INSPECTION PROCEDURE 87117

RADIOPHARMACY PROGRAMS

PROGRAM APPLICABILITY: 2800

87117-01 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.

87117-02 INSPECTION REQUIREMENTS

A review of the licensed activities will be commensurate with the scope of the licensee's program. A determination regarding safety and compliance with NRC requirements 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.

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.

Some of the following areas may not be applicable to all radiopharmacy licenses.

02.01 Preparation. The inspector should allow adequate time to prepare for the inspection. Preparation will include reviewing documents, making travel arrangements, coordinating with appropriate personnel, notifying appropriate State agencies, and selecting necessary equipment. In particular, the inspector shall identify whether any license amendments have been issued since the last inspection, or whether the licensee has informed NRC of any major program changes since the last inspection. The inspector shall also review any regional event logs, files, and NMED to determine if the licensee has had any incidents or events since the last inspection. State agencies should be encouraged to accompany inspectors.

02.02 Entrance Briefing. When the inspector arrives at the licensee's facility, he/she will inform the radiopharmacy manager of the purpose and scope of the inspection. This notification should be made as soon as practical after arriving on site. However, in certain instances (i.e., inspections during off-normal hours) the inspector may choose to inform the

licensee management of his/her presence on site after initial observations of licensed activities currently in progress.

02.03 General Overview

a. Organization. Interview cognizant licensee representatives about the current organization of the program. Examine the licensee's organization with respect to changes that may have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Identify the reporting relationship and management structure between the licensee's executive management and the Radiation Safety Officer (RSO).

b. Scope of Program. Interview the cognizant personnel to determine the types and quantities of licensed materials received, distributed, and redistributed, numbers of facilities served, staff size, etc.

c. Management Oversight. In the course of interviewing cognizant personnel, determine if management oversight is sufficient to provide the licensee staff with adequate resources and authority to administer the licensed program.

1. RSO - Determine whether the RSO has sufficient authority and fulfills the appropriate duties commensurate with the size and scope of licensed activities.

2. Audits - Verify that audits are performed as required. Verify that the results of the audit are reviewed and addressed.

d. Authorized Nuclear Pharmacists. Verify that authorized nuclear pharmacists (ANPs) meet the criteria described in 10 CFR 32.72(b), and have been approved by the licensee to perform and/or supervise licensed activities. Ensure that notifications regarding changes in ANPs, if applicable, have been made in accordance with 10 CFR 35.14 Determine that the licensee is registered/licensed by U.S. Food and Drug Administration (FDA), or a State agency, as a nuclear pharmacy.

02.04 Walk-Through Orientation Tour. Perform a walk-through tour of the licensed facility to make general observations about the condition of the facility and the licensed activities being performed.

02.05 Facilities. Verify that the facility conforms to that described in the license application; that material receipt, use, and storage areas are secured; and that the licensee uses processes or other engineering controls (e.g., negative pressure) to maintain doses as low as is reasonably achievable (ALARA).

02.06 Equipment and Instrumentation

a. Verify that equipment and instrumentation is appropriate, operable, calibrated, adequately maintained, and conforms to that described in the license.

b. Verify that the licensee has established and implemented procedures to identify and report safety component defects per the requirements of 10 CFR Part 21.

02.07 Materials

a. Receipt and Transfer of Licensed Material. Verify that the licensee is receiving packages and making transfers of licensed material in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license

conditions. Verify pick up of unit doses returned by customers is performed according to procedures. Verify that the licensee has an adequate method to account for all materials received, possessed, stored, and used to ensure compliance with possession limits.

b. Authorized Uses. Determine, by observing the use of licensed material, discussing the activities with licensee personnel, and reviewing records, that the type, quantity, and use of licensed material at the licensee's facility are authorized by the license. To the extent practical, ensure, by physical confirmation, that the licensee's inventory is complete and accurate.

c. Material Security and Control. Verify that the licensee has established procedures for maintaining security and control of licensed material, and that these procedures are understood and implemented by appropriate personnel. Verify that licensed material in storage, in controlled or unrestricted areas, is secure from unauthorized removal or access. Verify that licensed material, not in storage, in controlled or unrestricted areas, is controlled and under constant surveillance. Verify that access to restricted areas is limited by the licensee.

