INSPECTION PROCEDURE 87115

NUCLEAR MEDICINE PROGRAMS

PROGRAM APPLICABILITY: 2800

87115-01 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.

87115-02 INSPECTION REQUIREMENTS

A review of the licensed activities should be commensurate with the scope of the licensee's program. A determination regarding safety and compliance with requirements will be based on direct observation of work activities; interviews and discussions with workers and management; demonstrations by workers performing tasks regulated by NRC; and independent and confirmatory measurements of radiation conditions at the facility rather than exclusive reliance on a review of records. Under no circumstances will an NRC Inspector knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to occur or continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent and unsafe situation, direct observation of work activities should be conducted such that the inspector’s presence does not interfere with patient care or the patient’s privacy. Discussion of the inspector’s observations of work activities with the workers and interviews with the workers should not occur during the preparation for, or delivery of medical treatment. Inspector’s interviews should not be conducted in the presence of the patient.

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

Specific inspection requirements follow; however, some of the areas may not be applicable to all nuclear medicine licensees.

02.01 Preparation. Before the inspection, the inspector shall do the following:

Review the licensee's licensing history, including identifying any amendments issued since the last inspection, pending licensing actions, and whether the licensee has informed NRC of any major program changes since the last inspection.

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 the Nuclear Materials Events Database (NMED) and any regional event logs and files to determine whether the licensee was involved in any incidents, recordable events, or misadministrations. 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.

Preparation should also include determining the dates that the licensee submitted the most recent financial assurance instrument and decommissioning plan (if applicable); notifying the appropriate State radiation control program personnel; and selecting appropriate documents and equipment to take. In addition, the appropriate calibrated instruments should be selected and source checks performed on them before the inspection.

02.02 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. This notification should be made as soon as practical after arriving on site.

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 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; the Radiation Safety Officer (RSO); the Chairperson of the Radiation Safety Committee (RSC); and the other members of the RSC. Determine whether the RSO has sufficient access to licensee management. Through discussions with licensee staff and management, the inspector should determine if changes in ownership or staffing have occurred or are anticipated to occur. Confirm (to the inspector's satisfaction) with personnel that no

changes have taken place. 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.

b. Scope of Program. Interview cognizant personnel to determine the locations of use, types and quantities of licensed byproduct material used for medical uses, frequency of use, staff size, and any other factors, as necessary, to determine the scope of the licensee's operations.

If a mobile nuclear medicine program is being inspected, information concerning letters of contract with the licensee's client management should be discussed and reviewed.

Determine if the licensee conducts research involving human subjects using byproduct material. If so, verify that the licensee obtains informed consent from the human subjects and that the licensee has obtained prior review and approval of the research activities by an "Institutional Review Board."

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. In particular, the inspector should verify that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC, to implement corrective actions, including termination of operations that pose a threat to health and safety.

1. RSC - Review the committee meeting minutes for topics of discussion, membership, frequency, and attendance. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector should also review the meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness.

   The inspector should interview some RSC members to determine the depth of their involvement in the radiation safety program.

2. RSO - Determine whether the RSO has been appointed, is named on the license, has sufficient authority, and fulfills the appropriate duties commensurate with the size and scope of licensed activities. 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.

3. Audits - At a minimum, medical institution licensees are required, by 10 CFR 35.22(b)(6), to review the radiation

safety program content and implementation at least annually. Verify that audits are performed as required. Verify that the results of the audits are documented, reviewed, and addressed. 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 noncompliance with regulatory requirements.

4. ALARA (As Low As Is Reasonably Achievable) - Verify that the licensee's radiation protection program includes provisions for keeping doses ALARA and that ALARA reviews are conducted, as required by 10 CFR 35.20.

d. Authorized Individuals. Determine that only authorized individuals (users and nuclear pharmacists) perform and/or supervise licensed activities. Verify that authorized individuals perform an appropriate level of supervision, as required by 10 CFR 35.25.

02.04 Walk-Through Orientation Tour. Perform a walk-through tour of the licensed facility to make general observations of the condition of the facility and the licensed activities to determine that materials are being safely handled and that good health physics practices are followed.

02.05 Facilities. Verify that the facility conforms to that described in the license application and that material receipt, use, and storage areas are secured. Verify that the licensee uses process or other engineering controls to maintain doses ALARA and has implemented a maintenance program for the engineering controls.

02.06 Equipment and Instrumentation

a. Verify that equipment and instrumentation are appropriate, operable, properly calibrated, adequately maintained, and conform to the scope of the licensed program.

b. Verify that, if molybdenum-99/technetium-99m generators are utilized, the licensee measures the molybdenum-99 concentration of each eluate/extract used for preparing a technetium-99m radiopharmaceutical and limits usage to those eluates/extracts with <0.15 microcuries of molybdemum-99 per millicurie of technetium-99m.

c. Verify that vials and syringes are properly labeled and shielded.

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

e. If gamma-emitting unit doses supplied by a licensed radiopharmacy are used, make sure the licensee measures the activity of each syringe and compares it with the activity

marked on the syringe label before the dose is administered to a patient.

02.07 Material Use, Control, and Transfer

a. Authorized Uses. Determine, from observing the use of licensed material, discussing the activities with licensee personnel, and reviewing records of receipt and transfer, that the type, quantity, and use of licensed material at the licensee's facility are authorized by the license. To the extent practical, physically examine the licensee's inventory of radioactive material to determine if it is complete and accurate, and review the licensee's receipt and transfer records.

b. 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.

c. 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.

02.08 Training

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

Verify that authorized users and workers understand the mechanism for raising safety concerns.

Randomly examine records of training and periodic retraining 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.

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.

Examine the licensee's emergency procedures, to determine that these procedures are as approved by NRC.

Examine revised procedures. Through discussions with workers, verify that licensee personnel understand and implement the established operational and emergency procedures and are aware of procedural revisions.

c. Radiopharmaceutical Therapy Training. Verify that the licensee provides radiation safety instruction for all personnel caring for patients receiving radiopharmaceutical therapy, in accordance with 10 CFR 35.310.

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 surveys are performed, as required by 10 CFR 35.70. Verify that the licensee has established trigger levels and that the licensee decontaminates at the appropriate trigger levels.

b. Leak Tests. Verify that the procedures for and frequency of leak tests of sealed sources are in accordance with 10 CFR 35.59(b)(2). Also verify that the leak test is analyzed in accordance with the license. If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels), verify that the licensee made appropriate notifications per 10 CFR 35.59(e) and removed the source from service.

c. Contamination Control. Verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination. 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 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. Determine whether the licensee was required by 10 CFR 35.13 to apply for license amendments for any of

these changes.

c. Personnel Dosimeters. Verify that personal dosimetry devices are worn by appropriate licensee personnel. Verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program (NVLAP)-approved and accredited processor.

d. Exposure Records. Verify that, pursuant to 10 CFR 20.2106, the licensee maintains records of doses received by all individuals for whom monitoring is required.

e. Patient Release. Determine by observing, and discussing with the licensee, that a process exists to establish that a patient administered radioactive material is releasable from control under 10 CFR 35.75. Determine that written instructions are provided to released individuals on actions recommended to maintain doses ALARA, if doses to other individuals are likely to exceed 1 mSv (100 mrem). Verify that the licensee is recording: (a) the basis for release of patients, when necessary; and (b) that instructions are provided to breast-feeding women when required.

