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

Report Nos.: 52-01946-07/90-01 and 52-01946-09/90-01

Licensee: University of Puerto Rico
San Juan, Puerto Rico

Docket Nos.: 030-13584 and 030-31462 License Nos.: 52-01946-07 and 52-01946-09

Facility Name: University of Puerto Rico
Medical Science Campus

Inspection Conducted: April 2 - 3, 1990

Inspectors: _____ _____
L. A. Franklin, Radiation Specialist Date Signed
Radiation Safety Projects Section

_____ _____
J. M. Pelchat, Radiation Specialist Date Signed
Nuclear Materials Safety Section

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

Scope:

This routine, unannounced inspection of activities under NRC License Nos. 52-01946-07 and 52-01946-09 included a review of corrective actions for Previous Violations, licensee organization, radiation safety training, personnel radiation protection, radioactive material handling procedures, teletherapy, 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 resulted from a lack of knowledge of

19 pp.

regulatory requirements by the individuals involved in the program, and the licensee's failure to have a full time radiation safety officer (RSO) actively involved in the oversight of the radiation safety program. Particular concerns included the failure to perform the required surveys associated with brachytherapy, failure of the teletherapy physicist to perform the full calibration of the teletherapy unit, failure of the RSO to review the dose calibrator test and failure to secure licensed material against unauthorized removal.

Within the areas inspected, the following apparent violations were identified:

Failure to survey patient room and contiguous areas after implantation of brachytherapy sources (Section 6);

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

Failure to secure licensed radioactive material against unauthorized removal (Section 6);

Failure to leak test sealed sources and brachytherapy sources at the required frequency (Section 6);

Failure to conduct adequate physical inventories of sealed sources and brachytherapy sources at the required frequency (Section 6);

Failure to survey sealed source and brachytherapy source storage areas (Section 6);

Failure to adequately evaluate process and engineering controls used to limit airborne concentrations of radioactive material (Section 5);

Failure to evaluate ventilation rates in rooms used for the administration of radioactive gas at the required frequency (Section 6);

Failure to perform radioactive material package receipt surveys (Section 6);

Failure of Radiation Safety Committee and Radiation Safety Officer to perform annual radiation safety program review (Section 3);

Failure of Radiation Safety Officer to review and sign records of dose calibrator accuracy, linearity, and geometric dependency tests (Section 6);

Failure of Teletherapy Physicist to perform full calibration of teletherapy system (Section 7);

Failure of Teletherapy Physicist to review results of teletherapy system monthly spot checks (Section 7); and

Failure to leak test teletherapy system sealed source at the required frequency (Section 7).

REPORT DETAILS

1. Persons contacted

* Onelio Nunez, Dean of Administration and Acting Chancellor
* Ida Nilsa Guzman, Assistant Dean of Administration
* Jose A. San Inocencio, Auxiliary Dean of Administration
Heriberto Torres, Ph.D., Radiation Safety Officer and Teletherapy Physicist
Frieda M. Silva, M.D., Director of Nuclear Medicine and Chairman, Radiation Safety Committee
Victor A. Marcial, M.D., Director of Radiation Oncology
Cecilia Ramirez, Radiation Therapy Dosimetrist
Julio Caraballo, Chief Teletherapy Technologist
Vilma Perez, Chief Nuclear Medicine Technologist
Marisol Rivera, Staff Teletherapy Technologist
Jose Robles, Health Physics Technician
Santiago Gomez, Health Physics Technician

* - denotes persons present at exit interview

2. Licensee Action on Previous Enforcement Matters (92702)

(OPEN) VIOLATION (Inspection No. 52-01946-08/89-02): Failure of the Teletherapy Physicist (RSO) to perform a full calibration of teletherapy system on annual basis and after teletherapy system repairs. In a letter dated December 12, 1989, the licensee admitted the violation and stated that the designated teletherapy physicist would perform a special full calibration of the teletherapy system to substitute for the calibration performed by an unauthorized individual. The inspector reviewed the licensee's response and determined that as of April 3, 1990, the teletherapy physicist had not performed the special calibration.

(OPEN) VIOLATION (Inspection No. 52-01946-07/89-01): Failure to secure licensed radioactive material against unauthorized removal. In a letter dated July 20, 1989, the licensee stated that the occasion upon which the inspector observed the open, unattended nuclear medicine hot lab was an isolated occurrence. The licensee stated that corrective actions would include training of the nuclear medicine staff and increased supervision by the RSO. The inspector observed that on April 2, 1990, the nuclear medicine hot lab was again found to be open and unattended for more than 15 minutes.

