U. S. NUCLEAR REGULATORY COMMISSION

REGION II

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Licensee:	University of Puerto Rico
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Approved:	John P. Potter, Chief Materials Licensing/Inspection Branch 2 Division of Nuclear Materials Safety

Enclosure 2

EXECUTIVE SUMMARY

University of Puerto Rico

NRC Inspection Report 52-01946-07/97-01

This routine, unannounced inspection included discussions with cognizant licensee representatives, reviews of documents, and direct observations of licensed activities. Aspects included in this report are management oversight, organization and scope of the program, facilities, equipment and instrumentation, training, retraining and instruction to workers, area radiation detection surveys and contamination surveys, personnel radiation protection, radioactive waste management, transportation, posting and labeling, quality management program, and some miscellaneous issues. The report covers operations conducted by the licensee between February 1, 1996 and January 30, 1997.

Management Oversight

- The licensee had maintained reasonable management oversight of the radiation safety program. Efforts by the Radiation Safety Committee and the Radiation Safety Office with regard to radiation safety were adequate, professional and thorough.

Organization and Scope of the Licensee Program

- Use of licensed materials occurred in three areas including the Radiation Safety Office, nuclear medicine, and research, and the organization of those areas was found adequate and, in most cases, in accordance with standard practices and the license application.

Facilities

- The inspectors found the facilities to be as stated in the licensee's application.

Equipment and Instrumentation

- The inspectors identified a violation regarding the checking of face velocity for the Nuclear Medicine fume hood (Section 3.2). Although cited differently, a similar violation was identified in Research Laboratories (Section 3.2).

- The inspectors identified a violation involving the use of an out-of-calibration survey meter in the Nuclear Medicine Department (Section 4.2).

Training, Retraining, and Instructions to Workers

- Licensee personnel were found to have been properly trained, and radiation workers had received the minimum instructions commensurate with their involvement in licensed activities.

Area Radiation Surveys and Contamination Surveys

- Surveys conducted by the licensee were found acceptable, individuals performing such surveys were found knowledgeable of the survey requirements and correct survey techniques. The handling of isotopes was observed by the inspectors and was found to be in accordance with the licensee procedures and standard practices. Leak test and inventories were found to have been conducted in accordance with regulatory requirements.

Personnel Radiation Protection

- The inspectors identified a violation regarding the exchange of dosimetry (Section 7).

Radioactive Waste Management

- The inspectors found that the licensee adequately maintained radioactive material waste for decay in storage and/or properly disposed of it in accordance with regulatory requirements.

Transportation

- The inspectors observed that transportation activities involving licensed materials were conducted in accordance with regulatory requirements of the NRC and the Department of Transportation (DOT).

Posting and Labeling

- Areas observed were properly posted/labeled and radiation hazards were clearly identified. No violations of regulatory requirements were identified in this area.

Quality Management Program (QMP)

- The licensee's QMP was found to be implemented as written. The licensee's annual review of the QMP was found to be adequate. Supervised individuals were found to be knowledgeable of the program.

Miscellaneous Issues

- The inspectors found that the licensee corrected previous violations effectively.

REPORT DETAILS

01. Management Oversight (87100)

0.01 Radiation Safety Committee

The inspectors discussed the role of the Radiation Safety Committee (RSC) with licensee representatives and reviewed RSC meeting minutes from February 1, 1996 to January 30, 1997. From those discussions and reviews the inspectors determined that the RSC had met quarterly since the last onsite inspection conducted on February 1, 1996. The RSC met with a quorum that included a representative from management and nursing, the Radiation Safety Officer (RSO), the RSC Chairman, research and other individuals involved with radiation safety activities at the licensee's facility. The RSC reviewed personnel radiation exposures, radiation safety audits, approved authorized users, and other radiation related activities associated with the licensee's facilities. Based on those discussions and reviews, the inspectors concluded that the licensee's RSC was adequately reviewing those radiation safety activities associated with the licensee's NRC byproduct materials license to ensure regulatory compliance.

0.02 Audits and Reviews

Through discussions with cognizant licensee representatives and a review of radiation safety audit records from February 1, 1996 to the date of the onsite inspection, the inspectors determined that the licensee's Radiation Safety Office conducted monthly audits of all users of radioactive materials. From those reviews and discussions the inspectors determined that the auditors reviewed radiation safety records for nuclear medicine, and research laboratories to include radiation surveys, inventory, radioactive waste disposal, and instrument quality control checks. Based on those discussions and reviews, the inspectors concluded that the auditors were knowledgeable in radiation safety practices and the licensee's NRC license and regulatory requirements. Furthermore, the inspectors found that the licensee was conducting comprehensive audits of authorized users. Cooperation between the Radiation Safety Officer, the Nuclear Medicine Department, and research personnel appears to be good. This is an improvement from previous inspections.