02.11 Quality Management Program (QMP) and Misadministrations

a. Written QMP. Verify that a written QMP, commensurate with the licensee's activities, has been established and implemented. Also, verify that the QMP procedures address all of the applicable modalities on the license and all of the applicable objectives set forth in 10 CFR 35.32.

b. Review. Verify that the licensee has reviewed the QMP at least annually. If the reviews indicated that changes should be made in the QMP program, verify that such modifications were made and implemented.

c. Records. Verify that records of each review are maintained in an auditable form for 3 years.

d. Misadministrations and Recordable Events. Through review of the licensee's records, determine if the licensee is in compliance with the requirements for identification, notification, reports, and records for misadministrations and recordable events in 10 CFR 35.33.

02.12 Waste Management

a. Waste Storage and Disposal. Verify that written procedures for waste storage and disposal have been established in a manner approved by management and are readily available to any persons having responsibility for low-level waste classification and preparation for transfer of such wastes to land disposal facilities. 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 10 CFR 35.92 and license conditions. Verify that the licensee is conducting appropriate surveys and defacing radioactive material labels before disposing of the waste.

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.

Review the licensee's procedures and records to verify that each shipment of radioactive waste intended for offsite disposal is accompanied by a shipment manifest that includes all the information required by Section I of Appendix F to Part 20.

Review the licensee's procedures and records to verify that each package of radioactive waste 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 [Subsection III.A.2 of Appendix F to 10 CFR 20].

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 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: (1) are within the licensee's ALARA goals (as described in its radiation protection program); (2) exceed the licensee's ALARA goals; or (3) are 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.

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.

Randomly select procedures for both liquid and airborne systems and determine the quality of the relevant procedures, determine the degree to which ALARA techniques are incorporated into them, and verify that the licensee's procedures are being followed. 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 unmonitored 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)."

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

d. Records. Review the records of waste storage, transfer, and disposal to verify that disposals are made in accordance with the requirements of Part 20 and the license, and that the records are complete and accurate for each type of disposal.

e. Financial Assurance and Decommissioning. 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. Perform confirmatory measurements to verify that radiation and contamination levels are below release limits. Document the location of the released rooms in the inspection record, and document your findings regarding the adequacy of the licensee's decontamination.

Through observations, discussions with licensee personnel, and records review, 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. If changes that may affect the financial assurance instrument or decommissioning plan are

identified, immediately contact regional management from the licensee's site, to discuss the situation.

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. On all inspections, review compliance with the Decommissioning Timeliness Rule requirements in 10 CFR 30.36(d) through (h).

02.13 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.

02.14 Posting and Labeling. Verify that the licensee has posted the appropriate license documents, regulations, notices, procedures, and forms. Examine locations where notices to workers are posted. Determine whether proper caution signs are posted at access points to areas containing radioactive materials, radiation areas, and areas containing airborne radioactive materials. Verify that containers of licensed material are labeled appropriately.

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

| 02.16 Notifications and Reports. Determine compliance with the regulations and license requirements for notification and reports to NRC and individuals. Verify that the licensee is in compliance with the requirements in 10 CFR 35.14, for medical licensees, to notify the Commission about changes in the authorized user, authorized nuclear pharmacist, or RSO.

Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually.

| 02.17 Special License Conditions. If applicable, verify that the licensee is in compliance with any special license conditions and that the licensee understands any additional requirements they impose.

| 02.18 Research Involving Human Subjects. Verify that research involving human subjects is conducted in conformity with the provisions of 10 CFR 35.6.

| 02.19 Independent and Confirmatory Measurements. Conduct independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility. 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 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.

02.20 Exit Meeting. Conduct an exit meeting with senior licensee management and the RSO to discuss the preliminary inspection findings, including any apparent violations, safety-related concerns, or any unresolved items identified during the inspection; the status of any previously identified violations; and any negative Performance Evaluation Factors (PEFs). Ensure that the licensee understands any safety significant concerns identified during the inspection and initiates prompt corrective actions.

02.21 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, to discuss the licensee's PEF results, or to give feedback on how the licensee has addressed special license amendments or recent licensing actions. This meeting shall be documented in the inspection record.

Additionally, in some instances, inspection findings will warrant communication with NRC Enforcement staff, Office of Investigations staff, State liaison staff, or other Federal agencies with whom NRC has Memoranda of Understanding (MOUs). In the latter case, ensure that the exchange of information is made in accordance with the appropriate MOU.

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 (MC) 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 MC 0620, Section 04.06.b.).

87115-03 INSPECTION GUIDANCE

General Guidance

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 will be a better indicator of the licensee's overall radiation safety program than a review of records alone. Under no circumstances will an NRC Inspector knowingly allow an unsafe work practice or a

violation which could lead to an unsafe situation to occur or continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent and unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or the patient's privacy.

When records are reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of radioactive materials, training, utilization logs, and air sampling should 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 more detail. The type of records that were reviewed and the time periods covered by these records should be noted in the inspection record.

Retain a copy of each pertinent record that is needed to substantiate an inspection finding, such as a violation. Those copies should be attached to the inspection record. When an inspector identifies an apparent violation, he/she should obtain copies from the licensee, while on site, of all records that are needed to support the apparent violation. In general, 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 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.

NOTE: In the guidance which follows, *additional items* that should be considered for review, but are not specifically mentioned in the text, are identified, where appropriate,

Specific Guidance

03.01 Preparation. Before the inspection, the inspector should discuss the licensee's program with previous inspector(s) and/or license reviewer(s), as necessary.

In selecting the appropriate documents to take on the inspection, the inspector should consider taking the applicable regulations,

inspection record, generic communications, license copy, NRC forms, etc.

In selecting the appropriate instrumentation and equipment, the inspector should consider the licensed activities to be inspected. The equipment may include sample vials, wipes, pocket dosimeters, survey 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. It is not always possible to meet with licensee management, on arrival, because of the early hours that the inspection may be conducted. In those instances, the inspector may need to inform the licensee's management of his/her presence on site after initial observations of the licensed activities have begun. Personnel involved in the entrance briefing are to be identified in the Inspection Record.

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 apprise management that an exit briefing will be conducted, at the end of the inspection, which will detail the inspection findings.

This is often an opportune time for the inspector to identify personnel to be interviewed. Scheduling interviews will enhance inspector efficiency and give the licensee the opportunity to have the most knowledgeable individuals present to respond in the areas being inspected.

Certain inspection items involving visual observations and/or records review are better performed unannounced; therefore, these types of items need not be addressed during the entrance briefing.

03.03 General Overview. Interviews of cognizant licensee representatives can provide information about the 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.
The inspector should be sensitive to changes in the organization 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. If the licensee distributes radiopharmaceuticals to several facilities, the inspector should consider the need to inspect using IP 87117,"Radiopharmacy Programs and complete IP 87117 Appendix A, Radiopharmacy Inspection record."

