
INSPECTION PROCEDURE 87127

RADIOPHARMACY PROGRAMS

PROGRAM APPLICABILITY: 2800

87127-01 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.

Note: Radiopharmacies may possess and operate an accelerator that produces Positron Emission Tomography (PET) radionuclides used to manufacture PET radioactive drugs. Inspection Procedure (IP) 87125 provides guidance on inspecting radionuclide production activities within these radiopharmacy facilities.

87127-02 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.

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

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

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

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

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

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

02.06 The licensee should ensure that workers are:

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

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

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

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

87127-03 INSPECTION GUIDANCE

General Guidance.

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

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever

possible, verification should be accomplished through discussions, observations, and demonstrations.

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

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

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

Specific Guidance.

Each of the following areas should be reviewed during each inspection of a radiopharmacy.

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

Facilities.

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

- b. Through observations, verify that use and storage areas, including radioactive waste storage facilities, are locked and have limited and controlled access. At a minimum, radioactive material use areas should be under constant surveillance during normal business hours when licensee personnel are present or physically secured against unauthorized access. Storage areas must be physically secured when unattended.

Receipt and Transfer of Licensed Materials.

- a. Through observations and interviews of licensee personnel, verify that the licensee: 1) properly secures package receipt areas, such as loading docks or other shipping and receiving areas; 2) inspects packages for damage; 3) performs appropriate package receipt surveys; 4) opens packages in a safe manner; 5) assures that packages are properly prepared for transport; and 6) controls packages in a secure manner prior to pickup by courier personnel or transport by licensee personnel. If unable to observe the receipt of packages, 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 in Focus Element 5 (Section 03.05, below).
- b. Through interviews of licensee personnel and review of selected transfer documentation, verify that the licensee has an adequate method of determining that recipients of radioactive shipments are licensed to receive such materials.

Inventory Control.

- a. Through observation, physically examine the inventory of radioactive material on hand and review selected records of receipt and transfer to verify that quantities and forms are as authorized on the license. Compare the possession of selected sealed sources with inventory records. Verify that the licensee's use of byproduct material is limited to that which is authorized in the license.
- b. Through interviews of the RSO and selected licensee personnel, determine whether the licensee has experienced any events since the last inspection, involving lost, missing, or stolen licensed materials.
 - 1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be

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

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

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

Process and Engineering Controls.

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

- a. For hot cells and mini cells, determine that the licensee controls: the access into hot cells or mini cells; the removal of material from process enclosures; and contamination originating within the hot cells or mini cells.
 1. If any weaknesses in hot cell and/or mini cell operations are identified, review the records of radiation surveys and/or air monitoring around the hot cell and/or mini cell area.
 2. 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 FE 03.04.
- b. 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.
 1. 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.
 2. 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 FE 03.04.

- c. For temporary or portable shielding, verify that the licensee adequately controls the movement of the shielding to prevent inadvertent or unauthorized removal.
- d. For all processes where shielding is used, assess the adequacy of shielding during maximum loading of hot cells, mini cells, and glove boxes. Determine, by surveying the areas near manufacturing processes to ensure the continued adequacy of shielding. If the licensee initiates new processes in existing hot cells, mini cells or glove boxes, or utilizes new or additional transfer lines, determine whether the licensee has evaluated the adequacy of existing shielding before beginning the new process.
- e. For transfer of material, verify that the system(s) used for the transfer of materials has adequate shielding to keep exposures ALARA. Radiopharmacies that manufacture and/or handle PET radiopharmaceuticals generally use transfer lines and/or shielded containers to transfer radioactive material from the accelerator (if applicable) to the chemistry synthesis/compounding area and then to the drug dispensing area. If unable to observe the transfer of material, request that personnel describe the material transfer process. Also, request personnel to describe the procedures that would be used if material in the transfer line became trapped and/or leaked during transfer.

Product Shielding

Ambient radiation levels should be determined for areas normally occupied by workers. If higher than expected readings are found, the inspector should determine the source of the higher dose rates.

- a. 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.
- b. 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 unit dose vials and syringes, and that licensee personnel use the shields when handling the containers. Verify that unit shields are adequate for the quantities and types of radioactive materials typically contained in them.
- c. Randomly select a number of finished products that are ready for distribution and verify that the external radiation levels are consistent with expected values.
 - 1. 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.

2. Verify that the licensee has not made changes to the size, shape, or contents (i.e., lead versus stainless steel or tungsten) of the shielding materials without prior approval of the NRC or an Agreement State.

