INSPECTION PROCEDURE 87118

BRACHYTHERAPY PROGRAMS

PROGRAM APPLICABILITY: 2800

87118-01 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.

87118-02 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, non-compliance, or high radiation exposures.

This inspection procedure is applicable to all forms of brachytherapy (temporary and permanent implants, remote afterloaders, eye applicators and plaques, etc.). However, all the following areas may not be applicable to each brachytherapy program.

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. For brachytherapy program inspections, it is not always practical to meet with licensee management, on arrival, because of the early hours during which the inspection may be conducted. However the entrance briefing should be conducted as soon as practicable.

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 licensed material, frequency of use, staff size, etc. Determine if the licensee has multiple places of use, especially for licensees with remote afterloaders, and verify that all locations are authorized by the license. If warranted, consider performing inspections at all sites of use.

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 - If the licensee is required to have an RSC, review the committee meeting minutes for topics of discussion, membership, frequency, and attendance. The inspector should interview some members of the RSC to determine their involvement in the radiation safety program. For

licensees with remote afterloaders, verify that the RSC: (1) has approved any afterloaders currently in use; (2) reviews the use of afterloaders at each quarterly RSC meeting; (3) reviews the remote afterloader program during annual audits of the as low as is reasonably achievable (ALARA) program; and (4) implements corrective actions recommended for deficiencies noted during audits.

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 qualified, authorized individuals perform and/or supervise licensed activities. Verify that authorized users of brachytherapy sources perform an appropriate level of supervision, as required by 10 CFR 35.25. Verify that remote afterloaders are used by or under the direct supervision of an authorized user. See Section 02.09 b. and c. for supervisory responsibilities of authorized users during remote afterloader use.

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

a. Requirements for All Brachytherapy Licensees. 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 ALARA.

b. Additional Requirements for Licensees with Remote Afterloaders. Verify that unauthorized individuals are prevented from entering the use area, that the device and all associated sources are stored against unauthorized use or removal, and that the console keys are inaccessible to unauthorized persons. Also, if other radiation-producing devices are located within the treatment room, ensure that only one device can be placed in operation at a time.

c. Additional Requirements for Licensees with High-, Medium-, and Pulsed-Dose- Rate Remote Afterloaders. Verify that use of the afterloaders is limited to the areas approved by the license. Determine whether each dedicated treatment room is equipped with a continuous viewing and intercom system to allow for patient observation and communication during treatment. Verify that these systems are checked for operation at the beginning of each day of use, and that either a backup system is available or the licensee suspends further treatments if the primary system requires repairs.

Verify that electrical interlock systems are installed and operational at each entry. The activation of the interlock will result in the source automatically being retracted. Also verify that, once activated, the automatic interlock must be reset before the afterloading device can be activated. Determine whether interlocks are tested daily for proper operation, and whether records verifying interlock operation are maintained for 3 years.

d. Additional Requirements for Licensees with Low-Dose-Rate-Remote Afterloaders. Verify that such devices are only used in locations (rooms) within a single building that are approved by the license and that the licensee possesses and uses either fixed or portable shields during procedures. Determine whether the licensee has the capability to monitor the patient and device during treatment to ensure that the sources and catheter guide tubes are not disturbed during treatment/use.

02.06 Equipment and Instrumentation

a. Verify that equipment and instrumentation are appropriate, operable, calibrated, adequately maintained, and conforming to descriptions in the license and 10 CFR Part 35.

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.

c. Additional Requirements for Licensees with Remote Afterloaders. Verify that the licensee has only used the remote afterloader authorized by the license. Verify that: (1) the backup battery for the remote afterloader is tested monthly, in accordance with the manufacturer's instructions to verify emergency source retraction capability, upon power failure; and (2) the source position indicators are checked periodically, using a dedicated check source or the afterloader's source, to verify proper operation and accuracy.

Only persons licensed by NRC or an Agreement State may perform maintenance, repair, and inspection on remote afterloaders. Verify that each afterloader is fully inspected and serviced at intervals not to exceed 1 year, to ensure proper function of the device and to ensure that scheduled service recommended by the manufacturer has been performed in accordance with the manufacturer's instructions.

Verify that the licensee has implemented a calibration program for its remote afterloaders. Calibrations are to be performed by the authorized physicist or other individual specified in the license application either by name or by training and experience. Verify that these calibrations are performed following installation of a new source, before patient

treatment is resumed, and monthly thereafter. Also verify that the dosimetry system used to perform calibration measurements has been calibrated by the National Institute of Standards and Technology, or by a calibration laboratory accredited by the American Association of Physicists in Medicine, within the previous 2 years and after any servicing that may have affected system calibration.

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.

c. Inventories. Verify that the licensee is conducting inventories of all sealed sources and brachytherapy sources, in accordance with 10 CFR 35.59 and 35.406. To the extent practical, assure, by physical confirmation, that the licensee's inventory is complete and accurate and that inventory records are maintained as required.

d. 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.

e. Additional Requirements for Licensees with Remote Afterloaders. Verify that only those sources approved by the license are possessed by the licensee. Sources used in afterloaders are to be checked by the licensee for source homogeneity before being used for patient treatments. The sources are also to be leak-tested at intervals not to exceed 6 months. Inventories of all sources, including those in use, in storage, and (any depleted uranium) in shielding, must be conducted quarterly. Verify that installation and/or replacement of sealed sources contained in remote afterloaders is only performed by persons specifically authorized by NRC or an Agreement State.

