UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

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Report No: 41-00119-08/90-01

Licensee: Veterans Affairs Medical Center
Memphis, Tennessee

Docket No.: 030-03253 License No. 41-00119-08

Facility Name: Veterans Affairs Medical Center
Memphis, Tennessee

Inspection Conducted: September 18, 1990

Inspector: _____ 10/10/90
John M. Pelchat, Radiation Specialist Date Signed
Nuclear Materials Safety Section

Approved by: _____ 10/10/90
Charles M. Hosey, Chief Date Signed
Nuclear Materials Safety Section
Nuclear Materials Safety and Safeguards Branch
Division of Radiation Safety and Safeguards

REPORT SUMMARY

Scope:

This routine unannounced inspection of activities conducted under NRC License No. 41-00119-08 included a review of corrective actions for previous violations, licensee organization, radiation safety training, personnel radiation protection, radioactive material handling procedures, and radioactive waste storage and disposal.

Results:

Numerous weaknesses were identified in the Radiation Safety Program. Failure to perform the required radiation protection activities may have been the result of a lack of knowledge of regulatory requirements by the individuals involved in the radiation safety program, and the lack of sufficient management oversight and audits to ensure that licensed radioactive materials were possessed and used in accordance with the NRC's and the licensee's radiation safety requirements. Particular concerns included the failure to perform required radiation surveys before and after brachytherapy procedures, the failure to evaluate extremity radiation exposures of research personnel routinely handling millicurie quantities of phosphorus 32, and the failure to adequately evaluate dose calibrator performance as well as the failure to take corrective actions when such evaluations indicated the dose calibrator was not functioning properly.

Within the scope of the inspection, the following apparent violations were identified:

Failure to make surveys to assure compliance with 10 CFR 20.101(a) [extremity radiation exposure limits] (Section 5);

Failure to survey patient and place of use immediately after implantation of brachytherapy sources (Section 6);

Failure to survey patient after removal of brachytherapy sources (Section 6);

Failure to test dose calibrator constancy at the beginning of each day that it was used to assay patient radiopharmaceutical doses (Section 6);

Failure to evaluate the results of dose calibrator constancy tests to assure that measured values were within ± 5% percent of the expected value (Section 6);

Failure to evaluate dose calibrator linearity over its range of use down to 10 microcuries (Section 6);

Failure to repair or recalibrate the dose calibrator when measured linearity errors exceeded ± 10% (Section 6);

Failure to wear protective gloves while unpacking a radiopharmaceutical shipment (Section 6);

Failure to restrict the consumption of food and beverages in radioactive material use areas (Section 6)

Failure to perform daily surveys of radiopharmaceutical preparation and injection areas (Section 6);

Failure to perform adequate daily surveys of radiopharmaceutical injection areas located in the nuclear cardiology imaging room (Section 6);

Failure of the Radiation Safety Officer to establish and implement written policies for the safe handling of radioactive materials [failure to wear protective gloves while handling unsealed radioactive material] (Section 5);

Failure to notify the Radiation Safety Officer of areas in which weekly surveys identified levels of removable radioactive contamination in excess of actions limits (Section 6);

Failure to evaluate counting system used for the assay of weekly radioactive contamination samples to assure it had a minimum detectable activity of 2,000 dpm/100^2;

Failure to include source location information in quarterly sealed source and brachytherapy source physical inventory records (Section 6); and,

Failure to include date of radioactive waste storage or the identity of the radionuclides disposed of in records of radioactive materials disposed of by Decay in Storage (Section 7).

REPORT DETAILS

1. Persons Contacted

   * Kenneth Mulholland, Director
   * Charles C. Irving, M.D., Ph.D., Chairman, Radiation Safety Committee
   * Randall Scott, M.D., Chief, Imaging Service
   * Stefan Cowles, M.D., Chief, Nuclear Medicine Section
   Albert Wheatley, Jr., Ph.D., Radiation Therapy Physicist
   Ray Cox, Ph.D., Research Service
   Jerry Seyer, Ph.D, Research Service
   * Sam Lott, Radiation Safety Officer
   * Robert Wilson, Alternate Radiation Safety Officer
   * Gail Collins, Administrative Chief, Imaging Service
   * Dale Tinner, Chief Nuclear Medicine Technologist
   Rita Russell, Nuclear Medicine Technologist
   JoAnne Reser, Nuclear Medicine Technologist
   Margaret Hefner, Nuclear Medicine Technologist

   * - denotes persons present at the exit conference

2. Licensee Action on Previous Enforcement Matters (92702)

   (CLOSED) VIOLATION (Inspection No. 41-00119-08/87-01):
   Failure to perform quarterly evaluation of dose calibrator linearity during the fourth quarter of 1986. The inspector reviewed the records of quarterly dose calibrator linearity tests and noted that since the fourth quarter of 1986, instrument linearity tests were performed each calendar quarter.

