fire detection and suppression systems, fire extinguishers appropriate for the hazards present, and activities related to fire prevention;
- facility operational conditions (temperature, humidity, vibration, noise level, etcetera) that are appropriate for the workers in the area, and maintained within the within the equipment manufacturer's or industry consensus operational limits for the process equipment in use;
- preventive maintenance activities performed routinely of equipment used in the manufacturing process or used with radioactive material; or if necessary, equipment is not functional for long periods of time without repair or replacement, resulting in increased dose to workers or the public.
- If the licensee is required to implement an emergency plan in accordance with 10 CFR 30.32(i), the inspector should determine if the licensee is implementing the training to staff and performing the exercises as required by the emergency plan submitted with the license application. If the licensee established other emergency procedures, verify that the plan includes consideration of other hazards, as appropriate, as initiating events. [10 CFR Part 30.32(i), or license commitment]

g. 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. [49 CFR]
- Observe the preparation of radioactive materials for shipment. Verify that:
 - the proper packaging is used for the type of materials/devices shipped. [49 CFR 173]
 - the licensee properly marks and labels packages in accordance with DOT requirements. [49 CFR 172, subparts D and E]
 - the licensee performs appropriate examinations to confirm that package radiation and contamination levels are within applicable DOT limits prior to offering them for transport. [49 CFR 173.442 and 173,445]
 - proper shipping papers are prepared for each package/shipment and that, if necessary, the licensee maintains and offers appropriate placards to common carriers. [49 CFR 172 Subpart C]
- 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. [49 CFR 173.411 and 173.412]

- 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. [10 CFR Part 71]
- If the licensee reported any transportation incidents, review the licensee's actions in response to the incidents.

Inspectors have identified:

Comingling of hazardous wastes and radioactive wastes in poorly organized waste storage areas, such as radioactive waste and flammable wastes stored in the same areas, or radioactive waste containers stored against electrical panels or heating equipment.

Waste stored in appropriate areas, such as outside areas without protection from weather; under leaking pipes; in basement areas prone to water intrusion.

Licensees not performing exercises of the emergency plan as required by 10 CFR 30.32(i).

Product packaging that did not meet DOT requirements (e.g., packages marked or labelled incorrectly; package certification not available; packages re-used without all the packaging required by the certification; packages not surveyed as required).

03.03 RM-3: Surveys for Contamination and Exposure Control

At a typical processor/manufacturer facility, surveys may be performed by authorized users and workers under their supervision; radiation safety staff members; and/or persons contracted to perform surveys. Persons performing surveys should be observed doing surveys or demonstrating surveys. Discuss with the licensee which surveys are official records for license compliance (typically those performed by the radiation safety staff) and which are performed for contamination control (typically those performed by manufacturing staff). The level of detail of observations, discussions, and review of records of surveys and the instrumentation used will depend on the types, forms, and quantities of licensed materials actually used since the last inspection as well as the level of sensitivity necessary for the surveys. [10 CFR 20.1501]

- Observe licensee staff perform routine surveys and monitoring for radiation, contamination, and any other applicable activities such as leak testing and waste processing.
 - Verify if adequate survey procedures are implemented, and surveys are performed, to demonstrate compliance with the regulations and with pertinent license requirements.
 - Determine which surveys are performed for qualitative (detection) or quantitative (measurement) purposes.

- Determine whether due consideration is given to energy, beta exposure, and extremity exposure, and whether neutron surveys are performed, if appropriate. Pay particular attention to surveys for radionuclides that are difficult to detect and/or have very low screening criteria for release for unrestricted use, such as most alpha emitters.
- Observe if appropriate survey and monitoring instruments are readily available and operable. Observe if staff use instrumentation properly (checking the survey instrument for proper operation prior to use; conducting radiation surveys at appropriate speed and distance).
- Perform comparative measurement with licensee personnel by spot-checking radiation levels in selected areas using the licensee's instrumentation and compare the results with those obtained using the NRC's instruments.
- Verify that the licensee has established schedules for periodic surveys, and that surveys are conducted using approved procedures. Review a random selection of survey records to verify that surveys are performed according to schedules, reviewed by appropriate supervision; and corrective actions were taken, as appropriate.

Inspectors have identified:

Decay-in-storage surveys performed with inappropriate instruments and performed in areas of elevated background.

Measurable radiation levels in waste containers marked as only holding tritium and carbon-14.

Licensees who analyzed wipe samples using GM detectors attached to portable survey instruments in ratemeter mode but could not demonstrate adequate sensitivity of the instrument for the radionuclide assessed.

Results of leak tests, reported as "less than MDA" but the licensee did not know that the MDA was above the required sensitivity of 0.005 microcuries (and similar issues with removable contamination, and other samples).

Incorrect results when leak tests for Ni-63 sources were performed on instrumentation calibrated only for Cs-137 and Co-60.

Incorrect calibration factors used in software input for analytical systems, resulting in incorrect output results.

Inadequate calibration of instruments (instrument not calibrated for the energies of the radionuclide to be analyzed; samples analyzed in a geometry for which the instrument was not calibrated; calibration not performed).

Licensees who used incorrect or inappropriate values for "background."

Licensees who did not understand the calculations performed by the software in analytical equipment, resulting in errors such as performing additional subtraction of background; and using default efficiency factors used in the software for typical radionuclides, when analyzing other radionuclides.