0.2 Organization and Scope of the Licensee Program (87100)

The inspectors reviewed records from February 1, 1996, to the date of the onsite inspection, and discussed with licensee representatives the organization and program activities associated with the NRC broad scope medical license. From those discussions and reviews the inspectors determined that the licensee currently used radioactive material in different forms for various activities associated with radiation safety, nuclear medicine, and research areas.

02.1 Radiation Safety Office

The licensee Radiation Safety Office maintains oversight of all radiation safety activities at the licensee's facility. The Radiation Safety Office is responsible for conducting audits of users of radioactive material, inventorying radioactive material possessed by the licensee, conducting and maintaining survey instrument calibrations, leak testing sealed sources, and radioactive waste management. The licensee's organization regarding radiation safety activities was identified as follows:

- Dean of Administration
- Radiation Safety Officer
- Radiation Safety Technicians (3)

02.2 Nuclear Medicine

Nuclear Medicine activities involve radio-pharmaceuticals for diagnostic and therapeutic purposes. This included the daily use of technetium-99m labeled radiopharmaceuticals for routine diagnostic studies such as bone, thyroid, gastrointestinal, gallbladder, liver, lung and heart scans. Also, the licensee uses Iodine-131 for thyroid therapy and whole body studies and Iodine-125 for blood volume studies. The licensee utilizes Iodine-131 with activities less than 30 millicuries on a weekly basis. The licensee's organization with regards to nuclear medicine activities was identified as follows:

- Hospital Administrator
- Director of Radiology
- Nuclear Medicine Manager
- Nuclear Medicine Supervisor
- Staff Nuclear Medicine Technologists (7)

02.3 Research

At the time of the inspection, the licensee had approximately 27 authorized users and approximately 24 laboratories that periodically used radioactive material. Each Authorized User had assigned laboratory technicians responsible for maintaining the radiation safety program and related activities. The Authorized Users conducted research utilizing microcurie to millicurie amounts of various radioisotopes in different forms, including Carbon-14, Chromium-51, Hydrogen-3, Phosphorus-32, and Sulfur-35.

03. Facilities (87100)

03.1 Nuclear Medicine

Through discussions with licensee representatives and direct observations made by the inspectors, the inspectors determined that the Nuclear Medicine department had three imaging rooms with one imaging camera in each room. The hot laboratory maintained the radioactive material that included diagnostic and therapeutic radiopharmaceuticals.

One violation was identified in the Nuclear Medicine area. Fume hood face velocity in the Nuclear Medicine Department had not been checked for approximately 18 months. The licensee had committed to performing these checks at six month intervals.

03.2 Research Laboratories

Through discussions with cognizant licensee representatives, direct observations made by the inspectors, and a review of records from February 1, 1996, to the date of the onsite inspection, the inspectors determined that the licensee currently maintained approximately 20 active research laboratories at various locations at the licensee's facility. On January 30, 1997, the inspectors randomly inspected five laboratories and discussed research activities associated with each of those laboratories. From those reviews and discussions, the inspectors determined contamination surveys, inventory, and waste management practices had been adequately maintained for those laboratories.

Through those discussions with licensee representatives and direct observations made by the inspectors, the inspectors determined that the licensee conducted licensed activities in various areas throughout the licensee's facilities to include the Nuclear Medicine Department, and Research Laboratories. Based on those discussions and direct observations, the inspectors concluded that the facilities observed during the onsite inspection were the same as those described in the licensee's NRC license and application material. In addition, the inspectors found the facilities to be adequate for conducting those activities authorized by the license with one exception. Face velocity of fume hoods in some active research laboratories had not been checked for up to four years.

04. Equipment and Instrumentation (87100)

04.1 Dose Calibrator

The inspectors reviewed dose calibrator records from February 1, 1996, to the date of the onsite inspection and discussed those records with cognizant licensee representatives. The inspectors determined that the licensee had two dose calibrators and conducted quarterly linearity tests, annual accuracy tests and

daily constancy checks for the dose calibrators since the last onsite inspection. Based on those reviews and discussions the inspectors did not observe any measurements or results that exceeded NRC regulatory requirements or would have necessitated repair of the instrument. During the onsite inspection, the inspectors discussed with licensee personnel those procedures for conducting dose calibrator checks. Based on those reviews, discussions, and observations the inspectors concluded that the licensee had conducted adequate tests and checks on the dose calibrator to ensure that it operated and measured radiopharmaceuticals accurately.

