

# NRC INSPECTION MANUAL

MSTB

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## INSPECTION PROCEDURE 87130

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### NUCLEAR MEDICINE PROGRAMS

Effective Date: 05/16/2022

PROGRAM APPLICABILITY: IMC 2800

#### 87130-01 INSPECTION OBJECTIVES

- 01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public, and patients.
- 01.02 To determine if licensed activities are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements using a risk-informed, performance-based regulatory approach.

#### 87130-02 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 to 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.

A typical license of a nuclear medicine facility authorizes the use of unsealed radiopharmaceuticals for human use that includes general nuclear medicine with positron emission tomography (PET) studies and therapeutic treatments. A variation of a nuclear medicine licensee is a mobile medical service provider where the service provider transports dosages to or receives the dosages at a client site for use by either the mobile medical service provider or the client. Additional information on mobile medical service providers may be found in the Appendix. Using a risk-informed approach, the inspector should choose the activities that carry the highest risk to inspect first. Activities associated with PET studies (hospital, clinic, or mobile van) and therapeutic treatments carry higher risk of exposure and therefore should be evaluated during every inspection.

The structure and the emphasis of the inspection should be on the following risk modules that describe the outcomes of an effective nuclear medicine radiation safety program. Risk modules (RMs) are defined as program areas that present higher risk, or expected to effectively reduce risk, to health, safety, and security that are identified in each inspection procedure in order to focus inspection effort on these particular program areas. 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 in the Appendix 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 or, if multiple violations were identified through review of the following RMs.

#### 02.01 RM-1: Observation of Licensed Activities

The inspector should observe a representative sample of the range of licensed activities that may be ongoing during the inspection, with emphasis on those of higher risk. In a typical nuclear medicine facility, PET studies and therapy treatments pose the greatest risk. The inspector should observe a range of activities, from ordering licensed materials through the disposal or transfer of licensed materials.

#### 02.02 RM-2: Safety and Security of Licensed Material

The inspector should observe a representative sample of facilities to determine if licensed materials are appropriately attended when in use or secured when in storage. 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: Therapy Procedures and Written Directives

The inspector should observe therapy activities whenever possible to evaluate the licensee's radiation safety practices, use of written directives, and evaluation of patient release following administration of therapeutic radiopharmaceuticals.

#### 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 license for which monitoring of radiation workers is required. Particular attention should be paid to verifying assessments of internal dose, if applicable, 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.

#### 02.05 RM-5: Surveys for Contamination and Exposure Control

The inspector should observe radiation workers 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.

#### 02.06 RM-6: Management Oversight

The Radiation Safety Officer (RSO) at most medical facilities is commonly an Authorized User, for which the RSO responsibilities are an ancillary task, or a consultant, neither of whom may be present at the facility on a daily basis. Each requires the support of senior management for resources and implementation of the radiation protection program. The inspector should evaluate management's awareness of, and involvement with, the

radiation protection program to determine if assessments of past performance, reportable medical events, present conditions and future needs are evaluated, and appropriate action taken when needed.

## 87130-03 INSPECTION GUIDANCE

### General Guidance

The following inspection guidance is designed to assist the inspector in evaluating the performance of the licensee's radiation safety program. The guidance is organized by the individual 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 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 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, may 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.
- 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 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 may be found in Inspection Manual Chapter (IMC) 2800.

Given the advancements of medical research and development, emerging medical technologies are always on the forefront of providing medical care to patients. In accordance with NRC regulations, the licensee may use unsealed byproduct material, sealed sources, or devices approved for medical uses addressed in Subparts D through H of Part 35 or approved in

Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material. For any emerging medical technologies approved for use under Subpart K, licensees should use the material in accordance with the regulations and specific conditions contained in the applicable Title 10 of the Code of Federal Regulation (10 CFR) 35.1000 licensing guidance document. Approved 10 CFR 35.1000 licensing guidance documents are posted to the NRC's [Medical Toolkit](#). During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter emerging technologies being used that have not been specifically added to the license. If an inspector encounters such activity and uses, the inspector should contact NRC regional management as soon as practicable to independently verify that such use is authorized under NRC regulatory requirements. If further verification of such use is needed, the region should contact NMSS for further guidance.

Each of the following elements should be reviewed, as appropriate, during each inspection of a medical facility.

### Specific Guidance

#### 03.01 RM-1: Observation of Licensed Activities

The primary inspection activity for a medical facility should be the observation of procedures in progress. Observation begins as soon as the inspector arrives on-site. Medical facilities range from private practices that perform cardiac studies only to large regional hospitals that perform a wide range of diagnostic and therapeutic procedures.

Technetium-99m (Tc-99m) is the most common radioisotope used for imaging, making up over 80 percent of all related diagnostic imaging. It is used for imaging the cardiac muscle and patient's skeleton, as well as, to gather images of the liver, spleen, brain, lung, thyroid, bone marrow, gall bladder, salivary glands, lacrimal glands, infection, heart blood pooling, and other specialized studies. Tc-99m is commonly produced in a molybdenum-99 generator. However, most medical facilities do not use generators and purchase their Tc-99m from radiopharmacies in unit dosages in a vial or syringe. Tc-99m is used under 10 CFR 35.100 for uptake, dilution, and excretion studies and 35.200 for imaging and localization studies.

