INSPECTION PROCEDURE 87119

MEDICAL BROAD-SCOPE PROGRAMS

PROGRAM APPLICABILITY: 2800

87119-01 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 requirements.

87119-02 INSPECTION REQUIREMENTS

A review of the licensed activities will be commensurate with the scope of the licensee's program. A determination regarding safety and compliance with NRC requirements will be based on direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and independent measurements of radiation conditions at the facility, rather than exclusive reliance on a review of records. 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 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 from the last to the current inspections. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

Some of the following areas may not be applicable to all medical broad-scope licensees. Inspectors are also expected to exercise judgment in emphasizing or de-emphasizing areas to inspect based on information obtained in preparation of the inspection, and from conditions observed during the inspection. Not all areas specified in this procedure will necessarily be inspected during each inspection.

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

02.02 Entrance Briefing. When the inspector arrives at the licensee's facility, he/she will inform an available senior management representative of the purpose and scope of the inspection.

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.

b. Scope of Program. Interview the cognizant personnel to determine the types, quantities, and use of licensed material, frequency of use, staff size, etc.

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

    1. RSC - Review the committee meeting minutes for topics of discussion, membership, frequency, and attendance. Inspector should interview some RSC members to determine their involvement in the radiation safety program.

    2. RSO - Determine whether the RSO has been appointed; is named on the license; has sufficient authority, adequate assistance, and support of the RSC and management to ensure that radiation safety activities are performed in accordance with approved policies, procedures, and regulatory requirements; and fulfills the appropriate

duties commensurate with the size and scope of licensed activities.

3. Audits - Verify that audits are performed as required and are of sufficient detail and scope to cover all major facets of the broad- scope program. Verify that the results of the audits are reviewed and addressed.

4. Human Research Subcommittees - If licensed material is being used for human research studies, determine whether the licensee has established the appropriate committees, in accordance with the U.S. Food and Drug Administration (FDA) criteria, [e.g., Radioactive Drug Research Committee(s) (RDRCs) or Institutional Review Boards (IRBs)] to evaluate research requests. Verify that the appropriate committee has reviewed current protocols.

d. Authorized Users. Determine that only authorized individuals perform and/or supervise licensed activities. Verify that these users are qualified. Also verify that authorized users perform an appropriate level of supervision, as required by the license or regulations.

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 being performed.

02.05 Facilities. Verify that the facility conforms to that described in the license application, reflecting changes authorized by subsequent license amendments; that material receipt, use, and storage areas are secured; and that the licensee uses processes or other engineering controls to maintain doses as low as is reasonably achievable (ALARA). Verify that a maintenance program is being implemented for engineering controls (e.g. flow rates, filter changes, etc.).

02.06 Equipment and Instrumentation

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

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

02.07 Materials

a. Receipt and Transfer of Licensed Material. Verify that the licensee is receiving packages and making transfers of licensed material in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license conditions. Verify that the licensee has a system to account for all materials received, possessed, stored, and used, to ensure compliance with possession limits.

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

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

02.08 Training

a. General Training. Verify that appropriate training, both initial and refresher, as specified in the license and/or regulations, is being accomplished.

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

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

c. Specialized Training. Specialized, duty-specific training is generally required for individuals involved in such activities as radioactive waste handling and processing, incinerator operations, animal research, and individuals attending patients receiving therapeutic quantities of radioactive material. Verify through discussion, observation, and record review, that these individuals receive the appropriate training.

d. Therapy Training. Verify that the licensee provides radiation safety instruction for all personnel caring for patients receiving therapy, in accordance with 10 CFR 35.310 and 10 CFR 35.410. 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.