02.08 Training

a. General Training. Verify that appropriate training and initial instructions are being accomplished as specified in the license and/or regulations.

b. Operating and Emergency Procedures. Verify that operational procedures are being followed by observing licensee personnel perform tasks at selected work stations and by a comparison of their activities with established procedures. Also examine the licensee's emergency procedures to determine that these procedures are as approved by NRC. Through discussions with workers, verify that licensee personnel understand and implement the established procedures and are aware of procedural revisions. Document in the inspection record what activities the inspector observed.

Discuss with the licensee's representatives, or observe, the conduct of periodic tests and drills, especially for scenarios involving fires and large releases of radioactive material.

02.09 Area Radiation and Contamination Control

a. Area Surveys. Verify, during observations and by direct measurements, that the radiation levels are within the limits of 10 CFR Part 20, and that these areas are properly posted. Confirm that the licensee representatives conduct surveys in accordance with procedures described in the license documents.

b. Leak Tests. Verify that leak tests of sealed sources are performed at the required frequency. Also verify that leak tests are analyzed in accordance with the license. If records of leak test results show contamination in excess of the regulatory requirements, verify that the licensee made appropriate notifications and removed the source from service.

c. Contamination Control. Verify that the licensee performs weekly surveys for removable contamination in all areas where radiopharmaceuticals are routinely prepared, administered, or stored. If the licensee has had spills or other incidents of contamination exceeding the licensee's trigger levels, verify that the licensee has taken appropriate actions.

d. Protective Clothing. Verify that radiation workers are provided with, and wear, the appropriate protective clothing, commensurate with activities being performed.

02.10 Radiation Protection

a. Radiation Protection Program. Verify that the licensee has developed and implemented a written radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed at least annually, both for content and implementation.

b. Radiation Protection Procedures. Verify that changes in the radiological protection procedures made since the last inspection are consistent with regulations and license requirements. [Note that some procedures may require prior NRC approval before the licensee can make changes.]

c. Instruments and Equipment. Verify that radiation protection instruments and equipment are operable, have the proper alarm settings (if applicable), and are calibrated and checked for appropriate response in accordance with 10 CFR 32.72 requirements, license requirements, and licensee procedures.

d. Personnel Dosimeters. Verify that personnel dosimetry devices are worn by appropriate licensee personnel. Dosimetry devices appropriate to the type, energy or emitted radiation, and the anticipated radiation fields should have been issued to facility personnel. Verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program- approved and-accredited processor.

Confirm that the assigned SDE reflects the dose to the portion of the extremity likely to receive the highest exposure. Confirm that extremity monitoring device processing (collection, process, and assessment) is performed in a timely manner, so that this information can be used to prevent noncompliance with occupational limits.

Verify that pursuant to 10 CFR 19.13(b), the licensee advises each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to the provisions of 10 CFR 20.2106, "Records of individual monitoring results."

e. Bioassays. Verify that bioassays are performed in accordance with license and regulatory requirements. Verify that the methods and the equipment used to perform bioassays have been approved and calibrated.

02.11 Waste Management

a. Waste Storage and Disposal. Verify that the 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 the limits of 10 CFR 20.1301, "Dose limits for individual members of the public." Verify that disposal of decay-in-storage waste is performed in accordance with the regulations and license conditions. Verify that the licensee is conducting appropriate surveys and defacing radioactive material labels before disposing of the waste.

Review the licensee's procedures and records to verify that each shipment of radwaste intended for offsite disposal is accompanied by a shipment manifest that includes all the required information.

Review the licensee's procedures and records to verify that each package of radwaste intended for shipment to a licensed land disposal facility is labeled, as

appropriate, to identify it as Class A, B, or C waste (in accordance with the classification criteria of 10 CFR 61.55).

Verify through review of records and procedures that releases into a public sanitary sewerage system, if any, are consistent with the form and quantity restrictions of 10 CFR 20.2003. Pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water.

b. Effluents. Verify that effluent releases to sanitary sewerage and septic tanks are according to 10 CFR 20.2003 and 20.1003, respectively, and that treatment or disposal of waste by incineration is according to 10 CFR 20.2004.

Review and verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within the limits established by the license and other regulatory requirements, and are ALARA.

Determine the quality of the relevant procedures and the degree to which ALARA techniques are incorporated into them. Determine the extent to which process and engineering controls are used to minimize effluents.