3. Program Scope and Licensee Organization

   The Veterans Affairs Medical Center is a 600-bed facility and is authorized to possess and use licensed radioactive material for diagnostic and therapeutic nuclear medicine, brachytherapy, and in vitro research.

   The nuclear medicine program performs an average of 10 - 15 diagnostic procedures per day. The nuclear medicine section staff is made up of six nuclear medicine technologists, all of whom rotate through clinical and in vitro diagnostic laboratory activities. The licensee averages one to two iodine 131 (I-131) (>30 millicuries) therapy procedures per year and performs an average of four to six temporary implant brachytherapy procedures per year using either iodine 125 (I-125) or iridium 192 (Ir-192) sources. The licensee currently has approximately 20 active principal investigators performing research activities involving the use of radioactive materials.

The licensee also operates a self-contained irradiator loaded with 4,000 curies (Ci) of Cesium 137 (Cs-137) [as measured on November 1, 1988].

The Radiation Safety Officer (RSO) named on the license as well as the Alternate Radiation Safety Officer (ARSO) and others provide the licensee with radiation protection services under an arrangement with the University of Tennessee Medical School. The RSO stated that while he attempts to evenly split his time between the two facilities, he has recently spent almost all of his time performing radiation safety duties related to the licensee's various programs which use ionizing and non-ionizing radiation. The ARSO is detailed to provide the nuclear medicine section with radiation safety oversight and spends approximately eight percent of his time performing in this role.

The Chief of the Cancer Research Laboratory serves as the Chairman of the Radiation Safety Committee. The membership of the Radiation Safety Committee includes representatives from the imaging (nuclear medicine) and radiation oncology services as well as the nursing staff, various individuals from the research service, and the Chief of Staff's office.

Review of the Radiation Safety Committee meeting minutes indicated that the committee meets at the required quarterly frequency. The committee meeting minutes describe routine ALARA reviews including the results of investigations concerning high dosimetry results, reviews of new radioactive material use applications, unusual events involving the use of radiation (including X-rays as well as radioactive materials), and the disposal of radioactive waste.

The RSO stated that a review of the radiation safety program is presented to the Radiation Safety Committee on an annual basis. The report is presented orally, and no written copy of the report is maintained other than brief notations in the Radiation Safety Committee meeting minutes.

The licensee presents an approximately 90-minute long general radiation safety orientation to all radiation workers such as nuclear medicine technologists and research laboratory technicians prior to their beginning work in a restricted area. Research investigators are responsible for providing their staff with any specialized safety training required by their individual activities. Members of the security and housekeeping staffs are given approximately 30 minutes of radiation safety training on an annual basis to familiarize them with the precautions to be observed when entering restricted areas. Refresher radiation safety training is also provided to appropriate licensee staff members annually. The RSO maintains records documenting the dates of training, the topics reviewed, and the names of the individuals who received the training.

Interview of the chief nuclear medicine technologist indicated that radiation safety training for the nuclear medicine section staff is conducted on a annual basis. The ARSO is periodically available in the

nuclear medicine area to discuss radiation safety issues as they come up on an informal basis.

Interviews with members of the nursing staff assigned to the floor on which brachytherapy patients are housed revealed that they were knowledgeable of the precautions to observed when caring for patients containing implanted radioactive material.

No violations or deviations were identified.

5. Personnel Radiation Protection (83822)

The licensee issues dosimetry to about 200 persons who are routinely involved in nuclear medicine, brachytherapy, and research. Whole body film badges and extremity thermoluminescent dosimeters are exchanged on a monthly basis. A member of the University of Tennessee physics group is responsible for the review of dosimetry results for all licensee activities which involve the use of ionizing radiation sources, both X-ray and radioactive materials. A summary of radiation dosimetry results is presented to the Radiation Safety Committee on a quarterly basis.