Other common radiopharmaceuticals used in general nuclear medicine studies include: iodine-131 for thyroid function imaging and identifying thyroid metastases, gallium-67 to detect the presence or extent of various diseases, thallium-201 for myocardial perfusion imaging, indium-111 used to detect infection, and xenon-133 to image the lungs and evaluate pulmonary function. All the above-mentioned isotopes are used under 10 CFR 35.100 for uptake, dilution, and excretion studies and 35.200 for imaging and localization studies.

In addition to general nuclear medicine imaging, medical licensees may also utilize radioisotopes for PET studies. Medical facilities that perform PET studies generally use fluorine-18 (F-18 FDG) to diagnose cancer, evaluate the effectiveness of cancer treatment, and diagnose coronary artery disease. The high energy photons from F-18 (511 keV) require more robust shielding than Tc-99m (140.5 keV). Inspectors should observe and assess the adequacy of vial shields, syringe shields, dose drawing stations and dose administration shields specifically designed for F-18 use. In addition, inspectors should assess the adequacy of the structural shielding based off of the submitted shielding calculations and design during the licensing process.

Occasionally, the inspector may see licensees using rubidium-82 (Rb-82). Rb-82 is a diagnostic radionuclide used for PET imaging to evaluate cardiac perfusion. Because of Rb-82's short half-life (76 seconds), it is produced in a Rb-82/Sr-82 generator, in a specially designed cart, at the medical facility. The NRC has a rulemaking underway to address specific regulatory requirements for measurement of doses when Rb-82/Sr-82 generators are used, because the current requirements are not directly applicable. The NRC has issued a Regulatory Issue Summary and Enforcement Guidance Memorandum to address these issues. Therefore, inspectors should review the following guidance for additional guidance on the measurement of dosages:

- [RIS 2013-12](#), "Notice of Issuance of Enforcement Guidance Memorandum—Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages," August 23, 2013; and
- [EGM-13-003](#), "Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages," April 18, 2013

Fluorine-18 and rubidium-82 are used under 10 CFR 35.200 for imaging and localization studies. The inspector should have an initial plan of the activities to be observed, but this plan may change as a result of new information gathered at the entrance meeting about actual activities that are expected to occur during the time of the inspection. The activities to be observed should be selected based on the types, forms and quantities of materials being used; the activities being performed; and the size of the program.

Common unsealed radioisotopes used in radiopharmaceutical therapy include:

		Brand Name	Indication	Treatment Types	Administration	35.300 Authorization
Sodium iodide Iodine-131	I-131		Hyperthyroidism, Graves' Disease	Capsule	10-30 mCi, typical 15 mCi	35.392
Sodium iodide Iodine-131	I-131		Thyroid carcinoma	Capsule	Up to 500 mCi, 100-150 mCi is typical	35.394
Lutetium-177	Lu-177	Lutathera	Neuroendocrine tumors of the digestive track	Infusion	200 mCi, up to 4 infusions 8 weeks apart	35.396
Radium-223	Ra-223	Xofigo	Prostate cancer that has spread to the bone	Injection	Weight based, up to 6 injections 4 weeks apart	35.396

The inspector should visit areas of the facility where licensed materials are prepared for use, administered, used, and stored including: hot lab(s) (some facilities may have a PET hot lab in addition to a general nuclear medicine hot lab), injection rooms, treadmill

rooms, camera rooms, and waste storage areas. If multiple locations of use are listed on the license, the inspector should determine if inspections should be performed at these sites based on IMC 2800. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition as submitted by the licensee in accordance with 10 CFR 35.13 or notifications to the NRC submitted in accordance with 10 CFR 35.14.

Interviews of radiation workers should not occur during the preparation for, or delivery of medical treatment, if possible. Prior to observing patient administrations, the inspector should identify themselves and gain the patient's consent to observe the procedure. In general, inspectors should not interfere with licensee staff administration of patient care. However, there may be instances when it is appropriate to ask questions to licensee staff while patient care is ongoing to determine if the licensee's administration of the radiation safety program is adequate.

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

- confirm that the facilities are as described in the license;
- discuss the scope of the program including types and number of procedures, staffing, and equipment;
- observe if radiation levels are as expected (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); if unusual or unexpected radiation levels are detected, discuss them with the RSO and staff;
- conduct surveys and make comparative measurements with licensee staff where appropriate;
- observe if facilities for the use and storage of licensed materials are appropriately secured or attended;
- confirm consumption of food and beverages is limited to areas where radioactive materials are not used and stored;
- confirm areas of use and storage are properly posted and packages/dosages are properly labeled (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 effort should be expended));
- confirm appropriate shielding material is available and utilized (syringe and vial shields, L-blocks, shielded waste containers);
- observe radiation workers using licensed materials and confirm the technologist verifies patient identifiers (if there is no use at the time of the inspection, a demonstration of selected activities may be requested);
- confirm, if applicable, that licensees using generators evaluate the concentration of molybdenum-99, strontium 82, or strontium 85 in the radiopharmaceutical, in accordance with 10 CFR 35.204 or applicable 10 CFR 35.1000 licensing guidance;

- watch for use of appropriate protective equipment, dosimetry, survey and monitoring techniques; and
- interview licensee radiation workers and selected ancillary persons working in the vicinity of licensed materials (ask questions to determine if their understanding of radiation safety practices is commensurate with their tasks);

Some records of interest may be maintained in the hot lab and other work areas (waste storage areas) and may be reviewed while visiting these locations. Typical records may include:

- package receipt surveys;
- dose calibrator quality control checks (constancy, linearity, accuracy, geometry);
- sealed source inventory and leak tests;
- area surveys;
- calibration records for survey instruments; and
- waste storage records.