- Observe the licensee's sampling and monitoring equipment for release of effluent air or water, and/or releases to the public sanitary sewerage system. [10 CFR Part 20.1302, 20.1501, 20.2003]
 - The inspector should examine air flow patterns and building air intakes and release points to understand the potential for spreading contamination and the need to monitor release pathways.
 - The inspector should review any liquid effluent releases to the environment and/or the public sewerage system. The inspector should observe, if possible, and discuss the licensee's method of sampling [or otherwise assessing] concentrations of licensed materials in liquid effluents to ensure they are within regulatory limits.
 - The inspector should observe and discuss with licensee staff the selection of monitoring locations, selection of monitoring equipment, and use of the equipment. The inspector should discuss the sample collection methods used, or if an evaluation is performed by calculation.
 - In rare instances, such as at production cyclotrons, licensees also may be releasing volumetrically contaminated materials. The inspector should confirm that the licensee is implementing release surveys and release criteria approved by the NRC for volumetrically contaminated materials.

Inspectors have identified:

Licensees who did not account for potential airborne and/or particulate contamination from manufacturing activities, resulting in uptakes and spread of contamination.

Licensee staff unfamiliar with the operation of sampling equipment; sampling and monitoring equipment not operating correctly; unmonitored effluent release points; effluent monitors that were not properly calibrated; use of equipment not sensitive to the radionuclides being analyzed; and errors in data entry, assumptions, and calculations.

Licensees who analyzed air samples using GM detectors attached to portable survey instruments in ratemeter mode but could not demonstrate adequate sensitivity of the instrument for the radionuclide assessed.

- If the licensee calibrates its own survey and monitoring instruments, the inspector should visit the calibration facility and review the program to determine if instruments are appropriately and correctly calibrated (see IP 87143). [10 CFR 20.1501(c)]

Inspectors have identified:

Survey instruments in use that were not calibrated or not working.

Air monitoring systems that were improperly calibrated and air monitoring readouts that provided inaccurate information because licensee staff did not understand the software used to operate the system.

03.04 RM-4: Assessment of Dose to Workers and the Public

The inspector should review the results of dose assessment for all activities under the processor/manufacture license for which monitoring of radiation workers is required. Particular attention should be paid to verifying assessments of internal dose to ensure that appropriate procedures are implemented, and results are accurate. The inspector should also review results of assessments of public dose due to use of licensed materials and releases of effluents.

Manufacturing activities with licensed materials may result in doses that require monitoring of workers, depending on the types, forms and quantities of licensed material, and the manufacturing process. If worker doses are not required to be monitored, and public doses are not likely to be exceeded, this RM may be considered supplemental. [10 CFR Part 20.1302, 20.1501, 20.1502]

- External radiation and contamination monitoring
 - During the inspection, observe how radiation workers use the dosimeters and where they are stored. If applicable, observe staff performing contamination monitoring of themselves and their work area. [10 CFR Part 20, Subparts C, D, F, G, and J]
 - Review records of external monitoring results with year-end totals for the past 3 years, and a sampling of records from dosimetry wear periods throughout the most recent year. Look for unusual or unexpected doses; missing dosimeters in various wear periods; and actual frequency of exchange. Interview staff to determine what follow-up activities were performed.

Inspectors have identified:

Licensees who ignored lost dosimeters and did not account for dose to the worker for that wear period.

Unusual doses due to incorrect storage of the dosimeter, which then requires adjustment of the dose record of the individual.

Incorrect use of dosimeters by radiation workers (dosimeter not worn, finger rings worn on wrong hand, dosimeters stored near radiation sources, spare dosimeters used by multiple persons, etc.).

Incorrect storage of control dosimeters in areas in which radiation was present, resulting in higher than expected dose on the control dosimeter, subsequently subtracted from the doses of all other dosimeters.

Staff performing poor or incorrect contamination surveys.

Manufacturers who were unaware of the annual reporting requirement.

a. Internal Monitoring

- During the inspection, observe any equipment for internal monitoring, such as thyroid monitoring systems, personal air samplers, and, if applicable, whole-body counters. Observe persons being scanned or demonstration of scans.
- Review internal monitoring results for the past 3 years, and a sampling of individual internal dose assessments performed. This includes direct bioassay such as whole-body counting or thyroid assay; samples collected from individuals (urine, blood, etc.); and indirect assessments such as breathing zone air samples. Look for unusual or unexpected doses and interview staff to determine what follow-up activities were performed. Discuss the method(s) of internal dose sample collection used and interview staff about sample collection, handling, data collection, instrumentation used and its calibration, and any software or hand-calculations used to convert results of samples to dose.

Note: If respiratory protection is used, you will need to review their program to meet 10 CFR Part 20, Subpart H requirements.

Inspectors have identified:

Poor or incorrect bioassay samples collected (delays in obtaining bioassay samples, grab samples collected instead of total samples; lung counting performed instead of fecal samples collected for an alpha-emitter; etc.).

Analytical methods not sensitive to the types and quantities of radioactive materials in the sample; lack of calibrated equipment for collection and/or analysis of bioassay.

Use of software that does not contain the relevant radionuclides; use of the wrong radionuclide Class (D, W, Y) because the chemical form and biological pathway of the radionuclide was not considered.

