INSPECTION PROCEDURE 87116

MEDICAL TELETHERAPY PROGRAMS

PROGRAM APPLICABILITY: 2800

87116-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers and the general public.

01.02 To determine if licensed programs are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements.

87116-02 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 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 teletherapy licensees.

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 cognizant personnel to determine the types, quantities, and use of byproduct 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, and fulfills the appropriate duties commensurate with the size and scope of licensed activities.
    3. Audits - Verify that audits are performed as required. Verify that the results of the audits are reviewed and addressed.

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 10 CFR 35.25.

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

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

02.06 Equipment and Instrumentation

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

    1. Verify that the survey instruments meet the requirements of 10 CFR 35.620, and have been calibrated per 10 CFR 35.51.

    2. Verify that the dosimetry system used to perform full calibration measurements meets the requirements of 10 CFR 35.630.

    3. Verify that the safety systems required by 10 CFR 35.615 are checked as required in 10 CFR 35.634 and 35.636.

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.

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 are authorized by the license.

    1. Verify that the teletherapy source activity does not exceed the maximum activity authorized either in the license or in the design specifications of the device’s sealed source device registration certificate.

2. Verify that the license authorizes depleted uranium shielding if used in the shielding of the teletherapy unit.

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.

d. Teletherapy Unit Inspection and Servicing. Verify that the teletherapy unit has been inspected and serviced at the frequency required under 10 CFR 35.647 and NRC Bulletin 92-02, by persons specifically licensed to do so by NRC or an Agreement State.

02.08 Training

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

b. Operating and Emergency Procedures. Verify that operational procedures are being followed by observing licensee personnel perform tasks at selected work stations and by a comparison of their activities with established procedures. Also examine the licensee's emergency procedures to determine that these procedures are as approved by NRC. These procedures are required by 10 CFR 35.610 to be posted at the teletherapy unit console. Through discussions with workers, verify that licensee personnel understand and implement the established procedures and are aware of procedural revisions. Document in the inspection record what activities the inspector observed.

Discuss with the licensee's representatives, or observe, the conduct of periodic tests and drills, especially for scenarios involving fires and stuck sources.

c. Teletherapy Physicist Training. Verify that teletherapy physicists meet the training and experience requirements of 10 CFR 35.961.

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 Part 20, and that these areas are properly posted.

b. Leak Tests. Verify that leak tests of sealed sources are performed at the required frequency found 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 the appropriate notifications per 10 CFR 35.59 (e) and removed the source from service.

c. Source Replacement Surveys. Verify that the licensee performed the surveys required in 10 CFR 35.641 after the last source replacement.

02.10 Radiation Protection

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

b. Radiation Protection Procedures. Verify that changes in the radiological protection procedures made since the last inspection are consistent with regulations and license requirements. Determine whether the licensee is 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 10 CFR 35.51, license requirements, and licensee procedures.

d. Personnel Dosimeters. Verify that personal 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."

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 of the applicable modalities on the license and all of the applicable objectives set forth in 10 CFR 35.32.

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

c. Records. Verify that records of each review are maintained in an auditable form for three 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. Transfer. Verify that replaced teletherapy sources are transferred to an authorized recipient specifically licensed to receive teletherapy sources.

b. Records. Verify that records of source transfer are maintained in accordance with the requirements of Part 20 and the license.

c. 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 rooms have been released since the last inspection. If areas have been released, verify that the licensee has adequately decontaminated each room and documented the basis for releasing each room. Document the location of the released rooms in the inspection record, and document your findings regarding the adequacy of the licensee's decontamination.

Verify whether radiological conditions at the facility have changed since the financial assurance instrument and/or decommissioning plan was submitted such that either document needs to be changed to address the new radiological conditions. Examples of changes are radiological incidents, such as process upsets. Unauthorized changes by the licensee to processes, types of licensed materials, or possession limits 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.

d. Decommissioning Timeliness. Review compliance with the Decommissioning Timeliness Rule requirements in 10 CFR 30.36(d) through (h). This is one area of the inspection record that should be completed on all inspections. If the license to conduct principal activities has expired or has been revoked; if the licensee has made a decision to permanently cease principal activities at the site or in any separate building; or if there has been a 24-month duration when no principal activities were conducted at the site or in any separate building, then the decommissioning timeliness requirements in 10 CFR 30.36, 40.42, 70.38, or Part 72 apply. If this is the case, complete in full the "Decommissioning Timeliness Inspection 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 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 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 for notification and reports to NRC and individuals. Verify that the licensee is in compliance with the requirements in 10 CFR 35.14 for medical licensees to notify the Commission about any changes in the authorized user(s) or RSO.

