INSPECTION PROCEDURE 87132

BRACHYTHERAPY PROGRAMS

PROGRAM APPLICABILITY: 2800

87132-01 INSPECTION OBJECTIVES

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

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

87132-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight; 8) Licensee review of licensed activities performed by contracted personnel; and 9) Other medical uses of byproduct material or radiation from byproduct material. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should conduct a more thorough review of that aspect of the licensee's program. The increased inspection effort may include additional sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

The NRC inspector shall not under any circumstances knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to continue in his/her presence in order to provide a basis for enforcement action. 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 a patient's privacy.

Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable, the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program.

In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, 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 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below NRC regulatory limits.

02.02 Shielding of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records that the licensee's performance has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

02.03 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.04 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.05 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.06 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has ensured that workers are knowledgeable of radiation uses and safety practices; skilled in

radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

02.07 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, as low as is reasonably achievable (ALARA) practices are implemented when appropriate, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.08 Licensee Review of Licensed Activities Performed by Contracted Personnel. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records that the licensee is providing oversight of licensed activities performed by contracted personnel.

02.09 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with NRC regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35, if the licensee has submitted the information required by the Code of Federal Regulations (CFR) in 10 CFR 35.12(b) through (d), and the licensee has received written approval from the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used that have not been specifically amended to a licensee's license. If an inspector encounters such activity and use, the inspector should contact NRC regional management as soon as practicable to independently verify that such use is authorized under NRC regulatory requirements. If further verification of such use is needed, the region should contact the Office of Federal and State Materials and Environmental Management Programs (FSME) for further guidance.

87132-03 INSPECTION GUIDANCE

03.01 General Guidance. A determination regarding safety and compliance with NRC requirements should be based on direct observation of work activities; interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NRC, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

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

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the Abig picture@) and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety.

However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records review, the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses. Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for those areas of concern, the records may or may not substantiate his/her concern. If the inspector substantiates a significant safety concern regarding a particular matter, it may be more appropriate to discuss this matter with NRC regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation of the radiation safety program for that particular element of a focus area.

If the inspector finds it appropriate when an apparent violation has been identified, the inspector 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 Inspection Manual Chapter (IMC) 0620. Especially ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information pursuant to the requirements of 10 CFR 2.790(b)(1).

The inspector should keep the licensee apprised of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

Whenever possible the inspector should keep NRC regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate NRC guidance under such circumstances.

03.02 Security and Control of Licensed Material

a. Adequate and Authorized Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition as submitted by the licensee in accordance with 10 CFR 35.13. Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored

is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain ALARA exposures.

1. Additional Requirements for Licensees with Remote Afterloaders. Through direct observations made during tours of the licensee's facility and discussions with cognizant licensee representatives, the inspector should 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 console keys are inaccessible to unauthorized persons. The inspector should note 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.

2. Additional Requirements for Licensees with High-, Medium-, and Pulsed-Dose-Rate Remote Afterloaders. Through discussions with cognizant licensee representatives and direct observations, the inspector should verify that the use of the afterloaders is limited to the areas approved by the license. From those discussions and observations, the inspector should determine whether each dedicated treatment room is equipped with a continuous viewing and intercom system to allow for patient observation and communication during treatment. In addition, the inspector should 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.

   Through further discussions and observations, the inspector should 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, the inspector should verify that, once activated, the automatic interlock must be reset before the afterloading device can be activated. In addition, the inspector should determine whether interlocks are tested at the required frequency.

   During the conduct of the inspection, 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 licensee staff when the backup system is non-operational.

3. Additional Requirements for Licensees with Low-Dose-Rate Remote Afterloaders. Through discussions with cognizant licensee representatives and direct observations, the inspector should 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.

b. Adequate Equipment and Instrumentation. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should independently

check interlock systems and other systems for continuous observation of the patient. For unit operation, the inspector should check the control of console keys. These activities can best be reviewed by the inspector by having an appropriate licensee representative demonstrate how these systems operate while the inspector observes those actions to ensure that the systems operate as designed and that the individual conducting the activity is knowledgeable in those areas. If appropriate, the inspector should verify that these various systems and checks operate appropriately to ensure compliance to 10 CFR 35.61, 615, 633, and 643.

During the conduct of the inspection, the inspector should discuss with cognizant licensee representatives the routine maintenance and calibration performed on the units. If practicable, the inspector should ask appropriate licensee personnel to demonstrate some or all of the steps of the calibration procedure. If the inspector identifies concerns from those direct observations, a review of selected maintenance and calibration log may be necessary. If a review is necessary, the inspector should look for recurring problems/repairs and generic problems. If recurring problems are identified and of significance, the inspector should contact NRC regional management for further guidance. If applicable, the inspector should verify that the Radiation Safety Committee (RSC) was aware of the problem. The inspector should then review the matter with cognizant licensee representatives to determine if adequate action was taken by the licensee to address the problem. From those discussions and reviews, if necessary, the inspector should determine if any malfunctions should have been reported to the NRC, pursuant to 10 CFR 21.21.

1. Remote Afterloader Unit Inspection, Servicing, Calibration and Spot Checks. Through direct observations made during the onsite inspection, the inspector should visually inspect the control console and unit for indications that alterations may have been performed by unauthorized persons. These indications may include off-the-shelf switches and timers, as well as wire jumpers and taped micro switches to bypass safety systems of the unit. If the inspector determines that alterations have been performed by unauthorized persons, the inspector should contact NRC regional management as soon as practicable for further guidance.

   Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has properly calibrated the remote afterloader, the unit is calibrated at the required intervals (not to exceed one quarter or one year, whichever one is applicable), and before first patient use and after source exchange, relocation, and major repair or modification. The calibration of the unit should include all items listed in 10 CFR 35.633. In addition, the inspector should verify that spot checks are conducted on the unit at the required frequency, and as required by 10 CFR 643. Also, the inspector should verify that additional technical requirements are conducted on the unit at the required frequency as required by 10 CFR 35.647. Furthermore, the inspector should verify that the licensee has performed acceptance testing on the treatment planning system in accordance with 10 CFR 35.657.