Determine whether 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 manufacturer's recommendations and good health physics practices.

Determine if all significant release pathways are monitored, all un-monitored pathways have been characterized, and all surveillance procedures for effluents are being implemented.

Additional inspection requirements are specified in Inspection Procedure (IP) 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)." Verify whether U.S. Environmental Protection Agency (EPA) referral forms for air effluents have been sent to the appropriate EPA regional office, with a copy to NRC Headquarters, per IP 87102.

c. Transfer. Verify that wastes are transferred to an authorized recipient specifically licensed to receive radioactive waste.

d. Records. Verify that records of waste storage, transfer, and disposal are maintained in accordance with the requirements of Part 20 and the license.

e. Financial Assurance and Decommissioning. For all licensees, including sealed source licensees, review the licensee's records of information important to the safe and effective decommissioning of the facility. Verify that the records are complete, updated, and assembled appropriately, in accordance with the requirements in 10 CFR 30.35(g). Review the licensee's list of restricted areas required under 10 CFR 30.35(g)(3) and determine whether laboratories or other rooms have been released since the last inspection. If areas have been released, verify that the licensee has adequately decontaminated each room and documented the basis for releasing each room. Document the location of the released rooms in the inspection record, and document your findings regarding the adequacy of the licensee's decontamination.

Verify whether radiological conditions at the facility have changed since the financial assurance instrument and/or decommissioning plan was submitted such that either

document needs to be changed to address the new radiological conditions. Examples of changes are radiological incidents such as spills or process upsets. Unauthorized changes by the licensee to processes, types of licensed materials, possession limits, or chemical or physical forms of licensed materials may also prompt a reevaluation of whether the financial assurance instrument and/or decommissioning plan remains sufficient. If the inspector identifies changes that may affect the financial assurance instrument or decommissioning plan, he/she should immediately notify regional management.

If a parent company guarantee or a self-guarantee is used to ensure decommissioning financial assurance, review the licensee's financial assurance file to ensure that 10 CFR Part 30, Appendix A or Appendix C requirements are met.

f. Decommissioning Timeliness. Review compliance with the Decommissioning Timeliness Rule requirements in 10 CFR 30.36(d) through (h). This is one area of the inspection record that should be completed on all inspections. If the license to conduct principal activities has expired or has been revoked; if the licensee has made a decision to permanently cease principal activities at the site or in any separate building; or if there has been a 24-month duration when no principal activities were conducted at the site or in any separate building, then the decommissioning timeliness requirements in 10 CFR 30.36, 40.42, 70.38, or Part 72 apply. If this is the case, complete in full the "Decommissioning Timeliness Inspection record," Attachment A to Appendix A.

02.12 Transportation. Verify that the licensee's procedures and documentation are sufficient to ensure that licensed material is transported in accordance with 10 CFR Part 71 and DOT regulations for transportation of radioactive materials.

02.13 Posting and Labeling. Verify that the licensee has posted the appropriate documents, notices, forms, and caution signs, as required. Also verify that containers of licensed material are labeled appropriately.

02.14 Generic Communications of Information. Confirm that the licensee is receiving the applicable bulletins, information notices, NMSS Newsletter, etc. Verify that the licensee has taken appropriate action in response to these notices.

02.15 Notifications and Reports. Determine compliance with the regulations and license requirements for notification and reports to NRC.

02.16 Special License Conditions. If applicable, review the licensee's compliance with any special license conditions.

02.17 Independent and Confirmatory Measurements. Compare and verify, on a sampling basis, survey results or data that are used by the licensee to show compliance with the regulations or license conditions. Conduct independent measurements to ascertain the radiological conditions of the facility. Conduct these independent measurements on all inspections under this inspection procedure (IP), unless warranted by special circumstances. If independent measurements were not made, provide a justification in the inspection record explaining why independent measurements were not performed. The inspector shall use radiation detection instruments that are calibrated, at a minimum, on an annual basis.

02.18 Exit Meeting. The inspector will conduct an exit meeting with radiopharmacy management and the RSO to discuss the preliminary inspection findings including any apparent violations, safety-related concerns, and any unresolved items identified during the inspection.