Additional Items:

- Mobile Nuclear Medicine Service

  (1) Administrative requirements [10 CFR 35.29]
  (2) Technical requirements [10 CFR 35.80]
  (3) Compliance with 10 CFR 20.1301 dose limits
  (4) Records of surveys

- Limited distribution of pharmaceuticals under 10 CFR Part 35 license

  (1) Type of operation

    (a) Registered or licensed with U.S. Food and Drug Administration as a drug manufacturer
    (b) Registered or licensed with State agency as a drug manufacturer
    (c) Licensed as a pharmacy by State Board of Pharmacy
    (d) Operating as a nuclear pharmacy within a Federal medical institution

  (2) Licensee distributes

    (a) Sealed sources
    (b) Alpha and beta emitters
    (c) Generators
    (d) Photon emitters

- Research involving human subjects

  (1) Research is conducted, funded, supported, or regulated by another Federal agency that has implemented "Federal Policy for Protection of Human Subjects" (as defined or described in the "Federal Policy for the Protection of Human Subjects." The licensee may affirm the use of this policy).
  OR
  Licensee has license amendment authorizing human research.

  (2) Informed consent from human subjects

(3) Approval of research activities from an Institutional Review Board or Radioactive Drug Research Committee

c. Management Oversight. The degree of management oversight can be determined by the 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. RSC [10 CFR 35.22, 35.23, 35.31, license condition (L/C)] - If an RSC is applicable to this licensee, topics of discussion at RSC meetings should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, and misadministrations and recordable events, as defined in 10 CFR 35.2.
The RSC should be aggressive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trending analyses to appropriate personnel performing licensed activities.

Additional Items:

- Membership as specified
- Meetings held quarterly
- Quorums established
- Records of meetings maintained
- Has sufficient authority
- Approve/disapprove credentials of individuals before allowing them to work as an authorized user or authorized
nuclear pharmacist

2. RSO [10 CFR 35.21, 35.23, 35.900] - The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program.

3. Audits [10 CFR 25.22, 20.1101, 20.2102; L/C] - Records should be reviewed with particular attention to deficiencies identified by the auditors and any corrective actions taken as a result of these deficiencies.

4. ALARA [10 CFR 35.20] - Medical licensees must conduct reviews to ensure that efforts are made to maintain individual and collective doses ALARA.

For additional guidance, refer to IP 87102, "Maintaining Effluents From Materials Facilities As Low As Is Reasonably Achievable (ALARA)."

d. Authorized Users. Authorized users may either be named in the license application or be appointed by the licensee, depending on the type of license issued and/or the wording in the license. For those appointed by the licensee, verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties.

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. The regulations in 10 CFR 35.11(c) allow an individual to prepare unsealed byproduct material for medical use "under the supervision of" an authorized nuclear pharmacist or authorized user. These regulations do not specifically require that the authorized user/nuclear pharmacist 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 35.25(a and b), and is responsible for the supervision of operations involving the preparation/use of radioactive materials whether he/she is present or absent.

Additional Items:

- Radiopharmacy Rule [10 CFR 35.13]

(1) Compliance is established by meeting at least one criterion under each category.

(a) Authorized user

Certified by organization in 10 CFR 35.910, 920, 930, 940, 950, 960
Identified on NRC or Agreement State license
Identified on permit issued by broad-scope licensee
Listed on facility license

(b) Authorized nuclear pharmacist

Does not apply to facilities that are registered/licensed by FDA/State Agency as a drug manufacturer and distribution is regulated under Part 32.

Certified by organization in 35.980
Identified on NRC or Agreement State license
Identified on permit issued by broad-scope licensee
Listed on facility license

(c) Radiation Safety Officer

Listed on facility license

03.04 Walk-Through Orientation Tour. The inspector should observe 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.

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.

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. When applicable, the inspector should also randomly examine signals and alarms to determine operability.

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 be aware of potential industrial safety hazards for referral to the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA).

Processing equipment, ventilation, and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use. Examination of periodic flow rate checks of ventilation and exhaust systems should be performed.

03.06 Equipment and Instrumentation

a. Dose calibrators for photon-emitting radionuclides and equipment used to assay alpha- and beta-emitting radionuclides should be possessed, used, and tested at the appropriate intervals, in accordance with 10 CFR 35.50 and 35.52, respectively, and the licensee's procedures; and appropriate actions should be taken when errors are identified. Tests to be conducted by the licensee on dose calibrators are constancy, accuracy, linearity, and geometric dependence.

   Operable survey instrumentation should be possessed and readily accessible, per 10 CFR 35.120, 35.220, 35.320, or 35.520, or available, per license conditions, to show compliance with Part 35. Survey instruments are required to be calibrated before first use, annually, and after repairs, and checked for response with a dedicated check source each day of 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.

b. Licensees that use molybdenum-99/technetium-99m generators are required to measure and record the molybdenum-99

concentration in each eluate or extract, to ensure that humans are not administered a pharmaceutical containing more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m.

c. No inspection guidance.

d. No inspection guidance.

Additional Items:

- Dose calibrator - Photon-emitting radionuclides [10 CFR 35.50, L/C]

  (1) Performed appropriate checks and tests after adjustment or repair of the dose calibrator [10 CFR 35.50(c)] .
  (2) Dosage readings over 10 μCi mathematically corrected for geometry or linearity errors greater than ±10 percent [10 CFR 35.50(d)].
  (3) Repaired or replaced when constancy or accuracy errors exceeded ±10 percent [10 CFR 35.50(d)].
  (4) Approved procedures followed [10 CFR 35.21, 35.25; L/C]
  (5) Records maintained and include identity of individual performing test [10 CFR 35.50(e)].

- Instrumentation - Alpha- or beta-emitting radionuclides

  (1) Procedures for use of instrumentation [10 CFR 35.52(b)]
  (2) Appropriate action taken when calibration errors in excess of limits are identified [L/C]
  (3) Records maintained [L/C]

- Survey instruments

  (1) Calibrated per [10 CFR 35.51, L/C]

    (a) Within 20 percent in each scale or decade of interest [10 CFR 35.51(b), L/C]
    (b) Records maintained [10 CFR 35.51(d)]

03.07 Material, Use, Control, and Transfer

a. Authorized Uses. Authorized uses of licensed material are in the licenses and license applications. Licenses list the isotopes, physical or chemical forms, and the maximum possession limits.

Additional Items:

- Licensee uses unit doses.

- Use of radiopharmaceuticals [L/C]

(1) Licensee measures activity of each dosage of photon-emitting radionuclide before use [10 CFR 35.53(a)].

(2) Licensee administers alpha- or beta- emitting radionuclides.
    (a) Licensee receives unit doses and relies on assay data supplied by manufacturer or properly licensed organization [10 CFR 35.53(b)]
    AND/OR
    (b) Licensee measures, by direct measurements or combination of measurement and calculation, each dosage of alpha- or beta-emitting radionuclide, before medical use [10 CFR 35.53(b),L/C]

(3) Unsealed material used under 10 CFR 35.100, 200, or 300:
    [10 CFR 35.100(b), 35.200(b), 35.300(b)]

    (a) Obtained from manufacturer or properly licensed organization
    AND/OR
    (b) Prepared by authorized nuclear pharmacist or physician user or individual under the supervision of an authorized nuclear pharmacist or physician user [35.920]

b. Material Security and Control. Examine areas where radioactive materials are used and stored. Storage areas should be locked and have limited and controlled access. Radioactive material use areas should be 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.

c. Receipt and Transfer of Licensed Materials. Depending on the size of the licensed program, the package receipt and transfer procedures (a few or many) will be found in the license application. These procedures should be carefully reviewed before an inspection is conducted. Procedures for transfer and shipment should include surveying all sources before shipment or transfer, transferring among the licensee's authorized users or locations, and maintaining survey and receipt/transfer records. Through discussions with the licensee, determine if the procedures are followed or 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 application, and determine whether these changes warrant a license amendment.