02.09 Area Radiation and Contamination Control

a. Area Surveys. Verify, during observations and by direct measurements, that the radiation levels are within the limits of 10 CFR Part 20, and that these areas are properly posted. Confirm that area surveys are performed in accordance with 10 CFR 35.70, where applicable, and procedures described in the license documents.

b. Leak Tests and Inventories. Verify that leak tests of sealed sources are performed at the required frequency stated in 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 performs surveys for removable contamination at the required frequencies (e.g., weekly surveys), for contamination control must be made 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 action 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, gloves, shields, etc., 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. Instruments and Equipment. Verify that radiation protection instruments and equipment are operable, have the proper alarm settings (if applicable), and are calibrated and checked for appropriate response in accordance with license requirements and licensee procedures.

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

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

e. Internal Dosimetry. Verify that measurements for internal deposition of licensed materials are performed and evaluated in accordance with license and regulatory requirements.

02.11 Quality Management Program (QMP)

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 the applicable modalities on the license and all 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 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 (medical licensees are specifically authorized to dispose of waste by decay-in-storage for waste with a half life of less than 65 days). Verify that the licensee is conducting appropriate surveys and defacing radioactive material labels before disposing of the waste.

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

Review the licensee's procedures and a representative sample of the licensee's 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 20.1001-20.2401].

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

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

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

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

Determine whether effluent monitoring systems and the associated analytical equipment are adequate to detect and quantify effluents with sufficient sensitivity, and whether they are maintained, calibrated, and operated in accordance with manufacturer's recommendations and good health physics practices.

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

Additional inspection requirements are specified in Inspection Procedure (IP) 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)."

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

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

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

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

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

f. Decommissioning Timeliness. Review compliance with the Decommissioning Timeliness Rule requirements in 10 CFR 30.36(d) through (h). This is one area of the inspection report that should be completed on all inspections. 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. If this is the case, complete in full the "Decommissioning Timeliness Inspection Attachment," Attachment A to Appendix A.

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 documents, notices, forms, and caution signs, as required. Also verify that containers of licensed material are labeled appropriately.

02.15 Generic Communications of Information. Confirm that the licensee is receiving the applicable bulletins, information notices, NMSS Licensee Newsletter, etc. 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 regarding 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.

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

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

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

02.20 Exit Meeting. The inspector will conduct an exit meeting with senior licensee management and the RSO to discuss the preliminary inspection findings. These will include any apparent violations, safety-related concerns, and any unresolved items identified during the inspection. Discuss any negative Performance Evaluation Factors (PEFs) and encourage the licensee to respond to the PEFs of concern. For further guidance, refer to IP 87101, "Performance Evaluation Factors."

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 recent licensing actions. This meeting shall be documented in the inspection report.

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

The inspector will ensure that inspection findings are clearly documented, and reported to the licensee as appropriate. The inspector shall also follow the requirements of Inspection Manual Chapter (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.).

87119-03 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, etc., will be a better indicator of the licensee's overall radiation safety program than a review of records alone.

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, observations, and demonstrations. 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 patient’s privacy.

In the records reviewed, look for trends such as increasing doses or effluent releases. Records such as surveys, waste disposal, effluent releases, receipt and transfer of licensed materials, training, utilization logs, and air sampling may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail. The type of records that were reviewed and the time periods covered by these records should be noted in the appropriate "Basis for Findings" section(s) of the inspection inspection report.

Retain a copy of each pertinent record that is needed to substantiate an inspection finding, such as a violation. Those copies shall be attached to the inspection inspection report or, when applicable, to a written inspection report. When an inspector identifies an apparent violation, he/she should gather copies from

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

The inspector should keep the licensee 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.

Specific Guidance

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

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

- Review the Nuclear Materials Events Database (NMED) and regional event/incident logs, event/incident files, and the docket file 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 report;

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

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

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

- Prepare an inspection plan;

- Notify the appropriate State radiation control program personnel;

- Review pending licensing actions;
- Obtain a map of the area and/or directions;
- Make travel arrangements and prepare itinerary;
- Select calibrated instruments and perform source check;
- Select appropriate documents; and
- Select appropriate equipment to take.

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

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

During the inspection, focus (among other areas) on whether the licensee is in compliance with any license amendments issued since the last inspection or with any program changes described by the licensee since the last inspection. This requires review of documentation submitted in support of the licensing action, before the inspection. The inspection represents NRC's first opportunity to verify whether the licensee has enacted the most recent changes to the license.