(OPEN) VIOLATION (Inspection No. 52-01946-08/89-01): Failure of the Teletherapy Physicist to review and sign monthly teletherapy system spot check result records. In a letter dated July 20, 1989, the licensee admitted the violation and stated that the records of monthly spot checks would be

reviewed by the teletherapy physicist. The inspector determined that as of April 3, 1990, the Teletherapy Physicist had not reviewed the results of monthly teletherapy system spot checks.

(CLOSED) VIOLATION (Inspection No. 52-01946-08/89-03): Failure to limit quarterly whole body radiation exposures to less than 1.25 Rems. Review of the monthly radiation dosimetry results by the RSO for the period of September 1 - 30, 1989 indicated that a teletherapy technologist had received a whole body exposure of 1.820 Rems during that period. Interviews of the technologist indicated that he did not recall any unusual occurrences involving the teletherapy system during the period in question. Investigations including surveys and interviews of involved individuals by the licensee and NRC were not able to establish the cause of the high dosimeter result.

(CLOSED) VIOLATION (Inspection No. 52-01946-08/89-02): Failure to evaluate radiation doses received by patient and nursing staff after a patient removed brachytherapy implant sources and placed them into a night stand in the room. In a letter dated December 18, 1989, the licensee admitted the violation and stated that members of the radiation safety, nursing, and physician staffs would receive remedial training in brachytherapy emergency procedures. Interview of various licensee employees indicated that they were familiar with normal and emergency brachytherapy radiation safety procedures.

(CLOSED) VIOLATION (Inspection No. 52-01946-08/89-01): Unauthorized teletherapy physician user. The licensee has amended the license to include the physician.

(CLOSED) VIOLATION (Inspection No. 52-01946-07/89-01): Failure to record the results of thyroid bioassays. In a letter dated July 20, 1989, the licensee admitted the violation and stated that the RSO would be assigned supervisory responsibility to assure that thyroid bioassays were performed and recorded as required. The inspector verified that the specified corrective action had been implemented.

(CLOSED) VIOLATION (Inspection No. 52-01946-07/89-01): Failure to perform radiation surveys of research laboratories using radioactive material. The inspector reviewed the licensee's response dated July 20, 1989, and determined that the specified corrective actions had been implemented. The licensee now has two full-time health physics technicians and another technician is in training to support the research and nuclear medicine radiation safety programs. This violation has not recurred.

(CLOSED) VIOLATION (Inspection No. 52-01946-07/89-01): Failure to calibrate radiation survey instrumentation at the required six month frequency. The inspector reviewed the licensee's response dated July 20, 1989, and verified that the specified corrective action had been implemented. The license was amended to permit annual radiation survey equipment calibration.

3. Program Scope and Licensee Organization

The Licensee is authorized to possess and use licensed radioactive material for diagnostic and therapeutic nuclear medicine, brachytherapy, teletherapy, and in vitro research.

The nuclear medicine program performs an average of 25 diagnostic procedures per day. The teletherapy program treats an average of 16 - 20 patients per day. The licensee also averages approximately one iodine-131 (I-131) thyroid therapy procedure and one brachytherapy procedure using either cesium-137 (Cs-137) or iridium-192 (Ir-192) each month. The licensee currently has approximately 39 active principal investigators performing research activities involving the use of licensed radioactive material.

The Radiation Safety Officer (RSO) was appointed to his post on April 10, 1989 and is an associate professor on the University of Puerto Rico faculty. The RSO is also an authorized user of radioactive materials in research activities as well as the licensee's designated teletherapy physicist. The RSO stated that he spent approximately 50 percent of his time performing radiation safety related duties. The Radiation Safety staff also includes two full time health physics technicians, one of whom is the former RSO. An additional full time health physics technician is currently receiving on-the-job training.

The Director of Nuclear Medicine serves as the Chairman of the Radiation Safety Committee. The membership of the Radiation Safety Committee includes representatives from the nuclear medicine and radiation oncology departments as well as the nursing staff, research, and the university administration.

