INSPECTION PROCEDURE 87131

NUCLEAR MEDICINE PROGRAMS, WRITTEN DIRECTIVE REQUIRED

PROGRAM APPLICABILITY: 2800

87131-01 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.

87131-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The NRC Inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be

conducted such that the inspector's presence does not interfere with patient care or a patient's privacy.

Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable, the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program.

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

02.01 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below NRC regulatory limits.

02.02 Shielding of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records, that the licensee's performance has implemented 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 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has ensured 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.

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, ALARA practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with NRC regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35, if the licensee has submitted the information required by 10 CFR 35.12(b) through (d), and the licensee has received written approval from the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used that have not been specifically amended to a licensee's 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.

87131-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with NRC requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NRC, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

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, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be

appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records reviewed the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses. Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for those areas of concerns, the records may or may not substantiate his/her concerns. If the inspector substantiates a significant safety concern regarding a particular matter, it may be more appropriate to discuss this matter with NRC regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation the radiation safety program for that particular element of a focus area.

If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (e.g., licensee materials inventories), or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, follow the requirements of MC 0620. Especially ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information pursuant to the requirements of 10 CFR 2.790(b)(1).

The inspector should keep the licensee apprised of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

Whenever possible the inspector should keep NRC regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate NRC guidance under such circumstances.

03.01 Security and Control of Licensed Material

a. Adequate and Authorized Facilities. 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. Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).

b. Adequate Equipment and Instrumentation

1. Through discussion with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee is appropriate to the scope of the licensed program. The inspector should independently verify through direct observations that

survey instruments have been calibrated in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected.

2. If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects in accordance with 10 CFR 21.

c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license conditions.

Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has methods for picking up, receiving, and opening packages that address how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are taken if surveys reveal that packages are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should observe, when practical, personnel performing the package receipt surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with NRC and DOT regulatory requirements for transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported to DOT and NRC.

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

e. Material Security and Control. Through direct observations made during tours of the licensee's facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee has maintained adequate security and control of licensed material. From those observations, the inspector should note areas where radioactive materials are used and stored. From further observations and discussions, the inspector should verify that licensed material in storage, in controlled or unrestricted areas, is secured from unauthorized removal or access. Also, the inspector should verify that the storage areas are locked and have limited and controlled access. For licensed material not in storage, in controlled or unrestricted areas, the inspector should verify that such material is controlled and under constant surveillance or physically secured. Controls may include a utilization log to indicate when, in what amount, and by whom, radioactive material is taken from and returned to storage areas. In addition, the inspector should verify that access to restricted areas is limited by the licensee.

f. Written Directives. During the onsite inspection, the inspector should observe and interview individuals as they perform applicable duties to determine that individuals are knowledgeable about the need for written directives and if the licensee's written directives, as implemented, effectively ensure that radiation from byproduct material will be administered as directed by the authorized user in accordance with 10 CFR 35.41. 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 necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with 10 CFR 35.2040.

g. Patient Release. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected records, the inspector should determine if a licensee is knowledgeable about patient release criteria and that a process exists to establish that a patient administered radiopharmaceuticals or therapeutic quantities of radioactive material is releasable from control in accordance with 10 CFR 35.75.

1. The inspector should note that the patient release criteria permits licensees to release individuals from control if the TEDE for any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with 10 CFR 35.75.

2. 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.

3. Through discussions with cognizant licensee representatives 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).

h. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by NRC regulatory requirements. If necessary, the inspector should conduct a review of selected records to independently verify those discussions with such individuals. If from those reviews a previously unidentified medical event is identified by the inspector, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045, "Report and Notification of a Medical Event;" 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 given and matters are reviewed before completing the inspection.

i. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. The

inspector should determine that areas occupied by radiation workers for long periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are 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 in accordance with 10 CFR 19.11, 20.1902, and 21.6.

j. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources in accordance with 10 CFR 35.67(g). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

k. Waste Storage and Disposal. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that radioactive waste is stored and controlled in a secure and safe manner, and that radiation levels in unrestricted areas surrounding the storage area do not exceed NRC regulatory limits. Through further discussions, observations, and reviews, if necessary, the inspector should verify that disposals of decay-in-storage waste are performed in accordance with NRC regulatory requirements.

The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less and can be decayed in storage until surveys are indistinguishable from background, then be disposed of as non-radioactive waste.

Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify the following areas, when appropriate:

1. Waste disposed in accordance with 10 CFR 35.92;

2. Waste compacted in accordance with license conditions;

3. Waste storage containers properly labeled and area properly posted in accordance with 10 CFR 20.1902 and 20.1904; and

4. Waste was returned from a landfill due to radioactive contamination.

For further inspection guidance, the inspector should refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61" and Information Notice (IN) 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20."

l. Effluents. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that releases into a public sanitary sewerage system and septic tanks, if any, are consistent with the form and quantity restrictions of NRC regulatory requirements. If the inspector determines that a review of selected records is necessary, the inspector should pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water. If a review of selected records is necessary, the inspector should examine the waste release records generated since the last inspection, annual or semiannual reports, pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records.

For liquid wastes, the inspector should determine through further discussions, observations and reviews, if necessary, if the licensee has identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complies with the regulatory requirements for disposal into sanitary sewerage.

Through further discussions, direct observations made during tours of the licensee's facility, and reviews, if necessary, the inspector should verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within NRC regulatory requirements and are ALARA (This should include xenon or other gas waste, also).

In addition, from those discussions, observations and reviews, if necessary, the inspector should verify that effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with the manufacturer's recommendations.

Furthermore, from those discussions, observations and reviews, if necessary, the inspector should verify that all significant release pathways are monitored, all unmonitored pathways have been characterized, and all surveillance procedures for effluents are being implemented by the licensee.

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

03.02 Shielding of Licensed Material

In an application for a license, a licensee must commit to develop, implement, and maintain procedures under 10 CFR 20.1101 and 10 CFR 20.1301 for safe use of unsealed byproduct material. Through observations and interviews, the inspector should assess the actual implementation of ALARA procedures which include shielding of licensed material.

a. Syringe and Vial Shields. Determine a sufficient number, type, and condition of syringe and vial shields are being used to protect workers and members of the public from unnecessary radiation. Verify labeling of syringe and vial shields required by 10 CFR 35.69.

b. Shielding in the Hot Lab. Determine use of shielding for waste receptacles, storage containers, generator systems, and work areas to protect workers in the hot lab.

c. Shielding for Nuclear Medicine Therapy. Determine use of shielding for administration of therapeutic quantities of byproduct material to protect workers and family members of the patient who may be present. To limit doses to workers and individual members of the public, a licensee may use portable shielding in patient rooms or the licensee may have installed permanent shielding in certain patient rooms designated for patients that cannot be released under 10 CFR 35.75. In an application for a license, the applicant would have described the shielding along with calculations to estimate dose levels. For portable shields, an applicant would also commit to develop administrative procedures for proper use and placement of the shields within a patient room.

If shielding is not evident, then the inspector should assess the licensee's procedure and further evaluation of radiation doses to workers and members of the public respectively under 10 CFR 20.1201, 20.1301, and 20.1302. The inspector should verify that the licensee instructed workers under 10 CFR 19.12 about shielding. The licensee may have determined that shielding was not indicated under certain conditions to protect the patient or human research subject from a non-radiological hazard which has significant health and safety consequences to the patient or human research subject.

03.03 Comprehensive Safety Measures

During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U.S. Department of Labor's Occupational Safety and Health Administration.

During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.04 Radiation Dosimetry Program

The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

a. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.

b. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within NRC regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and

discussions the inspector determines that a worker had exceeded an NRC regulatory limit, the inspector should immediately contact NRC regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

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 cognizant 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).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor.

Through discussions with cognizant licensee representatives and a review of selected records, the inspector should evaluate the adequacy of the licensee's methods used to assess the SDE to the portion of the skin of the extremity expected to have received the highest dose. The inspector should give particular attention to the distance between the location that is likely to have received the highest dose when sources are manipulated manually (even when shields are used) and where the extremity monitor is worn.

d. Internal Dosimetry. Through interviews with cognizant licensee representatives, and records review, if appropriate, verify that measurements for internal deposition of licensed materials are performed and evaluated in accordance with 10 CFR 20.1501.

03.05 Radiation Instrumentation and Surveys

a. Equipment and Instrumentation

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with NRC regulatory requirements and the manufacturer's recommendations. The inspector should verify that:

(a) The radiation survey instruments have been calibrated in accordance with10 CFR 35.61;

(b) The instruments used to measure the activity of unsealed byproduct material meet the requirements of 10 CFR 35.60;

(c) Licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with 10 CFR 35.204, to ensure that humans are not administered a pharmaceutical containing more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m.

The inspector should independently verify through direct observations that survey instruments have been calibrated at the required frequency in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee's that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee's calibration procedures.

2. When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects in accordance with Part 21. This will vary dependent upon the scope of the licensee's program.

b. Area Radiation Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within NRC regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. However, the inspector must use NRC radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the NRC regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

If practical and when appropriate, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

c. Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed or contained sources are performed at the required frequency found in 10 CFR 35.67(b) or license conditions. Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.67(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels) or approved level included in a license condition, the inspector

should verify that the licensee made the appropriate notifications per 10 CFR 35.67 (e) and removed the source from service.