03.02 Entrance Briefing. After arriving on site, the inspector should contact the RSO or radiation safety staff to arrange an entrance briefing with licensee management. This notification should be made as soon as practical after arriving on site. However, in certain instances (e.g., unannounced inspections at hospitals, which may begin at early hours before management arrives on site) the inspector may choose to inform the licensee of his/her presence on site after initial observations of the licensed activities currently in progress.

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 should not be discussed during the entrance briefing.

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

a. Organization. The licensee's organizational structure will usually be found in the license documents. Determine the reporting structure among executive management, the RSO, the Chairperson of the RSC, and the other members of the RSC. Determine whether the RSO has sufficient access to licensee management. Through discussions with licensee staff, the inspector should determine if changes in ownership or staffing have occurred. If individuals named in the license have changed, determine whether the licensee has submitted appropriate notification to NRC. Ask licensee management if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have taken place. If there have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail.

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

b. Scope of Program. Through discussions with licensee personnel, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc., which can not always be gained by reviewing records alone. This is also an opportunity for the inspector to discern the actual size and scope of the licensee's program, and to determine if significant changes in activities have occurred since the previous inspection. To determine program scope, the information obtained should include the numbers of laboratories, permit holders, lab personnel, and locations of use; human research and medical use activities; mobile nuclear medicine services; distribution of pharmaceuticals under 10 CFR Part 35 license; and principal types and quantities of licensed materials used.

c. Management Oversight. The inspection is a verification of the licensee's implementation of the required program. In the review to verify implementation, the inspector should pay particular attention to the scope of the program; frequency of licensee audits and the use of qualified auditors; procedures for recording and reporting deficiencies to

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

1. RSC - Topics of discussion should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, reportable events, misadministrations and recordable events, as defined in 10 CFR 35.2, etc. The committee should be made up of a representative from each type of program area, the RSO, and a representative from management. The inspector should review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness. The RSC must meet at least quarterly.

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

   Broad-scope medical programs may be authorized to conduct research involving the use of radioactive drugs or radiation-emitting devices in humans. Such research may require U.S. Food and Drug Administration (FDA) approval. In addition, approval to conduct research studies also requires input from an IRB, an RDRC, or other appropriate committee(s), including the RSC. The inspector should confirm that the licensee has received FDA approval, if required, and that studies involving the use of radioactivity in humans have been reviewed by the appropriate committee(s). The inspector should review the interaction between the RSC and the IRB and/or RDRC to assure that patient safety, ethical considerations, and scientific merit are examined.

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

The RSO should be supported by a staff of health physics professionals who assist in the maintenance and control of the licensed program. The number and qualifications of these professionals will vary with the size of the program. The inspector should, through observation and interviews with staff, evaluate whether staffing appears sufficient to adequately administer the program. Any perceived deficiencies in this element should be forwarded to the inspector's management.

3. Audits - The frequency and scope of audits of the licensed program will vary. However, note that at a minimum, medical institution licensees are required by 10 CFR 20.1101(c) and 10 CFR 35.32(b)(1) to review the radiation safety program content, implementation, and QMP at least annually. The results of audits should be documented. Examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

d. Authorized Users. Authorized users of licensed material for non-human use are generally designated by the RSC. The inspector should review the process of approving users through interviews with users, RSC members, and the RSO. The procedure for designating users can be found in the license documents. Authorized users of licensed material for medical purposes and human research may either be named in the license or designated by the RSC. For those designated by the RSC, verify that the authorized user received training in accordance with approved criteria and/or Part 35, 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. These regulations do not specifically require that the authorized user be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.25(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

03.04 Walk-Through Orientation Tour. The inspector should make initial observations of licensed activities to determine that materials are being safely handled and that good health physics practices are followed. The inspector should look at areas of receipt, use, storage, and disposal to make an initial assessment of the licensee's ALARA program with regard to facility design, engineering controls, house-keeping practices, etc.