02.17 Special License Conditions. If applicable, review the licensee's compliance with any special license conditions, specifically those dealing with inspection of cast-iron C-arms, and restriction of occupancy in areas where dose limits to members of the public may exceed 10 CFR 20.1301.

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 record explaining why independent measurements were not performed. The inspector shall use radiation detection instruments that are calibrated, at a minimum, on an annual basis.

02.19 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, including 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 record.

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

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

87116-03 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. Records such as surveys, receipt and transfer of licensed materials, training, and utilization logs may be examined randomly until the inspector is satisfied that the records are being maintained and are complete. Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in detail. The type of records that were reviewed and the time periods covered by these records should be noted in the appropriate "Basis for Findings" section(s) of the inspection record.

Retain a copy of each pertinent record that is needed to substantiate an inspection finding, such as a violation. Those copies shall be attached to the inspection record or, when applicable, to a written inspection record. When an inspector identifies an apparent violation, he/she should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations; expedite the inspection (e.g., licensee materials inventories); or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, follow the requirements of MC 0620. Especially ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information pursuant to the requirements of 10 CFR 2.790(b)(1).

The inspector should keep the licensee apprised of the inspection findings throughout the course of the inspection and not wait until the exit meeting.

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

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

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

- Review regional event/incident logs, 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 record;

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

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

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

- Notify the appropriate State radiation control program personnel;

- Review pending licensing actions;

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

- Make travel arrangements and prepare itinerary;

- Select calibrated instruments and perform source check;

- Select appropriate documents; and

- Select appropriate equipment to take.

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

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

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

03.02 Entrance Briefing. After arriving on site, the inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This notification should be made as soon as practical after arriving on site. However, in certain instances (i.e., unannounced inspections) the inspector may choose to inform the licensee of his/her presence on site following initial observations of 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 application and may involve one or more individuals. Determine the reporting structure between 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 the owner or individuals named in the license have changed, determine whether the licensee has submitted appropriate notification to NRC. This information must be provided whenever changes in ownership or personnel named in the license are made. 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 upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with licensee personnel, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. which cannot always be gained by reviewing records alone. This is also an opportunity for the inspector

to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection.

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, audits, misadministrations, and recordable events, as defined in 10 CFR 35.2, etc. The committee should be made up of a representatives 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 committee has been aggressive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. Determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also consider the effectiveness of the RSC to communicate the results of audits and trending analyses to appropriate personnel performing licensed activities.

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.

3. Audits - The frequency and scope of audits of the licensed program will vary. However, note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. 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 (teletherapy physicians and physicists) may either be named in the license application or appointed by the licensee. For those appointed by the licensee, verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties.

The regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. 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 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. The inspector should ensure that observations of activities are documented in the inspection record.

03.05 Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition. The actual or as-built facility should be configured to provide safe working areas separated from unrestricted areas and sufficient access controls to preclude unauthorized entry. The inspector should also be aware of potential industrial safety hazards for referral to the U.S. Department of Labor's Occupational Safety and Health Administration.

For teletherapy rooms, check interlock systems, beam condition indicators, and system for continuous observation of the patient. For unit operation, check control of console keys and operation of source head in various orientations. Check any self-contained dry-source-storage irradiators and/or survey instrument calibrators.

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 found in (10 CFR 35.620). The inspector should also verify that the survey instruments are calibrated at the required frequency and checked for operability before use, in accordance with 10 CFR 35.51. All survey 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.

Inspectors should verify that the licensee has access to a dosimetry system for performing the full calibration and spot-check measurements of the teletherapy unit output. The system must be calibrated in accordance with the requirements of 10 CFR 35.630. The inspector should review a few of the dosimetry worksheets from the previous full calibration measurements required by 10 CFR 35.632. Mistakes often made when performing these calibrations are misreading of barometric pressure and using the wrong value for the chamber composition and volume. The local weather station or airport can give a good indication of the accuracy of the licensee's barometer readings in comparison to the actual air pressure. If the licensee participates in intercomparison of dosimetry measurements, review the licensee's performance results to determine that systemic measurement errors are identified and corrected.