The procedures for picking up, receiving, and opening packages should include 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). The procedures also should include what actions are to be 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.

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 inspector should also examine the licensed materials accounting system. A relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility will need a sophisticated accounting system that 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. The accounting systems should also consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the licensee should perform routine physical audits to ensure the accuracy of the system.

Additional Items:

- Arrangements made for packages containing quantities of radioactive material in excess of Type A quantity [10 CFR 20.1906(a)]

- Package receipt/distribution activities evaluated for compliance with 10 CFR 20.1301, “Dose limits for individual members of the public.” [10 CFR 20.1302]

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 application).

Pursuant to 10 CFR 19.12, instructions must be provided to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's

responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements.

Of the training program elements in the license application, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. One or more users of radioactive materials should be observed while using licensed material or 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 radioactive material in research studies. Training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities. 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 assure that appropriate training was actually received by these individuals. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

Additional Items:

- Individual's understanding of procedures, regulations, and instructions.

  (1) Use of survey instrumentation
  (2) Manufacturer’s instructions available and followed for sealed sources [10 CFR 35.59(a)]

- Supervision of individuals by authorized user in accordance with [10 CFR 35.25]

  (1) Supervised individuals[1] are instructed in preparation of material, principles, and procedures for

[1] Applies to individuals that receive, possess, use, transfer, or prepare byproduct material for medical use under supervision of authorized user or nuclear pharmacist.

radiation safety and quality management (QM) program, as appropriate.

(2) Licensee periodically reviews supervised individuals' uses of byproduct material and records kept to reflect these uses.
(3) Authorized nuclear pharmacist or user periodically reviews work and records of work of supervised individual, as then pertain to preparing byproduct material.

- Workers cognizant of Part 20 requirements for:

(1) Radiation safety program [10 CFR 20.1101]
(2) Annual dose limits [10 CFR 20.1301, 20.1302]
(3) NRC Forms 4 and 5
(4) 10 percent monitoring threshold [10 CFR 20.1502]
(5) Declared pregnant worker provisions and dose limits to embryo/fetus [10 CFR 20.1208]
(6) Procedures for opening packages [10 CFR 20.1906]
(7) Sewer disposal limits [10 CFR 20.2003]

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. The procedures will be approved by NRC and reviewed and updated by the licensee. Minor changes in radiation safety procedures may be made in accordance with 10 CFR 35.21(b)(6), 35.22, and 35.31. Any major revisions require an amendment to the license, in accordance with 10 CFR 35.13.

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.

c. Radiopharmaceutical Therapy Training [10 CFR 35.310, L/C]. Licensees that administer radiopharmaceutical therapy must provide radiation safety instructions for all personnel caring for such therapy patients and retain records of such training for 3 years. The instructions must describe the licensee's procedures for control of patients, visitors, contamination, and waste and for notification of the RSO in case of the patient's death or medical emergency.

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.

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 released patient rooms, hot lab bench tops, sinks used for disposal, and storage areas. The survey activities should be performed in accordance with 10 CFR 35.70. Independent measurements should be performed, as needed, to verify licensee assumptions or measurements.

Additional Items:

- Surveys performed as required [10 CFR 20.1501(a), 35.70; L/C]

  (1) Daily with survey instruments in all areas where radiopharmaceuticals areprepared or administered]
  (2) Weekly with survey instruments in all areas where radiopharmaceuticals or radiopharmacy waste are stored
  (3) Survey techniques can detect 0.001 mSv/hr (0.1 mrem/hr);
  2000 dpm.
  (4) Trigger levels
  (a) Exceeded
  (b) Corrective action taken
  (5) Records maintained [10 CFR 35.70(h), 20.2103; L/C]

- Protection of members of the public

  (1) Licensee made adequate surveys to demonstrate either: (1) that the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose does not exceed 1 mSv (100 mrem) in a year; or (2) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 0.02 mSv (2 mrem) in any hour and 0.5 mSv (50 mrem) in a year [10 CFR 20.1301(a)(1), 1302(b)].
  (2) Unrestricted area radiation levels do not exceed 0.02mSv (2 mrem) in any one hour [10 CFR 20.1301(a)(2)] .
  (3) Records maintained [10 CFR 20.2103, 2107]

b. Leak Tests [10 CFR 35.59]. Through a random review of the records, the inspector should determine if records of leak tests are maintained and signed by the RSO and if an inventory of the sealed sources is performed quarterly.

c. Contamination Control. 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.

Additional Items:

- Handling and use of radioactive materials for contamination control [L/C]

  (1) Personnel routinely monitor themselves after procedures or before leaving.
  (2) No eating/drinking/smoking in use/storage areas
  (3) No food, drink, or personal effects kept in use/storage areas
  (4) Radioactive waste disposed of in proper containers
  (5) Use of shielding/distance while using/storing material

d. Protective Clothing. Observation of the protective clothing worn by nuclear medicine personnel or other applicable staff during work activities should provide the inspector with an acceptable means of reviewing this requirement. Requirements for protective clothing may be found in the licensee's procedures. Typical protective clothing may include disposable gloves, laboratory coats, eye/face shields, and shoe covers.

03.10 Radiation Protection

| a., b., and d. Specific guidance is set forth in IP 83822, "Radiation Protection."

c. Personnel Dosimeters. Dosimetry devices appropriate to the type, energy, or emitted radiation, and the anticipated radiation fields, should have been issued to facility personnel.

Additional Items:

- Licensee performed exposure evaluation [10 CFR 20.1501].
- External dosimetry

  (1) Monitoring of workers [10 CFR 20.1502(a), L/C]
  (2) External exposures account for contributions from airborne activity [10 CFR 20.1203]
  (3) Dosimeters exchanged at required frequency [L/C]

- Internal dosimetry

  (1) Monitoring of workers [10 CFR 20.1502(b), L/C]
  (2) Air sampling [L/C, 10 CFR 20.1204]
  (3) Monitoring/controlling program implemented [10 CFR 35.205, 35.315(a)]
  (4) Respiratory protection equipment [10 CFR 20.1703, L/C]

- Records

  (1) Prior dose determined for individuals likely to receive doses [10 CFR 20.2104]
  (2) Maximum exposures TEDE
  (3) Maximum committed dose equivalent (CDE)
  (4) Maximum committed effective dose equivalent (CEDE)
  (5) Licensee sums internal and external [10 CFR 20.1202]

  (6) TEDEs and total organ dose equivalents (TODEs) within limits [10 CFR 20.1201]
  (7) NRC forms or equivalent [10 CFR 20.2104(d), 20.2106(c)]

- If licensee had a declared pregnant woman during inspection period, then declaration was made in writing (review records).

  (1) Licensee in compliance with dose to embryo/fetus [10 CFR 20.1208] and records maintained [10 CFR 20.2106(e)]

e. Patient Release. The inspection of the patient release criteria is to be performance-based. The inspector should be familiar with the contents of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials." Four distinct objectives should be addressed in establishing compliance with 10 CFR 35.75.