02.19 Post-Inspection Actions. After an inspection, the inspector shall summarize the findings with his/her appropriate NRC supervisor. This is especially important if there are, or are expected to be, controversial issues arising from the findings.

Inspectors shall also meet with regional licensing staff when any pertinent licensing issues are raised during the inspection, when inspection findings impact on any licensing actions,, or to give feedback on how the licensee has addressed recent licensing actions. This meeting shall be documented in the inspection record.

Additionally, in some instances, inspection findings will warrant communication with enforcement staff, Office of Investigations staff, State liaison staff, or Federal agencies with whom NRC has Memoranda of Understanding (MOUs).

The inspector will ensure that inspection findings are clearly documented and reported to the licensee, as appropriate. The inspector shall also follow the requirements of Inspection Manual Chapter (IMC) 0620, "Inspection Documents and Records," regarding notifying the licensee that retained information is subject to public disclosure and giving the licensee the opportunity to request withholding it (see IMC 0620, Section 04.06.b.).

87117-03 INSPECTION GUIDANCE

General. 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.

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.

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. The type of records that were reviewed and the time periods covered by these records should be noted in the appropriate "Basis for Findings" section(s) of the inspection record.

Retain a copy of each pertinent record that is needed to substantiate an inspection finding, such as a violation. Those copies shall be attached to the inspection record. When an inspector identifies an apparent violation, he/she 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 IMC 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 apprized of the inspection findings throughout the course of the inspection and not wait until the exit meeting.

Whenever possible the inspector should keep NRC management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection.

03.01 Preparation. Before the inspection, the inspector should do the following:

- Review the licensee's previous inspection history (at a minimum review the past two inspections), the license, and the status of any allegations or incidents. Note the licensee's commitments in response to previous violations, for follow-up during the inspection;

- Review regional event/incident logs, the docket file, and NMED to determine whether the licensee was involved in any incidents or events. If NRC did receive notification of an incident, review that incident during the inspection and document the licensee's follow-up in the inspection record;

- In the inspection record, complete the administrative information, the inspection compliance history, the listing of any license amendments or program changes since the last inspection, and the description of any incidents or events that have occurred since the last inspection;

- Determine the dates that the licensee submitted the most recent financial assurance instrument and decommissioning plan (if applicable);

- Discuss the licensee's program with previous inspector(s) and/or license reviewer(s), as necessary;

- Notify the appropriate State radiation control program personnel. State representatives should be encouraged to accompany inspectors.;

- Review pending licensing actions;

- Obtain a map of the area and/or directions;

- Make travel arrangements and prepare itinerary;

- Select calibrated instruments and perform source check;

- Select appropriate documents; and

- Select appropriate equipment to take.

In selecting the appropriate documents, the inspector should consider taking the applicable regulations, inspection record, generic communications, license, NRC forms, etc.

In selecting the appropriate equipment the inspector should consider the type of licensee to be inspected. The equipment may include safety glasses and shoes, sample vials, wipes, pocket dosimeters, alarming rate meters, etc.

During the inspection, focus (among other areas) on whether the licensee is in compliance with any license amendments issued since the last inspection or with any program changes described by the licensee since the last inspection. This requires review of documentation submitted in support of the licensing action, before the inspection. The inspection

represents NRC's first opportunity to verify whether the licensee has enacted the most recent changes to the license.

03.02 Entrance Briefing. After arriving on site, the inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. Radiopharmacies are open for business very early in the morning (e.g., 1:00 a.m.). Every effort will be made to perform the inspection during the processing of the first-run doses. This is an excellent time to observe the licensee's activities even though the pharmacy staff will be very busy and the manager may not be available. During early morning inspections , the inspector should not disrupt the flow of production, but should use this time to observe the activities of the pharmacists, drivers, dispatchers, and office personnel.

The purpose of the entrance briefing is to inform licensee management that an inspection is being conducted, and to indicate the tentative schedule for discussing or reviewing selected inspection items with various licensee staff personnel. However, in some instances, the inspector may only need to inform management of NRC's presence on site, and apprize management that an exit briefing will be conducted, at the end of the inspection, which will detail the inspection findings.

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

a. Organization. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. Determine the reporting structure among executive management, the RSO, and the other members of the staff. Determine whether the RSO has sufficient access to licensee management. Through discussions with licensee staff, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, determine whether the licensee has submitted appropriate notification to NRC. This information must be provided whenever changes in ownership or personnel are made (except for some licenses where only responsibilities are defined). Ask licensee management 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.