   During the conduct of the inspection, if the inspector identifies equipment or instrumentation that has failed to perform as designed, the inspector should

ensure that licensee operations are stopped immediately and that such equipment or instrumentation be appropriately repaired and tested prior to the next treatment. In some cases it may be appropriate to contact NRC regional management as soon as practicable to discuss the equipment or instrument failure and determine what appropriate steps should be taken to follow up on this matter.

2. Additional Requirements for all Licensees with Remote Afterloaders.

During the conduct of the inspection, 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.

In addition, during the inspection, the inspector should ask an appropriate licensee staff personnel to demonstrate how the backup battery for the device and the source position indicators are checked for proper operation.

During tours of the licensee's facilities, the inspector should independently verify that emergency equipment is available near each treatment room to respond to a source dislodged from the patient or lodged within the patient following completion of the treatment. This equipment should include such items as shielded containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient, including scissors and cable cutters.

3. Additional Requirements for Licensees with Strontium-90 (Sr-90) Eye Applicators. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and a review of selected records, the inspector should 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 ophthalmic applicator in its possession. Certificates of calibration must be supplied by either:

(a) The manufacturer/vendor of the Sr-90 applicator; or

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

From those discussions, observations, and reviews, the inspector should verify that each certificate of calibration, or source identification plate, must match, by source serial number, the source for which its data are being used.

Through further discussions, observations, and reviews, the inspector should verify that the source output (dose rate) is being properly corrected for source decay. The inspector should confirm this by independent calculation to ensure the adequacy of the licensee's corrections for the radioactive decay of Sr-90 sources.

4. Licensee Evaluation of Equipment Defects or Failures to Comply That Are Associated with Significant Safety Hazards. The inspector should verify a licensee developed procedures under 10 CFR 21.21 to identify and report safety component defects and, when needed, the procedures were implemented and NRC is also aware of the report.

c. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license conditions.

Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a relatively small facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large facility may 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. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

If a records review is necessary, the inspector should verify that the licensee's procedures for receiving replacement sealed sources include how and when they will be picked up, radiation surveys and wipe tests of source containers to be done upon receipt, and procedures for opening source containers (such as the location in the facility where they are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are to be taken if surveys reveal source containers that are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If replacement sources arrive during the course of an inspection, the inspector should observe, when practical, personnel perform the package receipt surveys as well as the area surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

d. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with NRC and DOT regulatory requirements for

transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported to DOT and NRC.

For further inspection guidance, the inspector should 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.

e. Material Security and Control. During tours of the licensee's facilities, the inspector should note areas where radioactive materials are used and stored. From those direct observations, the inspector should verify that the storage areas are locked and have limited and controlled access. The inspector should verify that radioactive materials, afterloaders, and storage devices are properly labeled. If from those observations, the inspector identifies concerns regarding access to storage areas, a review of the licensee's administrative controls may be necessary. For some licensee's the controls may include a utilization log to indicate when radioactive material is taken from and returned to storage areas.

The inspector should determine through direct observations that the treatment rooms containing remote afterloaders are under constant surveillance or physically secured when not in use. The inspector should discuss with appropriate licensee representatives the licensee's procedures for access controls in order to verify that adequate controls are in place and working effectively.

The inspector should note that for some licensees the key to the unit console is often left in the console over the course of the day dependent on the licensee's patient work load. The inspector should interview appropriate licensee operators to determine their normal control of the console key during the periods that they are away from the console in accordance with 10 CFR 35.610.

f. Written Directives. During the onsite inspection, the inspector's observation of the patient administration is contingent upon the patient's acceptance of being observed. The inspector should interview individuals as they perform applicable duties to determine that individuals are knowledgeable about the need for written directives and if the licensee's written directives, as implemented, effectively ensure that radiation from byproduct material will be administered as directed by the authorized user in accordance with 10 CFR 35.41. The review should include the licensee's implementation of its written procedures to provide high confidence that each administration is administered in accordance with the written directive and associated treatment plan. The inspector should sample selected brachytherapy cases and determine if the licensee implements actions to verify that: (1) prior to treatment, the treatment plan, if applicable, is in accordance with the written directive; (2) prior to treatment, the treatment parameters (e.g., source positioning, high dose-rate remote afterloader (HDR) unit settings, applicator type and size, etc.) are in accordance with the written directive and the treatment plan; and (3) after treatment, the treatment

parameters used were in accordance with the written directive and the treatment plan, if applicable (e.g., post treatment imaging to verify correct source positioning, etc.). If the inspector identifies a concern(s) regarding the licensee's implementation of its written procedures to provide high confidence that each administration is in accordance with the written directive and associated treatment plan, then the inspector should review the licensee's procedures to determine if they are adequate and/or not fully implemented. See Appendix B (Reviewing Licensees' Implementation of Procedures for Permanent Implant Brachytherapy Administrations) for more information.

g. Patient Release. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify the licensee's methods for establishing compliance with 10 CFR 35.75.

1. The inspector should note that the patient release criteria permit licensees to release individuals from control if the total effective dose equivalent (TEDE) to any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with 10 CFR 35.75.

2. Through further discussions the inspector should verify that the licensee is 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. The inspector should note that, 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 discussing the content of the instructions with appropriate licensee staff. If concerns are identified from those discussions, the inspector may find it necessary to review the sample instructions given to patients. If the licensee is required by the rule to provide instructions to breast-feeding women, the inspector should verify through further discussions and reviews, if necessary, that the instructions include guidance on the interruption or discontinuation of breast-feeding and information on the potential consequences of failure to follow the guidance.

3. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that if the TEDE to a breast-feeding child could exceed 0.5 rem if the breast-feeding were continued, the licensee has maintained documentation that instructions were provided in accordance with 10 CFR 35.75(d).

h. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by 10 CFR 35.3045. The inspector should assess the licensee's ability to effectively identify and respond to different types of medical events (e.g., administered dose that differs by 20 percent or more from the prescribed dose) through interviews with selected staff and a review of selected records. The inspector should verify that

licensee staff is aware of the person within the organization: 1) to whom they should report a medical event or treatments that may have resulted in a medical event; and 2) who is responsible for reporting medical events to the NRC. If during the inspection a previously unidentified medical event is identified, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045, "Report and Notification of a Medical Event;" and 2) follow the guidance provided in Management Directive 8.10, "NRC Medical Event Assessment Program." Upon identification of such an event, the inspector should notify NRC regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

For permanent implant brachytherapy administrations, the inspector may use the criteria in the Interim Enforcement Policy "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)", henceforth abbreviated as IEP, and exercise discretion to not cite a violation in two situations. If the inspector determines that a licensee used total source strength and exposure time to evaluate the existence of medical event and the criteria in the IEP were met, the inspector may exercise enforcement discretion to not cite a violation for failure to use a dose-based calculation. If the inspector determines that the licensee used absorbed dose to evaluate the existence of a medical event, the total dose to the treatment site equaled or exceeded 120 percent of the prescribed dose, and the criteria in the IEP were met, the inspector may exercise enforcement discretion to not cite a violation for failure to report a medical event. The IEP does not require inspectors to document the use of this enforcement discretion. It also does not require the licensee to make a medical event report in accordance with 10 CFR 35.3045 or to take any corrective actions. See Appendix C (Use of the Interim Enforcement Policy for "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)") for more information.

i. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. The inspector should note that 10 CFR 20.1903 provides exceptions to posting caution signs. During those tours, the inspector should selectively examine signals and alarms to determine adequate operability. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that radiation areas have been conspicuously posted, as required by 10 CFR 20.1902. Depending on the associated hazard, the licensee's controls may include tape, rope, or structural barriers to prevent access. The inspector should verify that high radiation areas have been 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. The inspector should determine that areas occupied by radiation workers for long periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply in accordance with 10 CFR 19.11, 20.1902, and 21.6.

During tours of the licensee's facility, the inspector should verify that emergency procedures for remote afterloaders are appropriately posted at the control console in accordance with 10 CFR 35.610.

j. Waste Storage and Disposal. Through discussions with cognizant licensee representatives and direct observations made during tours of the licensee's facility, the inspector should verify that the licensee has appropriately disposed of brachytherapy sources. From those discussions and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that recipients of radioactive wastes are licensed to receive such waste (e.g., licensee obtains a copy of the waste recipient's current license before the transfer). Sealed sources, used in afterloaders, are exchanged on receipt of a new source. In addition, through further discussions, observations and reviews, if necessary, the inspector should verify that the licensee has appropriate methods to track the items in storage.

From those discussions and direct observations, the inspector should verify that radioactive wastes are disposed of in proper containers.

For further inspection guidance in this area, the inspector should refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61."

k. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources and brachytherapy sources in accordance with 10 CFR 35.67(g). If appropriate, the inspector should independently verify through direct observations or a review of selected records of receipt and transfer to determine that the quantities and forms of licensed material possessed and used by the licensee are as authorized in the license.

03.03 Shielding of Licensed Material. An inspector should determine that a licensee has maintained shielding of licensed materials in a manner consistent with operating procedures and design and performance criteria for devices and equipment.

In an application for a license, an applicant must indicate the location and description of shielding along with calculations of estimated radiation levels. Through observations and interviews, an inspector should determine availability and placement of shielding, and inquire about unshielded activities and radiation exposure levels for the following areas:

a. Manual Brachytherapy. Determine use of manual brachytherapy source storage shields and body shields for applicator loading and unloading areas;

b. Patient Treatment Rooms. Facility shielding may have been installed for certain patient treatment rooms to reduce radiation levels in adjacent areas and areas above and below the room. If a viewing window is observed, check for leaded glass in the viewing window. Use of portable shielding in patient rooms may have been indicated. The inspector should visually confirm that the licensee has portable shields and should interview staff to confirm that the shields are set to the approved configuration for the room during procedures;

c. Sr-90 Eye Applicators. Determine the source is properly shielded or stored to prevent bremsstrahlung radiation or high ambient dose rates.

If shielding is not evident, then the inspector should assess the licensee's procedure to use shielding and the licensee's further evaluation of radiation doses to workers and members of the public respectively under 10 CFR 20.1201, 20.1301, and 20.1302. The inspector should verify that the licensee instructed workers under 10 CFR 19.12 about use of shielding. In certain cases, a licensee may have determined that shielding was not indicated under particular conditions to protect the patient or human research subject from a non-radiological hazard which has significant health and safety consequences to the patient or human research subject.

03.04 Comprehensive Safety Measures. During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration.

During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.05 Radiation Dosimetry Program. The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

a. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.

b. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within NRC regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and discussions the inspector determines that a worker had exceeded an NRC regulatory limit, the inspector should immediately contact NRC regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

c. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy of emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor in accordance with 10 CFR 20.1501.

03.06 Radiation Instrumentation Surveys and Leak Tests.

a. Equipment and Instrumentation.

1. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with NRC regulatory requirements and the manufacturer’s recommendations.

The inspector should independently verify through direct observations that survey instruments have the appropriate range of use in accordance with 10 CFR 35.61. The inspector should also verify that the survey instruments are calibrated at the required frequency and checked for operability before use, in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff conduct the check for operability to ensure that these individuals are knowledgeable in how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee’s that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee’s calibration procedures.

2. During the inspection, the inspector should independently verify that the licensee has access to a dosimetry system for performing the full calibration and spot-check measurements of remote afterloader unit output. The system must be calibrated in accordance with the requirements of 10 CFR 35.633 and 643. During the inspection, the inspector should review selected dosimetry worksheets from the previous full calibration measurements required by 10 CFR 35.633 and 643. If the licensee participates in intercomparison of dosimetry measurements, the inspector should review the licensee's performance results to determine that systemic measurement errors are identified and corrected.