During the course of the inspection, the inspector should randomly visit a number of research laboratories to observe workers using all types and quantities of licensed material. This is an excellent time to ask workers to demonstrate certain procedures or to observe activities in an effort to evaluate the effectiveness of the licensee's training program. The inspector should ensure that observations of activities are documented in the inspection record.

03.05 Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition. The actual or as-built facility should be configured to provide safe working areas separated from unrestricted areas and sufficient access controls to preclude unauthorized entry. Describe any self-contained dry-storage or instrument calibrators. 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.

03.06 Equipment and Instrumentation

a. Equipment and instrumentation should be appropriate to the scope of the licensed program. The inspector should verify that survey instrumentation has the appropriate range of use. The inspector should also verify that the survey instruments are calibrated at the appropriate frequency and checked for operability before use. All survey, sampling, and monitoring instruments should have current calibrations appropriate to the types and energies of radiation to be detected. The technical adequacy of calibration procedures at facilities that perform their own calibrations should be examined. Processing equipment, fume hoods, ventilation, and exhaust systems should be sufficient to provide safe use, handling, and storage of the materials in use.

b. The inspector should determine if dose calibrators for photon-emitting radionuclides and equipment used to assay alpha- and beta-emitting radionuclides are 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 if appropriate actions are taken when errors are identified. Tests to be conducted on dose calibrators are linearity, geometric dependence, accuracy, and constancy. If molybdenum-99/technetium-99m generators are used, determine that each eluate/extract used for preparing a technetium-99m radiopharmaceutical has <0.15 microcuries of molybdenum-99 per millicurie of technetium-99m in accordance with 10 CFR 35.204. Also determine that vials and syringes are properly labeled and shielded per 10 CFR 35.60 and 35.61, respectively.

c. Inspectors should verify that licensees have procedures for reporting defects in accordance with 10 CFR Part 21. The complexity of the procedures will vary.

03.07 Materials

a. 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. By discussions with the licensee, determine if the procedures have been changed or modified. Some changes may 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, or if they warrant a license amendment. If procedural changes have occurred, verify that they were approved by the RSC.

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 packages that 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 perform 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 the materials possessed.

The licensee should have an accounting system that suits the type of licensed program. For example, 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 for all licensed material that provides accurate information on the receipt, 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 licensed 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.

b. Authorized Uses. Authorized uses of radioactive material will be found in the license and referenced license documents. Licenses list the isotopes, physical form, and the maximum possession limit. The inspector should physically examine the inventory of radioactive material on hand or examine records

of receipt and transfer to determine that possession limits have not been exceeded. Additionally, the inspector should verify that the licensee's use of licensed material (i.e., cell labeling, iodinations, animal research) is limited to that which is authorized in the license, and in accordance with current procedures.

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

d. Use of Pharmaceuticals. Examine the licensee's procedures for assay and use of radiopharmaceuticals, including photon-, alpha-, and beta-emitting radionuclides. Examine the methods used by the licensee to ensure the administration of the correct dosages of radiopharmaceuticals. Ensure that radioisotopes are used in research in accordance with current procedures.

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). Training and instruction should be commensurate with the potential radiological hazards involved.

Verify, pursuant to 10 CFR 19.12, that initial instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem). Under the basic instructions, it is management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements. Also verify that authorized users and workers understand the mechanism for raising safety concerns.

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 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 or in production. Note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

Randomly examine records of training of personnel and attendant examinations or tests (if applicable) to the extent that the inspector is satisfied that the training program is being implemented as required. Where examinations are required, read a few of the examination questions to ascertain that they are indicative of what the worker should know to carry out his/her responsibilities.

The inspector should also observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. Authorized users and supervised individuals should understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, and "dry runs" for more complex or hazardous operations.

b. Operating and Emergency Procedures. Operating and emergency procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures for lower-inspection-priority licenses. The emergency procedures will be approved by NRC and reviewed and updated by the licensee.