   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 ask licensee management and the RSO about the RSO's authority and about any changes that may impact on the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with licensee personnel, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. which cannot always be gained by reviewing records alone. This is also an opportunity for the inspector to discern the actual size and scope of the licensee's program, and to determine if significant changes in activities have occurred since the previous inspection. The information obtained should include the number of staff, number of customers served, number of doses dispensed daily, pharmacy duty hours, number and activity of generators received, etc.

c. Management Oversight. The inspection is a verification of the licensee's implementation of the required program. In the review to verify implementation,

the inspector should pay particular attention to the scope of the program; frequency of licensee audits and the use of qualified auditors; 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 verify 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 that, when deficiencies are identified, the RSO has sufficient authority, without prior management approval, 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, note that, at a minimum, licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. Typically, larger radiopharmacy licensees have a corporate radiation safety staff who conduct periodic audits covering all aspects of the licensed program. The results of all audits should be documented. 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, 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. 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)(2) 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 35.25(b), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

03.04 Walk-Through Orientation Tour. The inspector should make initial observations of licensed activities to determine that materials are being safely handled and that good health physics practices are followed. The inspector should look at areas of use, storage, and disposal to make an initial assessment of the licensee's ALARA program with regard to facility design, engineering controls, housekeeping practices, etc. In addition, observations should include dose preparation and quality control activities, package surveys before transfer to the end users, waste handling, and iodine encapsulations. The inspector should ensure that observations of activities are documented in the inspection record.

03.05 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. The actual or as-built facility should be configured to provide safe working areas separated from unrestricted areas and sufficient access controls to preclude unauthorized entry. The inspector should also be aware of potential industrial safety hazards for referral to the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA).

03.06 Equipment and Instrumentation

a. Equipment and instrumentation should be appropriate to measuring the radioactivity of radioactive drugs and be in accordance with 10 CFR 32.72(c). The inspector should verify that survey instrumentation has the appropriate range of use. The inspector should also verify that the survey instruments are calibrated at the appropriate frequency and checked for operability before use. All survey, sampling, and monitoring instruments should have current calibrations appropriate to the types and energies of radiation to be detected. The technical adequacy of calibration procedures at facilities that perform their own calibrations should be examined. Processing equipment, fume hoods, ventilation, and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use. Appropriate shielding should be available for syringes and vials, and should be appropriate for photon and beta emitters.

   The inspector should verify that dose calibrators are calibrated in accordance with procedures and at the appropriate intervals. These calibrations include linearity, geometric dependence, accuracy, and constancy tests. Appropriate performance criteria for these checks may be found in the license. If generators are used, the inspector should verify that molybdenum-99 breakthrough tests are performed on each elution in accordance with 10 CFR 30.34(g) and licensed procedures. If practical, the inspector should ask licensee representatives to demonstrate a constancy test and/or breakthrough procedure to ensure compliance with procedures.

b. Inspectors should verify that licensees have procedures for reporting defects in accordance with Part 21. The complexity of the procedures will vary.

c. Verify that the required records are maintained for instrument checks and calibrations.

03.07 Materials

a. Receipt and Transfer of Licensed Materials. Package receipt and transfer procedures will be found in the license documents. These procedures should be carefully reviewed before an inspection is conducted. By discussions with the licensee, determine if the procedures have been changed or modified. Some changes will require a license amendment, whereas other minor changes (updating telephone numbers, editing procedures for clarity, etc.) may not require NRC approval. Randomly examine procedures used by the licensee to determine if they are in accordance with those identified in the license documents, and determine whether these changes warrant a license amendment.

   The procedures for picking up, receiving, opening, and transferring packages should include how and when packages will be picked up, radiation surveys and wipe tests, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). The procedures also should include what actions are to be taken if surveys reveal packages that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected limits. The inspector should, when practical, observe personnel perform the package receipt and transfer procedures. Pick-up of customer returns should be performed according to written procedure.

   The inspector should randomly examine records of package surveys and also determine if inventories for each radionuclide are within the license limits. In this regard, records of inventories after receipt and transfer should indicate/demonstrate that the materials on hand at any one time are within the licensee's possession

limit. When practical, the records examined should be compared with a physical inventory of materials possessed.