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

### 03.02 RM-2: Safety and Security of Licensed Material

During the inspection of a medical facility, the inspector should observe licensee oversight of licensed materials safety and security and discuss identification and corrective actions for material the licensee identified as not being appropriately secured from access by the public. The inspector should observe how the nuclear medicine technologists maintain security of licensed material at the various locations where licensed materials are used and stored. The inspector should discuss licensee practices to prevent unauthorized access to licensed materials.

- At medical facilities, inspectors commonly observe licensed materials stored in the hot lab. Waste held for decay-in-storage may be stored in the hot lab or other secured area. Inspectors commonly observe material in use attended by licensee staff. [10 CFR 20.1801 and 20.1802]

Inspectors have identified instances where: (1) the hot lab door was propped open or the door did not automatically close when the technologist left the area, (2) licensed material was unattended when staff left the room (injection or treadmill areas), and (3) mobile medical staff have left radioactive material in an unsecured area (transport van) while transporting equipment between the van and the client site.

- During the licensing process, the licensee typically commits to developing written procedures for accountability and control of licensed material. The inspector should review and discuss the licensee's procedures for tracking licensed materials received, used, stored, and transferred or disposed of. Inspectors should confirm

that the total inventory includes both unsealed and sealed materials. [10 CFR 30.41 and 30.51]

Inspectors have identified situations where: (1) licensees have not developed and documented procedures for material accountability; (2) licensed material was transferred to an unauthorized recipient; (3) licensees did not follow their written waste disposal procedures resulting in a number of sealed sources being improperly disposed of; and (4) licensees accumulated flood sources that have not been returned to the manufacturer and were not included in the inventory.

- During the inspection the inspector should observe if postings of areas are available and appropriate to the radiological hazard. Inspectors at these facilities most commonly observe “Caution – Radioactive Materials” postings as well as other required postings. Required postings include: NRC Form 3, “Notice to Employees,” 10 CFR 19, 10 CFR 20, a copy of the licensee’s license, operating procedures, any notice of violation involving radiological working conditions, proposed civil penalties and licensee responses, if applicable. [10 CFR 19.11, 10 CFR 20, Subpart J]

Inspectors have identified “Caution- Radiation Area” signs although no radiation area exists. Although this may not seem significant, first responders who are trained to observe postings may respond to emergencies inappropriately if the posting is incorrect. Inspectors have also identified areas that are posted that are not required to be posted, for example rooms that contain radioactive materials for periods of less than 8 hours and that are under constant surveillance by the licensee staff.

### 03.03 RM-3: Therapy Procedures and Written Directives

The inspector should observe therapy activities whenever possible to evaluate the licensee’s radiation safety practices, use of written directives, and evaluation of patient release following administration of therapy radiopharmaceuticals.

Medical facilities authorized for 10 CFR 35.300 materials are required to develop and implement procedures for administrations that require a written directive. The purpose of the written directive and procedures in accordance with 10 CFR 35.41 is to provide high confidence that licensed material is administered as directed by the authorized user. This procedure or process (e.g., checklists, worksheets) is not reviewed as part of the licensing review and approval. Therefore, it is important that the inspector review the procedure or process and interview staff to determine if the procedure or process includes: (1) verification of patient identity before each administration; (2) confirmation that the administration is done in accordance with the written directive; and (3) definitive criteria for evaluating the dose delivered compared to the prescribed dose to determine if a medical event occurred. [10 CFR 35.40 and 35.41]

Patients that have been administered therapy doses are not required to be admitted to the hospital and may be released from the licensee’s care if the total effective dose equivalent to any other individual does not exceed 500 millirem. If there is the potential for the released patient to expose others to a total effective dose equivalent of greater than 100 millirems, the license must provide the patient with written instructions on the actions recommended to maintain doses to others as low as reasonably achievable. In addition, if the patient is a nursing mother, guidance must be provided that discusses the



potential consequences if breast-feeding is not discontinued or interrupted following the administration of the therapeutic drug. The inspector should discuss with the licensee staff their procedures for the release of patients including: (1) when the licensee may authorize the release of a patient who has been administered radiopharmaceuticals; (2) when instructions are required; and (3) when records are required to be maintained. [10 CFR 35.75]

If the licensee treats radiopharmaceutical therapy patients in house, see the Appendix for additional guidance.

Inspectors have identified instances where: (1) written directives were signed by someone other than the authorized user; (2) staff members did not follow the established procedure for written directives; (3) staff have released patients who received a higher dose than what was documented in their patient release criteria; (4) patients were released based on an inadequate dose rate survey; (5) the patient-specific calculation was completed following the patient's release; and (6) instructions were not provided to the released individuals, as required.