- If the licensee believes that monitoring is not required, review the licensee's basis for that decision and verify the data and assumptions they used for the determination. Note that some licensees will monitor radiation workers even if monitoring is not required by regulation. If they do perform monitoring, observe if workers are using and storing dosimeters correctly and review a sampling of dosimetry records. [10 CFR Part 20.1502]
- If the licensee is required to monitor effluent air, review their results for the past 3 years. Interview staff about their methods for sampling or assessment of releases to determine if data and assumptions are reasonable for the program; review the calibration of any monitoring equipment that affect the dose assessment; and their use of the software to convert sample results to dose. [10 CFR Part 20.1101(d), 20.1301, 20.1302]

Inspectors have identified:

Licensees with problems such as non-working air samplers or air monitoring equipment.

Uncalibrated air samplers and rotameters.

Incorrect factors in the input data for software.

Sample analysis not sensitive for the types and quantities of licensed materials used.

- Interview licensee staff members to determine if any incidents or events occurred since the last inspection. Through interviews and review of records, determine if they incidents or events involved exposure to workers or to members of the public. Through interviews and records review, determine if the licensee took prompt and effective corrective actions, and performed sufficient investigation to assess doses, identify the cause, and prevent recurrence. [10 CFR Part 20.2103, 2106, 2107, 2201, 2202, 2203; 30.50, 30.52, 40.60, 70.50]

Inspectors have identified events with unsealed materials, such as a spill, which was cleaned up but not assessed to determine if any workers had skin contamination, external or internal exposures.

- The inspector should confirm that certain processors/manufacturers, if required by 10 CFR 20.2206(a)(7), report doses to the NRC annually. [10 CFR 20.2206]

Inspectors have identified processor/manufacturers who were unaware of the reporting requirements.

03.05 RM-5: Assessment of Quality Assurance of Product(s)

The inspector should observe performance of quality assurance (QA) activities that ensure the licensees manufacture and distribute products in accordance with the requirements of NRC regulations, the license, and the sealed source and device registration where applicable. [10 CFR Part 30 Subparts B, D and D 40.54, 40.55, 70.39]

If the licensee manufactures radiochemicals, radiopharmaceuticals, sealed or plated sources or devices using licensed material, the licensee will have committed to programs for quality assurance (QA), which includes quality control (QC) activities, in either its license or in the device registration documentation. In addition, the licensee may be required to provide QA/QC activities to meet other regulatory requirements such as those of the Food and Drug Administration (FDA) or other agencies.

- Verify that the licensee is implementing the QA program by observation and discussion with members of the QA staff or management, to determine if they are familiar with their responsibilities.
- Most QA programs will generate audit or inspection reports. Inspectors should review a sample of such reports to determine the effectiveness of the QA program. If licensee reports identified issues, review the licensee's corrective actions through

observation and discussion with staff. 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.

Products that Require a Source or Device Review

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 inspector should determine whether the licensee is deviating from the provisions of the registration certificate and the processes and procedures, as described in the references listed in the source or device registration certificates. The manufacturer must have copies of the registration certificate as well as the references available in order to be able to meet the provisions of the certificate and the commitments that the licensee made in the application. [10 CFR Part 32, Subpart B, "Generally Licensed Items"; Subpart C "Specifically Licensed items"; Subpart D "Sealed Source and Device Registration"]

- Through discussions with licensee management and workers, and by observing licensee practices:
 - verify that the sources/devices being manufactured conform to the registration certificate;
 - determine if recent models of a source/device have been changed from previous versions (includes any changes, whether or not they affect safety), and, if so, whether the changes were submitted for amendment of the registration;
 - determine if the licensee is manufacturing any different sources/devices that are not registered with NRC or an Agreement State.
- Through observations and interviews of licensee personnel, determine the nature of any unapproved source/device changes or unregistered devices. Determine the licensee's basis for making the change or not registering the device.

If any sources/devices: 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 NRC regional management. The region should then contact the NRC program office for further guidance, if possible, while the inspector is still on site, so the inspector may follow up during the remaining course of the inspection.

- Verify that distributed products include affixed, durable, and clearly visible labels that conform to those described in the license application as well as in the sealed sources and device registration, as well as any other instructions required by the applicable regulations in 10 CFR Part 32.

Products that do not require a Source or Device Review

The inspection is the main source of information to NRC that the manufacturer is still manufacturing unsealed materials, such as radiochemicals for research or radiopharmaceuticals for medical use, and/or sources or devices that do not require

registration as described in 10 CFR 32.210(g). The products to be manufactured and distributed may be described in the license and the commitments made in the application. The inspection should determine whether the licensee is deviating from the provisions of the license and commitments that the licensee made in the application. [10 CFR Part 32, Subpart B “Generally Licensed Items”; Subpart C “Specifically Licensed items”]

- Through discussions with licensee management and workers, and by observing licensee practices:
 - verify that the materials being manufactured conform to the provisions of the license, the commitments that the licensee made in the application, and any applicable regulations. [10 CFR Part 32, Subpart B “Generally Licensed Items”; Subpart C “Specifically Licensed items”; Subpart D “Sealed Source and Device Registration”]
 - determine if products have been changed from previous versions (includes any changes, whether or not they affect safety), and, if so, whether the changes were submitted for amendment of the license.
- Through observations and interviews of licensee personnel, determine the nature of any products not described in the license or application, and determine the licensee’s basis for making the change or not registering the device.

If any products are not authorized by the license or the commitments, immediately contact the NRC regional management to determine if further actions are needed while the inspector is still on site.