02.08 Training

a. General Training. Verify that appropriate training and initial instructions are being provided to personnel as

specified in the license and as required by 10 CFR 19.12 and 35.410.

b. Operating Procedures. Verify that licensee personnel are aware of operating procedures by observing personnel perform tasks at selected work stations and by a comparison of their activities with established procedures.

c. Emergency Procedures. Through discussions with workers, verify that licensee personnel understand and implement the established emergency 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 (for the higher-priority licensees), the conduct of periodic tests and drills, especially for scenarios involving fires and incidents involving device failures or loss of sources.

d. Safety Instruction. Verify that the licensee is providing and documenting radiation safety instructions, in accordance with 10 CFR 35.410, for all personnel caring for patients or human research subjects undergoing implant therapy.

e. Guidance for Permanent Implants. Verify that the licensee is providing radiation safety guidance, in accordance with 10 CFR 35.415(a)(5), to all patients or human research subjects administered permanent implants.

f. Additional Requirements for Licensees with Remote Afterloaders. The administrative and technical staff, including device operators, should be provided initial training and periodic retraining specific to the device model(s), at intervals not to exceed 12 months. This should include routine training required by 10 CFR 19.12 and training described in the license application. The licensee should also provide ancillary staff (nurses, security staff, custodians, etc.) with initial training and refresher training, at intervals not to exceed 12 months. Verify that the required training is being provided, that the individual(s) providing instruction in the use of the afterloader is (are) named in the license application, and that records of the training are maintained for 3 years.

Also verify that device operators, physicians, and medical physicists are provided emergency training, including a dry run.

02.09 Operating and Emergency Procedures for Remote Afterloaders

a. Operating Procedures Common to All Remote Afterloaders. Verify that operating procedures are available at the console used to operate the remote afterloader. Posted operating procedures should be the same as those approved by NRC in the licensing process. If they are not the same, verify that any revisions to the procedures do not relax restrictiveness or

degrade safe operation of the unit and have been approved by the RSC. Note, if the licensee is not required to have an RSC, the RSO should approve procedure changes.

b. Operations Specific to High-, Medium-, and Pulsed-Dose-Rate Remote Afterloaders. At least one individual trained in the safe use of the device and who has practiced the emergency procedures for use of the device must be physically present while the device is in use. Verify that both the authorized user and either a medical physicist or the RSO is physically present while the device is in use. Confirm that only the patient is in the treatment room during activation of the remote afterloader.

c. Operations Specific to Low-Dose-Rate Remote Afterloaders. During patient treatments that extend over a period of several hours, a device operator trained in the emergency procedures must be physically present at the licensee's facility or be available by telephone. Verify that the medical physicist or RSO and the authorized user are available for prompt assistance in case a source appears to have decoupled or becomes jammed in the catheter guide tube. Also verify that written instructions are provided to nurses before use of the afterloading device.

d. Emergency Procedures Common to All Remote Afterloaders. Observe whether emergency procedures are posted at the device console or in a conspicuous location within the treatment area. Individuals entering a treatment room should carry a functional radiation detection survey meter if the room monitor is non-functional. Verify that appropriate source recovery equipment is available for use.

e. Patient Release. Determine by observing, and discussing with the licensee, that a process exists to establish that a patient administered permanent implants containing radioactive material is releasable from control under 10 CFR 35.75. Determine that written instructions are provided to released individuals on actions recommended to maintain doses ALARA if doses to other individuals are likely to exceed 0.1 rem. Verify that the licensee is recording (a) the basis for release of patients, when necessary, and (b) that instructions are provided to breast-feeding women when required.

02.10 Area Radiation and Contamination Control

a. Area Surveys

1. For All Brachytherapy Programs. Verify, by observations and direct measurements, that the radiation levels are within the limits of 10 CFR Part 20, and that survey instruments are possessed in accordance with 10 CFR 35.420.

Immediately on completion of the therapy procedure, and before removal of the patient from the treatment room (or removal of the portable shields used during low-dose-rate remote afterloader procedures), licensees should perform a radiation survey of the device and the patient to ensure that the source has been returned to the shielded position. Examine the licensee's records of these surveys to verify that these surveys are performed and that records of these surveys are maintained for 3 years.

2. Additional Requirements for Licensees with High- and Medium-Dose- Rate Afterloaders. Verify that surveys are conducted to ensure compliance with 10 CFR 20.1301, before initiating a treatment program and subsequent to each source exchange or replacement or relocation of the device. Also verify that survey records are retained for 3 years.

3. Additional Requirements for Licensees with Low- and Pulsed-Dose- Rate Afterloaders. Verify that surveys are conducted to ensure compliance with 10 CFR 20.1301 at the time of treatment program initiation and subsequent to each source exchange or replacement or relocation of the device. Also verify that survey records are retained for 3 years.

b. Leak Tests. Verify that leak tests of sealed sources are performed at the required frequency found in 10 CFR 35.59(b)(2) and are 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. Protective Clothing. Verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed.

02.11 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.

1. Additional Requirements for Licensees with Remote Afterloaders. Verify that the licensee has in its possession portable survey instruments as specified in 10 CFR 35.420. These instruments must be calibrated in accordance with 10 CFR 35.51, and they must be checked for proper operation with a dedicated check source each day.