(1) The patient release criteria permit licensees to release individuals from control if the TEDE to any other individual is not likely to exceed 5 mSv (500 mrem). The quantities of radiopharmaceuticals (dosage) administered to patients for most, if not all, diagnostic studies will deliver less than 5 mSv (500 mrem to other individuals. The licensee should be familiar with Regulatory Guide 8.39. The inspector should bring this Regulatory Guide to the attention of appropriate individuals if the licensee is not familiar with the Guide. In particular, the licensee should be familiar with the table of activities and dose rates for authorizing patient release and giving instructions. If the licensee is not using the tables in the Regulatory Guides as the basis for releasing the patient, the licensee's practices should be reviewed.

(2) The licensee should be 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 1 mSv (0.1 rem). 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 reviewing sample instructions and/or discussing the content of the instructions with applicable staff. If the licensee is

required by the rule to provide instructions to breast-feeding women, the instructions should include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance.

(3) Licensees are required to maintain, for 3 years, a record of the release if the patient's TEDE has been calculated: (1) using the retained activity rather than the activity administered, (2) using an occupancy factor less than 0.25 at 1 meter (39.4 inches): (3) using the biological or effective half-life, or (4) considering the shielding by tissue. If the licensee is not using these criteria, no record of the release is required.

(4) If the TEDE to a breast-feeding child could exceed 5 mSv (500 mrem) if the breast-feeding were continued, licensees are required to document that instructions are being provided per 10 CFR 35.75(d).

03.11 QMP and Misadministrations [10 CFR 35.32]. This guidance applies to nuclear medicine licensees who are authorized to possess and use: (1) quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; and/or (2) therapeutic quantities of radiopharmaceuticals, other than sodium iodide I-125 or I-131.

a. QMP Directives. Inspectors should observe and interview individuals as they perform applicable duties, to determine if the licensee's QMP, as implemented, effectively ensures that byproduct material will be administered as directed by the authorized user. 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.

b. Review. The frequency of the QMP review may vary. However, 10 CFR 35.32 requires that a review of the QMP be performed at intervals of no greater than 12 months. The annual review of the licensee's QMP should include: (1) a representative sample of patient (and human research) administrations; (2) all recordable events; and (3) all misadministrations.

c. Records. Records of the QMP annual review should include each written directive, a record of each administered dose or dosage, and the evaluations and findings.

d. Misadministrations and Recordable Events. If, during the inspection, a previously unidentified misadministration is identified by the inspector: (1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.33, "Notifications, reports, and records of misadministrations"; and (2) follow the procedure for reactive inspections and the guidance provided in Management Directive 8.10, "NRC Medical Event Assessment Program."

For recordable events, verify that an evaluation was performed within 30 days after discovery of a self-identified (identified by the licensee) event, and note the corrective actions that were taken. If no, or inadequate, corrective actions were taken, determine whether the lack of corrective action caused the license to be in noncompliance with regulatory requirements. If a recordable event is identified by the inspector, bring the event to the attention of the licensee. The licensee has 30 days in which to evaluate the event and take any necessary corrective action.

03.12 Waste Management

a. Waste Storage and Disposal. Generally, radionuclides used in nuclear medicine facilities have half-lives of 65 days or less and can be decayed in storage for 10 half-lives, surveyed and, when indistinguishable from background, can be disposed of as non-radioactive waste.

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 Information Notice (IN) 94-07, “Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20.”

Additional Items:

- Disposal records maintained [10 CFR 20.2103(a), 20.2108; L/C]

- Waste compacted [L/C]

- Waste storage area(s)

  (1) Containers properly labeled and area properly posted [10 CFR 20.1902, 20.1904]
  (2) Package integrity maintained [L/C]

- Packaging, Control and Tracking [App. F.III] [10 CFR 20.2006(d)]:

  Note: The licensee's waste is likely to be Class A.

  (1) Not packaged for disposal in cardboard or fiberboard boxes [10 CFR 61.56(a)]
  (2) Liquid wastes solidified (i.e., less than 1 percent freestanding liquid), and void spaces minimized [10 CFR 61.56(a), (b)]
  (3) Does not generate harmful vapors [10 CFR 61.56].
  (4) Structurally stable (will maintain its physical dimensions and form under expected disposal conditions) [10 CFR 61.56(b)] .
  (5) Packages properly labeled [10 CFR 20, App. F.III.A.2]
  (6) Licensee conducts a quality control (QC) program to ensure compliance with [10 CFR 61.55, 56] and

includes management evaluation of audits [10 CFR 20, App. F.III.A.3].

(7) Shipments not acknowledged within 20 days after transfer are investigated and reported [10 CFR 20, App. F.III.A.8].

b. Effluents. The verification of the licensee's compliance with the requirements for effluent releases and the treatment or disposal of waste can be made through observations of an operation, a review of selected records, interviews with workers, etc. The review of records should include 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 further inspection guidance, refer to IP 87102.

Additional Items:

- Release into sanitary sewer [10 CFR 20.2003]

(1) Material is readily soluble or readily dispersible [10 CFR 20.2003(a)(1)].
(2) Monthly average release concentrations do not exceed Appendix B values [10 CFR 20.2003(a)(2), 20.2003(a)(3)].
(3) No more than 5 Ci of hydrogen-3 (H-3); 1 Ci of carbon-14 (C-14); and 1 Ci of all other radionuclides combined released in a year [10 CFR 20.2003(a)(4)]
(4) Procedures to ensure representative sampling and analysis properly implemented [10 CRF 20.1501, L/C]

- Release to septic tanks [10 CFR 20.1003]

(1) Within unrestricted limits [10 CFR App B,Table 2]

- Waste incinerated [10 CFR 20.2004]

(1) License authorizes [10 CFR 20.2004(a)(3)]
(2) Licensee directly monitors exhaust.
(3) Airborne releases evaluated and controlled [10 CFR 20.1501, 20.1701]

- Control of air effluents and ashes [10 CFR 20.1201, 20.1301, 20.1501, 20.2001; L/C] {See also IP 87102, Regulatory Guide (RG) 8.37}

(1) Basis for determination of compliance with air emission requirements in Part 20:

(a) Measured concentrations of radionuclides in air effluents are below Appendix B, Table 2,

concentrations [and external dose <0.5 mSv/yr (50 mrem/yr)].

(b) Bounding calculations show that air effluents could not exceed Appendix B, Table 2, concentrations [(and external dose < 0.5 mSv/yr (50 mrem/yr)].

(c) Dose modeling shows that the TEDE to the individual member of the public likely to receive the highest dose will not exceed 0.1 mSv/yr (10 mrem/yr) from these emissions.

(d) Licensee does not possess sufficient radioactive material to exceed Part 20 requirements.

c. Transfer [10 CFR 20.2001, 20.2006]. Licensees must have 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).

Additional Items:

- Transfers to land disposal facilities

(1) Each shipment accompanied by a manifest prepared as specified in Section I of Appendix F [10 CFR 20.2006(b), 10 CFR 20, App. F.III.A.4]

(2) Manifests certified as specified in Section II of Appendix F [10 CFR 20.2006(c)]

d. Records. Each licensee is required to maintain records of the disposal of licensed material made under 10 CFR 20.2002-2005, Part 61, and disposal by burial in soil. These records must be retained until the Commission terminates each pertinent license requiring the record. For nuclear medicine waste that is decayed in storage for 10 half-lives, surveyed, and disposed of in the normal waste stream, records are required to be retained for 3 years from the date of disposal.