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

c. Verify operability of permanent radiation monitors, availability of backup power supply, daily checks, service and maintenance of units, and records.

03.07 Materials

a. Receipt and Transfer of Licensed Materials. The source receipt and transfer procedures 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 will require a license amendment whereas other minor changes (updating telephone numbers, editing procedures for clarity, etc.) may not require NRC approval. Randomly examine procedures used by the licensee to determine if they are in accordance with those identified in the license application and whether any of these changes warrant a license amendment.

The procedures for receiving replacement teletherapy sources should include how and when they will be picked up, radiation surveys and wipe tests of source containers to be done upon receipt, and procedures for opening source containers (such as the location in the facility where they are received, surveyed, and opened). The procedures also should include what actions are to be taken if surveys reveal source

containers that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If replacement sources arrive during the course of an inspection, the inspector should observe, when practical, personnel perform the receipt surveys.

b. Authorized Uses. The inspector should verify that the licensee's use of byproduct material is limited to that which is authorized in the license. Uses of teletherapy units for other than human use would require the licensee to comply with 10 CFR Part 36.

c. Material Security and Control. The teletherapy suite should be under constant surveillance or physically secured. The licensee should have procedures for access controls. The inspector should verify that adequate controls are in place and working effectively.

The key to the teletherapy unit console is often left in the console over the course of the day. Interview the operators to determine their normal control of the console key during the periods that they are away from the console.

d. Teletherapy Unit Inspection, Servicing, Calibration and Spot Checks. Visually inspect the control console and unit for indications that alterations have been performed by unauthorized persons. These indications include off-the-shelf switches and timers, as well as wire jumpers and taped micro switches to bypass safety systems of the unit. The inspector should ask the licensee to demonstrate that stops and electronic controls used to limit the orientation of the head are operational.

Verify that proper calibration procedures are used for calibrating the teletherapy unit; the unit is calibrated at the required intervals (not to exceed 1 year); and before to first patient use and after source exchange, relocation, and major repair or modification. The calibration should include all items listed in 10 CFR 35.632. Verify that spot checks are conducted at the required frequency, and as required by 10 CFR 35.634.

If the unit is a Theratron-60 or Theratron-80 with a cast-iron arm, the licensee was required by NRC Bulletin 92-02, to commit to perform the special inspections per Theratronic's revised "Survey and Inspection I 1024 G091G10 REV C."

If the unit is a Picker model C-9 or an Advanced Medical System (AMS) model C-9, be aware that a generic malfunction of the source retraction mechanism had been identified as described in Information Notice 99-27.

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).

Verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). 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. 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 personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

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. The emergency procedures will be approved by NRC and reviewed and updated by the licensee. These procedures are required by regulation and license condition to be posted at the teletherapy unit console. Any non-ministerial revision requires an amendment to the license. Interview the operators of the unit to determine that actions required to be

performed in the event of abnormal operation of the device are known.

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. Teletherapy Physicist Training. The inspector should verify that the teletherapy physicist(s) meet(s) the certification requirement or educa-tion and work experience requirement, in accordance with 10 CFR 35.961.

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. When measuring dose rates near a teletherapy unit head, the inspector should not use an open window Geiger-Muller tube, because the depleted uranium used in the trimmer bars, collimators, and shielding is a beta emitter that will cause the survey instrument to give a faulty measurement. The survey activities should be at a specified frequency, in accordance with the related licensee procedures. The inspector should also perform independent measurements, as needed to verify licensee assumptions or measurements.

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

c. Source Replacement Surveys. Verify by direct measurement that shielding surveys of the unit head and treatment room are in compliance with the requirements of 10 CFR 35.641. Indications of higher than expected dose levels may indicate that the source is a higher activity than authorized or that the source is not fully shielded on retraction.