2. Additional Requirements for Licensees with High-, Medium-, and Pulsed-Dose-Rate Remote Afterloaders. Verify that the licensee has installed a permanent radiation monitor capable of continuously monitoring the source status in each dedicated treatment room. The monitor must: provide visible notice when the source is exposed or partially exposed; be visible to an individual entering the treatment room; and be provided with a backup power supply separate from the power supply used to operate the remote afterloader. Verify that the radiation monitor is checked daily, or on an as-used basis, for proper operation with a dedicated check source, and that records verifying the radiation monitor's operation are maintained for 3 years.

d. Personnel Dosimeters. Verify that personnel dosimetry devices are worn by appropriate licensee personnel. For licensees with remote afterloaders, verify that all personnel entering restricted areas (treatment rooms) wear whole body badges. Dosimetry devices appropriate to the type, energy, or emitted radiation, and the anticipated radiation fields, should be 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. Patient Release. Determine by observing, and discussing with the licensee, that a process exists to establish that a patient administered permanent implants containing radioactive material is releasable from control under 10 CFR 35.75. Determine that written instructions are provided to released individuals on actions recommended to maintain doses ALARA if doses to other individuals are likely to exceed 0.1 rem. Verify that the licensee is recording (a) the basis for release of patients, when necessary, and (b) that instructions are provided to breast-feeding women when required.

02.12 Quality Management Program (QMP) and Misadministrations

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

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

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

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

02.13 Strontium-90 (Sr-90) Eye Applicators. For licensees authorized to possess and use Sr-90 as a sealed source in an applicator for treatment of superficial eye conditions, include the following elements in routine inspections. (Some elements are not exclusive to this class of sources. Refer to corresponding sections in this inspection procedure for expanded explanations for those brachytherapy program inspection elements that are common.)

a. Verify that the licensee has in its possession, and uses, a certificate of calibration, or data from a manufacturer-supplied source identification plate, for each Sr-90 opthalmic applicator in its possession. Certificates of calibration must be supplied by either:

1. The manufacturer/vendor of the Sr-90 applicator; or

2. A calibration laboratory with established traceability to the National Institute of Standards and Technology (NIST) for performing Sr-90 opthalmic applicator calibrations.

Each certificate of calibration, or source identification plate, must match, by source serial number, the source for which its data are being used. In addition, verify that the applicator meets 10 CFR 35.49.

b. Determine if source output (dose rate) is being properly corrected for source decay. Confirm, by independent calculation, using the table in Appendix C [from NRC Information Notice (IN) 96-66], the adequacy of the licensee's corrections for the radioactive decay of Sr-90 sources.

c. Sample records of patients' exposures times, to verify that the calculated administered doses correspond to the prescribed doses.

d. Verify that the licensee possesses, and is following, radiation safety and handling instructions supplied by the manufacturer/vendor.

e. Verify that the licensee is conducting leak tests at intervals not exceeding 6 months, or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source. Determine that the user's method of eye applicator sterilization does not compromise source integrity.

f. Verify that the licensee is conducting quarterly inventories of the sources.

g. Survey the licensee's source storage area and evaluate the potential for excessive occupational or public dose. Verify that the licensee is measuring ambient dose rates at source storage areas on a quarterly basis or otherwise, as authorized.

h. Verify that the licensee issues extremity dosimetry, if warranted. Verify that ALARA techniques are used to minimize occupational exposure during treatment and applicator sterilization.

i. Verify that, commensurate with the licensee's activities, the licensee is meeting applicable QMP requirements. Refer to Section 02.12, "Quality Management Program (QMP) and Misadministrations," of this IP.

j. Verify that the licensee maintains security and control of eye applicator sources.

k. Verify that the licensee is using eye applicators only in locations authorized by the license and for treatment specified in 35.400(e) or condition of the license. |

02.14 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 disposals of decay-in-storage waste are performed in accordance with the regulations 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). If applicable, review the licensee's procedures and records to verify that each shipment of radioactive waste intended for offsite disposal is accompanied by a shipment manifest that includes all the required information.

Review the licensee's procedures and records to verify that each package of radioactive waste intended for shipment to a licensed land disposal facility is labeled, as appropriate, to identify it as Class A, B, or C waste in accordance with

the classification criteria of 10 CFR 61.55 [Subsection III.A.2 of Appendix F to 10 CFR 20.1001-20.2401].

b. Transfer. Verify that radioactive sources are transferred to an authorized recipient and that wastes, if any, are transferred to a recipient specifically licensed to receive radioactive waste.

c. Records. Verify that records of waste storage, transfer, and disposal are maintained in accordance with the requirements of 10 CFR Part 20 and the license.

d. Financial Assurance and Decommissioning. Review the licensee's records of information important to the safe and effective decommissioning of the facility. Verify that the records are complete, updated, and assembled appropriately, in accordance with the requirements in 10 CFR 30.35(g). Review the licensee's list of restricted areas required under 10 CFR 30.35(g)(3) and determine whether rooms, laboratories, etc., 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, 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.

e. 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 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.

02.15 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.

02.16 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, along with remote afterloaders and/or any associated source storage containers, are labeled appropriately.

02.17 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.

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

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

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

02.21 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. In particular, confirm that radiation levels in restricted and unrestricted areas adjacent to treatment rooms meet the requirements of 10 CFR 20.1201 or 20.1301.
Conduct 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.

02.22 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."

| 02.23 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.).

87118-03 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. 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.

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

In the records reviewed, look for trends such as increasing doses. Records such as surveys, waste disposal, receipt and transfer of radioactive 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. 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.

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 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 licensed activities to be inspected.

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 (e.g., unannounced inspections at hospitals, which begin at early hours before management arrives on site), 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 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 on the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with licensee personnel, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc., which cannot always be gained by reviewing records alone. This is also an opportunity for the inspector to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection.

   The inspector should determine if multiple places of use are listed on the license. This information should be confirmed with knowledgeable onsite individuals. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials

Inspection Program," and regional policy for performing inspections at satellite facilities.

If the licensee authorizes use at satellite facilities, the inspector should determine if the licensee's radiation safety program adequately controls use of materials and devices at all locations. If onsite visits are performed during the inspection, the inspector should review all aspects of the radiation safety program to verify that the radiation safety programs at the satellite facilities are maintained in compliance with the radiation safety program described in the license application.