Review of the Radiation Safety Committee minutes indicated that the committee meets at the required quarterly frequency. The committee meeting minutes include reviews of routine radiation safety business such as radiation dosimetry reports, review and discussion of new radioactive material use applications, unusual events involving the use of radiation or radioactive materials, research laboratory survey and radiation safety audit results, low-level

radioactive waste disposal alternatives, and actions taken to correct program deficiencies identified during NRC inspections.

10 CFR 35.22(b)(6) requires that the Radiation Safety Committee perform with the assistance of the RSO, an annual review of the radiation safety program. The topics to be included in this review have been established in the licensee's radiation safety manual which was included as part of the licensee's application. Condition 20 of NRC Radioactive Material License No. 52-01946-07 requires that the licensee conduct its radiation safety program in accordance with the statements, representations, and procedures described in the radioactive material license application including the documents submitted in support of the application. Review of the Radiation Safety Committee minutes and interview of the RSO revealed that the committee had last performed a comprehensive annual review of the radiation safety program in April 1989.

No violations or deviations were identified.

4. Radiation Safety Training

The licensee provides one hour of initial radiation safety training to all radiation workers such as nuclear medicine technologists and research laboratory technicians prior to beginning their work in a restricted area. Members of the nursing, security and housekeeping staffs are given two hours of initial radiation safety training to familiarize them with the precautions to be observed when entering restricted areas. Refresher radiation safety training is provided to the appropriate staff members each year. The radiation safety office maintains records documenting the date of training, the topics reviewed, and the individuals receiving the training.

Interviews with members of the nuclear medicine and teletherapy staff indicated that in-service training is conducted on a periodic basis and that the RSO discusses radiation safety during these in-services about once each year. In addition, all members of the radiation oncology staff including nurses and technologists participate in weekly Chart Review meetings during which each patient's progress as well as a variety of therapy related subjects are discussed.

No violations or deviations were identified.

5. Personnel radiation protection

The licensee issues dosimetry to about 150 persons who are routinely involved in nuclear medicine, teletherapy, and research. Whole body film badge and extremity TLD dosimetry is exchanged on a monthly basis. The RSO is responsible for the review the dosimetry results for all licensee activities which involve the use of ionizing radiation sources, both X-ray and radioactive materials.

Radiation dosimetry records were reviewed for the period beginning January 1, 1989 through February 28, 1990. Other than the apparent overexposure discussed in Section 2 of this report, the maximum recorded quarterly whole body radiation exposure was 30 millirem (mRem). The maximum recorded quarterly extremity radiation exposure was 650 mRem.

During tours of the nuclear medicine, radiation oncology, and research areas, all persons working in restricted areas were observed to be wearing appropriate radiation dosimetry as well as gloves and other appropriate protective clothing.

Interviews of the RSO and licensee research personnel indicated that iodinations of research materials with volatile forms of iodine-125 (I-125) or iodine-131 (I-131) were no longer being performed. The RSO added that research with iodinated compounds now utilize commercially available materials which had been preiodinated with I-125.

Review of nuclear medicine department therapy records and thyroid bioassay result records revealed that thyroid bioassays were performed on all persons involved in the preparation or administration of therapeutic quantities of I-131 exceeding 30 millicuries (mCi). The results of these bioassays indicated no uptakes of I-131 in excess of the action limits established in Regulatory Guide 8.20, "Applications of Bioassays for I-125 and I-131".

Interviews with the RSO and a health physics technician indicated that air flow measurements had not been made of the nuclear medicine department fume hood since January 1989. This hood is used for the storage and handling of multiple dose vials containing millicurie quantities of I-131. 10 CFR 20.103(b)(3) requires in part that the licensee use adequate process and engineering controls to limit concentrations of radioactive material in air. Fume hoods in which volatile radioactive materials are handled and stored in are an example of engineering controls used to limit concentrations of airborne radioactive materials. Periodic measurements are necessary to assure that fume hood

Periodic measurements are necessary to assure that fume hood performance has not significantly degraded and to verify adequate air flow rates in varying conditions imposed by seasonal variations in building ventilation. Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions", states that where enclosures such as fume hoods are necessary to protect workers from unencapsulated radioactive material, measurements of the face velocity at the enclosure entrance should be made quarterly to ensure the airflow is adequate.