- Verify that distributed products include affixed, durable, and clearly visible labels that conform to those described in the license application as well as any other instructions required by the applicable regulations in 10 CFR Part 32.

03.06 RM-6: Management Oversight

The inspector should determine the effectiveness of the management of the processor/manufacturer radiation protection program for the scope of use. The inspector should verify that licensee staff is aware of the radiation protection program, and appropriately trained. The inspector should review the processor/manufacturer assessments of past performance, present conditions and future needs are performed, including that annual radiation program review; and confirm that appropriate action is taken when needed.

Some processors/manufacturers, such as those using a cyclotron to produce PET radionuclides for medical use, have multiple facilities and multiple licenses which are overseen by a corporate radiation safety office and/or health physics staff who support the individual locations. In such cases, the inspector should include review of the corporate oversight of the radiation protection program. Such oversight may include regular audits of the individual sites, assistance in monitoring of effluents and calibration of equipment, review of worker doses, and investigation of incidents including dose assessments.

- The inspector should interview licensee staff, including management representatives, to understand the licensee's organization and management of the persons who implement the radiation protection program and the persons who use and store licensed materials; and the level of involvement of licensee management in oversight of the radiation protection program; and the relationship and authority between the RSO, and the authorized users.
- The inspector should interview staff and review records to:
 - verify that the RSO is knowledgeable about the program; ensures that activities are being performed in accordance with approved procedures and the regulations; identifies deficiencies and implements 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; and
 - determine if radiation worker and radiation safety staff levels, including numbers and types of positions, are adequate to implement the radiation protection program. 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.
- The inspector should read all the annual radiation program reviews for at least the past 3 years and discuss the activities by the licensee staff that support the annual review of the radiation protection program. The inspector should review other licensee actions (such as corporate audits or other reviews) to identify problems, take corrective actions, and implement preventive measures. The inspector may review selected records of these activities. If deficiencies were identified, the inspector should determine if any corrective actions taken; if no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits. [10 CFR Part 20.1101]
- Through interviews of the RSO and selected licensee personnel, the inspector should determine whether the licensee has experienced any events since the last inspection.
 - The inspector should review any instances of lost, missing, or stolen licensed materials. [10 CFR Part 20.2201]
 - The inspector should review and evaluate any other incidents or unusual occurrences such as spills, releases, or other events that could have resulted in doses to workers or the public. If any of the incidents and events could have resulted in doses in excess of limits to workers or the public, the inspector should review the licensee's dose assessments to determine adequacy. If such incidents were required to be reported, the inspector should verify if a complete and timely report was made to the NRC. [10 CFR Part 20.2202, 20.2203, 20.2204, 20.2205, 30.50, 40.60, 70.50, 70.52, 70.59]

- The inspector should determine whether the licensee performed sufficient investigation to identify the cause of any events and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

Inspectors have identified:

Licensees who do not perform correct or adequate bioassay sampling and measurement, and therefore did not identify adequately assess dose.

Licensees who were unaware of various reporting requirements and did not report required events.

- The inspector should review selected operating and emergency procedures, using information about the radiological hazards of the activities authorized by the license and observations during the inspection. The inspector should discuss with licensee staff the methods used to develop, implement, and maintain operating and emergency procedures for the radiation protection program.

Inspectors have identified:

Staff unaware of procedures or not following procedures.

Changes that were made which required amendment of the license, or were not in accordance with license requirements.

RSOs who were primarily technical staff for the manufacturing process, with limited radiation safety knowledge, and/or too little time to perform the duties of the RSO and who were unaware of radiation safety issues (such as improper calibration of survey or monitoring equipment; improperly or non-operating survey and monitoring equipment; failure to follow up on missing dosimetry; failure to identify workers not following procedures).

High turnover of staff and inadequate training as contributing causes to events which resulted in unusually high doses to workers, and/or doses in excess of the limits.

Failures to implement corrective actions for inoperable process equipment which resulted in doses to workers high enough that workers were required to cease activities with licensed materials in order to remain below regulatory dose limits.

87125-04 RESOURCE ESTIMATE

The length of time necessary for this inspection will depend on three major factors:

1. The quantities and forms of licensed materials authorized on the license;
2. The range of activities authorized on the license to be performed, along with the range of activities able to be observed during the onsite inspection; and

3. The scope of the licensed program, including the variety products manufactured; the number and complexity of facilities approved for use by the licensee; the number of radiation workers; and the frequency of activities performed with licensed material. See appendix B of this IP for more information.

A typical processor/manufacturer may take a single inspector 1 to 2 days to complete the inspection. Large programs with multiple product lines and/or multiple locations and/or authorized by a license of broad scope may take multiple inspectors several days. A manufacturer/distributor who imports materials or devices that are manufactured elsewhere may take a single inspector 4 to 8 hours to complete the inspection, depending on the number of products that are distributed. Additional time will be needed if materials possessed require inspection using IP 87137, "10 CFR Part 37 Materials Security Programs." In addition, some manufacturers, such as accelerators producing PET radionuclides, work multiple shifts that may require inspection during night or very early morning hours when staff are present.

87125-05 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

Appendixes:

Appendix A: Additional Inspection Elements

Appendix B: Considerations for Selecting Activities to be Observed

Attachment:

Attachment 1: Revision History for IP 87125

Appendix A: Additional Inspection Elements

87125A-01 PURPOSE

The guidance in this appendix is intended to supplement inspection requirements and associated guidance provided in this procedure. The additional inspection guidance provided herein may be used as time allows or to assist in completing a rounded performance-based inspection.