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 - If an RSC is applicable to this licensee, topics of discussion should include ALARA reviews, incidents, generic communications, authorized users and uses, waste issues, audits, and misadministrations and recordable events, as defined in 10 CFR 35.2. The RSC must consist of at least three individuals. It must include an authorized user from each type of use permitted by the license. (If applicable, one of these authorized users should be directly involved with remote afterloader usage). It must consist of the RSO, a representative from the nursing service, and a management representative who is neither the RSO nor an authorized user. It must meet at least quarterly. The inspector should review meeting minutes (and interview selected committee members, when practical) to determine the committee's effectiveness.

   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 - All medical licensees, including brachytherapy and remote afterloader licensees, must have an 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 institution licensees are required by 10 CFR 35.22(b)(6) to review the radiation safety program content and implementation at least annually. If applicable, the inspector should verify that the remote afterloader program is included in any programmatic radiation safety audits. 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 may either be named in the license application or be 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.

For remote afterloader programs, verify that the afterloaders are used by or under the direct supervision of an authorized user through direct observation and interviews, or through review of utilization logs and written directives. It is important to note whether the appropriate individuals are present or available for assistance during treatments.

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

a. Requirements for All Brachytherapy Licensees. 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.

b. Additional Requirements for Licensees with Remote Afterloaders. Verify that console keys are inaccessible to unauthorized persons. The inspector should keep an eye out for remote afterloaders placed in treatment rooms with other radiation-producing devices and ask authorized licensee personnel to demonstrate that only one device can be placed in operation at a time.

c. Additional Requirements for Licensees with High-, Medium-, and Pulsed-Dose- Rate Remote Afterloaders. The inspector should ask an authorized licensee representative to demonstrate that interlock systems are operational and should inquire about what action is taken by the staff when the interlock systems are found to be non-operational. The inspector should also confirm that the backup system used to observe patients is operational and inquire about what action is taken by the staff when the backup system is non-operational.

d. Additional Requirements for Licensees with Low-Dose-Rate Remote Afterloaders. The inspector should visually confirm that the licensee has portable shields and should interview staff to confirm that the shields are used during procedures.

03.06 Equipment and Instrumentation

a. Radiation Detection Equipment. The inspector should be familiar with the radiation detection equipment that the licensee is required by regulation or license condition to have in its possession, including survey instruments. The inspector should visually inspect the equipment and have a licensee’s representative demonstrate that the equipment is operational. The inspector should ask several staff members to demonstrate how instruments are operated and how daily checks are performed. The inspector should also ask what actions are taken when radiation detection equipment is non-functional.

All afterloaders except those with low-dose rate must have installed radiation monitors, and these monitors must be checked and maintained in accordance with applicable requirements.

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

c. Additional Requirements for all Licensees with Remote Afterloaders

The inspector should visually inspect the remote afterloading device and/or any source storage devices to verify that only authorized devices are in use and that they are properly labeled.

The inspector should consider asking the licensee's staff to demonstrate how the backup battery for the device and the source position indicators are checked for proper operation.

In reviewing the maintenance logs, the inspector should look for recurring problems/repairs and generic problems. If recurring problems are identified, the inspector should note them in the inspection record and, if significant, notify NMSS. The inspector should verify that the RSC is aware of the problem and evaluate the action taken by the licensee to address the problems. In reviewing the reports, the inspector should determine if any malfunctions should have been reported to NRC, pursuant to Part 21.

The inspector should also review the calibration log to verify that the calibration procedures stated in the license application are followed. The inspector should consider asking the licensee's staff to provide a demonstration of some or all of the steps of the calibration procedure.

Verify that emergency equipment is available. This equipment includes such items as shielded containers, remote handling tools, scissors, cutters, etc.

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 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, or if they warrant a license amendment. When practical, the records of receipt and

transfer should be compared with a physical inventory of materials possessed.

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, when practical, observe personnel perform the package receipt surveys. The inspector should randomly examine records of package surveys.

Examine the licensed materials accounting system. A relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility will need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. The accounting systems should also consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the licensee should perform routine audits, to ensure the accuracy of the system.

b. Authorized Uses. Authorized uses of licensed material will be found in the licenses and license applications. Licenses will list the isotopes, physical or chemical forms, and the maximum possession limits. Additionally, the inspector should verify that the licensee's use of byproduct material is limited to that which is authorized in the license.

c. Inventories. Verify that the licensee is conducting a quarterly inventory of all sealed sources and brachytherapy sources; in accordance with 10 CFR 35.59. The inspector should physically examine the inventory of radioactive material on hand or examine records of receipt and transfer to determine that quantities and forms are as authorized.

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

e. Additional Requirements for Licensees with Remote Afterloaders. The inspector should review the method used by the licensee to confirm source homogeneity for sources used in the afterloading device. One acceptable method is autoradiography.

f. Manual Brachytherapy. Verify that safety precautions, in accordance with 10 CFR 35.415, are implemented. Patients should be surveyed and released, and records maintained, in accordance with Part 35 requirements.

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 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. 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 and 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 assure that appropriate training was actually

received by these individuals. For example, interview nursing staff to verify that radiation safety instruction required under 10 CFR 35.410 is provided. 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 Procedures. Operating procedures will be found in license applications and may vary from step-by-step procedures to more generalized procedures. The operating procedures will be approved by NRC and reviewed and updated by the licensee. Minor changes in radiation safety procedures may be made in accordance with 10 CFR 35.21(b)(6) or 35.31. Any major revision requires an amendment to the license, in accordance with 10 CFR 35.13. The inspector should examine records of procedure revisions.