10 CFR 20.201(b) requires that each licensee perform such surveys as may be necessary for the licensee to comply with the requirements of 10 CFR 20, and, are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. 10 CFR 20.201(a) defines "survey" as 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 conditions. When appropriate, such an evaluation includes physical survey of the location of materials and equipment, and measurements of levels of radiation and concentrations of radioactive material present.

The failure to evaluate the adequacy of engineering controls designed to limit airborne concentrations of radioactive material as required by 10 CFR 20.103(b)(3) was identified as an apparent violation of 10 CFR 20.201(b). The licensee was previously cited for this violation during the March 17, 1987 inspection.

6. Radioactive material handling procedures

The inspector observed upon arrival in the nuclear medicine department that the radiopharmaceutical storage and preparation laboratory (hot lab) door was wide open and that the area was unattended by licensee staff. The inspector observed this condition to exist for in excess of 15 minutes. The hot lab is situated at the end of a hallway adjacent to an exterior door which was also found to be wide open providing potential unauthorized individuals easy access to licensed radioactive material. 10 CFR 20.207(b) requires that licensed radioactive material not in secured storage be tended under the constant surveillance and immediate control of the licensee.

Failure to secure the hot lab and its contents against unauthorized access and licensed radioactive material against unauthorized removal is an apparent violation of 10 CFR 20.207(b). This apparent violation had been previously documented and cited during the April 11 - 12, 1989 inspection. The licensee stated in a letter dated July 29, 1989 that the previously documented finding was an isolated occurrence and that corrective actions would include supplemental training of the nuclear medicine staff and increased surveillance by the RSO. These actions have been apparently ineffective in correcting the violation.

The inspector observed that all areas in which licensed radioactive materials were used and stored were properly posted and that except for the hot lab discussed above, were adequately secured to prevent the unauthorized use or removal of licensed radioactive material.

All radioactive materials, including research materials and radiopharmaceuticals, are ordered and received by the radiation safety office staff. Radioactive material shipments are delivered to the radiation safety office located in the Radiation Oncology Building. Package delivery personnel have been issued a key with which to open the office and to leave radioactive material packages delivered after business hours in secured storage. Radioactive material package receipt survey records include the date of receipt, activity and isotope of material received, and the results of direct radiation and radioactive contamination surveys.

Review of radioactive material receipt survey records revealed that no receipt survey was performed on a package containing 16.6 mCi of Ir-192 in the form of temporary implant sources received on April 12, 1989. Condition 20 of NRC Radioactive Materials License No. 52-01946-07 requires that the licensee conduct its radiation safety program in accordance with the statements, representations, and procedures described in the radioactive materials license application and in the documents submitted in support of that application. Item 10.7, page 30, of the application dated August 29, 1988, states that packages containing radioactive material will be opened in accordance with the procedures described in Appendix L of Regulatory Guide 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs" (August 1987). Step 2.c of Appendix L requires that radiation dose rate measurements be made at one meter from the package and on contact with the package surface.

Failure to perform a receipt radiation survey of the package containing 16.6 mCi of Ir-192 is an apparent violation of License Condition 20.

Review of dose calibrator constancy test records and interviews with the nuclear medicine staff indicated that dose calibrator constancy was adequately evaluated before the instrument was used for the assay of Tc-99m elutions or prepared radiopharmaceuticals. Dose calibrator constancy test records included all required information. Review of dose calibrator quarterly linearity and annual accuracy test results indicated that these test were performed as required. The licensee repeated these tests as well as evaluate the instrument's geometric dependence before the dose calibrator was returned to service after maintenance. Review of these records and interview of the RSO indicated that the RSO had not reviewed or signed the records of these dose calibrator performance tests. The RSO also indicated that he was not aware of the requirement for him to review records of dose calibrator performance tests. 10 CFR 35.50(e)(2), (3), and (4) require that the radiation safety officer review and sign records of dose calibrator accuracy, linearity, and geometric dependence tests, respectively.

The failure of the RSO to review and sign records of dose calibrator accuracy, linearity, and geometric dependence tests is an apparent violation of 10 CFR 35.50(e)(2), (3), and (4), respectively.

The licensee procures a 1.8 curie molybdenum-99/technetium-99m generator each week. Review of generator elution records indicated that molybdenum-99 "breakthrough" is tested and evaluated for each elution as required. Interview of nuclear medicine staff indicated that they were knowledgeable of appropriate radiation safety precautions to be followed when eluting the generator. Prepared radiopharmaceuticals were contained in labeled vial shields.