3. During the conduct of the inspection, the inspector should independently check the installed radiation monitors to ensure that they have been maintained in accordance with the applicable requirements. In addition, the inspector should independently verify the operability of permanent radiation monitors, availability of backup power supply for the source-retract systems, source position indicators, daily checks, service and maintenance of units. During the inspection, the inspector may have cognizant licensee staff demonstrate the operability of those devices to ensure that they perform as designed.

4. When appropriate, the inspectors should confirm that the licensee is knowledgeable in identifying and reporting defects in accordance with Part 21. This will vary dependent upon the scope of the licensee's program.

b. Area Radiation Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within NRC regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. If during the conduct of the inspection a brachytherapy procedure is currently in progress, the inspector should make independent measurements in adjacent unrestricted areas to confirm that the requirements of 10 CFR 20.1301 are met. However, the inspector must use NRC radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the NRC regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

If practical and when appropriate, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured. The survey activities should be at a specified frequency, in accordance with the related licensee procedures. The inspector should also perform independent confirmatory measurements, as needed to verify licensee assumptions or measurements.

The inspector should verify by independent measurement that shielding surveys of the main source safe with the source in the shielded position and treatment room are in compliance with the requirements of 10 CFR 35.652. Indications of higher than expected dose levels by an inspector may indicate that the source is a higher activity than authorized or that the source is not fully shielded on retraction.

c. Source Replacement Surveys. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has performed surveys following source changes, device repair, or device maintenance for remote after loader programs.

Through further discussions, direct observations of license activities, and reviews, if necessary, the inspector should verify 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 temporary implant brachytherapy procedures, a radiation survey of the patient must be performed immediately after source removal.

If from those discussions and direct observations the inspector determines that individuals do not understand, perform checks or conduct activities appropriately to ensure compliance to NRC regulatory requirements, the inspector should discuss this matter with appropriate licensee representatives as soon as practicable to ensure that previous activities have been conducted appropriately and retraining of the individuals is conducted prior to using such instruments for such surveys.

d. Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed or contained sources are performed at the required frequency found in 10 CFR 35.67(b) or license conditions. Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.67(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels) or approved level included in a license condition, the inspector should verify that the licensee made the appropriate notifications per 10 CFR 35.67 (e) and removed the source from service.

03.07 Radiation Safety Training and Practices

a. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). The inspector should note that it is the licensee’s 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, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

Of the training program elements, training given to authorized users, and those individuals under the supervision of authorized users, is of primary importance. The inspector should interview one or more users of radioactive materials to independently verify that they have received the required training. The inspector should 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.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users and supervised individuals 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, videos, and “dry runs” for more complex or hazardous operations.

b. Operating and Emergency Procedures. Emergency procedures will be developed, implemented and maintained by the licensee in accordance with 10 CFR 35.610 and may vary from step-by-step procedures to more generalized procedures. During the conduct of the inspection, the inspector should verify that these procedures are posted at the remote afterloader unit console in accordance with 10 CFR 35.610. During the inspection the inspector should interview operators of the unit to determine that actions required to be performed in the event of abnormal operation of the device are known by such individuals.

From those interviews, the inspector should determine if such individuals are aware of the location of the operating procedures and what procedures to follow in the event of an emergency. In particular the inspector should determine if cognizant licensee staff is aware of the requirement to carry functional radiation detection devices into the room if the room monitor is non-functional. The inspector should determine if such 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. From further discussions, the inspector should determine if the individuals are aware that radiation surveys of the device and the patient are to be performed after a procedure is completed. In addition, from those interviews, the inspector should determine if cognizant staff is aware of the location of emergency source-recovery equipment. In addition, the inspector should attempt to interview nurses who have been involved in treatments using the device to determine their familiarity with the licensee’s emergency procedures.

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

c. Strontium-90 Eye Applicators

1. During the conduct of the inspection, the inspector should verify that the licensee is using the most recent calibration results. The inspector should note that a medical event 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. The inspector should not apply the dose rate results of a recent calibration to previous therapeutic administrations, for the purpose of identifying medical events, 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 ophthalmic applicators. They are NIST, itself, and the University of Wisconsin Accredited Dosimetry Calibration Laboratory. The inspector should note that the applicator is required to be a 10 CFR 35.49 source.

2. The inspector should also refer to Information Notice (IN) 96-66, ARecent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators,@ for additional inspection guidance. This IN discusses the need to ensure that the dose rate from the eye applicator is correct for assurance that the prescribed dose is the administered dose. The IN describes examples of medical events and includes a decay table for the source.

3. The inspector should note that 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. During discussions with cognizant licensee representatives, the inspector should verify that the licensee is not using liquids containing halogenated compounds. These liquids are to be avoided, as corrosion of typically-constructed applicators can occur.

4. Through direct observations made during the conduct of the inspection, the inspector should ensure that the licensee has properly shielded or stored the source to prevent bremsstrahlung radiation or high ambient dose rates.

5. The inspector should note that requirements for monitoring occupational exposure are specified in 10 CFR 20.1502. From direct observations made during the conduct of the inspection and discussions with cognizant licensee representatives, the inspector should ensure that proper ALARA techniques are used. Some techniques may include a method, such as the use of an ophthalmic speculum, to hold the patient's eye open during treatment, to minimize occupational exposure to the user's fingers.

6. The inspector should note that 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.

03.08 Management Oversight. The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

a. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management, the Radiation Safety Officer (RSO), and if applicable, the Chairperson of the RSC, and other members of the RSC. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to NRC. This information must be provided whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine 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. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and NRC regional staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

   Through discussions with cognizant licensee representatives, 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 discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

b. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program, and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. 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 IMC 2800, "Materials Inspection Program," and regional

c. policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with NRC regulatory requirements and the licensee's license. Also, the inspector should follow-up with this matter with appropriate NRC regional licensing staff to ensure that they apprised of this matter for proper licensing action.

d. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.