The inspector should interview staff to determine if it is aware of the location of the operating procedures and if it follows the operating procedures. In particular, the inspector should place emphasis on determining if radiation surveys of the device and the patient are performed after a procedure is completed.

c. Emergency Procedures. 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 the NRC and reviewed and updated by the licensee. For remote afterloaders, the inspector should verify that each operator has received a copy of the emergency procedures and that the procedures are posted at the afterloader console.

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

03.09 Operation of Remote Afterloaders

a. Operating Procedures Common to All Remote Afterloaders. For remote afterloaders, the inspector should verify: that afterloader devices and the associated sources are approved, authorized on the license, properly labeled, and that device calibrations are only performed by qualified authorized individuals (medical physicists); that device calibration measurements were performed following installation of a new source, before patient treatment and monthly thereafter; and that the afterloader is inspected annually.

Verify that patient and device are surveyed to ensure that the source is returned to the shielded position. Records of radiation surveys should be maintained for 3 years.

b. Operations Specific to High-, Medium-, and Pulsed-Dose-Rate Remote Afterloaders. The inspector should confirm, by observation and/or interviewing staff, that at least one individual trained in the safe use of the device and who has practiced the emergency procedure for use of the device, is physically present while the device is in use. In addition, confirm that both the authorized user and either a medical physicist or RSO are physically present while the device is in use. For the purpose of this Inspection Procedure (IP),"physically present" is defined as within audible range of normal human speech.

c. Operations Specific to Low-Dose-Rate Remote Afterloaders. The inspector should confirm by observation and or interviewing staff that at least one device operator trained in emergency procedures is physically present at the licensee's facility or available by telephone during device use. In addition, confirm that the medical physicist or RSO and the authorized user are available for prompt assistance in case a source appears to have decoupled or becomes jammed in the catheter guide tube.

The inspector should review the written instructions that are provided to nurses before use of the afterloading device. As part of this review, the inspector should attempt to interview nurses who have been involved in treatments using the device to determine their familiarity with the instructions.

d. Emergency Procedures Common to All Remote Afterloaders. The inspector should determine if any incidents have occurred at the facility that resulted in staff implementing facility emergency procedures. If so, the inspector should interview the staff that was involved in the procedures and determine how the incident was handled. In particular, the inspector should determine if NRC was notified and if not, why not.

The inspector should interview staff regarding the anticipated actions that would be taken in an emergency situation. In particular the inspector should determine if staff is aware of the requirement to carry a functional radiation detection devices into the room if the room monitor is non-functional. The inspector should determine if the staff is aware of the location of the alternative radiation detection devices since in an emergency the staff would not have time to look for the monitor.

The inspector should also interview staff to determine if it is aware of the location of emergency source-recovery equipment. At a minimum, emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient, including scissors and cable cutters.

03.10 Area Radiation and Contamination Control

a. Area Surveys. By interviews and review of records, the inspector should examine the licensee's performance in conducting timely patient and area surveys for brachytherapies (both permanent and temporary implants), as well as source-removal, patient-release, and room-release surveys. For most brachytherapy procedures, a radiation survey of the patient must be performed immediately after source removal. In addition to timely surveys, for afterloaders, the inspector should also verify that back-up batteries for the source-retract systems are tested monthly, and that source position indicators are checked periodically.

The inspector may ask the licensee to spot check radiation levels in selected areas, using the licensee's own instrumentation. For example, if a brachytherapy procedure is currently in progress, make measurements in adjacent unrestricted areas to confirm that the requirements of 10 CFR 20.1301 are met. However, the inspector must use NRC's instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be source-checked before he/she leaves the regional office and be calibrated within the frequency required for the licensee.)

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

Also, for remote afterloader programs, the inspector should verify, through interviews and/or record reviews, that the licensee has performed surveys following source changes, device repair, or device maintenance.

Verify that eating, drinking, and smoking are not permitted areas where radioactive materials in any form are being used. Verify that radioactive wastes are disposed of in proper containers.

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 10 CFR 35.59.

c. Protective Clothing. Observation of the protective clothing worn by brachytherapy personnel or other applicable staff 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 in precautions posted at the entrance to controlled areas.

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

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 TEDE to any other individual is not likely to exceed 0.5 rem. 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 0.1 rem. In general, the licensee is required to give instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable. The inspector may determine how the licensee is demonstrating compliance with this requirement by reviewing sample instructions and/or discussing the content of the instructions with applicable staff. If the licensee is required by the rule to provide instructions to breast-feeding women, the instructions should include guidance on the interruption or discontinuation of breast-feeding and information on the consequences of failure to follow the guidance.

(3) Licensees are required to maintain, for three 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, (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 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, 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).

| 03.12 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.

03.13 Strontium-90 Eye Applicators

a. Information Notice 94-17, "Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use," alerted licensees to possible discrepancies with the calibration and use of eye applicators. The manufacturer's original calibration results may differ from the results of competent measurement laboratories, using state-of the-art techniques, by considerably more than 10 percent.

The licensee should be using the most recent calibration results. A misadministration has occurred if: 1) the licensee, in prescribing a dose and planning its delivery, does not use the most recent calibration results available to it at the time; and 2) the administered dose, calculated from the most recent calibration results available at the time of dose prescription, differs from the prescribed dose by greater than 20 percent. Do not apply the dose rate results of a recent calibration to previous therapeutic administrations, for the purpose of identifying misadministrations, provided the previous calibration was considered valid at the time.

At this time, two calibration laboratories are known to be capable of providing the required NIST-traceable calibrations of Sr-90 opthalmic applicators. They are NIST, itself, and the University of Wisconsin Accredited Dosimetry Calibration Laboratory.