Review of daily and weekly area radiation survey records indicated that these surveys were performed as required and that the results of these surveys were properly recorded.

Review of sealed source leak test records indicated that leak tests had not been performed on sealed sources or brachytherapy sources since June 1989. The RSO stated that he had overlooked the fact that the sealed sources were overdue for leak tests. 10 CFR 35.59(b) requires that a licensee in possession of sealed sources or brachytherapy sources leak test such sources every six months or at other intervals approved by the NRC and described in the manufacturer's label or brochure that accompanies the sources.
Failure to leak test sealed sources every six months is an apparent violation of 10 CFR 35.59(b). The licensee was previously cited for this violation during the March 17, 1987 and the January 21, 1985 inspections.

Records of the most recent sealed source leak tests, performed in June 1989, indicated that all leak test results were less than 0.005 microcurie (uCi) of detectable activity.

Review of sealed source physical inventory records indicated that no quarterly inventory of either sealed sources or brachytherapy sources had been made since June 1989. Review of sealed source inventory records also indicated that physical inventories failed to include a 196 uCi Cs-137 source located in the nuclear medicine department hot lab. The RSO stated that the failure to perform the required sealed source inventories was an oversight. 10 CFR 35.59(g) requires that a licensee in possession of any sealed or brachytherapy sources conduct a quarterly physical inventory of such sources in its possession.

Failure to perform quarterly physical inventories of all sealed sources possessed is an apparent violation of 10 CFR 35.59(g). The licensee was previously cited for this violation during the January 21, 1985 inspection.

All radiopharmaceuticals are assayed in the dose calibrator prior to administration to patients. Nuclear medicine staff maintain records of these activities. The inspector observed the nuclear medicine staff utilizing syringe shields, gloves, and protective coats when handling radiopharmaceuticals.

The licensee uses xenon-133 (Xe-133) to perform diagnostic pulmonary ventilation studies. Interviews of the radiation safety staff indicated that no evaluation of the ventilation system for the room used for the administration of Xe-133 had been performed since January 1989. The RSO stated that the failure to evaluate the ventilation rates in the Xe-133 administration room was an oversight. 10 CFR 35.205(e)

requires that the licensee measure the ventilation rates available in areas in which radioactive gases are administered every six months.

Failure to evaluate the available ventilation rates every six months in the room in which Xe-133 is administered is an apparent violation of 10 CFR 35.205(e). This violation was previously cited during the March 17, 1987 inspection.

Review of radiopharmaceutical therapy records indicated that radiation surveys were performed immediately after the administration of large (greater than 30 mCi) therapeutic doses of I-131. Radiation surveys were also performed after the release of the therapy patient and before the room was released for unrestricted use.

Review of brachytherapy records indicated that no surveys were made of the radiation exposure rates in the patient's room and in adjacent unrestricted areas after the implantation of brachytherapy sources on three separate occasions: April 13, 1989; October 11, 1989; and January 4, 1990. Radiation safety personnel were not able to explain why these surveys were not performed. 10 CFR 35.415(a)(4) requires that a licensee promptly survey radiation dose rates in contiguous restricted and unrestricted areas after the implantation of sealed implant sources to demonstrate compliance with the requirements of 10 CFR 20.

Failure to survey radiation dose rates in contiguous restricted and unrestricted areas promptly after the implantation of therapy implant sources is an apparent violation of 10 CFR 35.415(a)(4).

Review of the therapy records for a temporary implant which began on April 13, 1989 and ended on April 17, 1989 indicated that no radiation survey was performed after the implant sources were removed to verify that all the sources had been removed from the patient and returned safely to the implant source storage shield. This procedure had utilized 9.28 Milligrams Radium Equivalent (16.6 mCi) of Ir-192. Radiation safety office staff were not able to explain why this survey was not performed, except to state that the health physics technician who routinely was responsible for such surveys was on vacation during these dates. All the Ir-192 sources were inventoried and accounted for the next day by a radiation therapy dosimetrist. 10 CFR 35.404(a) requires that immediately after removing the last temporary implant therapy source from a patient, a licensee shall make a radiation survey of the patient to confirm that all sources have been removed.

Failure to survey a temporary implant patient immediately after removal of the last implant source to verify that all sources have been removed is an apparent violation of 10 CFR 35.404(a).