87125A-02 BACKGROUND

Risk modules (RMs) are defined as components in the inspection procedures used to focus the inspection effort on: (1) licensed activities that present higher risk for a particular licensee type, and/or (2) radiation safety program areas that are expected to effectively reduce the risk associated with the use of radioactive material. The risk profile for each licensed program could be different and some programs may need more in-depth review. Therefore, the additional inspection elements included herein may be used to expand the scope inspection effort and/or supplement the risk modules in this procedure.

87125A-03 GUIDANCE

03.01 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 pick up by courier personnel or transport by licensee personnel. If possible, observe the receipt of packages. Otherwise, request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.
 1. If packages are left unattended, assess the licensee's receipt procedures, including instructions provided to couriers, to assure that packages are being delivered to the appropriate location(s).
 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, interview licensee staff and the RSO further to assess worker knowledge. Deficiencies regarding instrumentation should be reviewed in more depth.
- 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 such materials.

03.02 Comprehensive Safety Measures

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

IMC 1007). The focus should be on potential non-radiological hazards personally observed or brought to the inspector's attention by licensee staff.

- a. 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. Additional guidance for reporting fire protection concerns can be found in IMC 1007 "Interfacing Activities Between Regional Offices of NRC and OSHA."

- b. Industrial/Chemical Hazards. Through observations and interviews of licensee personnel, determine 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. Dosimetry. The licensee should implement a radiation dosimetry program to accurately measure, and record radiation doses received by workers or members of the public as a result of licensed operations. A radiation dosimetry program includes all of the licensee's activities that measure the radiation dose to workers and members of the public as the result of licensed activities. These activities would include for example, the measurement of quantities of licensed materials present, radiation and contamination levels, and the concentration of licensed materials in effluent streams.
- Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes.
 - If the licensee monitors worker exposures (internal and external), notwithstanding a prospective analysis indicating that monitoring was not required, review selected reports of monitoring results. Verify, based on the review of reports of

monitoring results, that worker doses adequately reflect the nature and scope of the licensee's activities. 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 their awareness of the disparity.

- Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.
- Through interviews of workers and observations of activities in progress, verify that radiation monitors are worn appropriately and are recording the highest dose for which they are intended.
 - If monitors are not (or cannot be) worn in the most appropriate location to record the highest dose received by the individual(s), through interviews of the RSO, verify that the licensee has performed assessments (through surveys, calculation, or both) of occupational exposures received and adjusted the dose of record for the worker(s).
 - Review the results of the licensee's assessment and verify the assumptions and outcomes. Verify that the dose of record for the affected worker(s) has been adjusted and that the adjusted dose is within the applicable regulatory limit and ALARA.
- Through interviews of the RSO and review of records of external monitoring results, determine whether processing (collection, process, and assessment) of monitoring devices is being performed in a timely manner.
- Through interviews of the RSO and workers who handle volatile radionuclides (i.e., radioiodine), verify that the licensee has established an appropriate monitoring frequency for the identification of intakes of radioactive materials. Verify that the licensee has established administrative action levels for investigating intakes. Through a review of bioassay records, verify that, when those levels are exceeded, the licensee appropriately investigates the intakes. Verify that the licensee's process for converting intake measurements to dose uses appropriate calculations and methodologies.
- Through observations of facilities and activities in progress, interviews of the RSO and workers, independent and confirmatory measurements, and reviews of records of licensee evaluations, verify that the licensee effectively uses procedures and engineering controls to maintain doses to members of the public and radiation levels in unrestricted areas within regulatory limits and ALARA.
- Through observations of facilities and activities in progress, interviews of the RSO and workers, and reviews of records of air monitoring results and licensee evaluations, verify that licensee releases of gaseous radioactive effluents to unrestricted areas are within the constraint value. Verify that air sampling equipment is calibrated and operational, and that sampling lines are intact and draw from their intended collection points.

- Through observations, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors in-line ventilation filtration systems for saturation. Determine whether filter systems are monitored for differential pressure to ensure that there is no bypass of the filters, including perforations/channels and worn or degraded seals.
- Through observations, independent measurements, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors the flow rates of fume and laminar flow hoods used to process licensed materials. Verify that licensee staff use calibrated instruments to measure flow rates. Verify that hood flow rates are adequate to prevent outflow of volatile, gaseous, and particulate materials into work areas, including the prevention of high eddy currents originating from excessive hood flow rates.
- Through observations, verify that respiratory protection equipment is certified by NIOSH/MSHA 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.
- 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.

03.03 Instrumentation

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 (± 20 percent).
- 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 (such as a barium-133 source to simulate iodine-131) 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.

03.04 Training

- 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 workstation. 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 the authorized user 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 their supervision have been properly trained and instructed and is responsible for the supervision of operations involving the use of licensed materials whether the authorized user/supervisor 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).
- c. 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.
- d. 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 if there are regulation changes and/or radiation safety program changes that affect the workers. Review workers' knowledge of the risks associated with the licensed activities.

03.05 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.

- a. 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."
- b. During interviews of selected licensee personnel, propose hypothetical emergency scenarios 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).
- c. If the licensee is required to have and implement an emergency plan, pursuant to 10 CFR 30.32(i), 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.

- d. 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.