Routine and Non-Routine Maintenance

By interviewing selected maintenance personnel, review the licensee's maintenance practices for equipment and components that include shielding for radiological safety. Determine that maintenance personnel verify, either through their own or health physics staff surveys, that radiological conditions are within acceptable limits prior to the removal of shielding from process equipment, or entering rooms or areas (such as bunkers, hot cells or accelerator vaults) 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.

Area Radiation Surveys

Through interviews of selected licensee personnel, including the RSO, verify that the licensee has established schedules for periodic surveys of work and storage areas of the facility site; verify that surveys are conducted using approved procedures; review a random selection of survey records to verify that surveys are performed according to schedules; verify that the survey results are reviewed by appropriate supervision; and verify that corrective actions have been taken, as appropriate. Attempt to observe surveys in progress by licensee personnel. Determine the adequacy of the surveyor's knowledge in checking the survey instrument for proper operation with a dedicated check source and in the use of the instrument for conducting radiation surveys. Verify specifically that schedule and procedural requirements for surveys are adequate to demonstrate compliance with the regulations and with pertinent license requirements. Determine whether due consideration is given to energy (particularly high energy photons from PET radiopharmaceuticals), beta exposure, and extremity exposure.

Request that licensee personnel spot-check radiation levels in selected areas using the licensee's instrumentation. Compare the results with those obtained using the NRC's instruments.

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

The inspector should be attentive to potential industrial safety hazards, for referral to the U.S. Department of Labor's Occupational Safety and Health Administration (see

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

- a. 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, 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 and 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.

Any problems/deficiencies noted should be promptly brought to the licensee's attention and discussed with Regional management.

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

2. 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.
3. 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.
4. If the licensee reported any transportation incidents, review the licensee's actions in response to the incidents.

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

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

- a. Through interviews of the RSO, determine whether the licensee had made a prospective analysis of anticipated annual doses (internal and external) to workers. If the licensee's analysis indicated that monitoring was not required, verify the assumptions and outcomes.
- b. 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.
 1. If monitoring results do not reflect the nature and scope of the licensee's activities, or if there is wide variability in the range of doses for specific job categories (i.e., one pharmacist consistently receives significantly more exposure than all other pharmacists each month), discuss this variability with the RSO to determine that he/she is aware of the disparity.
 2. Through interviews of workers and observations of activities in progress, determine the basis for the disparity in doses or verify the RSO's assessment of the disparity.
- c. 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.

1. 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).
2. 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.

Note: For radiopharmacies that handle and/or produce PET radiopharmaceuticals, direct and indirect reading pocket-type dosimeters (i.e. electronic or filament-type) may be used by the licensee to estimate real-time dose. However, the inspector should verify that such pocket dosimeters are not used as the primary radiation monitoring device for determining the dose of record.

- d. 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.
- e. 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.
- f. 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.
- g. 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/monitoring equipment is calibrated and operational, and that sampling lines (if applicable) are intact and draw from their intended collection points.
- h. 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.

- i. Through observations, independent measurements, and interviews of licensee personnel, including the RSO, determine whether the licensee periodically monitors the flow rates of hot cells, mini cells, fume hoods and/or laminar flow hoods used to process licensed materials. Verify that licensee staff use calibrated instruments to measure flow rates. Verify that 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 flow rates.
- j. 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.
- k. 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.
 1. Review and evaluate any such incident or unusual occurrence that took place since the last inspection. If such incidents were required to be reported, verify, through interview of the RSO and review of event reports, that a complete and timely report was made to the NRC.
 2. For incidents or unusual occurrences that were not required to be reported, verify that the licensee performed sufficient investigation to identify the cause of the incident, and took appropriate corrections to prevent recurrence of the situation leading to the incident or unusual occurrence.

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

- a. Through observations of portable radiation detection and measurement equipment in use and available for use, determine whether the quantity and type are adequate for the licensee's radiation detection and measurement needs. Verify that instruments used to meet regulatory requirements (area and transportation surveys) have been calibrated.