1. Radiation Safety Officer (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 independently verify through discussion and direct observations of licensed activities 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, if applicable, to implement corrective actions, including termination of operations that pose a threat to health and safety.

2. Audits. The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should 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, the inspector through discussions with cognizant licensee representatives should 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.

3. Radiation Safety Committee (RSC). Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should note if the licensee is required to maintain an RSC in accordance with 10 CFR 35.24(f). If applicable, through discussions with cognizant RSC representatives, the inspector should independently verify that topics of discussion during RSC meetings included ALARA reviews, incidents, generic communications,

authorized users and uses, safety evaluations, audits, and medical events, as defined in 10 CFR 35.2, etc. From those discussions, the inspector should verify that the committee is made up of representatives from each type of program area, the RSO, a representative of the nursing service, and a representative from management. If time permits, the inspector should review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness.

From those discussions, the inspector should determine if the RSC has been aggressive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. The inspector should also 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, the inspector should determine the effectiveness of the RSC to communicate the results of audits and trending analyses to appropriate personnel performing licensed activities.

e. Authorized Users. Authorized users (physicians and medical physicists) may either be named in the license application or appointed by the licensee dependent upon the scope of the licensed program. For those appointed by the licensee, the inspector should independently verify that the authorized user is trained in accordance with the approved criteria and has knowledge commensurate with operational duties.

The inspector should noted that 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. Also, 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 35.27(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent. Through discussions with cognizant licensee representatives, the inspector should verify that the appropriate individuals are present or available for assistance during remote afterloader treatments in accordance with 10 CFR 35.615(f).

f. Authorized Uses. Through discussions with cognizant licensee staff and direct observations made during tours of the licensee’s facilities, the inspector should independently verify that the licensee's use of byproduct material is limited to that which is authorized in the license. Uses of remote afterloader units for other than human use would require the licensee to comply with 10 CFR Part 36.

From direct observations of the use of licensed material, discussions with cognizant licensee personnel, and if necessary, a review of selected records, the inspector should determine that the type, quantity, and use of licensed material at the licensee's facility are as authorized by the license.

g. Financial Assurance and Decommissioning. The decommissioning recordkeeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform random confirmatory measurements for selected rooms (e.g., randomly sample selected areas, not survey 100 percent); 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. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have received radiation exposures that exceeded NRC regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NRC regulatory limits, the inspector should immediately contact NRC regional management for further guidance.

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. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, 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 contact regional management as soon as practicable 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.

h. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply.

The inspector should note that 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. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

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

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

For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to IMC 2602, " "Decommissioning Oversight and Inspection Program for Fuel Cycle Facilities and Materials Licensees;" IP 87104, "Decommissioning Inspection Procedure for Materials Licensees;" and NUREG-1757, "Consolidated Decommissioning Guidance."

i. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, FSME Newsletter, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.

j. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications following loss or theft of material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embryo/fetus or a nursing child, etc.

From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to NRC and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for follow-up and compliance to the appropriate NRC regulatory requirements.

k. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of remote afterloader equipment for non-medical purposes. In these instances, through discussions with cognizant licensee representatives, 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 may state an exemption to a particular NRC requirement.

l. Research Involving Human Subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented AFederal 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.

03.09 Licensee Review of Licensed Activities Performed By Contracted Personnel. Licensees may contract personnel to perform licensed activities. The licensee is responsible for any violations of NRC regulatory requirements that result from activities conducted by contract personnel operating under the license. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and as necessary, a review of selected records, that the licensee is reviewing work completed by contracted personnel who perform licensed activities in the same manner that all other licensed activities are reviewed. The inspector should verify that all parties to contractual arrangements are aware of their respective duties and are knowledgeable of and adhere to the licensee's specific procedures. All parties should also be aware of, the reporting and feedback mechanisms implemented to ensure that appropriate actions are taken to address the contractor's findings, particularly, potential regulatory violations.

Potential Problems. Though contract personnel can provide significant support to a radiation safety program, potential problems may be associated with their use. Common problems include: 1) Failure of the contract personnel to complete all required tasks in the specified manner or time frame; 2) Licensee assumes that all work was completed and fails to review the work of the contract personnel; 3) Licensee fails to correct problems identified by the contract

personnel; 4) Failure of licensee to review work performed by contract personnel who work outside of normal working hours; 5) Hiring contract personnel who are not qualified or experienced; and 6) Contract personnel are not able to dedicate time to fulfill the contract agreement.

03.10 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, a variety of new medical uses of byproduct material or radiation from byproduct material are always on the forefront of providing optimal medical care to patients. Due to the increase in these various new medical uses of byproduct material or radiation from byproduct material, the regulations were revised to allow licensees the ability to use such uses in order to provide optimal patient care. In accordance with the regulations in 10 CFR 35.1000, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if the licensee has submitted the information required by 10 CFR 35.12(b) through (d); and the licensee has received written approval from the NRC in a license or license amendment and uses the material in accordance with the regulations and specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter various new medical uses of byproduct material or radiation from byproduct material being used that have not been specifically amended to a licensee's license. If an inspector encounters such a use, the inspector should contact regional management as soon as practicable to independently verify that such use is authorized under the regulations. If further verification of such use is needed, the region should contact FSME for further guidance.

For further inspection guidance, refer to IMC 2800.