In addition, the applicator is required to be a 10 CFR 35.49 source.

b. IN 96-66, "Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators," discusses the need to ensure that the dose rate from the eye applicator is correct, to meet the requirements of the QMP for assurance that the prescribed dose is the administered dose. The IN describes examples of misadministrations and includes a decay table for the source.

c. Confirming that administered doses are in accordance with prescribed doses is verifying that the requirement of 10 CFR 35.32(a)(4) of the QMP is being met.

d. Requirements for brachytherapy sources are specified in 10 CFR 35.59 and requirements for use is specified in 35.400(e) or a condition of the license.

e. For convenience and because of physical characteristics of the device, eye applicator sterilization is usually accomplished by immersion/dwell in appropriate liquid, such as isopropyl alcohol, or by gentle sweeping contact with a liquid-saturated gauze pad. Use of liquids containing halogenated compounds are to be avoided, as corrosion of typically-constructed applicators can occur.

f. Improper shielding or storage of the source could result in bremsstrahlung radiation or high ambient dose rates.

g. Requirements for monitoring occupational exposure are specified in 10 CFR 20.1502. ALARA techniques should include a method, such as the use of an opthalmic speculum, to hold the patient's eye open during treatment, to minimize occupational exposure to the user's fingers.

h. Requirements of the QMP are found in 10 CFR 35.32. Refer to the guidance in Section 03.12, "Quality Management Program," of this IP.

| i. Requirements for security and control of licensed material are specified in 10 CFR 20.1801 and 20.1802.

| j. In accordance with 10 CFR 71.9, the transportation of eye applicators between license-authorized offices or hospitals is to be conducted by a physician licensed by a State to dispense drugs in the practice of medicine, and licensed under 10 CFR part 35 or the equivalent Agreement State regulations.

03.14 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."

b. 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). Generally, sources used for brachytherapy, including seeds and ribbons, are returned to the manufacturer. Sealed sources, used in afterloaders, are exchanged on receipt of a new source.

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

d. Financial Assurance and Decommissioning. The decommissioning record- keeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: (1) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site (when contamination remains after cleanup, or when

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

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

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

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

e. 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, the decommissioning timeliness requirements apply, and the inspector must complete the "Decommissioning Timeliness Inspection record," Attachment A to Appendix A.

The requirements of 10 CFR 30.36, 40.42, and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. However, in those cases, the inspector should follow the guidance in 03.13.d. 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 (failures to: notify NRC; meet decommissioning standards; complete decommissioning activities, in accordance with regulation or license condition; 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.”

03.15 Transportation. If applicable, 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. The DOT and NRC regulations for transportation of radioactive materials were recently revised, and the revisions generally became effective April 1, 1996.

For further inspection guidance, refer to IP 86740, "Inspection of Transportation Activities." 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.

03.16 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. 10 CFR 20.1903 provides exceptions to posting caution signs. When applicable, the inspector should randomly examine signals and alarms to determine operability. The inspector should also randomly observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

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

03.17 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.

03.18 Notifications and Reports. Through discussions with licensee personnel and by a review of representative records, the inspector should verify the licensee's compliance with submitting notifications and reports to the Commission. The licensee may be required to make notifications after loss or theft of material, overexposures, incidents, misadministrations and recordable events, high radiation levels, and safety-related equipment failure, etc.

03.19 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.

03.20 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.

03.21 Independent and Confirmatory Measurements. Confirmatory measurements are those whereby the inspector compares his/her measurements with those of the licensee's. Independent measurements are those performed by the inspector independently of the licensee's measurements. 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. In addition, measurements should be

taken in licensed material use and storage areas. To perform the independent or confirmatory measurements, use NRC radiation detection instruments that are calibrated at least as frequently as required for the licensee being inspected.

03.22 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 performed by telephone conference call.

During the exit meeting, the licensee representatives should be told the preliminary inspection findings--including any negative PEFs, any apparent violations of regulatory requirements, any 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 concern is fully understood by the licensee and corrective action has been initiated. If the inspector and the licensee disagree over how significantly the concern impacts continued safe operation of the facility, regional management should be notified immediately.

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

03.23 Post-Inspection Actions. Regional office policy will dictate with whom the inspector will review his/her inspection findings (e.g., the inspector's supervisor), following the guidance in MC 2800. 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 and/or inspection report, 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.

87118-04 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. 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 "Brachytherapy Inspection References" Appendix to this IP.

END

Appendices:

A. "Brachytherapy Inspection Record"
B. “Brachytherapy Inspection References”
C. “Decay Factors for Strontium-90 Sources”

APPENDIX A

BRACHYTHERAPY 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 U.S. 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 (IP) 87118, Appendix B, "Brachytherapy 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 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 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. MANAGEMENT OVERSIGHT:
(Management support to radiation safety; RSC; RSO; program audits or inspections; as low as reasonably achievable (ALARA) reviews; control and supervision by authorized users)

3. FACILITIES:
(Facilities as described; uses; control of access; engineering controls; shielding; maintenance by authorized persons; remote afterloader facilities; pulsed-dose-rate afterloader facilities; low-dose-rate afterloader facilities; interlocks; patient monitoring; approved locations of use)

4. EQUIPMENT AND INSTRUMENTATION:
(Operable and calibrated survey instruments and dosimetry; procedures; 10 CFR Part 21 procedures; calibration records; fixed radiation monitors; backup power supplies for monitors and afterloaders; equipment inspected as scheduled; emergency equipment; calibration and maintenance by authorized persons)

5. MATERIAL USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; afterloader sources approved; security and control of licensed materials; procedures for receipt and transfer of licensed material; source installation and replacement by authorized persons; patient surveys and release)

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL :
(Radiological survey locations and frequencies; leak tests; inventories; handling of radioactive materials; records and reports; public doses; unrestricted area surveys; use of protective clothing; proper waste disposal; shielding)

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

8. OPERATING AND EMERGENCY PROCEDURES FOR REMOTE AFTERLOADERS:
(Operating and emergency procedures posted; procedures approved; required persons present during afterloader use; surveys in unrestricted areas; leak testing; inventories)

9. 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)

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

11. STRONTIUM-90 EYE APPLICATORS
(Source calibration; source decay correction; QM program; radiation safety and handing instructions; leak tests; quarterly inventories; source storage area surveys; ALARA; security and control; locations of use; transportation)

12. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents and compactors; license conditions for special disposal methods)

13. DECOMMISSIONING:
(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; 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 (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.)