03.06 Posting and Labeling

- a. 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. 10 CFR Section 20.1903 provides exceptions to posting caution signs. The inspector should also selectively observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.
- b. 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.
- c. 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 Senior Management Responsibilities

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 (10 CFR 30.34(b)).
 - 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.

END

Appendix B: Considerations for Selecting Activities to be Observed

87125B-01 PURPOSE

The purpose of this appendix is to identify and describe three factors to be considered in determining the activities to be observed during a risk-informed performance-based inspection of facilities that may be authorized for a wide range of uses of licensed materials. The programs that have a wide range of uses may include licensees performing research and development (R&D), or licensees performing manufacturing. The three factors are: 1) the quantities and forms of materials used; 2) the activities performed; and 3) the size of the program (number of locations and persons). A description of the variations that have been observed in inspections is listed in order of higher to lower probable risk from the licensed activities.

87125B-02 BACKGROUND

Programs that authorize a wide variety of radioactive materials and forms, a wide variety of uses, and/or a large number of locations with a large number of users may provide a challenge to inspectors in determining the activities to be observed during the inspection. Such programs were more common in the past. Diverse and changing research activities introduce new uses of radioactive materials, therefore inspectors may not be familiar with the range of activities discussed in this appendix. The appendix describes the range of materials, uses, and program sizes that have been observed by inspectors of such programs, arranged in order of higher to lower complexity and risk. Each section provides guidance to inspectors who are inspecting a program that may include that activity. This information may be used by inspectors to select the activities to be observed during the inspection, and to perform the inspection.

87125B-03 GUIDANCE

The inspector should consider the following areas for selecting activities to be observed at licensee facilities where primarily unsealed materials are used for activities covered by this inspection procedure: a) the quantities and forms of the licensed materials; b) the activities performed; and c) the size of the program.

- a. Quantities and forms of licensed materials handled. Below is a prioritized list of the quantities and forms of licensed materials that may be used by licensees. The inspector should prioritize observations of materials that present the highest risk to the health safety of workers and the public.
 1. Unsealed beta/gamma emitters in curie quantities that require remote handling and containment such as hot cells or glove boxes.

The inspector should observe the use of remote handling equipment, and the use of other radiation protection equipment (lab coats, gloves, dosimetry, survey instruments, etc.). The inspector should perform surveys to confirm adequacy of the containment shielding. The inspector should identify the location(s) of effluent release points and monitoring systems if applicable. The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory maintenance, use, and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. If the licensee has multiple areas using

these types and quantities of materials, the inspector should determine if all need to be reviewed, or if a sample is sufficient.

2. Unsealed beta/gamma emitters in tens-to hundreds of millicuries that may require remote handling and/or containment in glove boxes or hoods.

The inspector should observe the use of remote handling equipment and other radiation protection equipment [lab coats, gloves, dosimetry, survey instruments, etc.), and should observe licensee staff perform surveys. The inspector should perform surveys to confirm adequacy of the containment. The inspector should identify the location(s) of effluent release points and monitoring systems if applicable. The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory maintenance, use, and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. If the licensee has multiple areas, the inspector should determine if all need to be reviewed, or if a sample is sufficient.

3. Unsealed beta emitters in millicurie quantities that may become (i) airborne as dusts or volatile gases, and may require use of a hood or glove box; (ii) high-energy beta emitters that could result in extremity doses, and may require use of beta-shields; and/or (iii) chemical/physical forms that may absorb through skin or react with other chemicals in the area. See IP 87141.

The inspector should observe the use of hoods or other equipment to control potentially airborne materials; determine through observation and discussion if any effluent releases (air, sewer, or other effluent) require monitoring and evaluation; confirm that licensee staff use appropriate shielding and dosimetry if medium/high-energy beta emitters are used; observe the use appropriate radiation protection for handling the material; and observe staff performing surveys. The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory maintenance, use, and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. If larger programs have multiple facilities for such studies, if all need to be reviewed, or if a sample is sufficient.

4. Unsealed alpha emitters, especially in forms that could become airborne or volatile, and whose energies require careful surveys in order to determine if use results in contamination of areas. This includes byproduct, source, and special nuclear material. See IP 87140.

The inspector should observe the licensee staff appropriately control and contain alpha emitters. The inspector should pay particular attention to the methods used to survey for alpha contamination to determine if surveys are performed slowly enough and have sufficient sensitivity to identify the spread of alpha contamination. This is especially important if surveys for release for unrestricted use are performed, because the NRC screening values for most alpha emitters is very small (examples are 101 dpm/100 cm² for uranium, 7 dpm/100cm² for thorium). The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory maintenance, use, and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. If multiple laboratories handle

alpha-emitting material, the inspector should determine if all areas need to be inspected or if a sample is sufficient. Note: NRC screening values for release may be found in NUREG-1757 "Consolidated Decommissioning Guidance, Volume 2."

5. Unsealed beta emitters in microcurie quantities which do not likely require airborne containment. See IP 87141.

The inspector should observe licensee staff use appropriate handling methods and radiation protection equipment (typically: have absorbent material on the work area bench, wear gloves and lab coats, use low-Z material shielding); use of available survey instruments and liquid scintillation counters (LSC); and perform surveys. The inspector should discuss routine and emergency safety procedures with licensee staff in this area. The inspector should review laboratory use and survey records, if maintained in the area. The inspector should determine if material is appropriately secured and controlled in use and in storage. Most licensees will have multiple laboratories in this category, and a sample of 5-10 laboratories or 10-20 percent of all such laboratories, whichever is larger, is usually sufficient.