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. Specialized Training. Authorized users and research laboratory personnel should receive periodic radiation safety training commensurate with their use of licensed materials. For example, these individuals should know how and when to use radiation survey instrumentation, fume hoods, and protective gear. They should know procedures concerning waste disposal, bioassays, surveys, inventories, etc. Also, if the licensee uses licensed material for therapeutic purposes, training specific to the types of therapy performed should be provided to the nursing staff and others caring for these patients. This training should include personnel who do not directly deal with patients, such as housekeeping, maintenance, security, etc. The training should also include such topics as contamination control, ALARA, emergency procedures, and sealed source identification. The inspector should determine that personnel are appropriately trained through interviews, demonstration, and observation of licensed activities.

d. Therapy Training. Licensees that provide radiation therapy must provide radiation safety instructions for all personnel caring for such therapy patients and retain records of such training for 3 years.

03.09 Area Radiation and Contamination Control

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

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

The inspector should determine if workers take smears or instrument readings in areas that are readily accessible to facility personnel. Particular attention should be given to released patients rooms, bench tops, sinks used for disposal, and storage areas. The survey activities should be performed in accordance with 10 CFR 35.70, where applicable. The inspector should also perform independent measurements, as needed to verify licensee assumptions or measurements.

b. Leak Tests and Inventories. Through discussions with licensee personnel and/or by demonstration of leak test procedures, the inspector should verify that leak tests are performed in accordance with the manufacturer's recommendations and/or license. Verify that inventories of sealed sources are performed at the required frequency.

c. Contamination Control. The inspector should verify that the licensee's survey procedures and counting equipment are adequate to detect and control radionuclide contamination. 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. Verify that eating, drinking, and smoking are not permitted in areas where radioactive materials in any form are being used. Also verify that mouth pipetting is not practiced. Verify that personnel check for contamination on leaving these areas.

d. Protective Clothing. If practical, the observation of the protective clothing that research lab personnel or other applicable staff wear during their 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 or on precautions posted at the entrance to controlled areas.

03.10 Radiation Protection. Specific guidance for this element is set forth in IP 83822, "Radiation Protection." Additional guidance is as follows.

The inspection of the patient release criteria is to be performance-based. The inspector should be familiar with the content 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 total effective dose equivalent (TEDE) to any other individual is not likely to exceed 5 mSv (0.5 rem). The quantities of radiopharmaceuticals (dosage) administered to patients for most, if not all, diagnostic studies will deliver less than 5 mSv (0.5 rem) 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 ALARA. 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 (0.5 rem) if the breast-feeding were continued, licensees are required to document that instructions are being provided per 10 CFR 35.75(d).

Section 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose as shown in dose records

maintained by the licensee. Verify, that proper dosimetry is worn as required by license or regulations. Verify, through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of internal and external doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

03.11 QMP

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, or radiation from 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 subject administrations; (2) all recordable events; and (3) all misadministrations.

c. Records. Records of QMP annual reviews should demonstrate that each review included: (1) a representative sample of patient and human research subject administrations; (2) all recordable events; and (3) all misadministrations since the last review. The licensee should also have available for audit: (1) each written directive and a record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required (for three years after the date of administration); and (2) for each recordable event in the previous three years, the relevant facts and what corrective actions, if any, were taken.

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

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

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.”

b. Effluents. Examine the waste release records generated since the last inspection, all annual or semiannual reports, all pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records. Randomly select procedures for both liquid and airborne systems and verify that the licensee's procedures are being followed. The verification can be made by observations of an operation, a review of selected records, interviews with workers, etc.

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

For airborne radioactivity, determine if the license has identified all routes of airborne releases to the environment and complies with the regulations and all applicable license restrictions. For those licensees authorized to dispose of radioactive material by incineration, determine compliance with 10 CFR 20.2004 and license requirements.

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.

For further inspection guidance, refer to IP 87102.