Radiation dosimetry records were reviewed for the period beginning November 1, 1989 through July 31, 1990. The maximum recorded quarterly whole body radiation exposure was 80 millirem (mRem). The maximum recorded quarterly extremity radiation exposure was 460 mRem.

The inspector observed a nuclear medicine technologist preparing syringes containing radioactive material to used as "point" sources for performing quality assurance tests on imaging cameras. These sources typically contain 200 - 300 microcuries of technetium 99m (Tc-99m). It was further observed that a number of other nuclear medicine technologists were not wearing protective gloves while handling these "point" sources. Interviews with members of the nuclear medicine staff indicated that their understanding of the Nuclear Medicine Section's radiation safety procedures did not require protective gloves to be worn when handling "small" quantities of unsealed radioactive materials such as "point" and "flood" sources. 10 CFR 35.21(b)(2)(v) requires that the RSO establish and implement written policies and procedures for using radioactive materials safely. Model procedures and rules for using radioactive materials safely are described in Appendix I of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs". Item 2 of Appendix I requires that disposable gloves be worn at all times while handling unsealed radioactive materials.

The failure to implement procedures requiring the wearing of disposable gloves during all unsealed radioactive material handling operations was identified as an apparent violation of 10 CFR 35.21(b).

Interview of the ARSO and review of iodine use and bioassay records indicated that thyroid bioassays of persons handling volatile forms of radioactive iodine were done 24 - 72 hours after performing thyroid therapy or research iodination activities. Results of these thyroid bioassays were below the investigative action limits specified in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131".

Interview of a senior research investigator in room BB-120 indicated that the individual routinely worked with up to five millicuries of phosphorus 32 (P-32) on a biweekly basis. The investigator stated he had never worn TLD extremity dosimetry to monitor radiation exposure to his hands and forearms during P-32 handling operations. Interview of the RSO indicated that extremity dosimetry was provided only to those investigators who had requested it and that the licensee had not performed an evaluation of the extremity exposures resulting from various research activities with P-32 to ensure such exposures did not exceed the limits specified in 10 CFR 20.101(a).

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a) "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of circumstances.

The failure to perform an evaluation of the extremity radiation exposures to the hands and forearms resulting from research activities using P-32 to ensure that the resultant doses did not exceed the limits established in 10 CFR 20.101(a) was identified as an apparent violation of 10 CFR 20.201(b).

6. Radioactive Material Handling Procedures (87100)

The inspector observed upon arrival in the nuclear medicine area that all radiopharmaceutical use and storage areas were securely locked and properly posted.

The licensee receives radiopharmaceuticals from a commercial nuclear pharmacy. The inspector observed a nuclear medicine technologist opening and examining the contents of an incoming radiopharmaceutical shipment. The technologist examined each syringe shield and verified the contents against the package's shipping papers. The technologist was not wearing protective gloves while performing this activity. Condition 17 of NRC Radioactive Materials License No. 41-00119-08 requires that the licensee possess and use licensed radioactive materials in accordance with the statements, representations, and procedures contained in the license application dated September 23, 1983 and in the documents submitted in support of that application. Item 14(B)(1)(b) of the application dated

September 23, 1983 requires that individuals unpacking radioactive material shipments wear protective gloves.

The failure to wear protective gloves while unpacking radioactive material shipments was identified as an apparent violation of License Condition 17.

Interviews with the chief nuclear medicine technologist indicated that the licensee did not perform radioactive material package receipt surveys of radiopharmaceutical shipments. Review of the licensee's procedures revealed that the licensee had developed and implemented radioactive material shipment receipt procedures in accordance with 10 CFR 20.205(d) but these procedures specifically excluded shipments of radiopharmaceuticals. The inspector discussed the experience of other nuclear medicine licensees which have received contaminated radiopharmaceutical shipments from commercial nuclear pharmacies. The inspector also noted that the adoption of radiopharmaceutical receipt survey procedures such as the model procedures in Appendix L of Regulatory Guide 10.8, Revision 2 would reduce the potential for the hospital unknowingly receiving a contaminated shipment.