6. Small sealed sources and/or devices (electron capture detector (ECDs) used in gas chromatographs or chemical monitors, x-ray fluorescence (XFR) devices, Mossbauer sources, check sources, calibration sources and standards, or other sources not covered by other inspection procedures). This includes sources and devices possessed under a general license. See IP 87142.

The inspector should observe if such sources and devices are present in laboratories during the inspection. The inspector can develop a list of sources/devices observed in the laboratories, for later review of physical inventory and leak test records, to be sure that such sources and/or devices observed are included. Another method of sampling, when the licensee possesses tens to hundreds of sources, is to select a random sample (10-20%) of such devices from the current inventory, then visit each designated location to confirm by observation that the sources are present and observe workers use of the sources and/or devices the sources at that time. The inspector may review inventory and leak test records by selecting a random sample of sources and devices to determine that the sources were consistently on the inventory and were leak tested if required.

- b. Activities performed. The following activities are not often performed at most licensed facilities and therefore may require additional review and preparation by the inspector. These activities often require more complex safety procedures and additional training which should be evaluated by the inspector.

1. Synthesis of compounds

Synthesis activities tend to generate more contamination and more waste products than most laboratory bench top activities. The inspector should, if possible, observe the process from opening the incoming material, through the various steps of the process to the collection and use of the final labelled compound and the disposal of waste materials. The inspector should determine if adequate surveys are performed in each step to protect workers and public during the process, and that material is accounted for, and secured. If multiple synthesis activities are performed, the inspector should gather information to determine if the activities are performed with different materials and/or by different persons, in order to determine if all such facilities should be inspected or if a sample is sufficient.

2. Use of licensed material in animals. See IP 87141 and IP 87144.

There are many ways in which licensed materials may be introduced into animals for study; each has its own safety and security issues according to the type of animal, the route of introduction, and the biological fate of the radionuclide. The inspector should, if possible, observe: animal handling with licensed materials; animal housing, use and waste areas for adequate radiation protection and contamination control appropriate to the types of radionuclides and the compound labelled to determine that the route of excretion (e.g. urine, feces, exhalation, or uptake in tissue) of the radioactive material is appropriately monitored or controlled; surveys or evaluations for the release of the animal for unrestricted use, if that is done (return to owner after veterinary treatment or return to the vivarium animal population after laboratory testing). If multiple different studies with animals are performed, the inspector should gather information to determine if the animal studies are performed with different materials and/or by different persons, in order to determine if all such facilities should be inspected or if a sample is sufficient.

3. Effluent releases, monitoring, and evaluation (this includes any environmental monitoring of ground and surface water, soil, plants, and animal samples if necessary).

If the licensee releases effluents that require monitoring, the inspector should review the location of releases and monitoring points, and the equipment used, to ensure that the release is properly sampled and collected. The inspector should observe the equipment used for sample analysis, if performed on site (see below) to ensure that measurements of the samples are correct. The inspector should review the method used to convert the data from the measurement to a value for comparison to effluent release limits or dose to workers or public. If the licensee has multiple effluent releases, the inspector should evaluate at least one of each type of release (air, water, sewer).

4. Internal dose assessment – This may be a direct assay or may be indirect through sample collection. Bioassay may be required routinely, or only if an uptake is suspected.

If the licensee is required to perform internal dose assessment, the inspector should observe direct measurements used to support internal dose assessment (thyroid monitoring is common for persons handling millicuries of radioiodines, or whole-body counters for gamma emitters). The inspector should evaluate direct measurement systems to ensure they are used correctly and in calibration. Indirect measurement used to evaluate internal dose could include collection of samples of urine, feces, or exhaled air, according to the route of excretion of the radionuclide and the compound to which it was attached. The inspector should review indirect assessment collection method(s) (such as grab sample, 24-hour total collection), and other relevant data to be collected (time of collection start/end, time of suspected intake, results of contamination surveys etc.) to determine if good sample collection methods are employed. Poor bioassay sample collection is usually the major source of error in a bioassay evaluation. If samples are analyzed by the licensee, the inspector should observe the equipment and method(s) used (see below). The inspector should review the licensee's method of assessing dose from the sample results (hand calculations, computer codes, etc.).

5. Analysis of samples (such as unrestricted release wipes, leak test, bioassay, effluent, soil, etc.) by the licensee. See Section 03.03.

If the licensee is performing analysis of samples they collect (or analysis of samples as a commercial activity), the inspector should observe the instruments available for analysis of the samples collected and analyzed by the licensee. The inspector should determine if the instruments are appropriately calibrated for the types of material(s) and the geometry(ies) of the sample(s); and if the analyses are performed with sufficient sensitivity for the material being evaluated. The inspector should review a sample of control charts and calibration records for analytical instruments, and results of any cross-check analysis programs in which the licensee may participate (this is most likely for laboratories analyzing effluent, environmental and bioassay samples). If instrumentation is not appropriately calibrated, then the sample results are not meaningful.

6. Waste processing.

Some higher-risk waste processes that may be used at typical laboratory facilities are: compaction of solid dry waste; solidification of liquid wastes; treatment of mixed wastes to remove one of the hazards; crushing of liquid scintillation vials to consolidate the scintillation fluid; incineration of wastes, such as animal carcasses. Lower-risk waste activities include disposal of 10 CFR 20.2005 specific wastes, release of soluble materials by sewer disposal, packaging of dry waste, and decay-in-storage activities.