03.10 Radiation Protection. Specific guidance is set forth in IP 83822, "Radiation Protection."

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

maintained by the licensee. Verify through discussions with workers and management, and through records review, that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required (and, therefore, dose records are required). The licensee must advise these workers of 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 Quality Management Program (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 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 twelve months. The annual review of the licensee's QMP should include: (1) a representative sample of patient (and human research) administrations; (2) all recordable events; and (3) all misadministrations.

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

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

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

03.12 Waste Management

a. Transfer. Ascertain if the licensee has an adequate method of determining that recipients of replaced sources are licensed to receive them. Ordinarily this is not a concern because sources are replaced by a service company authorized by NRC or an Agreement State.

b. Records. Each licensee is required to maintain records of transfer in accordance with the requirements of 10 CFR 30.51. The inspector should review these records as appropriate.

c. 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 unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; (2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and (3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. Inspectors should identify the rooms that have been released since the last inspection and perform confirmatory measurements to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records.

Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify NRC. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to NRC. Then during the

inspection, through observations, discussions with licensee personnel, and records review, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to NRC. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should immediately contact regional management from the licensee's site to discuss the situation.

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

d. 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 which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply, 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 Section 03.12.c, regarding confirmatory measurements of the released area. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The Decommissioning Timeliness Rule became effective on August 15, 1994. In completing the Attachment A inspection record, 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 (failure to notify NRC, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may be classified as a Severity Level III violation and may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

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

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

03.13 Transportation. The 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. The DOT and NRC regulations for transportation of radioactive materials were recently revised, and the revisions generally became effective April 1, 1996. However, this area is not a concern for most teletherapy licensees because most of them are not authorized to perform these operations.

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 radioactive materials and radiation areas. Section 20.1903 provides exceptions to posting caution signs. The inspector should also randomly examine signals and alarms to determine operability.

Areas with radiation hazards should be conspicuously posted, as required by 10 CFR 20.1902. 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. Many licenses have received exemptions from the requirement to post the treatment room with the sign "GRAVE DANGER, VERY HIGH RADIATION AREA," required by 10 CFR 20.1902, because of its unsettling effect. This exemption will be noted in the license. 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.

Verify that emergency procedures are posted at the control console.

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

03.16 Notifications and Reports. The inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, misadministrations, and recordable events, etc.

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

03.17 Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of teletherapy equipment for nonmedical purposes. 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 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, leak tests, etc. These measurements should be taken in licensed material use areas, storage areas, 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 conditions: (1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" [10 CFR 35.6], or the licensee is authorized to conduct such research; (2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and (3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.20 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 of the preliminary inspection findings--including any negative PEFs, any 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 the 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 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 inspectors 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 and/or 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 and/or inspection record. The inspection record should not be used as merely a checklist to note areas reviewed, but 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.

87116-04 REFERENCES

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

Specific references to regulatory requirements can be located in the "Medical Teletherapy Inspection References" appendix to this IP.

END

Appendices:

A. "Medical Teletherapy Inspection Record"

B. “Medical Teletherapy Inspection References”

APPENDIX A

MEDICAL TELETHERAPY INSPECTION RECORD

Region ___

Inspection record No._____ License No. _____

Licensee (Name & 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 Nuclear Regulatory Commission Form 591 or regional letter issued
( ) Non-cited violations
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector(s) _____ Date _____
(Sign Name)

_____
(Print Name)

Approved _____ Date _____
(Sign Name)

_____
(Print Name)

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

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

AMENDMENT #	DATE	SUBJECT

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.)

3. INCIDENT/EVENT HISTORY:
(List any incidents or events 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 87116, Appendix B, “Medical Teletherapy Inspection References.”

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during <u>each</u> inspection. However, for those areas <u>not covered</u> 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. <u>ORGANIZATION AND SCOPE OF PROGRAM:</u>
(Management organizational structure; Radiation Safety Officer (RSO) and chairman of Radiation Safety Committee (RSC); authorized locations of use; type, quantity, and frequency of byproduct material use)

2. <u>MANAGEMENT OVERSIGHT</u>:
(Management support to radiation safety; RSC; RSO; program audits or inspections; as low as is reasonably achievable (ALARA) reviews; control and supervision by authorized users)

3. FACILITIES:
(Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding; interlock systems; maintenance by authorized persons)