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
(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 the 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 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:

BRACHYTHERAPY 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 responsibility.
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 responsibility.
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 35.940 Training for use of brachytherapy sources.
10 CFR 35.941 Training for ophthalmic use of Sr-90.
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 35.415 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 21.21 Notification of failure to comply.
10 CFR 35.51 Calibration and check of survey instruments.
10 CFR 35.415 Safety precautions.
10 CFR 35.420 Possession of survey instruments.
Applicable license conditions.

B. Safety Component Defects

Applicable license conditions.

5. MATERIAL USE, CONTROL, AND TRANSFER

A. 10 CFR 35.400 Use of sources for brachytherapy.
License and applicable license conditions.
10 CFR 35.49 Suppliers for sealed sources of devices for medical use.

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.
10 CFR 35.406 Brachytherapy sources inventories.

C. Receipt and Transfer of Licensed Material

10 CFR 20.1302 Compliance with dose limits for individual members of the public.
10 CFR 20.1906 Procedures for receiving and opening packages.
10 CFR 20.1501 General.
10 CFR 20.2103 Records of surveys.
10 CFR 30.41 Tra0nsfer of byproduct material.
10 CFR 30.51 Records of receipt and transfer.

D. Manual Brachytherapy

10 CFR 35.75 Release criteria.
10 CFR 35.404 Release of patients.
10 CFR 35.406 Brachytherapy sources inventories.
10 CFR 35.415 Safety precautions.
RG 8.39 Release of Patients Administered Radioactive Materials.
Applicable license conditions.

6. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

A. Area Surveys

10 CFR 20.1301	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 35.51	Calibration and check of survey instruments.
10 CFR 35.70	Surveys for confirmation and ambient exposure rate.
10 CFR 35.420	Possession of survey instruments.

Applicable license conditions.

B. Leak Tests and Inventories

10 CFR 35.59	Requirements for possession of sealed sources and brachytherapy sources.
10 CFR 35.406	Brachytherapy sources inventories.

Applicable license conditions.

7. TRAINING AND INSTRUCTIONS TO WORKERS

General

10 CFR 19.12	Instruction to workers.
10 CFR 35.25	Supervision.
10 CFR 35.400	Use of sources for brachytherapy.
10 CFR 35.410	Safety instruction.
10 CFR 35.940	Training for use of brachytherapy sources.
10 CFR 35.941	Training for ophthalmic Sr-90 source.
10 CFR 35.970	Training for experienced authorized user.

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

8. OPERATING AND EMERGENCY PROCEDURES

10 CFR 35.404	Release of patients.

Applicable license conditions.

9. 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	Dose 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.

10. 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.

11. STRONTIUM-90 EYE APPLICATORS

Information Notice (IN) 94-17	"Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use."
IN 96-66	"Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators."
10 CFR 20.1101	Radiation protection programs.
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose.
10 CFR 20.1801	Security of stored material.
10 CFR 20.1802	Control of material not in storage.
10 CFR 35.32	Quality management program.
10 CFR 35.59	Requirements for possession of sealed sources and brachytherapy sources.
10 CFR 71.9	Exemption of physicians.

12. WASTE MANAGEMENT

A. Disposal

10 CFR 20.1904	Labeling containers.
10 CFR 20.2001	General waste disposal requirements.

10 CFR 20.2103 Records of surveys.
10 CFR 20.2003 Disposal by release into sanitary sewerage.

B. Effluents

1. General

IP 87102 Maintaining Effluents from Materials Facilities as Low As Is Reasonably Achievable (ALARA).

2. Release to septic tanks

10 CFR 20.1003 Definitions (sanitary sewerage).
10 CFR Part 20, App. B, Table 2 Limits.

3. Incineration of waste

10 CFR 20.2004 Treatment or disposal by incineration.

4. 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 Waste disposal: general requirements.
IP 84850 Radioactive Waste Management - Inspection of Waste generator Requirements of 10 CFR Part 20 and 10 CFR Part 61.

2. Waste Compaction

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 characteristics.

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	Waste disposal: general requirements.
10 CFR 20.2006	Transfer for disposal and manifests.

6. Records

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

13. 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.

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

IP86740, 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	Loading and unloading: Class 7 (radioactive) material.

15. NOTIFICATIONS AND REPORTS

10 CFR 19.13	Notifications and reports to individuals.
10 CFR 21.21	Notification of defects.
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.

Applicable license conditions.

16. 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 35.610	Safety instruction.
10 CFR 21.6	Posting requirements.

Applicable license conditions.