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

Typical nuclear medicine activities result in doses that are measurable and may require monitoring. Both whole body and extremity dosimeters may be used. The inspector should verify that dosimetry devices, if used, are appropriate to the type, energy of emitted radiation, and the anticipated radiation fields. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program (NVLAP) approved and accredited processor in accordance with 10 CFR 20.1501. Inspectors should review dose assessments for radiation workers required to be monitored, or in response to any events. In addition to technologist, authorized users, authorized medical physicists, and authorized nuclear pharmacists, monitored individuals may also include nurses and other ancillary staff. This may be done anytime during the inspection and will require review of records and interviews.

- External radiation and contamination monitoring:
  - During the inspection, observe how radiation workers use the dosimeters and where they are stored, including control badges. If applicable, observe staff performing contamination monitoring of themselves and their work area. [10 CFR 20.1501]
  - 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 (both too-high and too-low); missing dosimeters in various wear periods; and actual frequency of exchange. Interview staff to determine what follow-up activities were performed. [10 CFR 19.13; 10 CFR 20.2106]
- If the licensee determines that monitoring is not required, review the licensee's basis for that decision and verify the data and assumptions they used for the determination are reasonable for activities currently being performed.

- 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 20, Subpart C, 10 CFR 20.2106]

Note that the NRC issued Information Notice 2021-02, "Recent Issues Associated with Monitoring Occupational Exposure to Radiation from Licensed and Unlicensed Radiation Sources" on August 4, 2021, addressing improper use and implementation of dosimetry approaches at medical facilities.

Inspectors have identified: (1) licensees who ignore lost dosimeters and do not account for dose to the worker for that wear period; (2) unusual doses due to incorrect storage of the dosimeter, which then requires adjustment of the dose record of the individual; (3) incorrect use of dosimeters by radiation workers (e.g. dosimeter not worn, finger rings worn on wrong hand, dosimeters stored near radiation sources, spare dosimeters used by multiple persons, etc.); and (4) licensee's data and assumptions used to determine whether badges were required were inadequate (e.g. they did not include an assessment of ancillary staff dose or the assessment did not reflect current activities, (such as adding a new modality).

- Interview licensee staff members to determine if any incidents or events occurred since the last inspection. Through interviews and review of records, determine if any incidents or events have occurred involving 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 a sufficient investigation to assess doses, identify the cause, and prevent recurrence. [10 CFR Part 20, Subpart M; 10 CFR 30.50]

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. Inspectors have identified staff performing poor or incorrect contamination surveys.

### 03.05 RM-5: Dose Assessment and Surveys for Contamination and Exposure Control

At nuclear medicine facilities, dosages are typically assayed in a dose calibrator (although not required by 10 CFR 35.63), and surveys are performed by nuclear medicine technologists. Persons measuring dosages and performing surveys should be observed performing these tasks or demonstrating them if there is no use of radioactive materials during the inspection. The level of detail of observations, discussions and review of records will depend on the types, forms, and quantities of licensed materials used since the last inspection as well as the level of sensitivity necessary for the surveys. The survey activities should be at a specified frequency, in accordance with the related licensee procedures.

- Observe licensee staff assaying dosages, if performed, and performing (or demonstrating) surveys for contamination control and area radiation levels.
  - Observe and discuss their method for measuring dosages prior to patient administration, including a demonstration of decay correction if this is the method used to determine the dose. Discuss with the licensee staff how the dose

calibrator is calibrated, whether it is by the manufacturer's instructions or nationally recognized standard. [10 CFR 35.60 and 35.63]

- Observe or confirm that surveys are performed at the end of each day of use in areas where licensed material requiring a written directive are prepared or administered. [10 CFR 35.70]
- Observe and discuss their method of assessing removable contamination and analyzing the samples. Observe if appropriate fixed instrumentation, typically a well counter, is available for sample analysis. However, inspectors have occasionally seen thyroid probes and Geiger-Müller (GM) detectors used. Discuss with licensee staff how fixed instrumentation is calibrated, paying particular attention to instrumentation used to analyze samples to meet regulatory requirements, such as measurement of removable contamination for release for unrestricted use or transportation, bioassay samples, etc. [10 CFR 20.1501]
- Observe if appropriate portable instruments (such as a meter with a GM or low energy gamma (LEG) detector, or ion chamber or microR meter) are readily available and operable for radiation level surveys. Observe if staff use instrumentation properly and discuss if the instrumentation is used for qualitative (detection) or quantitative (measurement) purposes. Perform comparative measurements with portable instruments to determine if instruments are operating correctly. Discuss the licensee's action levels and procedures if they are exceeded. [10 CFR 20.1301 and 20.1302; 10 CFR 35.61]
- Review a sample of survey records to evaluate the typical levels of contamination, how often action levels are exceeded, and the licensee's response to exceeding action levels. [10 CFR 20.2103]

Inspectors have identified licensee staff: (1) using uncalibrated or inoperable instruments; (2) using the wrong scale or misreading the scale; and (3) performing surveys too quickly or at too great a distance from surfaces.

- Facilities for Waste Storage and/or Disposal
  - Observe licensee staff perform or demonstrate waste disposal activities. Typically, medical facilities dispose of radioactive waste by decay-in-storage. Observe and discuss contamination control and radiation monitoring for release of waste held for decay. Confirm by discussion and review of selected records how frequently waste disposal activities occur; the quantities of licensed materials disposed of; and the typical contamination and radiation levels in the areas where waste storage and handling occur. [10 CFR 35.92]
  - Discuss with licensee staff their procedures for disposal of sealed sources. Specifically, verify that calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153) are not being held for decay-in-storage. Even though sealed sources may have been held for a period of time where their radioactivity is indistinguishable from background, they are not permitted to be disposed of in the normal trash. These sources must be disposed of in accordance with 10 CFR Part 20 and Part 30.