Additional Items:

- Records of surveys and material accountability [10 CFR 20.2103, 2108]

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 contaminants may have spread to inaccessible areas); (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; (3) except for areas with only nonleaking 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).

Some licensees, but not all, 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. 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.

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, a Certified Public Accountant should 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. If the license to conduct principal activities has expired or 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. 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.

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 03.12.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.

The Decommissioning Timeliness Rule became effective on August 15, 1994. Specific guidance regarding the timing of the notification requirements is as follows: (1) 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); or (2) 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).

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 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."

03.13 Transportation. The inspection should include a review of the licensee's compliance with transportation requirements for the quantities and types of licensed material shipped; the mode of transportation used for licensee shipments; the licensee's hazardous material training; packages and associated documentation (marking and labeling) procedures for monitoring radiation levels and contamination levels of packages; package design requirements; vehicles (including placarding, cargo blocking, and bracing, etc.); shipping papers; HAZMAT training and communication procedures; records and reports; and any incidents reported to DOT. This is an ideal area for inspector observations of licensee practices. The DOT and NRC regulations for transportation of radioactive materials

were recently revised, and the revisions generally became effective April 1, 1996.

For further inspection guidance, refer to IP 86740, "Inspection of Transportation Activities," and Temporary Instruction (TI) 2515/133, “Implementation of Revised 40 CFR Parts 100-179 and 10 CFR Part 71.” 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.

Additional Items:

- Licensee returns radiopharmacy doses

  (1) Licensee assumes shipping responsibility.
  (2) Describe arrangements made between licensee and radiopharmacy for shipping responsibilities, if licensee does not assume shipping responsibility.

- Miscellaneous Requirements

  (1) No labeled packages carried in passenger compartments [10 CFR 173.448(c)]
  (2) Overpack requirements observed, if packages are offered in overpack
  (3) Expanded and changed A1/A2 values from the April 1, 1996, rule changes have been implemented [10 CFR 173.435] (verify only once per licensee).

03.14 Posting and Labeling. 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 posting would apply.

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers, to prevent access. If volatile radioactive materials are used in an area, such an area should be controlled for airborne contamination. Exceptions to posting caution signs can be found in 10 CFR 20.1903. The inspector should randomly observe labeling on packages or other containers, to determine that proper information (e.g., radionuclide, quantity, and date of measurement) is recorded.

03.15 Generic Communications of Information. NRC generic communications often alert licensees to potential health and safety issues as a result of or the potential for an event/incident.

| 03.16 Notifications and Reports. The licensee may be required to make notifications after loss or theft of material, overexposures, incidents, high radiation levels, etc. The inspector should use discussions with licensee personnel and

reviews of representative records to verify that notifications and/or reports were appropriately submitted to NRC.

The regulations in 10 CFR 19.13(b) require that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. 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 the information required in 10 CFR 19.13(a).

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. The inspector should also note that some special license conditions will state an exemption to a particular NRC requirement.

03.18 Research Involving Human Subjects. This type of research must 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.

03.19 Independent and Confirmatory Measurements. 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. 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 boundary of the restricted areas should be performed at the surface of the most accessible plane. Examples of measurements that may be performed include area radiation surveys, wipe samples, leak tests, air flow measurements, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, etc. To perform the independent or confirmatory measurement, use NRC radiation detection instruments that are calibrated at least as frequently as required for the nuclear medicine licensee being inspected.

03.20 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 formal exit meeting may be performed by telephone

conference call. Personnel involved in the exit meeting are to be identified in the Inspection Record.

The licensee should be encouraged to respond to the PEFs of concern. For further guidance, refer to IP 87101, "Performance Evaluation Factors."

If the inspector identifies safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee's facility, the licensee must immediately address any significant safety concerns and initiate prompt corrective action. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated. 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 (NOV).

| 03.21 Post Inspection Actions. Regional office policy indicates with whom the inspector will review his or her inspection findings (e.g., the inspector's supervisor), following the guidance in MC 2800, "Materials Inspection Program." The inspector should discuss the findings in detail, commensurate with the scope of the licensee's program. Violations, items of concern (e.g., negative PEFs), 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.

Discussion of the inspection findings with licensing staff can be particularly useful if the licensee is having its license renewed or has recently submitted a license amendment request. 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 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 MC 2800 and NRC’s Enforcement Manual. The findings should be 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 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. When the inspection did not include a major section on the inspection record form, the record should include remarks about why the section was not applicable or was not reviewed.

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

87115-04 REFERENCES

Specific references to regulatory and license requirements for nuclear medicine licensees are listed in Appendix B.

A listing of MCs and IPs, applicable to the inspection program for materials licensees, can be found in Section 2800-11 of MC 2800. These documents are to be used as guidelines for inspectors in determining the inspection requirements for operational and radiological safety aspects of various types of licensee activities.

END

Appendices:

A. "Nuclear Medicine Inspection Record"
B. “Nuclear Medicine Inspection References”

APPENDIX A

NUCLEAR MEDICINE INSPECTION RECORD

Region ___

Inspection record No._____ License No. _____

Licensee (Name and Address): Docket No. _____

_____

_____

_____

Location(Authorized Site) Being Inspected:

_____

Licensee Contact: _____ Telephone No. _____

Priority: _____ Program Code: _____

Date of Last Inspection: _____
Date of This Inspection: _____

Type of Inspection:

( ) Announced ( ) Unannounced
( ) Routine ( ) Special
( ) Initial

Next Inspection Date _____ ( ) Normal ( ) Reduced ( ) Extended

Justification for change in normal inspection frequency:

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector(s) _____ Date _____
(Sign Name)

_____
(Print Name)

Approved _____ Date _____
(Sign Name)

_____
(Print Name)

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

AMENDMENT # DATE SUBJECT

2. INSPECTION AND ENFORCEMENT HISTORY:

(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

3. INCIDENT/EVENT HISTORY:
(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

PART II - INSPECTION DOCUMENTATION

* References that correspond to each inspection documentation topic are in Inspection Procedure (IP) 87115, Appendix B, "Nuclear Medicine Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all areas indicated in this part are not required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

NOTE: *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 the patient's privacy.*

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organization; authorities and responsibilities; authorized locations of use; type, quantity, and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects)

2. MANAGEMENT OVERSIGHT:
(Management support to radiation safety; Radiation Safety Committee; Radiation Safety Officer; and program audits, including as low as is reasonably achievable (ALARA) reviews)

3. FACILITIES:
(Facilities as described; uses; control of access; and engineering controls)

4. EQUIPMENT AND INSTRUMENTATION:
(Dose calibrator; instrumentation for assaying alpha- emitting and beta-emitting radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation.)