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

Area (ft)	qt	Area (ft)	qt	Area (ft)	qt	Area (ft)	qt
.25	0.994	2.5	0.824	15.25	0.634	35	0.43
.5	0.989	2.75	0.819	15.5	0.629	35.25	0.428
.75	0.984	3	0.814	15.75	0.624	35.5	0.425
1	0.979	3.25	0.809	16	0.619	35.75	0.423
1.25	0.974	3.5	0.804	16.25	0.614	36	0.42
1.5	0.969	3.75	0.799	16.5	0.609	36.25	0.418
1.75	0.964	4	0.794	16.75	0.604	36.5	0.415
2	0.959	4.25	0.789	17	0.599	36.75	0.413
2.25	0.954	4.5	0.784	17.25	0.594	37	0.41
2.5	0.949	4.75	0.779	17.5	0.589	37.25	0.408
2.75	0.944	5	0.774	17.75	0.584	37.5	0.405
3	0.939	5.25	0.769	18	0.579	37.75	0.403
3.25	0.934	5.5	0.764	18.25	0.574	38	0.4
3.5	0.929	5.75	0.759	18.5	0.569	38.25	0.398
3.75	0.924	6	0.754	18.75	0.564	38.5	0.395
4	0.919	6.25	0.749	19	0.559	38.75	0.393
4.25	0.914	6.5	0.744	19.25	0.554	39	0.39
4.5	0.909	6.75	0.739	19.5	0.549	39.25	0.388
4.75	0.904	7	0.734	19.75	0.544	39.5	0.385
5	0.899	7.25	0.729	20	0.539	39.75	0.383
5.25	0.894	7.5	0.724	20.25	0.534	40	0.38
5.5	0.889	7.75	0.719	20.5	0.529	40.25	0.378
5.75	0.884	8	0.714	20.75	0.524	40.5	0.375
6	0.879	8.25	0.709	21	0.519	40.75	0.373
6.25	0.874	8.5	0.704	21.25	0.514	41	0.37
6.5	0.869	8.75	0.699	21.5	0.509	41.25	0.368
6.75	0.864	9	0.694	21.75	0.504	41.5	0.365
7	0.859	9.25	0.689	22	0.499	41.75	0.363
7.25	0.854	9.5	0.684	22.25	0.494	42	0.36
7.5	0.849	9.75	0.679	22.5	0.489	42.25	0.358
7.75	0.844	10	0.674	22.75	0.484	42.5	0.355
8	0.839	10.25	0.669	23	0.479	42.75	0.353
8.25	0.834	10.5	0.664	23.25	0.474	43	0.35
8.5	0.829	10.75	0.659	23.5	0.469	43.25	0.348
8.75	0.824	11	0.654	23.75	0.464	43.5	0.345
9	0.819	11.25	0.649	24	0.459	43.75	0.343
9.25	0.814	11.5	0.644	24.25	0.454	44	0.34
9.5	0.809	11.75	0.639	24.5	0.449	44.25	0.338
9.75	0.804	12	0.634	24.75	0.444	44.5	0.335
10	0.799	12.25	0.629	25	0.439	44.75	0.333
10.25	0.794	12.5	0.624	25.25	0.434	45	0.33
10.5	0.789	12.75	0.619	25.5	0.429	45.25	0.328
10.75	0.784	13	0.614	25.75	0.424	45.5	0.325
11	0.779	13.25	0.609	26	0.419	45.75	0.323
11.25	0.774	13.5	0.604	26.25	0.414	46	0.32
11.5	0.769	13.75	0.599	26.5	0.409	46.25	0.318
11.75	0.764	14	0.594	26.75	0.404	46.5	0.315
12	0.759	14.25	0.589	27	0.399	46.75	0.313
12.25	0.754	14.5	0.584	27.25	0.394	47	0.31
12.5	0.749	14.75	0.579	27.5	0.389	47.25	0.308
12.75	0.744	15	0.574	27.75	0.384	47.5	0.305
13	0.739	15.25	0.569	28	0.379	47.75	0.303
13.25	0.734	15.5	0.564	28.25	0.374	48	0.3
13.5	0.729	15.75	0.559	28.5	0.369	48.25	0.298
13.75	0.724	16	0.554	28.75	0.364	48.5	0.295
14	0.719	16.25	0.549	29	0.359	48.75	0.293
14.25	0.714	16.5	0.544	29.25	0.354	49	0.29
14.5	0.709	16.75	0.539	29.5	0.349	49.25	0.288
14.75	0.704	17	0.534	29.75	0.344	49.5	0.285
15	0.699	17.25	0.529	30	0.339	49.75	0.283
15.25	0.694	17.5	0.524	30.25	0.334	50	0.28
15.5	0.689	17.75	0.519	30.5	0.329		
15.75	0.684	18	0.514	30.75	0.324		
16	0.679	18.25	0.509	31	0.319		
16.25	0.674	18.5	0.504	31.25	0.314		
16.5	0.669	18.75	0.499	31.5	0.309		
16.75	0.664	19	0.494	31.75	0.304		
17	0.659	19.25	0.489	32	0.299		
17.25	0.654	19.5	0.484	32.25	0.294		
17.5	0.649	19.75	0.479	32.5	0.289		
17.75	0.644	20	0.474	32.75	0.284		
18	0.639	20.25	0.469	33	0.279		
18.25	0.634	20.5	0.464	33.25	0.274		
18.5	0.629	20.75	0.459	33.5	0.269		
18.75	0.624	21	0.454	33.75	0.264		
19	0.619	21.25	0.449	34	0.259		
19.25	0.614	21.5	0.444	34.25	0.254		
19.5	0.609	21.75	0.439	34.5	0.249		
19.75	0.604	22	0.434	34.75	0.244		
20	0.599	22.25	0.429	35	0.242		

FRACTION (EXPRESSED AS DECIMAL) OF ORIGINAL
SR-90 ACTIVITY REMAINING AFTER (t) YEARS

TABLE I

Attachment 1
Decompet 13, 1988
N DE-88
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