- Licensees may dispose of licensed material by transfer to an authorized recipient. The inspector should: (1) verify that the licensee obtained a copy of the recipient's license to confirm they are authorized to receive the licensed material and (2) review shipping papers to determine the transfer was appropriately documented. [10 CFR 20.2006]

Inspectors have identified: (1) waste surveys performed in areas of elevated background; (2) licensees retaining sealed sources (with half-lives greater than 120 days) with the intent to dispose of them by decay-in-storage; and (3) licensees not verifying that recipients are authorized to receive the licensed material.

### 03.06 RM-6: Management Oversight

A nuclear medicine facility is required to have an RSO that performs activities as required by regulation and the license commitments. The RSO may be an authorized user, medical physicist, or a consultant, neither of which may be present at the facility on a daily basis. Important activities include developing and implementing the radiation safety procedures; responding to events with licensed materials; and reviewing the radiation protection program to ensure it is effective and to identify areas where improvement is needed.

The inspector should interview licensee staff, including management representatives, to understand:

- (1) the licensee's organization and management of the persons who implement the radiation protection program and the persons who use and store licensed materials;
- (2) the level of involvement of licensee management in oversight of the radiation protection program;
- (3) the relationship and authority between the RSO, and the authorized users, and licensee management;
- (4) how the RSO ensures that the inventory of licensed materials meet the license limits. The inspector should interview the RSO and other licensee staff to determine if the RSO is knowledgeable of the radiation protection program; ensures that activities are being performed in accordance with approved procedures and regulations; has reviewed and approved revisions to the radiation protection program, is aware of significant events such as the loss or theft of licensed materials, and has the authority to terminate operations that may pose a risk to health and safety. The inspector should determine if the RSO seeks out areas for improvement; responds to events; takes corrective and preventive actions; and implements improvements [10 CFR 35.24 and 35.26]; and
- (5) if the licensee has an Associate Radiation Safety Officer (ARSO), the inspector should review the ARSO's duties and tasks to ensure that they are restricted to the types of use for which the ARSO is listed on a license.

Inspectors have identified situations where the RSO was not aware of the duties associated with the position or the RSO delegated the responsibilities to others but failed to oversee their actions.

- Licensees may contract personnel (up to and including the RSO) to perform licensed activities. The licensee is responsible for any violations of NRC regulatory requirements that result from activities conducted by contract personnel operating under the license. The inspector should verify that the licensee is reviewing work completed by contracted personnel who perform licensed activities in the same manner that all other licensed activities are reviewed. The inspector should verify that all parties to contractual arrangements are aware of their respective duties and responsibilities, as well as the reporting and feedback mechanisms implemented to ensure that appropriate actions are taken to address the contractor's findings, particularly, potential regulatory violations.

Inspectors have identified situations where: (1) contract personnel failed to complete all required tasks in the specified manner or time frame; (2) licensee assumed that all work was completed and failed to review the work of the contract personnel; (3) licensee failed to correct problems identified by the contract personnel; (4) licensee failed to review work performed by contract personnel who work outside of normal working hours; (5) licensee hiring contract personnel who are not qualified or experienced; and (6) contract personnel are not able to dedicate time to fulfill the contract agreement.

- The inspector should review the radiation protection program audits since the last inspection to determine if the audits are being performed annually and that the review is a comprehensive look at the program content and implementation. Particular attention should be paid to deficiencies identified by the licensees and the actions taken to correct them. If no corrective actions were taken, the inspector should determine why the licensee disregarded the identified deficiencies and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements. [10 CFR 20.1101 and 20.2102]

Inspectors have identified audits of the radiation protection programs that were not being completed annually or did not review the entire radiation safety program.

- The inspector should review records of incidents and events, since the previous inspection, to determine if any of the incidents or events were reportable or rise to the level of a medical event. The inspector should discuss with licensee management the circumstances of the incident or event, the licensee's evaluation, and the corrective actions that have been implemented as a result. [10 CFR Part 20, Subpart M; 10 CFR 30.50; 10 CFR Part 35, Subpart M]

Inspectors have identified licensees who were unaware of various reporting requirements and did not report required events.

From the discussions and reviews noted above, the inspector should verify that notifications and/or reports were appropriately submitted to NRC and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for follow up and compliance to the appropriate NRC regulatory requirements.

#### 87130-04 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 number of areas of use; the number of radiation workers under the supervision of the authorized users named on the license; and the frequency of activities performed with licensed materials.

A typical inspection at a nuclear medicine facility may take a single inspector 2 to 8 hours to complete. Additional time may need to be allotted for licensees with multiple locations of use.

#### 87130-05 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

Appendix:

Appendix A: Additional Inspection Elements

Attachment:

Attachment 1: Revision History for IP 87130

## Appendix A: Additional Inspection Elements

### 87130A-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.

### 87130A-02 BACKGROUND

Risk modules are defined as program areas that present higher risk, or expected to effectively reduce risk, to health, safety, and security that are identified in each inspection procedure in order to focus inspection effort on these particular program areas. 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.