03.06 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, 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 milliSievert (100 mrem). The inspector should note that it is the licensee's 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, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

Of the training program elements, training given to authorized users and nuclear pharmacists, and those individuals under the supervision of authorized users and nuclear pharmacists is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should 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.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users, authorized nuclear pharmacists and supervised individuals 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, "dry runs" for more complex or hazardous operations, and authorized nuclear pharmacists instruction in the preparation of drugs.

b. Operating and Emergency Procedures. During the conduct of the inspection, the inspector should verify through direct observations of licensed activities, if practical, licensee personnel perform tasks at selected work stations to verify that such licensed activities are performed in accordance with the licensee's operating procedures. Through discussions with cognizant licensee staff, the inspector should verify that for those individuals interviewed understand and implement procedures establish by the licensee and are aware of procedural revisions. If

appropriate, the inspector should review the licensee's emergency procedures to determine that these procedures are adequate to ensure compliance to NRC regulatory requirements.

Discuss with cognizant licensee representatives, or if practicable, observe licensee personnel conduct periodic tests, especially for scenarios involving events that would require reporting to the NRC under 10 CFR 20.2202.

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

c. Safety Instruction for Personnel Caring for Non-Releasable Patients. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee provides radiation safety instruction for all personnel caring for patients who cannot be released under 10 CFR 35.75, in accordance with10 CFR 35.310. The inspector should note that radiation safety instruction must be conducted initially and at least annually an be commensurate with the duties of the personnel.

d. Protective Clothing. Through direct observations of licensed activities and discussions with cognizant licensee representatives, the inspector should verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed. The observation of the protective clothing that licensee staff wear during their work activities should provide the inspector with an acceptable means of reviewing this requirement. If the inspector identifies a concern with this practice, the inspector should discuss this practice with appropriate licensee representatives to ensure that licensee staff are following licensee procedures for wearing adequate protective clothing.

03.07 Management Oversight

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

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management and the RSO. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to NRC. This information must be provided

whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have taken place. If there have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and NRC regional staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials Inspection Program," and regional policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with NRC regulatory requirements and the licensee's license.

In reviewing the scope of the licensee's program in this area, the inspector should discuss information that includes lab personnel, locations of use, human research and medical use activities, mobile nuclear medicine services, distribution of pharmaceuticals under 10 CFR Part 35 license, and principal types and quantities of licensed materials used.

c. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting

deficiencies to management; and methods and completion of follow-up actions by management.

1. RSO. The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify authority, without prior approval of the that, when deficiencies are identified, the RSO has sufficient authority to implement corrective actions, including termination of operations that pose a threat to health and safety.

2. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Authorized Users. Authorized users (physicians, nuclear pharmacists, and medical physicists) are named on the license. The inspector should noted that the regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. Also, these regulations do not specifically require that the authorized user 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, pursuant to 10 CFR 35.27(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

e. Authorized Uses. The inspector should determine from observing the use of licensed material, discussing the activities with cognizant licensee personnel, and if necessary, from a review of selected records, that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license. From those observations, discussions, and reviews, if necessary, the inspector should verify that the total activity of licensed material does not exceed the maximum activity authorized either in the license or in the design specifications of the device's sealed source device registration certificate.

f. Financial Assurance and Decommissioning. The decommissioning recordkeeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built

drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100%), to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have been received radiation exposures that exceeded NRC regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NRC regulatory limits, the inspector should immediately contact NRC regional management for further guidance.

Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify NRC. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to NRC. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to NRC. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact regional management as soon as practicable from the licensee's site to discuss the situation.

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

and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

g. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply.

The inspector should note that the requirements of 10 CFR 30.36, 40.42 and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

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

The inspector should note that the NRC has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failure to notify NRC, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may be classified as a Severity Level III violation and may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should contact NRC regional management as soon as practicable for further guidance.

For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG/BR-0241. "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees."

h. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, NMSS Newsletter, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.

i. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embry/fetus or a nursing child, etc.

From those discussions and reviews, 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 followup and compliance to the appropriate NRC regulatory requirements.

j. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of equipment for non-medical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular NRC requirement.

k. Research Involving Human Subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and 3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.08 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. In accordance with the regulations in 10 CFR 35.1000, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct

observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee's license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently verify that such use is authorized under the regulations. If further verification of such use is needed, the region should contact NMSS for further guidance.

For further inspection guidance, refer to MC 2800.

END