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

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

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--e.g., seepage into concrete); (2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination (e.g., buried pipes); (3) except for areas with only non-leaking sealed sources or byproduct materials with half-lives of less than 65 days, a single document detailing restricted areas and formerly restricted areas, buried waste, areas, requiring decontamination, that are outside of restricted areas, and areas outside of restricted areas which, if the license expired, would have to be decontaminated or approved for disposal; and (4) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all inclusive of the information and requirements given in 10 CFR 30.35(g). On all inspections, including inspections of sealed source licensees, the inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release laboratories or other rooms within a building, or entire buildings, 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 or in other buildings on the site. Inspectors should identify the rooms that have been released since the last inspection and perform measurements (on a spot-check sampling basis, including questionable areas) to confirm that radiation and contamination levels in the rooms or areas appear to be below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records.

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

Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that the licensee has a certified public accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

f. Decommissioning Timeliness. Determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one that is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any

of the above conditions, AND, the separate building(s) or outdoor area(s) contains residual radioactivity such that the building or outdoor areas is unsuitable for release in accordance with NRC requirements, then the decommissioning timeliness requirements apply, and the inspector must complete in full the "Decommissioning Timeliness Inspection Attachment," Attachment A to Appendix A.

The requirements of 10 CFR 30.36, 40.42, and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. However, in those cases, the inspector should follow the guidance in 03.12.e. regarding confirmatory measurements of the released area. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect IF the building contains residual radioactivity such that it is unsuitable for release in accordance with NRC requirements.

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

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

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

For planning and conducting inspections of licensees undergoing decommissioning, refer to 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 Manual Chapter and Handbook Fuel Cycle and Materials Licensees.”

03.13 Transportation. The inspector should review: the licensee's hazardous material training; packages and associated documentation; vehicles (including placarding, cargo blocking, and bracing, etc.); shipping papers; and any incidents reported to DOT. This is an ideal area for the inspector to make observations of licensee practices. 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." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the NRC field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

03.14 Posting and Labeling. The inspector should determine whether proper caution signs are being used at access points to areas containing licensed materials, radiation areas, and those areas containing airborne radioactive materials. Section 20.1903 provides exceptions to posting caution signs. When applicable, the inspector should also randomly examine signals and alarms to determine operability. The inspector should also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded. If handling of potentially radioactively-contaminated objects is required to carry out this task, protective gloves should be worn.

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, controls may include tape, rope, or structural barriers to prevent access. If volatile licensed materials are used in an area, such an area should be controlled for airborne contamination. High radiation areas should be strictly controlled to prevent unauthorized or inadvertent access. Such controls may include, but are not limited to, direct surveillance, locking the high radiation area, warning lights, and audible alarms. Areas occupied by radiation workers for long periods of time and common-use areas should be controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

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

03.15 Generic Communications of Information. Through discussions with licensee management and the RSO, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, NMSS Licensee Newsletter, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. Also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.

03.16 Notifications and Reports. The inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications after loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, etc. Additionally, some licensees are required to make annual reports to NRC.

Verify, that notifications and/or reports were appropriately submitted to NRC. Through observations and discussions with licensee personnel, the inspector should gather information concerning events that were reported to NRC. The depth of onsite follow-up should be proportional to the severity of the event.

03.17 Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions will state an exemption to a particular NRC requirement.

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

03.19 Research Involving Human Subjects. This type of research must satisfy the following minimum 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 afore-mentioned Federal Policy; and (3) the licensee obtains prior review and approval from an IRB, as defined and described in the Federal Policy. For additional guidance on required associated inspection elements, see Section 03.03.c.1, "Management Oversight-RSC."

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 meeting will usually be held by telephone conference call.

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

If the inspector identifies safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility, the licensee must initiate prompt corrective action. The inspector should not leave the site until the licensee fully understands the concern and has initiated corrective action. If the inspector and the licensee disagree over how significantly the concern impacts continued safe operation of the facility, regional management should be notified immediately. Although deficiencies identified in some areas (e.g., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection record or Notice of Violation.