### 87130A-03 GUIDANCE

#### 03.01 Radiopharmaceutical Therapy and Written Directives

- a. Written Directives. The written directive (WD) is the authorized user's written order or prescription for the administration of unsealed byproduct material to a specific patient. The WD must be signed and dated by an authorized user prior to administration. The inspector should observe and interview individuals as they perform applicable duties to determine that the individuals are knowledgeable about the need for a WD and if the licensee's WD, as implemented, effectively ensure that the byproduct material will be administered as directed by the authorized user.

In addition to the Authorized User's signature and the date, the WD for unsealed byproduct materials must contain the following, in accordance with 10 CFR 35.40:

- For I-131 sodium iodide greater than 1.1 MBq (30  $\mu$ Ci):
  - Patient's Name
  - Dosage
    - Therapeutic dosage of unsealed byproduct material other than I-131 sodium iodide:
      - Patient's Name
      - Radioactive Drug
      - Dosage
      - Route of Administration

If the inspector identifies a concern(s) regarding the licensee's implementation of its written procedures to provide high confidence that each administration is in accordance with the WD, then the inspector should review the licensee's procedures to determine if they are adequate and/or not fully implemented.

The inspector should review the licensee's procedures to determine if criteria has been established for identification of medical events, in accordance with 10 CFR 35.41. Through staff interviews and a review of selected records, the inspector should assess the licensee's ability to effectively identify and respond to different types of medical events. The inspector should verify that licensee staff is aware of the person within the organization: (1) to whom they should report a medical event or treatments that may have resulted in a medical event; and (2) who is responsible for reporting medical events to the NRC. A sample of selected patient cases may be evaluated to determine if the licensee has reviewed patient cases against medical event criteria in 10 CFR 35.3045. The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If the inspector should identify a previously unidentified medical event, or a potential medical event, the inspector should: (1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045 and (2) follow the procedure for reactive inspections and the guidance provided in Management Directive 8.10, "NRC Medical Event Assessment Program." Upon identification of such an event, the inspector should notify NRC regional management as soon as possible to ensure that appropriate guidance is provided and matters are reviewed before completing the inspection.

- b. Patient Release. Licensees may release from their control a patient who has been administered unsealed byproduct material if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). If the released patients may expose others to a total effective dose equivalent of greater than 1 mSv (0.1 rem), the licensee is required to provide them with written instructions on how to maintain doses to others as low as reasonably achievable. Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials" (<https://www.nrc.gov/docs/ML1923/ML19232A081.pdf>) provides guidance to the licensee on determining: (1) when the licensee may authorize the release of a patient who has been administered radiopharmaceuticals; (2) when instructions to the patient are required by 10 CFR 35.75(b); and (3) when records are required by 10 CFR 35.75(c) and (d) to be generated and maintained. The guide lists activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.

During the onsite inspection, the inspector's observation of the patient administration is contingent upon the patient's acceptance of being observed. If permission is granted, the inspector should observe radiopharmaceutical procedures taking place during the inspection and interview staff to determine their knowledge of the patient release criteria.

The inspector should note that the patient release criteria allows licensees to release individuals from control if the TEDE for any other individual is not likely to exceed 0.5 rem. Through discussions with licensee staff and if necessary, a review of selected records, the inspector should determine the method used (administered dose, measured dose rate at a meter, or a patient specific calculation) to verify that patients have been released in accordance with 10 CFR 35.75. This may include a review of the licensee's policy for patients released in accordance with 10 CFR 35.75.

Through further discussions the inspector should verify that the licensee is familiar with the requirements in 10 CFR 35.75(b) to provide instructions to released individuals if the dose to any other individual is likely to exceed 0.1 rem. The inspector should note that,



in general, the licensee is required to give instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable. The inspector may determine how the licensee is demonstrating compliance with this requirement by discussing the content of the instructions with appropriate licensee staff. If concerns are identified from those discussions, the inspector may find it necessary to review the sample instructions given to patients. If the licensee is required by the rule to provide instructions to breast-feeding women, the inspector should verify through further discussions and reviews, if necessary, that the instructions include guidance on the interruption or discontinuation of breast-feeding and information on the potential consequences of failure to follow the guidance.

Through discussions with licensee staff and if necessary, a review of selected records, the inspector should verify that if the TEDE to a breast-feeding child could exceed 0.5 rem if the breast-feeding were continued, the licensee has maintained documentation that instructions were provided in accordance with 10 CFR 35.75(d).

- c. In-Patient Safety Precautions. For radiopharmaceutical therapy patients who are not permitted to be released under the provisions of 10 CFR 35.75, or are held for other reasons, the licensee must adhere to the requirements in 10 CFR 35.315. The patient must be housed in either a private room or with another patient that is receiving radiopharmaceutical therapy. The room must have a private sanitary facility, be posted with a "Radioactive Materials" sign, and a note posted on the door (or in the patient's chart) indicating how long visitors may stay in the patient's room.

It is likely the in-patient room, surfaces, bed linen, and bathroom will be contaminated. Therefore, either the items removed from the room must be surveyed to determine that their radioactivity is indistinguishable from background or the items must be treated as radioactive waste. Following treatment and the patient's release, the radiation safety staff or the nuclear medicine personnel are usually responsible for decontaminating and surveying the room. Once the room has been surveyed and determined to be free of radioactive materials, the "Radioactive Materials" sign may be removed and the housekeeping staff may be provided access for cleaning.