The licensee should have a system that accounts for all licensed material. The accounting system should provide accurate information on the receipt and transfer of material, its location, the quantity used and disposed of, and the amount transferred to customers. The accounting system should also consider radioactive material held for decay-in-storage.

b. Authorized Uses. Authorized uses of licensed material will be found in the license and referenced license documents. Licenses will list the isotopes, physical or chemical forms, and the maximum possession limits. The inspector should physically examine the inventory of radioactive material on hand or examine records of receipt and transfer to determine that quantities and forms are as authorized. Additionally, the inspector should verify that the licensee's use of licensed material is limited to that which is authorized in the license.

c. Material Security and Control. Examine areas where licensed materials are used and stored. Storage areas should be locked and have limited and controlled access. Licensed material use areas should be under constant surveillance or physically secured. The licensee should have procedures for access controls. Controls may include a utilization log to indicate when licensed material is taken from and returned to storage areas. The inspector should verify that adequate controls are in place and working effectively.

03.08 Training

a. 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 documents).

Verify, pursuant to 10 CFR 19.12, that initial instructions have been given to individuals who in the course of employment are likely to receive in excess of 100 millirem (1 mSv) in a year. 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. Through interviews with employees, assess worker appreciation and knowledge of risks associated with the tasks they perform. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. One or more users of licensed materials should be interviewed to determine that they have received the required training, both in the basic instructions, and in that specified in the license application. For some licensees, this includes specific training needed to perform infrequent procedures and prepare and use licensed 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.

Randomly examine records of training of personnel and attendant examinations or tests (if applicable), to the extent that the inspector is satisfied that the training

program is being implemented as required. Where examinations are required, read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities.

The inspector should also observe related activities and discuss the radiation safety training received by selected individuals, to ensure that appropriate training was actually received by these individuals. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations. Specialized training should be provided for drivers, dispatchers, and other personnel involved in such activities as delivery of licensed material to customers, handling and processing of radioactive waste, quality control of products, and production of iodine-131 capsules.

b. 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 lower-inspection-priority licenses. The emergency procedures will be approved by NRC and reviewed and updated by the licensee. Any revision requires an amendment to the license.

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

03.09 Area Radiation and Contamination Control

a. Area Surveys. The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation. However, the inspector must use NRC's instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the regional office.)

If practical, observe how licensees conduct surveys, to determine the adequacy of surveys. Also, note the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

The inspector should determine if workers take smears or instrument readings in areas that are readily accessible to facility personnel. Particular attention should be given to counter tops, dispensing areas, desks, waste processing rooms, and storage areas. The survey activities should be at a specified frequency in accordance with the related licensee procedures. Observe how tests are analyzed and the results obtained. The inspector should also perform independent measurements, as needed, to verify licensee assumptions or measurements.

b. Leak Tests. Through discussions with licensee personnel and/or by demonstration of leak-test procedures, the inspector should verify that leak tests are performed in accordance with the manufacturer's recommendations and/or license.

c. Contamination Control. The inspector should verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination. Verify that personnel are aware of prohibitions on eating, drinking, and smoking in areas where contamination may be present. Verify that proper procedures for checking personnel contamination are observed when leaving

contaminated areas. Also, verify that waste is being disposed of in proper containers, and that mouth pipetting is not practiced. The inspector may choose to examine the instrument calibration records (efficiency checks, lower limit-of-detection calculations, geometry, linearity, etc.), physical location of counting instruments, methods of detection, and wipe-sample locations. Additionally, when appropriate, the inspector should consider taking confirmatory wipe samples.

d. Protective Clothing. If practical, the observation of the protective clothing that personnel wear during their work activities should provide the inspector with an acceptable means of reviewing this requirement. Requirements for protective clothing and other devices may be found in the licensee's procedures or on precautions posted at the entrance to controlled areas.

03.10 Radiation Protection. Specific guidance is set forth in IP 83822,"Radiation Protection." 10 CFR 19.13(b) requires that each licensee shall advise each worker, annually, of the worker's dose, as shown in dose records maintained by the licensee. Verify through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all of the information required in 10 CFR 19.13(a).