87132-04 REFERENCES

IMC 0620 – "Inspection Documents and Records"

IP 86740 – "Inspection of Transportation Activities"

Management Directive 8.10, "NRC Medical Event Assessment Program"

IP 84850 – "Radioactive Waste Management – Inspection of Waste Generators Requirements of 10 CFR Part 20 and 10 CFR Part 61"

IP 83822, "Radiation Protection"

IN 96-66, "Recent Misadministrations Caused by Incorrect Calibrations of Strontium-90 Eye Applicators"

IMC 2800 – "Materials Inspection Program"

IMC 2602 – "Decommissioning Inspection Program for Fuel Cycle Facilities And Material Licensees"

IP 87104 – "Decommissioning Inspection Procedure for Materials Licensees"

NUREG-1757 – "Consolidated Decommissioning Guidance"

Interim Enforcement Policy for “Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)”, located in Section 9 of the NRC Enforcement Policy

Appendices:

A. Table 1, “Decay Factors for Strontium-90 Sources”

B. Reviewing Licensees’ Implementation of Procedures for Permanent Implant Brachytherapy Administrations

C. Use of the Interim Enforcement Policy for “Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)”

END

APPENDIX A

TABLE 1

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

Years (t)	df	Years (t)	df	Years (t)	df	Years (t)	df
.25	0.994	6.5	0.854	12.75	0.734	19	0.63
.5	0.988	6.75	0.849	13	0.729	19.25	0.626
.75	0.982	7	0.844	13.25	0.725	19.5	0.623
1	0.976	7.25	0.838	13.5	0.72	19.75	0.619
1.25	0.97	7.5	0.833	13.75	0.716	20	0.615
1.5	0.964	7.75	0.828	14	0.712	20.25	0.611
1.75	0.958	8	0.823	14.25	0.707	20.5	0.608
2	0.953	8.25	0.818	14.5	0.703	20.75	0.604
2.25	0.947	8.5	0.813	14.75	0.699	21	0.6
2.5	0.941	8.75	0.808	15	0.695	21.25	0.597
2.75	0.935	9	0.804	15.25	0.69	21.5	0.593
3	0.93	9.25	0.799	15.5	0.686	21.75	0.589
3.25	0.924	9.5	0.794	15.75	0.682	22	0.586
3.5	0.918	9.75	0.789	16	0.678	22.25	0.582
3.75	0.913	10	0.784	16.25	0.674	22.5	0.579
4	0.907	10.25	0.78	16.5	0.67	22.75	0.575
4.25	0.902	10.5	0.775	16.75	0.666	23	0.572
4.5	0.896	10.75	0.77	17	0.662	23.25	0.568
4.75	0.891	11	0.765	17.25	0.658	23.5	0.565
5	0.886	11.25	0.761	17.5	0.654	23.75	0.562
5.25	0.88	11.5	0.756	17.75	0.65	24	0.558
5.5	0.875	11.75	0.752	18	0.646	24.25	0.555
5.75	0.87	12	0.747	18.25	0.642	24.5	0.551
6	0.864	12.25	0.743	18.5	0.638	24.75	0.548
6.25	0.859	12.5	0.738	18.75	0.634	25	0.545

APPENDIX B

Reviewing Licensees' Implementation of Procedures for Permanent Implant Brachytherapy Administrations

The inspector should perform a general assessment of the licensee's radiation safety program for permanent implant brachytherapy based on discussions with licensee staff, a review of selected records and procedures, and selected observations of licensed activities (if available).

If the inspector concludes from this general assessment that licensee performance is adequate to ensure public health and safety, no further inspection effort is required. If the inspector determines that the licensee did not meet performance expectations, the inspector should conduct a more thorough review of that aspect of the licensee's program and consider expanding the items reviewed. The inspector should focus on determining whether the identified weakness resulted in a safety issue. If a previously unidentified medical event is found during the inspection, follow the steps described in section 03.02h of this inspection procedure.

The inspector should always attempt to review the following:

- Description of permanent implant brachytherapy program, including the method(s) used for treatment planning and treatment administration, and the roles and responsibilities of each member of the treatment team.

- Method used to verify that the target is accurately identified and sources are accurately positioned.

- A sampling of recent written directives. Confirm that written directives include all required information, including pre-implantation and post-implantation sections.

- Method used to verify that the treatment was administered in accordance with the written directive and, if applicable, the treatment plan. Include review of a sampling of recent records.

- Licensee staff's knowledge of NRC medical event reporting requirements and ability to recognize medical events, including consideration of both the treatment site and other organs and tissues.

The inspector may also review:

- Source ordering, verification of source strength and loading pattern, and source calibration.

- If computerized treatment planning is used, acceptance testing and calculation double-checks.

- Method used to verify patient identity.

- Method used to demonstrate compliance with patient release requirements

- Response to unusual circumstances such as equipment malfunctions, unavailability of personnel, atypical patient anatomy, or unexpected imaging results.

It is typically not possible for inspectors to observe permanent implant brachytherapy treatment administrations, however regulatory requirements can be verified pre- and post-procedure. Inspectors should note that source implantation is usually performed in a sterile, surgical environment. It may be necessary for an inspector to receive approvals in advance to observe a surgical procedure, including consent from the patient before they have been administered any sedation or anesthesia. Some licensees may require the inspector to sign a non-disclosure agreement. In addition, inspectors must follow all applicable licensee procedures for entering and observing activities in a sterile environment, including any special training.

APPENDIX C

Use of the Interim Enforcement Policy for "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)"

Note: The Questions and Answers (Q&As) in this Appendix replace/supersede the Q&As distributed as the enclosure to the memorandum to Division Directors dated May 17, 2011 (ADAMS accession ML111360037) and the Q&As in the revision of Inspection Procedure 87132 issued on April 16, 2012.

The following supplemental information is intended to clarify use of the Interim Enforcement Policy (IEP) for "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)." Although the examples pertain to permanent prostate implants, this information applies to permanent implant brachytherapy administrations anywhere in the patient's body.

Inspectors are reminded that IP 87132 provides all of the official inspection guidance for permanent implant brachytherapy programs and that this Appendix is designed only to provide the inspector with additional insight concerning application of the IEP. Please note that licensed programs are not required to "fit" the descriptions in the example cases and that these cases do not represent all possible scenarios in which the IEP may be applied.

In SRM-SECY-12-0053, Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs, the Commission directed the staff to pursue rulemaking to modify the requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical event reporting. This included defining separate medical event criteria for permanent implant brachytherapy for all treatment sites, with a source strength-based criterion for the treatment site and dose-based criterion for other organs and tissues. The Commission also directed the staff to develop an interim enforcement policy to allow use of enforcement discretion for existing and future violations of current Part 35 that do not result in the misapplication of byproduct material by those licensees that use total source strength and treatment time for determining the existence of a medical event.