#### 03.02 Mobile Medical Service Providers (10 CFR 35.80; 10 CFR Part 71; 10 CFR 150.20; 49 CFR 171-178)

Mobile medical service providers are a subset of medical licensees. There are two types of mobile medical service providers: ones that transport and use licensed material within the transport van by the service provider's employees; and providers that transport the licensed material to the client's site for use within the client's facility by either the mobile medical service's employees or the client's employees.

In addition to the inspection items in Sections 03.01 through 03.05, the inspector should review the following items relevant to mobile medical service providers. Through observations and discussions with licensee personnel and a review of selected records, the inspector should:

- Review the service agreement between the client and the mobile medical service provider. The agreement should clearly delineate the authority and responsibility of the mobile medical service provider and client;

- Verify the dose calibrator is checked for proper function before medical use at each client's address. At a minimum, the check for proper function must include a constancy check;
- Confirm operational checks of survey meters are being performed at each location of use;
- Verify surveys are completed in all areas of use to ensure compliance with the requirements in Part 20. Areas to be surveyed include, the service provider's van and any area within the client's facility that may have been used (dedicated patient bathrooms, storage areas, or use areas); and
- Interview licensee staff to determine if they have received training on applicable transportation regulations and emergency procedures.
  - The inspector should ensure that shipping papers are properly prepared and within arm's reach of the driver while the transport vehicle is in motion.
  - The inspector should verify that a copy of the emergency procedures has been provided to licensee personnel.
  - The inspector should confirm licensee personnel have received U.S. Department of Transportation Hazardous Materials (49 CFR 172.700) training triennially.

#### 03.03 Posting and Labeling (10 CFR 19.11; 10 CFR 20, Subpart J; 10 CFR 35.69)

The inspector should determine through observation whether proper caution signs are being used at access points to areas containing radioactive materials.

The inspector should also observe labeling on vials and syringes to determine that the radioactive drug is recorded. If the label is covered by a shield, the vial or syringe shield must also be labeled with the radioactive drug.

The inspector should examine locations where notices to workers are posted. Applicable documents, notices, or forms should be conspicuously posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to and from any particular licensed activity location to which the postings would apply. Required postings include: NRC Form 3, "Notice to Employees"; 10 CFR Part 1; 10 CFR Part 20; a copy of the licensee's license; operating procedures; any notice of violation involving radiological working conditions; proposed civil penalties; and licensee responses. However, if it is impractical to post all of the documents (e.g., 10 CFR 19, 10 CFR 20, a copy of the license, and operating procedures), the licensee may post a notice indicating where these documents may be examined. Postings of notices to workers may be found in the hot lab, breakroom, and other areas where workers frequent or radioactive materials are used or stored.

#### 03.04 Training (10 CFR 19.12; 10 CFR 35.27 and 35.310)

- a. Required Training. Verify, through interviews of selected licensee personnel, that instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 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. This training should be commensurate with the duties of the personnel. 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.

- b. Authorized User Supervision. An authorized user named on the license is considered to be supervising the use of licensed materials when he/she directs personnel in the conduct of operations involving the licensed material (i.e., nuclear medicine technologists). This does not mean that the authorized user is required to be present at all times during the use of licensed materials. The authorized user is responsible for assuring that personnel under his/her supervision have been properly trained and instructed in the licensee's written radiation protection procedures and preparation of byproduct material, and is responsible for the supervision of operations involving the use of licensed materials whether he/she is present or absent.
- c. Assessment of Training. Of the training program elements, training given to individuals under the supervision of authorized users is of primary importance. One or more nuclear medicine technologists should be interviewed to determine their understanding of the training that they have received. The inspector should evaluate the technologists understanding of dose preparation and acceptable dose ranges determined by the authorized user. In accordance with 10 CFR 35.63(d), dosages outside of the dose range or that differ from the prescribed dosage by more than 20 percent need approval by the authorized user prior to use. The inspector should observe related activities to assure that licensee staff applies the information provided in training. The licensee's radiation safety training may include, but is not limited to, formal lectures, on-line training, and/or discussions with the licensee's consultant.

Licensees are required to provide personnel caring for patients undergoing in-patient therapeutic treatment, that are not permitted to be released under 10 CFR 35.75, with safety instructions. Through interviews the inspector should evaluate the staff's knowledge of the safety instructions and verify the training is conducted initially and at least annually. Topics that should be covered include patient, visitor, contamination, and waste control and notification of the appropriate personnel (RSO or AU) if the patient experiences a medical emergency or dies.

In addition, the inspector should determine if ancillary workers such as clerical and janitorial staff are informed about basic radiation safety for the type of material used by the licensee.

#### 03.05 Receipt and Transfer of Licensed Materials (10 CFR 20.1906; 10 CFR 30.41; 10 CFR 71.5 and 71.13)

Through observations and interviews of licensee personnel, verify that the licensee's procedures are adequate for: (1) properly securing package receipt areas, such as hot labs, loading docks or other shipping and receiving areas; (2) inspecting packages for damage; (3) performing appropriate package receipt surveys; (4) opening packages in a safe manner; (5) assuring that packages are properly prepared for transport; (6) controlling packages in a secure manner prior to pick up by courier personnel or transport by licensee personnel; and (7) documenting receipt, transfer, and disposal of

licensed material. If the inspector is unable to observe the receipt of packages, the inspector should request that personnel who normally receive packages for the licensee demonstrate package receipt processes and surveys.