04.2 Radiation Detection Instrumentation

The inspectors reviewed radiation detection instrumentation records from February 1, 1996, to the date of the onsite inspection, and discussed those records with cognizant licensee representatives. From those reviews, discussions, and direct observations the inspectors determined that the licensee possessed numerous radiation detection survey instruments located in the Nuclear Medicine Department, Research Laboratories and Radiation Safety Office. Those instruments observed by the inspectors were capable of detecting dose rates over the range of 0.1 to 1,000 millirem/hr. Through further discussions, reviews and direct observations, the inspectors determined that the licensee possessed numerous radiation detection instruments used to count removable contamination survey samples in the Radiation Safety Office and Research Laboratories. From those reviews and discussions the inspectors determined that the instruments were capable of detecting contamination of 2,000 disintegrations per minute. The inspectors discussed with licensee personnel those procedures for operating radiation detection surveys and observed them demonstrating how to source check the survey instruments. From those reviews, discussions and observations, the inspectors concluded that the licensee maintained calibrated radiation detection instruments and that licensee personnel conducted source checks adequately to ensure that the instruments were capable of detecting radiation levels described in the regulations. One exception was found, the survey meter in use in the nuclear medicine hot lab on January 29, 1997, was out of calibration in excess of one month.

05. Training, Retraining, and Instructions to Workers (87100)

During the onsite inspection the inspectors discussed with licensee representatives radiation safety training given to licensee personnel and reviewed those topics discussed. From those reviews and discussions with licensee personnel, the inspectors determined that the licensee conducted training for hospital and research personnel who handled and used radioactive material, included good radiation safety practices and precautions, use of protective equipment and dosimetry, and updates in radiation safety and events. From those reviews and discussions with

licensee personnel, the inspectors determined that the licensee was adequately instructing hospital and research personnel in radiation safety and related activities associated with the NRC byproduct material license in accordance with NRC regulatory requirements.

06. Area Radiation Surveys and Contamination Control (87100)

06.1 Area Radiation and Contamination Surveys

The inspectors reviewed area radiation detection survey records conducted from February 1, 1996, to the date of the onsite inspection, for Nuclear Medicine, and Research Laboratories, and discussed those records with licensee representatives. In addition, the inspectors discussed area radiation detection survey procedures with nuclear medicine, radiation safety and research laboratory personnel. From those reviews, discussions and observations, the inspectors concluded that the licensee had conducted adequate area and removable contamination surveys on those days when licensed material had been used. Also, the inspectors found licensee personnel knowledgeable in the procedures and practices for conducting those surveys to ensure that removable contamination and area radiation levels were in accordance with NRC regulatory requirements.

06.2 Handling and Use of Radioactive Materials

The inspectors observed licensee personnel handling the receipt, use and disposal of radioactive material in Nuclear Medicine and Research Laboratories. In addition, the inspectors observed licensee nuclear medicine personnel administering radiopharmaceuticals to patients. The inspectors observed individuals using appropriate protective equipment that included gloves, and syringe shields. From those direct observations, the inspectors concluded that those individuals adequately handled and used radioactive material at the licensee's facility for those activities observed at the time of the onsite inspection.

06.3 Leak Tests and Inventories

The inspectors reviewed sealed source leak tests and inventory records conducted from February 1, 1996, to the date of the onsite inspection, and discussed those records with licensee representatives. Through those discussions and reviews of records the inspectors independently determined that sealed source leak tests and the quarterly inventories were adequately conducted by radiation safety personnel since the last onsite inspection, in accordance with NRC regulatory requirements.

07. Personnel Radiation Protection (83822)

The inspectors reviewed radiation exposure dosimetry records for calendar year 1996, and discussed those records with licensee

representatives. From those reviews and discussions, the inspectors determined that licensee personnel in Nuclear Medicine and Research were issued film badges and finger rings and were supposed to exchange the dosimetry on a monthly frequency, and that research personnel were issued dosimetry based on the amounts of radioisotope used. In reviewing these records, the inspectors found that a high percentage of badges were being exchanged bimonthly due to badges being turned into the Radiation Safety Office late. This was cited as a violation of License Condition 26. The maximum quarterly exposures noted during 1996 were 50 millirem whole body and 2790 millirem extremity. The inspectors observed licensee personnel wearing radiation dosimetry appropriately to detect radiation exposures from the handling and use of radioactive material at the licensee's facility. Based on those reviews, discussions and observations, the inspectors determined that the licensee was maintaining personnel radiation exposures As Low As Reasonably Achievable (ALARA), and no NRC regulatory radiation exposure limit had been exceeded for licensee personnel.