5. MATERIAL USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

6. RADIOPHARMACEUTICAL THERAPY:
(Safety precautions; surveys; and release criteria of patients and rooms)

7. QUALITY MANAGEMENT PROGRAM (QMP) AND MISADMINISTRATIONS:
(QMP - written directives, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records)

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; records; and public doses)

9. TRAINING AND INSTRUCTIONS TO WORKERS:
(Interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Part 20 requirements; therapy training and postulated emergency situations; supervision by authorized users)

10. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose records; and patient release)

11. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents and compactors; and records)

12. DECOMMISSIONING:
(Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements)

13. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; hazardous materials (HAZMAT) communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

14. NOTIFICATIONS AND REPORTS:
(Theft; loss; incidents; overexposures; change in Radiation Safety Officer (RSO), authorized user, or nuclear pharmacist; and radiation exposure reports to individuals)

15. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs) AND OTHER SAFETY ISSUES:
(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

18. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection [including those individuals contacted by telephone].)

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

19. PERFORMANCE EVALUATION FACTORS:

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight		( ) Y ( ) N
B.	RSO too busy with other assignments ( ) Y ( ) N		
C.	Insufficient staffing		( ) Y ( ) N
D.	Radiation Safety Committee (RSC) fails to meet or functions inadequately	( ) N/A	( ) Y ( ) N
E.	Inadequate consulting services or inadequate audits conducted	( ) N/A	( ) Y ( ) N

Remarks (consider the above assessment and/or other pertinent performance evaluation factors (PEFs) with regard to the licensee's oversight of the radiation safety program):

20. SPECIAL CONDITIONS OR ISSUES:
(Special license conditions)

PART III - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOW-UP ON PEFs:

2. DEBRIEF WITH REGIONAL STAFF:
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer)

END

APPENDIX B
NUCLEAR MEDICINE INSPECTION REFERENCES

1. ORGANIZATION AND SCOPE OF PROGRAM

10 CFR 35.6	Provisions for research involving human subjects.
10 CFR 35.29	Administrative requirements that apply to the provision of mobile nuclear medicine service.
10 CFR 35.80	Technical requirements that apply to the provision of mobile nuclear medicine service.

License application and applicable license conditions.

2. MANAGEMENT OVERSIGHT

A. Radiation Safety Committee

10 CFR 35.22	Radiation Safety Committee.
10 CFR 35.23	Statements of authority and responsibilities.
10 CFR 35.31	Radiation safety program changes.

Applicable license conditions.

B. Radiation Safety Officer

10 CFR 35.21	Radiation Safety Officer.
10 CFR 35.23	Statements of authority and responsibilities.
10 CFR 35.900	Radiation Safety Officer.

C. Audits, Reviews, or Inspections

10 CFR 35.22	Radiation Safety Committee.
10 CFR 20.1101	Radiation protection programs.
10 CFR 20.2102	Records of radiation protection programs.

Applicable license conditions.

D. As low as is reasonably achievable (ALARA)

10 CFR 35.20	ALARA program.

E. Authorized Users

10 CFR 35.11	License required.
10 CFR 35.13	License amendments.
10 CFR 35.25	Supervision.

Applicable license conditions.

3. FACILITIES

A. Access Control

10 CFR 20.1601	Control of access to high radiation areas.

Applicable license conditions.

B. Engineering Controls

10 CFR 20.1701 Use of process or other engineering controls.
10 CFR 35.90 Storage of volatiles and gases.
10 CFR 35.205 Control of aerosols and gases.
Applicable license conditions.

4. EQUIPMENT AND INSTRUMENTATION

A. Dose Calibrators - Photon-emitting radionuclides

10 CFR 35.50 Possession, use, calibration, and check of dose calibrators.
Applicable license conditions.

B. Instrumentation- Alpha- or beta-emitting radionuclides

10 CFR 35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.
Applicable license conditions.

C. Generators

10 CFR 35.204 Permissible molybdenum-99 concentration.

D. Syringes and Vials

10 CFR 35.60 Syringe shields and labels.
10 CFR 35.61 Vial shields and labels.

E. Survey Instruments

1. Possession

10 CFR 35.120 Possession of survey instrument.
10 CFR 35.220 Posession of survey instruments.
10 CFR 35.320 Possession of survey instruments.
10 CFR 35.520 Availability of survey instrument.
Applicable license conditions.

2. Calibration

10 CFR 35.51 Calibration and check of survey instruments.

F. Safety Component Defects

10 CFR 21.21 Notification of failure to comply or existence of a defect and its evaluation.

5. MATERIAL USE, CONTROL, AND TRANSFER

A. Authorized Uses

10 CFR 31.11 General license for use of byproduct material for certain in-vitro clinical or laboratory testing.

10 CFR 35.100	Use of unsealed byproduct material for imaging and localization studies.
10 CFR 35.200	Use of unsealed byproduct material for uptake, dilution, and excretion studies.
10 CFR 35.300	Use of unsealed byproduct material for therapeutic administration.
10 CFR 35.500	Use of sealed sources for diagnosis.
10 CFR 35.53	Measurement of dosages of unsealed byproduct material for medical use.
10 CFR 35.204	Permissible molybdenum-99 concentration.

License and applicable license conditions.

B. Security and Control

10 CFR 20.1003	Definitions (restricted area and unrestricted area).
10 CFR 20.1801	Security of stored material.
10 CFR 20.1802	Control of material not in storage.

C. Receipt and Transfer of Licensed Material

10 CFR 20.1302	Compliance with dose limits for individual members of the public.
10 CFR 20.1906	Procedures for receiving and opening packages.
10 CFR 20.1501	General.
10 CFR 20.2103	Records of surveys.
10 CFR 30.41	Transfer of byproduct material.
10 CFR 30.51	Records.

6. RADIOPHARMACEUTICAL THERAPY

10 CFR 35.75	Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.
10 CFR 35.315	Safety precautions.

Applicable license conditions.

7. QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS

10 CFR 35.2	Definitions (misadministration and recordable events).
10 CFR 35.32	Quality management program.
10 CFR 35.33	Notifications, reports, and records of misadministrations.

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

A. Area Surveys

10 CFR 20.1302	Compliance with dose limits for individual members of the public.
10 CFR 20.1501	General.
10 CFR 20.2103	Records of surveys.
10 CFR 35.70	Surveys for contamination and ambient radiation exposure rate.

Applicable license conditions.

B. Leak Tests and Inventories

10 CFR 35.59 Requirements for possession of sealed sources and brachytherapy sources.

Applicable license conditions.

9. TRAINING AND INSTRUCTIONS TO WORKERS

A. General

10 CFR 19.12 Instruction to workers.

Knowledge of 10 CFR Part 20 radiation protection procedures and requirements.

B. Specific

10 CFR 35.900	Radiation Safety Officer.
10 CFR 35.901	Training for experienced Radiation Safety Officer.
10 CFR 35.910	Training for uptake, dilution, and excretion studies.
10 CFR 35.920	Training for imaging and localization studies.
10 CFR 35.930	Training for therapeutic use of unsealed byproduct material.
10 CFR 35.932	Training for treatment of hyperthyroidism.
10 CFR 35.934	Training for treatment of thyroid carcinoma.
10 CFR 35.950	Training for use of sealed sources for diagnosis.
10 CFR 35.970	Training for experienced authorized users.
10 CFR 35.971	Physician training in a three month program.
10 CFR 35.972	Recentness of training.
10 CFR 35.980	Training for an authorized nuclear pharmacist.
10 CFR 35.981	Training for experienced nuclear pharmacists.