Review of daily dose calibrator constancy records and radiopharmaceutical use records as well as interviews with members of the nuclear medicine section staff revealed that dose calibrator constancy was not tested prior to the instrument's use for the assay of radiopharmaceutical doses on weekend days during which the "on-call" technologist was called back to the hospital to perform diagnostic studies. Specifically, on 16 occasions between January 1 and September 18, 1990, dose calibrator constancy was not tested prior to the instrument's use to assay patient doses. 10 CFR 35.50(b)(1) requires that the licensee test the dose calibrator for constancy at the beginning of each day of use.

The failure to test dose calibrator constancy before its use to assay radiopharmaceuticals was identified as an apparent violation of 10 CFR 35.50(b)(1).

The nuclear medicine technologist on duty in the nuclear medicine preparation laboratory was observed performing the daily dose calibrator constancy test. The technologist recorded the test results in a logbook used to maintain various radiation safety records. A chart documenting the test sources' theoretical decay on a monthly basis as well the acceptable limits of test result variance was maintained in the front of this logbook. It was observed that the technologist did not refer to this table or calculate the acceptable range of source measurement variation to assure that the dose calibrator was functioning properly. The technologist indicated that the measured value was compared to previous results to "make sure it looked right" and that no other quantitative evaluation was made. The chief nuclear medicine technologist stated that he frequently reviewed dose calibrator constancy test results but that it was not always possible to do so before the instrument was used for the assay of patient

doses. Item 10(a)(4) of the radioactive materials license application dated September 23, 1983 states that the results of daily dose calibrator constancy tests will be evaluated to verify that the measured result is within ± 5% of the expected value.

The failure to evaluate dose calibrator constancy test results to assure that the measured result is within ± 5% of the expected value was identified as an apparent violation of License Condition 17.

A review of quarterly dose calibrator linearity test records revealed that the evaluations performed on June 11, 1990 and July 15, 1987 indicated that the instrument's performance was apparently not linear. Records of the July 15, 1987 test indicated a 12% error in the 50 millicurie (mCi) range and an 8% error in the 5 mCi range. Records of the June 11, 1990, linearity test indicated a 31% error in the 5 mCi range but that licensee personnel suspected that the apparent error was the result of a mistake in transcribing the test data. In neither case, did licensee personnel take further action to verify that the dose calibrator was performing properly or determine if the instrument required repair and recalibration. In both instances, the licensee continued using the instrument for the assay of radiopharmaceuticals. Subsequent routine dose calibrator linearity tests indicated that the instrument was linear. Item 10(b)(5) of the radioactive materials license application dated September 23, 1983 states that dose calibrator linearity errors greater than ± 5% indicate the need for instrument repair or recalibration.

The failure to further evaluate the dose calibrator's performance after the July 15, 1987 and June 11, 1990 dose calibrator linearity tests indicated errors in excess of 5% was identified as an apparent violation of License Condition 17.

Review of the quarterly dose calibrator linearity test records indicated that between February 27, 1989 and June 11, 1990, instrument linearity was not evaluated down to 10 microcuries (uCi). 10 CFR 35.50(b)(3) requires that the licensee test the dose calibrator for linearity over its range of use between the highest radiopharmaceutical dosage that will be administered and 10 uCi.

The failure to evaluate dose calibrator linearity over the range of the instrument's use from the highest radiopharmaceutical dosage down to 10 uCi was identified as an apparent violation of 10 CFR 35.50(b)(3).

Review of annual dose calibrator accuracy measurements indicated that these tests were performed as required.

Review of daily area radiation survey records and radiopharmaceutical use records as well as interviews with members of the nuclear medicine section staff revealed that daily area radiation surveys were not performed on weekend days during which the "on-call" technologist was called back to the hospital to perform diagnostic studies. Specifically, on 16 occasions between January 1 and September 18, 1990, no area radiation surveys were

made of radiopharmaceutical preparation and injection areas on weekends during which radioactive materials were handled and administered to patients. Item 17(A) of the radioactive material license dated September 23, 1983 states that radiopharmaceutical preparation and injection areas will be surveyed daily after the use of radioactive materials.

The failure to survey radiopharmaceutical preparation and injection areas in the nuclear medicine area at the end of each day that radioactive materials were handled was identified as an apparent violation of License Condition 17.