4. EQUIPMENT AND INSTRUMENTATION:
(Operable and calibrated survey instruments and dosimetry; procedures; 10 CFR Part 21 procedures; calibration records; fixed radiation monitors)

5. TELETHERAPY FULL CALIBRATION:
(Proper procedures and calibration intervals; spot checks; output measurements; field checks; decay corrections; records)

6. TELETHERAPY SPOT CHECKS:
(Proper check frequency; acceptance criteria; safety checks; repair history and records)

7. TELETHERAPY SERVICING:
(Proper service intervals and criteria; authorized service personnel)

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

9. AREA RADIATION SURVEYS :
(Radiological survey locations and frequencies; leak tests; inventories; handling of radioactive materials; records and reports; public doses)

10. TRAINING AND INSTRUCTIONS TO WORKERS:
(Training and retraining requirements for authorized users, physicists, and operators; documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency response; use and supervision by authorized users)

11. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; access control; dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

12. QUALITY MANAGEMENT PROGRAM, MISADMINISTRATIONS, AND REPORTABLE EVENTS:
(Verify quality management program administration and records and reports of misadministrations and events)

13. WASTE MANAGEMENT AND DECOMMISSIONING:
(Waste Records should be considered under Section 8. Transfer; Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

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

15. NOTIFICATIONS AND REPORTS:
(Overexposure and misadministration reports; administrative changes in RSO, authorized users, and physicist; reports to individuals)

16. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; area postings; and labeling of containers of licensed material)

17. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas, both restricted and unrestricted, surveyed and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

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

19. 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

20. PERFORMANCE EVALUATION FACTORS:

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

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

21. 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

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. 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 to 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 to 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 TELETHERAPY INSPECTION REFERENCES

1. ORGANIZATION AND SCOPE OF PROGRAM

License application and applicable license conditions.

2. MANAGEMENT OVERSIGHT

A. Radiation safety Committee

10 CFR 35.22 Radiation Safety Committee.
10 CFR 35.23 Statements of authority and responsibilities.
Applicable license conditions.

B. Radiation Safety Officer

10 CFR 35.21 Radiation Safety Officer.
10 CFR 35.23 Statements of authority and responsibilities.
Applicable license conditions.

C. Audits, Reviews, or Inspections

10 CFR 20.1101 Radiation protection programs.
10 CFR 20.2102 Records of radiation protection programs.
10 CFR 35.22 Radiation Safety Committee.
10 CFR 35.32 Quality management program.
Applicable license conditions.

D. ALARA

10 CFR 20.1101 Radiation protection programs.
10 CFR 35.20 ALARA program.
Applicable license conditions.

E. Authorized Users

10 CFR 35.22 Radiation Safety Committee.
10 CFR 35.960 Training for teletherapy.
10 CFR 35.961 Training for teletherapy physicist.
Applicable license conditions.

3. FACILITIES

A. Access Control

10 CFR 20.1601,1602 Control of access to high/very high radiation areas.
10 CFR 20.1801 Security of stored material.
10 CFR 20.1802 Control of material not in storage.
10 CFR 35.615 Safety precautions.
Applicable license conditions.

B. Engineering Controls

10 CFR 20.1101 Radiation protection programs.
Applicable license conditions.

4. EQUIPMENT AND INSTRUMENTATION

A. Survey Instruments and Dosimetry

10 CFR 20.1501 General.
10 CFR 20.2103 Records of surveys.
10 CFR 35.615 Safety precautions.
10 CFR 35.620 Possession of survey instruments.
10 CFR 35.630 Dosimetry equipment.
Applicable license conditions.

B. Safety Component Defects

Applicable license conditions.

5. TELETHERAPY FULL CALIBRATION

10 CFR 35.632 Full cailbration measurements.

6. TELETHERAPY SPOT CHECK

10 CFR 35.634 Periodic spot-checks.
10 CFR 35.636 Safety checks for teletherapy facilities.

7. TELETHERAPY SERVICING

10 CFR 35.605 Maintenance and repair restrictions.
10 CFR 35.647 Five-year inspection.

8. MATERIAL USE, CONTROL, AND TRANSFER

A. 10 CFR 35.600 Use of a sealed source in a teletherapy unit.
License and applicable license conditions.

B. Security and Control

10 CFR 20.1003 Definitions.
10 CFR 20.1801 Security of stored material.
10 CFR 20.1802 Control of material not in storage.