C. Therapy Training

10 CFR 35.310	Safety instruction.
10 CFR 35.59	Requirements for possession of sealed sources and brachytherapy sources.

D. Supervision

10 CFR 35.25 Supervision.

10. RADIATION PROTECTION

A. Radiation Protection Program

1. Exposure evaluation

10 CFR 20.1501 General.

2. Programs

10 CFR 20.1101	Radiation protection programs.
10 CFR 35.20	ALARA program.

B. Dosimetry

1. Dose Limits

10 CFR 20.1201	Occupational dose limits for adults.
10 CFR 20.1202	Compliance with requirements for summation of external and internal doses.
10 CFR 20.1207	Occupational dose limits for minors.
10 CFR 20.1208	Doses to an embryo/fetus.

2. External

10 CFR 20.1203	Determination of external dose from airborne radioactive material.
10 CFR 20.1501	General
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose.

Applicable license conditions.

3. Internal

10 CFR 20.1204	Determination of internal exposure.
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose.
10 CFR 20, Subpart H	Respiratory protection and controls to restrict internal exposure in restricted areas.
10 CFR 35.205	Control of aerosols and gases.
10 CFR 35.315	Safety precautions.

C. Records

10 CFR 20.2102	Records of radiation protection programs.
10 CFR 20.2103	Records of surveys.
10 CFR 20.2104	Determination of prior occupational dose.
10 CFR 20.2106	Records of individual monitoring results.

D. Patient Release

10 CFR 35.75	Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

11. RADIOACTIVE WASTE MANAGEMENT

A. Disposal

10 CFR 35.92	Decay-in-storage.
10 CFR 20.1904	Labeling containers.
10 CFR 20.2001	General requirements.
10 CFR 20.2103	Records of surveys.
10 CFR 20.2108	Records of waste disposal.
IN 94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20

B. Effluents

1. General

IP 87102	Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable ALARA

2. Release into sanitary sewer

10 CFR 20.2003	Disposal by release into sanitary sewerage.

Applicable license conditions.

3. Release to septic tanks

10 CFR 20.1003	Definitions.
10 CFR Part 20, App. B, Table 2	Effluent Concentrations.

4. Incineration of waste

10 CFR 20.2004	Treatment or disposal by incineration.

5. Control of air effluents and ashes

10 CFR 20.1201	Occupational dose limits for adults.
10 CFR 20.1301	Dose limits for individual members of the public.
10 CFR 20.1501	General.
10 CFR 20.1701	Use of process or other engineering controls.

Applicable license conditions.

C. Waste Management

1. General

10 CFR 20.2001	General requirements.
IP 84850	Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61

2. Waste compacted

Applicable license conditions.

3. Waste storage areas

10 CFR 20.1801	Security of stored material.
10 CFR 20.1902	Posting requirements.
10 CFR 20.1904	Labeling containers.

Applicable license conditions.

4. Packaging, Control, and Tracking

10 CFR Part 20, Appendix F	Requirements for low-level waste transfer for disposal at land disposal facilities and manifests.
10 CFR 20.2006	Transfer for disposal and manifests.
10 CFR 61.55	Waste classification.

10 CFR 61.56	Waste characterization.

5. Transfer

10 CFR Part 20, Appendix F	Requirements for low-level waste transfer for disposal at land disposal facilities and manifests.
10 CFR 20.2001	General requirements.
10 CFR 20.2006	Transfer for disposal and manifests.

6. Records

10 CFR 20.2103	Records of surveys.
10 CFR 20.2108	Records of waste disposal.

12. DECOMMISSIONING

10 CFR 30.35	Financial assurance and recordkeeping for decommissioning.
10 CFR 30.36	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.
MC 2602	Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees.
IP 87104	Decommissioning Inspection Procedure for Materials Licensees.
MC 2605	Decommissioning Procedures for Fuel Cycle and Materials Licensees.
NUREG/BR-0241	NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees.

13. TRANSPORTATION

A. General

NRC Charts	Hazard Communication for Class 7 (Radioactive) Materials.
10 CFR 71.5	Transportation of licensed material.
TI 2515/133	Implementation of Revised 49 CFR Parts 100-179 and 10 CFR Part 71.

B. Shippers - Requirements for Shipments and Packaging

1. General Requirements

49 CFR Part 173, Subpart I	Class 7 (radioactive) materials.
49 CFR 173.24	General requirements for packagings and packages.
49 CFR 173.448	General transportation requirements.
49 CFR 173.435	Table of A_1 and A_2 values for radionuclides.

2. Transport Quantities

10 CFR 71.4 Definitions.

a. All quantities

10 CFR 71.4 Definitions.

49 CFR 173.410	General design requirements.
49 CFR 173.441	Radiation level limitations.
49 CFR 173.443	Contamination control.
49 CFR 173.475	Quality control requirements prior to each shipment of Class 7 (radioactive) materials.
49 CFR 173.476	Approval of special form Class 7 (radioactive) materials.

b. Limited quantities

49 CFR 173.421	Excepted packages for limited quantities of Class 7 (radioactive) materials.
49 CFR 173.422	Additional requirements for excepted packages containing Class 7 (radioactive) materials.

c. Type A quantities

49 CFR 173.412	Additional design requirements for Type A packages.
49 CFR 173.415	Authorized Type A packages.
49 CFR 178.350	Specification 7A; general packaging, Type A.

d. Type B quantities

IP 86740, Section 2	Inspection of Transportation Activities.

e. LSA material and SCO

49 CFR 173.403	Definitions.
49 CFR 173.427	Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO).

3. HAZMAT Communication Requirements

49 CFR 172.200-205	Shipping papers.
49 CFR 172.300-338	Marking.
49 CFR 172.400-450	Labeling.
49 CFR 172.500-560	Placarding.
49 CFR 172.600-604	Emergency response information.

C. HAZMAT Training

49 CFR 172.702	Applicability and responsibility for training and testing.
49 CFR 172.704	Training requirements.

D. Transportation by Public Highway

49 CFR 171.15	Immediate notice of certain hazardous materials incidents.
49 CFR 171.16	Detailed hazardous materials incident reports.
49 CFR 177.800	Purpose and scope of this part and responsibility for compliance and training.
49 CFR 177.816	Driver training.

49 CFR 177.842	Class 7 (radioactive) material.

14. NOTIFICATIONS AND REPORTS

10 CFR 19.13	Notifications and reports to individuals.
10 CFR 20.2201	Reports of theft or loss of licensed material.
10 CFR 20.2202	Notification of incidents.
10 CFR 20.2203	Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.
10 CFR 30.50	Reporting requirements.
10 CFR 35.14	Notifications.

15. POSTING AND LABELING

10 CFR 19.11	Posting of notices to workers.
10 CFR 21.6	Posting requirements.
10 CFR 20.1902	Posting requirements.
10 CFR 20.1903	Exceptions to posting requirements.
10 CFR 20.1904	Labeling containers.
10 CFR 20.1905	Exemptions to labeling requirements.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

No references.

17. VIOLATIONS, NON-CITED VIOLATIONS AND OTHER SAFETY ISSUES

NUREG/BR-0195, Rev.1	NRC Enforcement Manual.
NUREG-1600	General Statement of Policy and Procedures for NRC Enforcement Actions.

18. PERSONNEL CONTACTED

No references.

19. PERFORMANCE EVALUATION FACTORS

IP 87101	Performance Evaluation Factors.

20. SPECIAL CONDITIONS OR ISSUES:

No references

END