03.11 Personnel Dosimeters. Wearing dosimetry does not necessarily assure proper assessment of the highest exposure. 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. Particular attention should be given 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. The assigned dose should be based on the best available data, which may include, but are not limited to:

a. Extremity dosimetry (i.e., ring badges or fingertip badges);

b. Whole body dosimetry;

c. Survey data;

d. Correlations with other similarly employed persons for whom similar monitoring is provided;

e. Any combination of the above or other data that are appropriate for such calculations.

03.12 Waste Management

a. Waste Storage and Disposal. Verify that the waste is protected from fire and the elements, that package integrity is adequately maintained, that the storage area is properly ventilated, and that adequate controls are in effect to minimize the risk from other hazardous materials. Verify that the licensee has appropriate methods to track the items in storage.

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

or having responsibility for disposal by release into a public sanitary sewerage system.

For further inspection guidance, refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61" and IN 94-07, “Solubility Criteria for Liquid Effluent Releases to sanitary Sewerage Under the Revised 10 CFR Part 20.”

b. Effluents. Examine the radioactive material release records generated since the last inspection, all annual or semiannual reports, all pertinent non-routine event reports, and a random selection of liquid and airborne waste release records. Although radiopharmacies rarely release radioactive liquid effluents, the inspector should determine if such releases occur and whether they are in accordance with Part 20 limits.

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

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

c. Transfer. Ascertain if the licensee has an adequate method of determining that recipients of radioactive wastes are licensed to receive such waste (i.e., licensee obtains a copy of the waste recipient's current license before the transfer).

d. Records. Each licensee is required to maintain records of the disposal of licensed material made under 10 CFR 20.2002-2005, 10 CFR part 61, and disposal by burial in soil. These records must be retained until the Commission terminates each pertinent license requiring the record. The inspector should review these records to verify that disposals are made in accordance with the applicable regulations, and that records are complete and accurate for each type of disposal

e. Financial Assurance and Decommissioning. The decommissioning record- keeping 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 spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site (when contamination remains after cleanup, or when contaminates may have spread to inaccessible areas such as seepage into concrete); (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 (e.g., buried pipes); (3) except for areas with only non-leaking sealed sources or byproduct materials with half-lives of less than 65 days, a single document detailing restricted areas and formerly restricted areas, buried waste, areas requiring decontamination that are outside of restricted areas, and areas outside of restricted areas that, if the license expired, would have to be decontaminated or approved for disposal; and (4)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). On all inspections, including inspections of sealed source licensees, 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 laboratories or other 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. Inspectors should identify the rooms that have been released since the last inspection and perform confirmatory measurements 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.

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. Then during the inspection, through observations, discussions with licensee personnel, and records review, 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 immediately contact regional management, 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 10 CFR Part 30.

f. Decommissioning Timeliness. Determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, determine if the licensee has made a decision to cease principal activities at the site or in any separate building or outdoor area, including burial grounds. Finally, 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 that 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, and the inspector must complete the "Decommissioning Timeliness Inspection record," Attachment A to Appendix A.

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. However, in those cases, the inspector should follow the guidance in Section 03.11.e., above, regarding confirmatory measurements of the released area. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

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 immediately contact regional management.

For planning and conducting inspections of licensees undergoing decommissioning, refer to IMC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG 1727, "NMSS Decommissioning Standard Review Plan."

03.13 Transportation. The inspector should review: the licensee's hazardous material training; packages and associated documentation; vehicles (including placarding, cargo blocking, and bracing, etc.); shipping papers; and any incidents reported to DOT. This is an ideal area for the inspector to make observations of the licensee's drivers/couriers practices.

For further inspection guidance, 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.

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

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile licensed 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.

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

| 03.15 Generic Communications of Information. Through discussions with licensee management and the RSO, 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. Also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.

| 03.16 Notifications and Reports. The inspector should determine the licensee's compliance for notifications and reports to the Commission. For example, 10 CFR 32.72 requires the licensee to notify the Commission within 30 days of approving an ANP as user of licensed material. The licensee may be required to make notifications after loss or theft of material, overexposures, incidents, high- radiation levels, safety-related equipment failure, etc. Additionally, some licensees are required to make annual reports to NRC.