During the review of daily area survey records it was noted that on 65 occasions between January 1 and September 18, 1990, the entry "syringes" was made in the area for documenting the results of surveys performed in the 5th floor nuclear cardiac imaging room. The chief nuclear medicine technologist stated that the previous supervisor had permitted the practice of measuring the activity of used cardiac imaging agent syringes in the dose calibrator, and if no activity was measured, concluding that the cardiac imaging room was free of radioactive contamination. The chief technologist added that he was attempting to instruct the staff technologists that measurement of the empty syringes in the dose calibrator did not constitute an adequate survey of the cardiac imaging room but that the practice still persisted. 10 CFR 35.70(a) requires that a licensee survey all areas in which radiopharmaceuticals are prepared and administered at the end of each day of use with a radiation detection instrument. 10 CFR 35 defines a radiation detection instrument as an instrument capable of detecting dose rates over the range of 0.1 millirem per hour (mRem/hr) to 100 mRem/hr.

The failure to perform adequate area radiation surveys of the nuclear cardiac imaging room at the end of each day of use was identified as an apparent violation of 10 CFR 35.70(a).

Interviews of the ARSO and review of weekly area radioactive contamination survey records revealed that the licensee maintained the results of these surveys in counts per minute and that the licensee had established a 2,000 counts per minute per 100 square centimeters (cpm/100 cm^2) decontamination action limit. The ARSO showed the inspector a copy of the licensee's area survey procedures, entitled "in vivo wipe procedures," which stated that areas exceeding 2,000 cpm/100 cm^2 should be decontaminated and resurveyed. The ARSO stated that the counting system used for the evaluation of radioactive contamination wipe samples had an overall counting efficiency of approximately 60%, which would result in the licensee's action limit being equivalent to approximately 3,300 disintegrations per minute per 100 square centimeters (dpm/100 cm^2). The inspector noted that the licensee routinely counted a Cs-137 standard each time that the weekly wipe samples were evaluated. It was also noted that in April 1990, the results of the standard counts increased from approximately 6,000 cpm to approximately 17,000 cpm. During discussions with the inspector, the ARSO stated that in April 1990, the counting equipment was modified to permit

counting of all gamma rays with energies of 70 - 414 KeV, and that this increase in the counting window accounted for the increased count rates for the Cs-137 standard. The licensee had not determined the counting system's lower limit of detection. 10 CFR 35.70 required that weekly radioactive contamination surveys be able to detect 2,000 dpm/100 cm^2.

Failure to evaluate the counting system used for the assay of weekly radioactive contamination samples to assure it had a minimum detectable activity of 2,000 dpm/100 cm^2 was identified as an apparent violation of 10 CFR 35.70

Review of contamination survey records and interviews of the ARSO and nuclear medicine section personnel indicated that on eight occasions between July 1989 and July 1990, no action was taken to notify the RSO or to decontaminate areas in the nuclear medicine department after weekly surveys detected the presence of removable radioactive contamination ranging from 8,300 to 91,000 cpm/100 cm^2 (approximately 14,000 to 152,000 dpm/100 cm^2). 10 CFR 35.70 requires that the RSO be notified in the event of weekly radioactive contamination surveys detecting the presence of removable contamination in excess of the licensee's action limits.

The failure to notify the RSO or to take any other corrective actions after weekly surveys detected areas with radioactive contamination levels exceeding the licensee's action limit was identified as an apparent violation of 10 CFR 35.70.

Review of sealed source leak test records indicated that leak tests were performed quarterly. All sealed source leak test results were less than 0.005 uCi.

Review of sealed source inventory records indicated that inventories were performed quarterly. Inventory records did not include information regarding the physical location of each sealed source at the time of inventory. 10 CFR 35.59(g) requires that sealed source inventory records include the location of each source.

The failure to list the physical location of sealed sources on inventory records was identified as an apparent violation of 10 CFR 35.59(g).

Review of brachytherapy records and interview of the RSO indicated no radiation surveys were performed after temporary implant sources had been removed at the end of brachytherapy procedures performed on or about April 7 and December 18, 1989 using iridium 192 (Ir-192); and on or about March 26 and August 29, 1990 using iodine 125 (I-125). The RSO was not able to explain why these surveys were not performed. 10 CFR 35.404(a) requires that immediately after the removal of temporary implant therapy sources from a patient, a radiation survey be made to confirm that all the sources have been removed from the patient and returned safely to the implant source storage shield.