If the licensee is processing waste (as opposed to storage for transfer to a licensed facility, or storage for decay), the inspector should observe licensee staff performing processes if possible. The inspector should observe availability and use of remote handling equipment and/or shielding if applicable; use of personal protective equipment by licensee staff; performance of facility surveys; and the use of calibrated and operable monitoring equipment if applicable. NOTE: If waste disposal records are maintained in the waste storage and processing areas, the inspector should review selected records while at the location(s).

7. Calibration of portable survey instruments by the licensee. See IP 87143.

If the licensee calibrates their own portable survey instruments, it is important to review the capability of the licensee's calibration, to ensure that the survey instruments used are accurate. The inspector should observe licensee staff performing a calibration. The inspector should observe if access to the source and the beam are appropriately controlled during calibration and that any safety/warning indicators are operable and used. The inspector should perform surveys to confirm if radiation doses during calibration result in radiation levels in excess of public limits, if applicable (such as from sky shine or beam scatter through adjacent walls); or in excess of posting and monitoring requirements for workers. The inspector should discuss the calibration facility and monitoring with licensee staff, to ensure that the proximity of walls or other equipment in the room do not create backscatter that could affect the dose rate measurement within the beam. The inspector should perform comparative measurements with the licensee.

8. Broad scope procedures to approve their own authorized users, uses, and facilities.

If the licensee authorizes its own users and uses of licensed materials under a license of broad scope, the inspector should interview members of the Radiation Safety Committee (Type A broad scope) or responsible management (Types B and C broad scope) who oversee the radiation protection program, and interview the Radiation Safety Officer and radiation safety staff who implement the radiation protection program. The inspector should evaluate the level of involvement of committee members and/or management in the approval of new users and uses, criteria for approval, and in the annual review of the radiation protection program,

- c. The size of the program. Licensed programs that span multiple locations may require the inspector to prioritize facilities to be observed. The larger the program, the more information the inspector will need to gather at the beginning of the inspection regarding where and what activities are taking place in order to determine what, when, and where to inspect. Below the list of factors that should be considered in selecting sufficient activities to be observed.

1. The number of separate locations/campuses: broad scope licenses may have multiple campuses or locations (note in licensing, a contiguous property is considered a single location): If a licensee authorizes multiple locations, the inspector should review section 05.03.a. of IMC 2800 to determine the number of locations required to be inspected.
2. The number of buildings and the number of laboratories: Broad scope licenses usually authorize activities in multiple laboratory buildings or other locations. Typically, there will be multiple laboratories that use licensed materials in a given building. Limited scope licensees typically have all licensed activities in one building. Activities by authorized users usually occur in laboratories, but licensed materials also may be used or stored in locations such as shipping/receiving, the radiation safety staff analytical laboratory and/or storage areas, waste storage and handling areas, etc.

The inspector should gather information during the entrance meeting to determine the current number of buildings/laboratories authorized to use material, AND the number who are actively using material, to adjust the plan of inspection. The inspector should visit 5-10 active laboratories and use/storage areas, OR 10-20 percent of all active laboratories and use/storage areas, whichever is larger. Some of these locations may be selected based on the types, quantities, and activities performed, and others may be randomly selected.

3. The number of authorized users and other radiation workers: A broad scope license may approve its own authorized users who will use, or supervise the use of, licensed materials. A limited scope license usually names persons on the license who may use, or supervise the use of, licensed materials.

During the entrance meeting, the inspector should gather information about the number of persons who are considered "authorized users" actively using licensed materials, and the number of radiation workers who are under the supervision of authorized users. The inspector should interview 5-10 persons, OR 10-20 percent of all persons considered to be actively working with licensed materials, whichever is larger. Some of the persons may be selected according to the types, quantities, or activities performed with licensed materials, and others may be selected.

4. The frequency of work with licensed materials: use of unsealed materials for laboratory research has steadily declined over the past 20 years. Some broad scope programs that received 100-200 packages each week 10 years ago may now receive only 100-200 packages each year. Daily use of radionuclides in laboratories is rare. It is more usual for licensed materials to be used sporadically for a particular study over several days to a few weeks, then not at all for weeks or months.

During the entrance meeting, the inspector should gather information about the use of licensed materials expected to occur during the time of the inspection, so that activities may be observed. The inspector should also gather information about the frequency of use from discussion and review of package ordering and receipt records. The inspector may use this information to adjust the inspection plan on site.

END

Attachment 1: Revision History for IP 87125

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information)
	ML052730313 09/28/05 CN 05-027	Revised to refer to new information in IMC 2800, "Materials Inspection Program", (Enclosure 7) which incorporates guidance to physically confirm that the inventories of foreign-obligated source material and/or special nuclear material possessed by a licensee are appropriately reported and documented in the Nuclear Materials Management and Safeguards System.	N/A	N/A
N/A	ML23328A025 12/21/23 CN 23-039	Revised in its entirety. Specific changes include: (1) divided inspection guidance into risk-modules; (2) included inspectors' observations; (3) updated inspection guidance; (4) added an estimated level of effort to complete an inspection; (5) developed new appendix titled "Additional inspection elements"; and (6) developed new appendix titled: "Considerations for selecting activities to be observed."	N/A	ML23328A028