Through discussions with licensee personnel, and by a review of representative records, the inspector should verify that notifications and/or reports were appropriately submitted to NRC.

| 03.17 Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, 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 will state an exemption to a particular NRC requirement. Check if misadministrations occurred that were attributable to the pharmacy. If so, verify that appropriate corrective actions have been taken to prevent recurrence.

| 03.18 Independent and Confirmatory Measurements. The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility. Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (e.g., inspector's detection equipment malfunctions during an inspection trip). Measurements of dose rates at the boundaries of restricted areas should be performed at the surfaces of the most accessible planes. Examples of measurements that may be performed include area radiation surveys, wipe samples, soil samples, leak tests, air-flow measurements, etc. These measurements should be taken in licensed material-use areas, storage areas, effluent release points, etc. Confirmatory measurements are those whereby the inspector compares his/her measurements with those of the licensee's. Independent measurements are those performed by the inspector independently of the licensee's measurements. To perform the independent or confirmatory measurement, use NRC radiation detection equipment that is calibrated, at a minimum, on an annual basis.

| 03.19 Exit Meeting. When the inspection is over, there should be an exit meeting with the most senior licensee representative present at the facility. If a senior management representative is unavailable for the exit meeting, the inspector may hold a preliminary exit meeting with appropriate staff on site. However, there must be a formal exit meeting with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting) as soon as practical after the inspection. This meeting will usually be held by telephone conference call.

During the exit meeting, the licensee representatives should be told the preliminary
| inspection findings -- including apparent violations of regulatory requirements, safety related concerns, or unresolved items identified during the inspection -- and the status of any previously identified violations. The licensee must immediately address any significant safety concerns.

If the inspector identifies safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility, the licensee must initiate prompt corrective action. The inspector should not leave the site until the licensee fully understands the concern and has initiated corrective action. If the inspector and the licensee disagree over how significantly the concern impacts continued safe operation of the facility, regional management should be notified immediately.

Although deficiencies identified in some areas (e.g., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection record or Notice of Violation.

03.20 Post-Inspection Actions. Regional office policy will dictate with whom the inspector will review his or her inspection findings (e.g., the inspector's supervisor), following the guidance in IMC 2800, "Materials Inspection Program." The inspector should discuss the findings in the detail that is commensurate with the scope of the licensee's program. Violations, items of concern and unresolved items should be discussed in sufficient depth for management to make appropriate decisions regarding enforcement actions, referral to other State and Federal agencies, and decisions on the scheduling of future inspections of the licensee's facility.

The inspector should also discuss inspection findings with licensing staff. This information exchange can be particularly useful if the licensee is having its license renewed or has recently submitted a license amendment request. The inspector should inform licensing staff about how the licensee has addressed (or failed to address) special license amendments or recent licensing actions. Licensing information requested by the licensee should also be discussed with the licensing staff.

Inspectors should be aware that NRC has entered into several MOUs, with other Federal agencies, that outline agreements on items such as exchange of information and evidence in criminal proceedings. The inspector should ensure that the exchange of information relevant to inspection activities is made in accordance with the appropriate MOU.

The inspector may report the results of inspections to the licensee either by issuing an NRC Form 591 or a regional office letter to the licensee, following the guidance in IMC 2800. The inspector must also ensure that the findings are documented in the inspection record in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement, and when it was violated. Copies of all licensee documents needed to support the violation should be attached to the inspection record. The inspection record should not be used as merely a checklist to note areas reviewed. It should be used to describe what procedures or activities were observed and/or demonstrated by the licensee during the inspection, and any items of concern identified that were not cited as a violation of regulatory requirements.

Inspectors may complete the inspection record either by hand or electronically. If the inspector is documenting the inspection record in electronic format, the sub-items under major sections that are not applicable or not reviewed may be deleted. However, the heading itself (e.g., "Radioactive Waste Management," or "Transportation") should remain in the inspection record, and the inspector should enter appropriate remarks about why the section is not applicable or not reviewed.

For further inspection guidance, refer to Section 07.04 of IMC 2800.

87117-04 REFERENCES

A listing of IMCs and IPs applicable to the inspection program for materials licensees can be found in Section 2800-11 of 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.

Specific references to regulatory requirements can be found in Appendix B, "Radiopharmacy Inspection References," following this IP.

END

Appendices:

A. "Radiopharmacy Inspection Record"
B. “Radiopharmacy Inspection References”