- b. If the licensee uses a vendor to calibrate instruments, verify through interviews of the RSO that the vendor is authorized by the NRC or an Agreement State to perform that service.
- c. Through interviews and demonstrations, determine that licensee personnel who perform in-house instrument calibrations are knowledgeable of the calibration procedures for each type of instrument used by the licensee. Verify that calibrations include a determination of "as found" condition before adjustments are made. Verify that personnel understand how to maintain their doses (deep dose and extremity) ALARA during calibration procedures, especially if large activity sealed sources are used.
- d. If the licensee performs maintenance/repair on survey instruments, through interviews of appropriate licensee personnel and the RSO, determine whether the licensee possesses instrument manufacturer manuals and that any replacement parts used are "like-for-like."
- e. Through observations and demonstrations, determine whether selected licensee survey instruments in use and available for use are operational (battery check) and respond appropriately to radiation (instrument source check). Compare licensee instrument readings to NRC instrument. Verify that licensee's instrument response is comparable to NRC instrument ($\pm 20\%$).
- f. Through interviews of the RSO and workers, and by observation, determine whether the licensee has a system for tagging out inoperable and out-of-service survey instruments.
- g. Through observations and interviews of the RSO and workers, verify that the licensee's instrumentation for performing in vivo bioassay measurements is adequate for those measurements. Determine that bioassay probes and scalers are compatible. Determine 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 interviews of pharmacy staff and review of selected records, verify that the licensee performs appropriate checks and tests on each dose calibrator used to dispense dosages for distribution. Such checks and tests include constancy (to verify reproducible instrument response), linearity (to verify instrument response over the range of activities dispensed), accuracy (to verify appropriate energy response), and geometry dependence (to verify instrument response over the range of volumes and containers used to dispense radioactive materials). Verify that the licensee has established acceptance levels for each dose calibrator check and test, and that personnel performing the checks and tests are aware of them and understand the appropriate response if acceptance levels are not met. Determine whether any dose calibrators have been identified that failed a check or test and verify that

licensee's response was appropriate. The inspector should request that licensee personnel demonstrate a dose calibrator constancy check.

- i. For each dose calibrator used to measure and dispense beta-emitters, verify through observations, interviews, and reviews of selected records, that the licensee has performed geometry dependence testing for each source/container configuration used and that the licensee has established appropriate calibration factors for each configuration used.

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

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

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

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

- b. Authorized Nuclear Pharmacists (ANPs). ANPs may either be named on the license or appointed by the licensee. For those appointed by the licensee, verify that these individuals are qualified as ANPs in accordance with 10 CFR 32.72 (b) and have knowledge commensurate with their operational duties.

The regulations in 10 CFR 32.72(b)(1) permit the nuclear pharmacy licensee to have an individual "under the supervision of" an authorized nuclear pharmacist prepare radioactive drugs for medical use. These regulations do not specifically require that the authorized user be present at all times during the use of such materials. However, the authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.27(b), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

- c. General Training. Certain kinds of training and instruction are found in the regulations; how they are implemented will be found in the license. Discuss with the licensee how, and by whom, training is conducted and the content of the training provided to workers (generally found in the license application).

1. 10 CFR Part 19-Required Training. Verify, through interviews of selected licensee personnel, that initial instructions have been given to individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

2. Training Required by License Commitments. Of the training program elements in the license application, training given to **authorized nuclear pharmacists**, authorized users, and those individuals under the supervision of authorized users, is of primary importance. Through interviews of one or more users of radioactive materials, assess 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.

Through observation of related activities and discussions with selected licensee personnel, verify that they actually received radiation safety training. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

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

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

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

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

During interviews of selected licensee personnel, assess the worker's knowledge and understanding of the licensee's emergency procedures, through proposed hypothetical emergency scenarios (i.e., "what if" questions). 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 (e.g., 100 millicuries of iodine-131 or 1 curie of technetium-99m)).

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

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

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

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile radioactive materials are used in an area, such an 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.

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

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

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

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

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

incidents, generic communications, authorized users and uses, waste issues, audits, etc.

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

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

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

- 1. 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.
 - 2. If so, discuss these findings with the RSO and senior licensee management to determine the source of the staffing issues and the licensee's plans to address the deficiency. The issue should also be brought to the attention of regional management.
- c. Audits. Through reviews of audit records and interviews, verify that the radiation safety program content and implementation is reviewed at least annually. The results of all audits must be documented in accordance with 10 CFR 20.2102(a)(2). Examine these records with particular attention to deficiencies identified by the licensee's auditors, and note any corrective actions taken as a result of deficiencies found.
 - 1. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits.
 - 2. Determine if the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

87127-04 REFERENCES

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

END

Attachment 1
IP 87127 Revision History Page

| Commitment Tracking Number | Issue Date | Description of Change | Training Needed | Training Completion Date | Comment Resolution Accession Number |
|----------------------------|-----------------------|---|----------------------------|--------------------------|-------------------------------------|
| N/A | 07/01/08 CN-08-018 | This document has been revised to incorporate NRC's new definition of byproduct material and regulatory authority over naturally occurring and accelerator produced radioactive material (NARM) | Yes (H-401 NARM Course) | 8/29/2007 | ML080740192 |