As directed by the Commission, the staff is currently revising the regulations in 10 CFR Part 35 for permanent implant brachytherapy programs to eliminate dose-based medical event reporting for the treatment site. In *Federal Register* Notice (FRN) "Interim Enforcement Policy for Permanent Implant Brachytherapy Medical Event Reporting" (78 FR 41125), the NRC issued an Interim Enforcement Policy (IEP) allowing the staff to exercise discretion for certain violations of regulations for reporting medical events involving permanent implant brachytherapy.

The IEP allows for effective and objective criteria for medical event reporting for permanent implant brachytherapy until the rulemaking is finalized. It provides the option for licensees to use total source strength and exposure time instead of absorbed dose when evaluating the difference between delivered dose and prescribed dose, when use of these values does not result in misapplication of byproduct material by the licensee. The IEP also allows discretion,

only for licensees that use absorbed dose for determining the existence of a medical event, when the total dose to the treatment site equals or exceeds 120 percent of the prescribed dose and certain criteria are met. This discretion is offered because stakeholders have informed the NRC that absorbed dose is an unreliable metric for regulatory purposes and the clinical objective is to deliver as much dose to the treatment site as possible, without exceeding medically-recognized dose limits for nearby normal tissues and structures.

Following publication in the *Federal Register*, the IEP was incorporated into the Section 9 of NRC Enforcement Policy, with the title *Interim Enforcement Policy for "Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)."*

The IEP does not require the inspector to document use of this enforcement discretion. It also does not require the licensee to make a medical event report in accordance with 10 CFR 35.3045 or to take any corrective actions.

The following questions, answers, and example cases illustrate application of the IEP.

Question 1
Do the requirements in Title 10 of the Code of Federal Regulations (10 CFR) Part 35 require that the prescribed dose in the written directive be expressed in units of dose, or may licensees also express the prescribed dose in units of total source strength and exposure time?

Answer 1
In accordance with the definition of "prescribed dose" in 10 CFR 35.2, the licensee may express the dose in the written directive in terms of either 1) dose or 2) total source strength and exposure time. However, 10 CFR 35.3045(a)(1) requires that a licensee report as a medical event an administration involving a dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

Under the provisions of the IEP, inspectors may exercise enforcement discretion for licensees using total source strength and exposure time to compare the treatment site delivered dose to the prescribed dose to determine if a medical event has occurred for permanent implant brachytherapy administrations. Despite the criterion In 10 CFR 35.3045(a)(1), the FRN for the IEP noted that it is not necessary for the licensee to perform an assessment to compare the delivered dose to the prescribed dose, with both doses in units of Sv or rem. The treatment site doses for therapeutic uses are large enough that a 20 percent variance in total source strength and exposure time will always result in a dose variance exceeding the values in 10 CFR 35.3045(a)(1).

This enforcement discretion may be used if all of the following criteria are met:

a. The licensee's documented procedures required under 10 CFR 35.41 specify total source strength and exposure time as the regulatory evaluation values for treatment site dose comparisons;
b. The licensee entered both the prescribed dose and the delivered dose into the written directive as total source strength and exposure time; and
c. Per 10 CFR 35.3045, the licensee timely reported the event, if applicable, based on the treatment site dose comparison in terms of source strength and exposure time.

Note that the IEP applies only to medical event determination for the treatment site. If the dose to other organs and tissues exceeded the criteria in 10 CFR 35.3045(a)(3), a medical event has occurred and the IEP does not apply.

To further illustrate Question 1, Answer 1, the following hypothetical cases are provided:

Case Number 1-1

Pre-treatment imaging was performed six weeks in advance of a permanent prostate implant. The authorized user approved a treatment plan that called for permanent implantation of 75 sources of Iodine-125 (I-125), source strength of 0.5 millicuries (mCi) per source, and 37.5 mCi total source strength. The licensee's written program called for comparison of total source strength and exposure time. The authorized user signed a pre-implantation written directive for 75 sources of I-125, total source strength 37.5 mCi, and exposure time stated as "permanent." During the surgical implant procedure, the authorized user found that the size of patient's prostate had decreased and implanted a total of 65 sources. The authorized user signed a post-implantation written directive for 65 sources of I-125, total source strength 32.5 mCi, and exposure time stated as "permanent." A CT scan performed 30 days post-implant showed 65 sources within the prostate and a dose calculation showed that the dose to other organs and tissues did not exceed the medical event criteria in 10 CFR 35.3045(a)(3).

Enforcement discretion may be used in this hypothetical case. The case did not involve misapplication of byproduct material—the authorized user made a conscious decision to decrease the number of sources to be implanted. The licensee's documented procedures specified total source strength and exposure time as the regulatory evaluation values for treatment site dose comparisons; the authorized user entered both the prescribed dose and delivered dose into the written directive as total source strength and exposure time; post-implant evaluation showed that the source strength implanted into the treatment site was within 20 percent of the source strength in the written directive; and the dose to other organs and tissues did not exceed the medical event criteria in 10 CFR 35.3045(a)(3). It is not necessary for the licensee to perform an assessment to compare the delivered dose to the prescribed dose, with both doses in units of Sv or rem.

Case Number 1-2

The licensee performed permanent prostate implants using real-time intraoperative planning. The sources that were ordered and implanted each contained 0.43 mCi of I-125, however the physicist entered source strength into the treatment planning computer system in units of air kerma strength (μGy x m^2/hr, abbreviated as U) instead of mCi. An individual source strength of 0.43 U (equivalent to 0.34 mCi) was entered instead of the correct value of 0.43 mCi. The plan approved by the AU called for 100 sources totaling 34 mCi. The licensee's written program called for comparison of total source strength and exposure time and the authorized user signed a pre-implantation written directive for 100 sources of I-125, total source strength 34 mCi, and exposure time stated as "permanent." The authorized user implanted 100 sources. He then signed a post-implantation written directive for 100 sources of I-125, total source strength 34 mCi, and exposure time stated as "permanent." Licensee staff noticed the discrepancy later and realized that 43 mCi was implanted rather than 34 mCi, This was a 26 percent

variance from the source strength in the written directive.