The failure to survey temporary implant patients immediately after the removal of the last temporary implant source to verify that all sources have been removed was identified as an apparent violation of 10 CFR 35.404(a).

Review of brachytherapy records and interview of the RSO also indicated that no surveys were made after the implantation of I-125 temporary implant sources into a patient on August 29, 1990. 10 CFR 35.406(c) requires that immediately after the implantation of therapy sources into a patient, a radiation survey be made to confirm that no sources have been misplaced.

The failure to perform radiation surveys immediately after the implantation of brachytherapy sources into a patient was identified as an apparent violation of 10 CFR 35.406(c).

During a tour of the areas in which the licensee conducts in vitro research with licensed radioactive material, it was noted that all personnel observed handling radioactive materials were wearing protective gloves, laboratory coats, and required radiation dosimetry except as noted in Section 5 of this report. It was also observed that rooms in which radioactive materials were stored were adequately posted and were either locked or under the immediate supervision of a research worker.

The inspector noted a half-eaten brownie and a cup of coffee immediately adjacent to a radioactive material handling area located in room BB-103, a room in which unsealed hydrogen 3, carbon 14, and phosphorus 32 were stored and used. The senior research investigator working in the laboratory indicated that the food was being eaten by a research assistant working in the laboratory. The investigator added that the consumption of food and beverages in areas in which radioactive materials were stored and used was not permitted. The investigator then disposed of the food into a trash can. Both the investigator and the RSO confirmed that safe radioactive materials handling practices were included in the radiation safety training provided to research workers. Item 15(A)(7) of the radioactive materials license dated September 23, 1983 requires that individuals refrain from using food, beverages, cigarettes, cosmetics, medicines, or similar items in the vicinity of unsealed radioactive material.

The consumption of food and beverages in areas where unsealed radioactive materials were used and stored was identified as an apparent violation of License Condition 17.

Interview of a senior research investigator working in room BB-120 indicated that personnel working in his laboratory with P-32 did not maintain records of periodic radiation surveys. The investigator did confirm that such surveys were performed. Item 17(D) of the radioactive materials license application dated September 23, 1983 requires that periodic radiation surveys be performed of research areas in which radioactive materials are handled and that records of these radiation surveys be maintained.

The failure to maintain records of periodic radiation surveys was identified as an apparent violation of License Condition 17.

Interviews with several individuals working in research areas with radioactive materials indicated that they had an adequate knowledge of safe radioactive materials handling practices. All research personnel interviewed were familiar with the procedures to be followed and the persons to be contacted in the event of an incident involving radioactive materials.

The licensee possesses and operates a self-contained irradiator for the irradiation of research materials and small animals. The device is loaded with approximately 4,000 Ci of Cs-137 (as measured on November 1, 1988). The irradiator is located in a dedicated room which is kept locked at all times. The door of the room was observed to be adequately posted. The control panel of the irradiator is equipped with a keyed interlock and the key is maintained by the investigator responsible for the device's operation. Routine and emergency operating instructions were posted on the wall.

The RSO retrieved the irradiator control panel key and stated that the investigator would only release the key to individuals whom the investigator had trained in the device's operation. The RSO then demonstrated that all of the irradiator's safety interlocks and warning lights were functioning correctly. It was observed that the irradiator timer did not automatically return the device's source to the shielded position at the end of the intended irradiation period. The irradiator's interlocks prevented access to the source chamber and the source could be returned to the shielded position manually. The irradiator was cycled several times and in each instance, the source had to be returned to the shielded position manually. The RSO stated that he would contact the authorized maintenance representative for the irradiator to arrange for the device's repair. The RSO posted a notice on the irradiator that device was not be used without his prior approval. The RSO also stated that he notify the NRC if any generic problems were identified during the repair of the irradiator.

It was observed that an adequate number of NRC Form 3, "Notice to Employees," were posted as well as notices stating where copies of the NRC radioactive materials license and regulations were available for review.