C. Receipt and Transfer of Licensed Material

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

9. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

A. Area Surveys

10 CFR 20.1302	Compliance with dose limits for individual members of the public.
10 CFR 20.1501	General.
10 CFR 20.2103	Records of surveys.
10 CFR 20.2107	Records of dose to individual members of the public.
10 CFR 35.51	Calibration and check of survey instruments.
10 CFR 35.620	Possession of survey instruments.
10 CFR 35.641	Radiation surveys for teletherapy facilities.
10 CFR 35.645	Reports of teletherapy surveys, checks, tests, and measurements.

Applicable license conditions.

B. Leak Tests and Inventories

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

Applicable license conditions.

10. TRAINING AND INSTRUCTIONS TO WORKERS

General

10 CFR 19.12	Instruction to workers.
10 CFR 35.25	Supervision.
10 CFR 35.610	Safety instruction.
10 CFR 35.960	Training for teletherapy.
10 CFR 35.961	Training for teletherapy physicist.
10 CFR 35.970	Training for experienced authorized user.

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

11. RADIATION PROTECTION

A. Radiation Protection Program

1. Exposure evaluation.

10 CFR 20.1501	General.

2. Programs .

10 CFR 20.1101	Radiation protection programs.
10 CFR 35.31	Radiation safety program changes.

B. Dosimetry

1. Dose Limits.

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

2. External.

10 CFR 20.1501	General.
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose.

Applicable license conditions.

C. Records

10 CFR 19.13	Reports to workers.
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.

12. QUALITY MANAGEMENT PROGRAM, MISADMINISTRATIONS, EVENTS

10 CFR 35.02	Definitions.
10 CFR 35.32	Quality management program.
10 CFR 35.33	Notifications, reports, and records of misadministrations.

13. WASTE MANAGEMENT AND DECOMMISSIONING

10 CFR 30.41	Transfer of byproduct material.
10 CFR 30.51	Records of receipt and transfer.
10 CFR 30.36	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.
IMC 2602	Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees.
IP 87104	Decommissioning Inspection Procedure for Materials Licensees.
IMC 2605	Decommissioning Procedures for Fuel Cycle and Materials Licensees.
NUREG/BR-0241	NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees.

14. TRANSPORTATION

A. General

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

B. Shippers - Requirements for Shipments and Packaging

1. General Requirements.

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

2. Transport Quantities.

10 CFR 71.4 Definitions.

a. All quantities.

10 CFR 71.4	Definitions.
49 CFR 173.410	General design requirements.
49 CFR 173.441	Radiation level limitations.
49 CFR 173.443	Contamination control.
49 CFR 173.475	Quality control requirements prior to each shipment of Class 7 (radioactive) materials.
49 CFR 173.476	Approval of special form Class 7 (radioactive) materials.

b. Limited quantities.

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

c. Type A quantities.

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

d. Type B quantities.

IP 86740, Section 2	Inspection of transportation activities.

e. LSA material and SCO.

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

3. HAZMAT Communication Requirements.

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

C. HAZMAT Training

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

D. Transportation by Public Highway

49 CFR 171.15	Immediate notice of certain hazardous materials incidents.
49 CFR 171.16	Detailed hazardous materials incident reports.
49 CFR 177.800	Purpose and scope of this part and responsibility for compliance and training.
49 CFR 177.816	Driver training.
49 CFR 177.842	Class 7 (radioactive) material.

15. 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.
10 CFR 35.33	Notifications, reports, and records of misadministrations.

16. POSTING AND LABELING

10 CFR 19.11	Posting of notices to workers.
10 CFR 21.6	Posting requirements.
10 CFR 20.1902	Posting requirements.
10 CFR 20.1903	Exemptions to posting requirements.
10 CFR 20.1904	Labeling containers.
10 CFR 20.1905	Exemptions to labeling requirements.
10 CFR 35.610	Safety instruction.

17. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

No references.

18. 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.

19. PERSONNEL CONTACTED

No references.

20. PERFORMANCE EVALUATION FACTORS

IP 87101 Performance Evaluation Factors.

21. SPECIAL CONDITIONS OR ISSUES

No references.

END