08. Radioactive Waste Management (87100)

The inspectors reviewed radioactive waste records for Nuclear Medicine and Research Laboratories from February 1, 1996 to the date of the onsite inspection, and discussed those records with licensee personnel. From those discussions and reviews, the inspectors determined that the licensee maintained radioactive waste in three locations. For radionuclides with short half-lives such as technetium-99m and phosphorus-32, the licensee held the radioactive waste for storage-in-decay for periods that were greater than ten half-lives. After ten half-lives the licensee conducted radiation surveys to ensure that the waste was at or below background and disposed of the waste as regular trash. For radionuclides with long half-lives, the licensee held the radioactive waste in storage or disposed of it at an approved and licensed burial site. In addition, the inspectors observed the radioactive waste areas maintained by the licensee. The inspectors conducted area radiation detection surveys and did not observe any area radiation levels that would cause a member of the public to exceed any NRC regulatory radiation exposure limits. The licensee is authorized to incinerate radioactive material, however, to date only carbon-14 and hydrogen-3 vials are being incinerated. This is being performed in compliance with 10 CFR 20.2005. Based on those reviews, discussions and observations, the inspectors concluded that the licensee adequately maintained radioactive waste at the licensee's facility in accordance with NRC regulatory requirements.

At the present time the only transportation of radioactive material by the licensee is the return of small amounts of waste to the nuclear pharmacy. The pharmacy has agreed to accept responsibility for this waste.

10. Posting and Labeling (87100)

During the onsite inspection, the inspectors observed that those areas within the licensee's facility where radioactive material was used had been adequately posted with appropriate radiation postings to warn individuals of the radiation hazards associated with those areas. Also, the inspectors observed that sealed and unsealed sources, radiopharmaceuticals, and waste containers had appropriate labels to identify the radioactive materials in them. Based on those observations, the inspectors concluded that the licensee had adequately posted areas and labeled radioactive materials in accordance with NRC regulatory requirements.

11. Quality Management Program (QMP) (TI 2800/025)

During the onsite inspection, the inspectors reviewed a sample (five percent) of patient dose administrations records for Nuclear Medicine. Records reviewed included administrations performed during calendar year 1996. Based on those reviews, and discussions with licensee staff, the inspectors concluded that the licensee implemented the QMP as written. Also, the inspectors questioned members of the licensee staff regarding the purpose of the QMP and their general knowledge and found these individuals knowledgeable commensurate with their responsibilities within the program, and that they had been trained in the licensee's QMP. No misadministrations and/or recordable events were identified by the inspectors. In addition, the inspectors reviewed records of the licensee's annual review of its QMP and determined that the licensee conducted the review in a timely manner and did not identify deviations or any need to modify the existent QMP.

12. Miscellaneous Issues (92702)

12.1 (Closed) Violation 030-13584/96001-01: Minutes of the Radiation Safety Committee meetings were not distributed to the membership during calendar year 1995.

EXIT MEETING SUMMARY

The inspectors presented those inspection results available at the time of the onsite inspection to licensee representatives at the conclusion of the inspection on January 30, 1997. The inspectors informed those licensee representatives present that four apparent violations of NRC regulatory requirements had been identified regarding the use of a survey instrument being out of calibration, air flow checks of fume hoods, and the proper exchange of personnel dosimetry. The licensee acknowledged those inspection findings available at the time of the onsite inspection. Licensee representatives did not identify any documents or processes as proprietary in nature. Dissenting comments were not received from the licensee.

INSPECTION PROCEDURES USED

IP 87100:	Licensed Materials Program
IP 83822:	Radiation Protection
IP 86740:	Inspection of Transportation Activities
IP 92702:	Followup on Corrective Actions for Violations and Deviations
TI 2800/025:	Quality Management Program and Misadministration Rule, Rev. 1

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-13584/97001-01	VIO	Failure to check face velocity of fume hood in the nuclear medicine "hot lab".
030-13584/97001-02	VIO	Failure to calibrate a survey instrument in use at the nuclear medicine department.
030-13584/97001-03	VIO	Failure to exchange personnel dosimetry at the proper frequency.
030-13584/97001-04	VIO	Failure to check face velocity of fume hoods in use in the research laboratories.

Closed

030-13584/96001-01	VIO	Failure to distribute minutes of radiation safety committee meetings held during calendar year 1995.