Review of laboratory surveys indicated that adequate radiation surveys of each research laboratory using radioactive material were performed by the radiation safety staff on a monthly basis.

7. Teletherapy

The Picker Model C8M/80 cobalt-60 (Co-60) teletherapy system is located in the teletherapy department of the Radiation Oncology Building. The teletherapy staff consists of four teletherapy physicians, one part-time physicist (the RSO), two dosimetrists, two radiation oncology nurses, and seven teletherapy technologists. There is also a varying number of resident physicians on radiation oncology rotation on the staff.

Patients referred to the teletherapy department are examined by either a staff or resident physician to determine which therapy modality and dose is appropriate. All therapy prescriptions made by resident physicians are reviewed and verified by a staff physician. A dosimetrist will prepare a patient treatment plan which is then reviewed and approved by the attending physician. Once in progress, all treatment plans are reviewed by the entire teletherapy staff on a weekly basis and adjusted as needed.

Review of individual patient therapy treatment plans revealed that contrary to licensee policy, these plans did not include a photograph of the patient to assist the teletherapy technologist in positively identifying a particular patient. The dosimetrist stated that conventional photographs were taken, but that the resultant prints were often not available as the result of delays in having the film proce ed. The inspector discussed recent events at other licensee facilities where, for a variety of reasons, the wrong patient would answer when called and the technologist failed to positively identify the patient which then resulted in several significant therapeutic misadministrations. The inspectors recommended to licensee personnel that the licensee review their teletherapy patient identification procedures and consider possible identification aids including "polaroid" photographs in each patient's treatment folder.

Review of records indicated that the teletherapy system was

purchased from another hospital and installed in 1983. The teletherapy sealed source was installed in the system in 1977. The source had an initial installation activity of 7,745 curies (Ci) on December 5, 1977 and had decayed to 1,532 Ci as of April 2, 1990, the date of the inspection. Interviews with members of the teletherapy staff indicated that there were no plans to replace the source as the result of funding constraints despite the fact that typical patient treatment times routinely exceeded six minutes. Licensee staff also indicated that despite the increasing portion of the therapy workload being performed with a linear accelerator, there were no plans to retire the teletherapy system in the near future.
Review of teletherapy system maintenance records indicated that the teletherapy system source exposure mechanism most recently underwent major inspection and servicing on September 13, 1989. The previous major inspection and service of the teletherapy system source exposure mechanism had been performed May 23, 1985. This interval satisfies the required five year frequency specified in 10 CFR 35.647(a).

Review of annual full calibration records indicated that the last full calibration of the teletherapy system was performed on June 9, 1989 by one of the staff dosimetrists rather than by the teletherapy physicist designated on the NRC license. 10 CFR 35.632(f) requires that the annual full calibration of a cobalt teletherapy system be performed by the licensee's designated teletherapy physicist. License Condition 11.B of NRC Radioactive Material License No. 52-01946-09 specifies the licensee's designated teletherapy physicist by name.

The failure of the teletherapy physicist to perform the teletherapy system full calibration was initially documented during a Special Inspection on August 29, 1989. In a Notice of Violation dated October 12, 1989, the Licensee was cited for a violation of this requirement. In a letter dated December 18, 1989, the licensee stated that a full calibration of the teletherapy system would be performed by the designated teletherapy physicist to substitute for the calibration performed on June 9, 1989. As of the date of the inspection (April 2, 1990), no substitute full calibration had been performed which resulted in the licensee continuing teletherapy treatment activities without a valid set of full calibration measurements since June 9, 1989.

Failure of the teletherapy physicist to perform a full calibration of the teletherapy system is an apparent continuing violation of 10 CFR 35.632(f). In addition to the above listed dates, this finding has also been

documented during inspections on April 11 - 12, 1989 and September 17, 1987.

Review of teletherapy system monthly spot check records for the period beginning April, 1989 through March, 1990 revealed that these tests were performed by one of the staff dosimetrists. Results of the monthly teletherapy system output measurements showed good agreement with the values predicted by the annual full calibration measurements. Interviews with the dosimetrist and the teletherapy physicist as well as record review revealed that the teletherapy physicist did not review or sign the results of each monthly spot check after its completion. The teletherapy physicist stated that while he did occasionally discuss monthly spot check results with the dosimetrist, he did not have sufficient time to always do so. 10 CFR 35.634(c) requires that the teletherapy physicist review the results of each monthly teletherapy system spot check within 15 days of the completion of the spot check.