7. Radioactive Waste Disposal (84850)

Radioactive waste generated as the result of research activity is collected in appropriately shielded and labeled containers in each laboratory. When these containers are full, research personnel contact a member of the Research Service staff to arrange for the collection of the waste. The RSO stated that he occasionally goes along during these collections to assure compliance with the licensee's radioactive waste requirements. Liquid radioactive waste is released into the sanitary sewer system. The licensee maintains records of the quantities released

to assure the releases remain below the maximum permissible concentrations established in 10 CFR 20. Short lived radioactive research waste disposed of by Decay-in-Storage is held for a minimum of ten half-lives and is surveyed prior to disposal. The licensee is currently holding long lived solid radioactive research waste and intends to incinerate such waste upon approval of new incinerator facilities whose design is currently under NRC review as part of the licensee's radioactive materials license renewal.

All used radiopharmaceutical syringes and vials are returned to the nuclear pharmacy. All other nuclear medicine section radioactive waste is stored in a dedicated room. The room is appropriately posted and is kept locked at all times. All radioactive waste is held a minimum of ten half-lives. The waste is then surveyed to confirm the decay of radiation levels to background prior to disposal. Records of nuclear medicine radioactive waste disposed by Decay-in-Storage did not include the date on which the radioactive waste was placed into storage and the identity of the disposed radionuclides. 10 CFR 35.92(b) requires that licensees maintain records of radioactive materials disposed of in accordance with 10 CFR 35.92(a)(Decay-in-Storage) and that such records include the date on which the radioactive waste was placed into storage and the identity of the disposed radionuclides.

The failure to maintain adequate records of radioactive waste disposed of in accordance with 10 CFR 35.92(a) was identified as an apparent violation of 10 CFR 35.92(b).

8. Exit Interview (30703)

The inspection scope and findings, including apparent violations, were summarized and discussed in an exit conference with the individuals indicated in Section 1 at the conclusion of the inspection. The inspector reviewed the program areas inspected and discussed the inspection findings listed below. The importance of both management's and the Radiation Safety Committee's role in providing independent verification and validation of the radiation safety program through periodic audits and program reviews was discussed. It was pointed out by the inspector that a strong audit program should have identified all of the apparent violations identified during the NRC's inspection. The importance of a sound understanding of both the licensee's and the NRC s radiation safety requirements was also emphasized.

The NRC's enforcement policy was reviewed with the licensee's representatives. The licensee acknowledged the findings and provided no dissenting comments. No proprietary information was discussed during the inspection or was included in this report.

DESCRIPTION AND REFERENCE

Violation - Failure to make surveys to assure compliance with 10 CFR 20.101(a) [extremity radiation exposure limits] (Section 5);

Violation - Failure to survey patient and place of use immediately after implantation of brachytherapy sources (Section 6);

Violation - Failure to survey patient after removal of brachytherapy sources (Section 6);

Violation - Failure to test dose calibrator constancy at the beginning of each day it was used to assay patient radiopharmaceutical doses (Section 6);

Violation - Failure to evaluate the results of dose calibrator constancy tests to assure that measured values were within ± 5% percent of the expected value (Section 6);

Violation - Failure to evaluate dose calibrator linearity over its range of use down to 10 microcuries (Section 6);

Violation - Failure to repair or recalibrate the dose calibrator when measured linearity errors exceeded ± 10% (Section 6);

Violation - Failure to wear protective gloves while unpacking a radiopharmaceutical shipment (Section 6);

Violation - Failure to restrict the consumption of food and beverages in radioactive material use areas (Section 6)

Violation - Failure to perform daily surveys of radiopharmaceutical preparation and injection areas (Section 6);

Violation - Failure to perform adequate daily surveys of radiopharmaceutical injection areas located in the nuclear cardiology imaging room (Section 6);

Violation - Failure of the Radiation Safety Officer to establish and implement written policies for the safe handling of radioactive materials [failure to wear protective gloves while handling unsealed radioactive material] (Section 5);

Violation - Failure to notify the Radiation Safety Officer of areas in which weekly surveys identified levels of removable radioactive contamination in excess of actions limits (Section 6);

Violation - Failure to evaluate counting system used for the assay of weekly radiopharmaceutical contamination samples to assure it had a minimum detectable activity of 2,000 dpm/100cm^2.

Violation - Failure to include source location information in quarterly sealed source and brachytherapy source physical inventory records (Section 6); and,

Violation - Failure to include date of radioactive waste storage or the identity of the radionuclides disposed of in records of radioactive materials disposed of by Decay-in-Storage (Section 7).