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

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

information requested by the licensee should also be discussed with the licensing staff.

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

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

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

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

87119-04 REFERENCES

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

Specific references to regulatory requirements can be found in the "Medical Broad-Scope Inspection References" appendix, following this IP.

END

Appendices:

A. "Medical Broad-Scope Inspection Record"

B. “Medical Broad-Scope Inspection References”

APPENDIX A

MEDICAL BROAD-SCOPE 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; program changes (including major changes in facilities, activities, procedures, or personnel) 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 87119, Appendix B, "Medical Broad-Scope 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 patient's privacy.*

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organization; authorities and responsibilities; Radiation Safety Officer (RSO), Radiation Safety Committee (RSC) chairman and members; administrative controls, procedures, and management policies; 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; RSC, RSO; and program audits, including as low as is reasonably achievable (ALARA) reviews]

3. FACILITIES:
[Facilities as described; uses; control of access; engineering controls,(e.g., ventilation, hoods, filters, etc); irradiators and survey instrument calibrators; maintenance by authorized persons]

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

5. MATERIAL RECEIPT, 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. THERAPIES:
(Safety precautions; postings; contamination control; stay times; surveys; release criteria of patients and rooms, for sealed sources and Sr-90 eye applicators use IP 87118, Appendix A Inspection Record as applicable)

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:
(Radiation and contamination surveys; air sampling; leak tests; inventories; handling of radioactive materials; protective clothing; dosimetry; 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; retraining and periodic training programs; training of ancillary personnel such as housekeeping, security, and maintenance; adequacy of training and instruction)

10. RADIATION PROTECTION:
[Radiation protection program with ALARA provisions (worker and general public external and internal exposure control; effluent control); external and internal dosimetry program; exposure evaluations; dose records and reports; 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; 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 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 (PEFs):

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.	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 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 A - ATTACHMENT A
DECOMMISSIONING TIMELINESS INSPECTION ATTACHMENT

Licensee: _____

Date of Inspection: _____

1. COMPLIANCE WITH DECOMMISSIONING TIMELINESS RULE
(NOTE: Repeat the answers given in Section 12 of the main body of the inspection record. The issues in subsequent sections are dependent on the answers to these questions.)

A. License to conduct a *principal activity* has expired or been revoked. ( ) Y ( ) N

B. Licensee has made a decision to permanently cease *principal activities*, at the entire site, or any separate buildings, or any outdoor areas, including inactive burial grounds. ( ) Y ( ) N

C. A 24-month duration has passed in which no *principal activities* have been conducted under the license at the site, or at any separate buildings, or any outdoor areas, including inactive burial grounds. ( ) Y ( ) N

D. If "Yes" to either A or B or C above:

(1) Identify Site/Bldg/Area: _____

(2) Date of occurrence of A, B, or C: _____

2. NOTIFICATION REQUIREMENTS

A. Licensee has provided written notification to U.S. Nuclear Regulatory Commission (NRC) within 60 days of the occurrence of 1.A., 1.B., or 1.C., above. ( ) Y ( ) N

If "Yes," date of notification: _____

B. If the licensee is requesting to delay initiation of the decommissioning process, the licensee has provided written notification to NRC within 30 days of occurrence of 1.A., 1.B., or 1.C.,above ( ) N/A ( ) Y ( ) N

If "Yes," date of notification: _____

Basis for Findings:

3. DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS

A. Licensee is required to submit a decommissioning plan per 10 CFR 30.36(g), 40.42(g), 70.38(g), or 10 CFR Part 72? ( ) Y ( ) N

If "No" to 3.A., answer the following items B. - F.:

B. The decommissioning work scope is covered by current license conditions. ( ) Y ( ) N

C. Decommissioning has been initiated within 60 days of notification to NRC, or NRC has granted a delay. ( ) Y ( ) N

D. If licensee has initiated decommissioning, give date the decommissioning was initiated:

Initiation date: _____

E. If decommissioning has been completed, it was completed within 24 months of notification of NRC. ( ) N/A ( ) Y ( ) N

F. If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months of notification of NRC. ( ) N/A ( ) Y ( ) N

Basis for Findings:

If "Yes" to 3.A., answer the following items G. - J.:

G. The decommissioning plan has been submitted to NRC within 12 months of notification ( ) Y ( ) N

If "Yes," date of submittal: _____

If NRC approved, date of NRC approval: _____

H. Has the licensee submitted an alternative schedule request? ( ) Y ( ) N

If "Yes," date of submittal: _____

I. If decommissioning has been completed, it was completed within 24 months after approval of the decommissioning plan ( ) N/A ( ) Y ( ) N

J. If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months after approval of the decommissioning plan. ( ) N/A ( ) Y ( ) N

Basis for Findings:

Violations identified, if any:

APPENDIX B

MEDICAL BROAD-SCOPE INSPECTION REFERENCES*

1. ORGANIZATION AND SCOPE OF PROGRAM

10 CFR 35.6 Provisions for research involving human subjects.
10 CFR 35.29 Administrative requirements - mobile nuclear medicine service.
10 CFR 35.80 Technical requirements - mobile nuclear medicine service.
License application and applicable license conditions.

2. MANAGEMENT OVERSIGHT

A. Radiation Safety Committee

10 CFR 33.13 Requirements for issuance of a Type A specific license of broad scope
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. ALARA

10 CFR 35.20 Radiation protection programs.

E. Authorized Users

10 CFR 35.11 License required.
10 CFR 35.13 License amendments.
10 CFR 35.25 Supervision.
Applicable license conditions.

* These references correspond to the sections of IP 87119, Part II of Appendix A, the "Medical Broad-Scope Inspection Record ."

3. FACILITIES

A. Access Control

10 CFR 20.1601 Control of access to high-radiation areas.
10 CFR 20.1602 Control of access to very high-radiation areas.
Applicable license conditions.

B. Engineering Controls

10 CFR 20.1701 Use of process or other engineering controls.
10 CFR 20.1702 Use of other controls
10 CFR 35.90 Storage of volatile 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 concentrations.

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 Possession 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 35.53	Measurement of dosages of unsealed byproduct material for medical use.
10 CFR 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies.
10 CFR 35.200	Use of unsealed byproduct material for imaging and localization studies.
10 CFR 35.204	Permissible molybdenum-99 concentrations.
10 CFR 35.300	Use of unsealed byproduct material for therapeutic administration.
10 CFR 35.400	Use of sources for brachytherapy.
10 CFR 35.500	Use of sealed sources for diagnosis.

.

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 20.1906	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. THERAPIES

10 CFR 35.75	Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.
10 CFR 35.315	Safety precautions.
10 CFR 35.415	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 2.01301	Dose limits for individual members of the public.
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 20.2107	Records of dose to individual members of the public.
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 35.940	Training for use of brachytherapy sources.
10 CFR 35.941	Training for ophthalmic use of strontium-90.
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 35.410	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. General

IP 83822 Radiation Protection.

B. 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.

C. 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	Dosimetry processing.
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 - radiopharmaceutical therapy.

D. 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.

E. 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 waste disposal requirements.
10 CFR 20.2005	Disposal of specific waste
10 CFR 20.2103	Records of surveys.
10 CFR 20.2108	Records of waste disposal.

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 (sanitary sewerage).
10 CFR Part 20, App. B, Table 2 Limits.

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 and 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.
10 CFR 30.41	Transfer of byproduct material

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 record-keeping 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 material.
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 of quantities.

a. All quantities

10 CFR 71.4	Definitions of quantities.
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 packages.
49 CFR 172.400-450	Labeling packages.
49 CFR 172.500-560	Placarding vehicles.
49 CFR 172.600-604	Emergency response information and guidance.

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	Responsibility for compliance and training.
49 CFR 177.816	Driver training.
49 CFR 177.842	Loading and unloading: 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 (RSO, authorized users, and nuclear pharmacists).

15. POSTING AND LABELING

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