Failure of the teletherapy physicist to review the results of each monthly teletherapy system spot check within 15 days of the completion of the spot check is an apparent violation of 10 CFR 35.634(c). This finding was also documented during the inspection on April 11 - 12, 1989.

Interviews with the teletherapy staff and review of records indicated that the dosimetrist performed operational checks of the teletherapy system's safety systems including the door interlocks, control panel indicators and controls, patient viewing systems, and the treatment room area radiation monitor each morning before the teletherapy system was used for patient treatment. The dosimetrist demonstrated the use of a dedicated check source to confirm the proper operation of the area room monitor. The proper operation of these safety systems was verified by the inspector.

Interviews of the teletherapy technologists indicated that they had a good working knowledge of the operation of the teletherapy system's safety systems and of the licensee's therapy emergency procedures. Copies of these procedures were posted at the teletherapy system's control panel.

Review of teletherapy system sealed source leak test records revealed that the source had not been leak tested since June 1989. The RSO stated that the fact the teletherapy system sealed source was overdue for leak testing had been overlooked. 10 CFR 35.59(b) requires that a licensee in possession of sealed sources or brachytherapy sources leak test such sources every six months or at other intervals approved by the NRC and described in the manufacturer's label or brochure that accompanies the sources.

Failure to leak test the teletherapy system's sealed source every six months is an apparent violation of 10 CFR 35.59(b).
Records of the most recent teletherapy system sealed source leak test, performed in June 1989, indicated that the leak test results were less than 0.005 microcurie (uCi) of detectable activity.

8. Radioactive waste storage and disposal

A review of the licensee's radioactive waste disposal procedures revealed that the licensee stores all long and short lived radioactive waste, including waste originating in the nuclear medicine department. The licensee stores solid radioactive waste in two locations, the first in a shed located on the roof of the Medical Sciences Building and the second in a dedicated waste storage room. Licensee personnel stated that there were no plans to transfer the waste to another licensee or to begin disposing of any waste by DIS. Radiation safety office personnel pick up and package radioactive waste on an "as needed" basis.

No liquid radioactive waste is disposed of by research personnel to the sanitary sewer. Liquid radioactive waste suitable for disposal to the sanitary sewer is discarded by the radiation safety staff into a dedicated sink. Records of these disposals were maintained.

9. Exit Interview

The inspection scope and findings were summarized and discussed in an exit interview with the individuals indicated in Section 1 at the conclusion of the inspection. The inspectors reviewed the program area inspected and discussed in detail the inspection findings listed below. The importance of the Radiation Safety Committee's role in providing independent verification and validation of the radiation safety program through periodic audits and program reviews and the need for the RSO to dedicate sufficient time to oversee the program's day-to-day activities, especially

radiation safety program through periodic audits and program reviews and the need for the RSO to dedicate sufficient time to oversee the program's day-to-day activities, especially in teletherapy was discussed. 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 survey patient room and contiguous areas after implantation of brachytherapy sources (Section 6);

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

Violation - Failure to secure licensed radioactive material against unauthorized removal (Section 6);

Violation - Failure to leak test sealed sources and brachytherapy sources at the required frequency (Section 6);

Violation - Failure to conduct adequate physical inventories of sealed sources and brachytherapy sources at the required frequency (Section 6);

Violation - Failure to survey sealed source and brachytherapy source storage areas (Section 6);

Violation - Failure to adequately evaluate process and engineering controls used to limit airborne concentrations of radioactive material (Section 5);

Violation - Failure to evaluate ventilation rates in rooms used for the administration of radioactive gas at the required frequency (Section 6);

Violation - Failure to perform radioactive material package receipt surveys (Section 6);

Violation - Failure of Radiation Safety Committee and Radiation Safety Officer to perform annual radiation safety program review (Section 3);

Violation - Failure of Radiation Safety Officer to review and sign records of dose calibrator accuracy, linearity, and geometric dependency tests (Section 6);

Violation - Failure of Teletherapy Physicist to perform full calibration of teletherapy system (Section 7);

Violation - Failure of Teletherapy Physicist to review results of teletherapy system monthly spot checks (Section 7); and

Violation - Failure to leak test teletherapy system sealed source at the required frequency (Section 7).