- The inspector should determine who has access to the hot lab during off duty hours (radiopharmacy courier, facility security). Inspectors commonly observe deliveries of radiopharmaceuticals to the hot lab during normal operating hours. However, the first delivery of the day may be received before the nuclear medicine staff arrives at the facility. The inspector should discuss with licensee staff the procedure for after-hours deliveries (i.e. how does the courier gain access to the hot lab, what should a courier do with a damaged package, who should be notified if a package appears damaged).
- Inspectors have identified packages containing licensed material unattended in hallways and loading docks as a result of inadequate training provided to the radiopharmacy courier or facility security.
- If surveys of packages (whether during receipt or preparation for shipment) are not adequate to verify that radiation and contamination levels are within regulatory limits, the inspector should interview licensee staff and the RSO further to assess worker's knowledge of this area.
- Receipt of a contaminated package is a rare occurrence. However, the licensee should have procedures that address the handling of a contaminated package that includes notifying the shipper and the NRC Operations Center, as required by 10 CFR 20.1906; and
- If the licensee returns unused doses to the radiopharmacy or transfers licensed materials to other licensees, the inspector should interview staff to determine that the licensee staff: (1) has received hazardous material training; (2) correctly prepare packages for shipment based on the radioactive material contained; (3) prepare shipping papers in accordance with NRC and DOT regulatory requirements; and (4) have an adequate method of determining that recipients of radioactive shipments are licensed to receive the forms and quantities of such materials.

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

### 03.06 Reports to Workers

10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures,

accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

### 03.07 Operating and Emergency Procedures

Medical licensees are generally required to follow the guidance in NUREG 1556, Volume 9 and develop procedures for implementing this guidance that have do not need NRC review and approval. Typical procedures that inspectors should see at a medical licensee are: (1) instructions for opening packages containing licensed material; (2) instructions for conducting area radiation level and contamination surveys; (3) instructions for calibration of survey and dosage measuring instruments; (4) instructions for radioactive waste management; and (5) procedures for handling spills, leaking source, theft or loss of licensed material, medical event reporting or any other incidents. Operating and emergency procedures should be made available to all staff using radioactive material. If a written copy is not available, ensure that the licensee has a notice of where to find the procedure(s).

Review and evaluate the licensee's process for controlling documents (procedures) and documenting revisions to procedures. Revisions to operating procedures should be reviewed and approved by the RSO and staff affected by the revision should be trained on the revision prior to implementation. Verify that pertinent procedures are available to personnel, are current, and are in use. If no operations are being performed, ask workers to describe their work and the procedures that govern their work activities.

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 and spills during dose administrations).

### 03.08 Waste Management (10 CFR 20.1101, 20.1801, 20.1902, and 20.1904; 10 CFR 35.92)

Through observations and interviews with the nuclear medicine technologists, the inspector should verify that the licensee has developed and implemented written procedures for their waste management process. Medical licensees typically dispose of radioactive material by either decay-in-storage or transfer to an authorized recipient.

- a. Decay-in-Storage. Inspection efforts should be directed at verifying that radioactive waste is secured from unauthorized access and radiation levels in in surrounding areas do not exceed NRC regulatory limits. In addition, the inspector should verify that the waste room is properly posted and waste containers are properly labeled. The waste may be placed in the regular trash when the radiation levels reach background. The inspector should have the licensee perform a waste survey (or demonstrate) to determine that the licensee surveyed the waste in a low background area, set the meter to the most sensitive scale, surveyed the waste without any interposing shielding, and ensured that radioactive material labels had been removed or defaced.

- c. Transfer to an Authorized Recipient. Medical licensees may dispose of radioactive material by transfer to an authorized recipient. The licensee must obtain a copy of the authorized recipient's radioactive materials license to verify they are authorized to receive the specific radioactive material. Some examples of material that would be transferred to an authorized recipient would be sealed sources with a half-life greater than 120 days, flood sources, and used generators.

03.09 Senior Management Responsibilities (10 CFR 20.1101; 10 CFR 35.24 and 35.26)

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.
- Verifying that research involving human subjects is conducted in accordance with the requirements in (10 CFR 35.6).
- 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.
- 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.

END

Attachment 1: Revision History for IP 87130

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)
N/A	10/24/02 CN <a href="#">02-041</a>	IP 87130 is a new inspection procedure to assess a licensee's implementation of revised 10 CFR Part 35 for use of unsealed byproduct material for uptake, dilution, and excretion studies, and for imaging and localization studies for which a written directive is not required. IP 87130 replaces those portions of Temporary Instruction 2800/029 Revision 2 and IP 87115, Nuclear Medicine Programs, which are being delisted from the NRC Inspection Manual.	N/A	N/A
N/A	ML22063A454 04/26/22 CN 22-008	Revised in its entirety. This revision incorporates inspection guidance contained in IP 87131 "Nuclear Medicine Programs, Written Directive Required ". 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; and (5) developed new appendix titled "Additional inspection elements."	N/A	ML22063A455