Enforcement discretion may not be used in this hypothetical case in which the licensee used total source strength and exposure time as the regulatory evaluation values for treatment site dose comparisons. The criteria for application of the IEP were not met because the source strength implanted into the treatment site differed from the source strength in the written directive by more than 20 percent. It is not necessary for the licensee to perform an assessment to compare the delivered dose to the prescribed dose, with both doses in units of Sv or rem. Because this treatment meets the definition of a medical event in 10 CFR 35.3045(a)(1), it is not mandatory to perform an assessment of dose to other organs and tissues in comparison with the medical event criteria in 10 CFR 35.3045(a)(3).

Question 2

What relief can be provided to licensees from the requirement to report as a medical event an administration in which the dose delivered to the treatment site differs from the prescribed dose by 20 percent or more?

Answer 2

In accordance with the requirements found in 10 CFR 35.3045, if the dose that is ultimately delivered to the treatment site differs from the prescribed dose by 20 percent or more, the licensee is required to report that instance as a medical event. This applies to the treatment site defined by the authorized user in the written directive.

However, under the provisions of the IEP, inspectors can exercise enforcement discretion when the total dose delivered to the treatment site equals or exceeds 120 percent of the prescribed dose. This discretion applies only to licensees using absorbed dose to compare the treatment site delivered dose to the prescribed dose to determine if a medical event has occurred.

This enforcement discretion may be used if all of the following criteria are met:

a. The licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose;
b. Doses to normal tissues and structures did not exceed the regulatory dose limits for reporting medical events specified in 10 CFR 35.3045(a)(3); and
c. The total dose for the treatment site was expressed in the written directive as absorbed dose.

Note that this policy does not provide enforcement discretion for a delivered dose to the treatment site that is less than or equal to 80 percent of the prescribed dose. In addition, this discretion may not be exercised for licensees using total source strength and exposure time to compare the dose delivered to the treatment site to the prescribed dose.

To further illustrate Question 2, Answer 2, the following hypothetical cases are provided:

Case Number 2-1

The authorized user signed a pre-implantation written directive for a minimum dose of 145 Gy to be delivered to the treatment site for a permanent prostate implant. The medical

physicist prepared a treatment plan with 100 percent of the prostate volume receiving a minimum dose of 145 Gy and a minimum dose to 90 percent of the prostate of 165 Gy (e.g., D90 of 165 Gy) and the authorized user approved the treatment plan. The sources were implanted and the authorized user signed a post-implantation written directive for a minimum dose of 145 Gy to the treatment site. The licensee's written program called for comparison of absorbed dose, with D90 used to characterize the delivered dose. Post-implant CT imaging was performed 30 days later. Dose calculations based on this CT showed that 100 percent of the prostate volume received a minimum dose of 145 Gy and D90 was 180 Gy. The D90 for dose delivered to the treatment site was 124 percent of the prescribed dose documented in the written directive. The dose to other organs and tissues did not exceed the medical event criteria in 10 CFR 35.3045(a)(3).

Enforcement discretion may be used in this hypothetical case involving delivered dose to the treatment site that equaled or exceeded 120 percent of the prescribed dose. The authorized user's goal was to administer at least 145 Gy to the entire treatment site and this was achieved. The total dose for the treatment site was expressed in the written directive as absorbed dose; the licensee used absorbed dose to compare the dose delivered to the treatment site with the prescribed dose; and doses to normal tissues and structures did not exceed the regulatory dose limits for reporting medical events specified in 10 CFR 35.3045(a)(3).

Case Number 2-2

The authorized user signed a pre-implantation written directive for a dose of 110 Gy to be delivered to the treatment site for a permanent prostate implant. A treatment plan was developed based on ultrasound images obtained five weeks prior to treatment. During the surgical implant procedure, the authorized user noted that the patient's prostate was significantly larger than expected and chose to implant 20 percent more sources than originally planned. The authorized user signed a post-implantation written directive for a minimum dose of 110 Gy to the prostate. The licensee's written program specified absorbed dose as the regulatory evaluation parameter, with D90 used to characterize the administered dose. Post-implant CT imaging was performed 30 days later. The calculated delivered dose to the prostate was 137.5 Gy and there was a bunching of sources in one section of the prostate. The D90 for dose delivered to the treatment site was 125 percent of the prescribed dose documented in the written directive. The dose to a volume of normal tissue outside the treatment site, near the bunched sources, exceeded the medical event criteria in 10 CFR 35.3045(a)(3).

Enforcement discretion may not be used in this hypothetical case involving delivered dose to a treatment site dose that equaled or exceeded 120 percent of the prescribed dose. The criteria for application of the IEP were not met because dose to normal tissue exceeded the regulatory dose limits for reporting medical events specified in 10 CFR 35.3045(a)(3).

Attachment 1 - Revision History for Inspection Procedure 87132

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Accession Number (Pre-Decisional, Non-Public)
N/A	12/06/05	Revised to reflect current regulations in 10 CFR Part 35.633	N/A	
N/A	10/24/02	New IP that incorporates the revised 10 CFR Part 35. Replaces IP 87117	N/A	
N/A	ML111610511 08/24/11 CN 11-014	Researched commitments for 4 years and found none. Revised to incorporate text regarding licensee responsibility for contract personnel.	N/A	ML112093348
N/A	ML12006A148 04/16/12 CN 12-006	Revised to add directions specific to permanent implant brachytherapy.	Yes 4/2012	ML12006A148
N/A	ML14346A208 02/26/15 CN 15-003	Revised to reflect the Interim Enforcement Policy for “Enforcement Discretion for Permanent Implant Brachytherapy Medical Event Reporting (10 CFR 35.3045)” Near-complete rewrite of Appendices B and C.	N/A	ML14346A212 ML14346A311