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

JUL 2 3 1991

Report Nos.: 52-01946-07/91-01
52-01946-09/91-01
52-01986-01/91-01
52-01986-04/91-01
52-10510-04/91-01
52-19434-02/91-01

Licensee: University of Puerto Rico

License Nos.:	Docket Nos.:
52-01946-07	030-13584
52-01946-09	030-31462
52-01986-01	030-01182
52-01986-04	030-01183
52-10510-04	030-14313
52-19434-02	030-19550

Facility Names: Medical Sciences Campus
San Juan, Puerto Rico

College of Natural Sciences
Rio Piedras, Puerto Rico

Agricultural Experiment Station
Rio Piedras, Puerto Rico

Mayaguez Campus
Mayaguez, Puerto Rico

Caribbean National Forest
El Verde Research Station, Puerto Rico

Inspection Conducted: June 17 - 21, 1991

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Inspectors: _____ 7/23/91
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Nuclear Materials Safety and
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J. D. Ennis, Radiation Specialist — Date
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L. A. Franklin, Radiation Specialist — Date
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Accompanying Personnel:

C. M. Hosey, Chief, Nuclear Materials
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Approved by: _____ 7/23/91
C. M. Hosey, Chief — Date
Nuclear Materials Safety Section
Nuclear Materials Safety and
Safeguards Branch
Division of Radiation Safety
and Safeguards

Scope:

This special, announced inspection included a review of the organization and administration of each program, the radiation protection programs, radiation safety training of personnel, and radioactive waste storage and disposal. Special emphasis was placed on a review of management control and oversight of licensed activities.

Results:

Numerous weaknesses were identified in the radiation safety program. Failure to perform the required radiation protection activities appeared to result from a lack of effective oversight of the program by University management and the radiation safety committees at each campus, lack of knowledge of NRC requirements

by the staff, and failure to have an effective program for the identification and correction of violations of NRC requirements. Particular concerns included the lack of a comprehensive program at the University for the storage and disposal of radioactive waste, failure of management representatives to attend radiation safety committee meetings, failure to secure licensed material from unauthorized removal, failure to perform training or inadequate training of the staff, the use of licensed material for nonhuman research without authorization of the radiation safety committee, failure to have a formal Quality Assurance Program for preventing misadministrations, and failure to test sealed sources for leakage. Within the areas inspected, the following apparent violations were identified:

Failure to secure licensed material in an unrestricted area against unauthorized removal from the place of storage (Sections II.G. and V.D);

Failure to test sealed sources for leakage. (Section II.H);

Failure to evaluate the radiation dose received by individuals whose personnel dosimetry badges were non-readable by the dosimetry processor (Section II.E);

Failure to assure that licensed material for nonhuman use was used only by, or under the supervision of, individuals designated by the Radiation Safety Committee (Section II.C);

Failure to perform required surveys of radiopharmaceutical waste storage areas (Section II.H);

Failure to demonstrate that contamination action limits were not exceeded (Section IV.F);

Failure to perform surveys of laboratories at required frequencies (Sections IV.F and VI.D);

Failure to perform required surveys on packages upon receipt (Section IV.F);

Failure to perform source and/or device inventories every six months (Sections V.C. and VI.D);

Failure of Radiation Safety Committees to meet at required frequencies (Sections II.C and VI.C);

Failure of the Radiation Safety Committee to establish a quorum in order to conduct business (Section II.C);

Failure of the Radiation Safety Committee to perform annual audits of the radiation safety program (Section VI.C);

Failure to notify Radiation Safety Technician upon receipt of licensed material (Section IV.G);

Failure of Radiation Safety Technician to verify that researchers complete receipt and handling forms in compliance with the requirements of the license (Section IV.F);

Failure to place radioactive waste in receptacles which are appropriately marked with the standard radiation tag or label (Section II.G);

Failure to receive all packages containing radioactive materials at designated locations in the license (Section II.F);

Failure to label containers of radioactive materials (two examples) (Sections II.G and II.I);

Failure of the Radiation Safety Committee to assure that specified training and experience requirements were submitted prior to authorizing individuals for nonhuman uses of licensed material (Section II.C);

Failure to record actions taken when excessive dose rates or contamination were found during routine surveys and failure to record follow-up survey information (Section II.H);

Failure of the Radiation Safety Committee to provide copies of meeting minutes to its members (Section II.C);

Failure to record all required information on inventory records (Section II.H);

Failure to record all required information on sealed source leak test records (Section II.H);

Failure to post the room or area where licensed material is used or stored with "Caution - Radioactive Materials" (Section V.E); and

Failure to post the required documents and notices in accordance with 10 CFR Part 19.11 (Section VI.E).

REPORT DETAILS

I. Persons Contacted

*Dr. Jose M. Saldana, President, University of Puerto Rico
*Jairo Francisco Lascorro, Advisor for System & Physical Installation
*Ida Nilsa Guzman, Assistant for the President
Manuel Marina, M.D., M.P.H., Chancellor, Medical Sciences Campus
John M. Roman, Esq., Dean of Administration & Executive Assistant to the Chancellor, Medical Sciences Campus
Jose A. San Inocencio, Assistant Dean of Administration, Medical Sciences Campus
Ricardo Gonzalez Mendez, Ph.D., Chief, Physics Division, Radiological Sciences Dept., Medical Sciences Campus
Frieda M. Silva, M.D., Chief of Radiological Sciences Dept., Chairman of Radiation Safety Committee, Medical Sciences Campus
Jose V. Perez Bobonis, Radiation Safety Officer, Medical Sciences Campus
Victor Marcial, M.D., Chief, Radiotherapy Division, Radiological Sciences Dept., Medical Sciences Campus
Cecilia Ramirez, Dosimetrist, Physics Division, Radiological Sciences Dept., Medical Sciences Campus
Jose A. Negron, CNMT, Chief Technologist, Nuclear Medicine Division, Radiological Sciences Dept., Medical Sciences Campus
Elsa Marin, Assistant to the Chancellor, Rio Piedras Campus
Fernando Renaud, Ph.D., Radiation Safety Officer, Biology Professor, College of Natural Sciences, Rio Piedras Campus
Jose Rodriguez, Radiation Safety Technician, Administrative Assistant to Chairman of Biology Dept., College of Natural Sciences, Rio Piedras Campus
James A. Singmaster, III, Ph.D., Chemist, Agricultural Experiment Station, Rio Piedras
Dr. Caban, Acting Chancellor, Mayaguez Campus
Nimia Irizarry, Radiation Protection Officer, Mayaguez Campus
Jorge Corredor, Ph.D., Researcher, Marine Sciences Laboratory, Magueyes Island
Robert B. Waide, Head, Terrestrial Ecology Division, Caribbean National Forest, El Verde Research Station

* - denotes persons present at exit interview

Other personnel contacted or interviewed during the inspection included students, laboratory technicians, researchers, teletherapy machine operators, security guards, nurses and administrative personnel.

II. License No. 52-01946-07

A. Licensed Program (87100)

License No. 52-01946-07 is a broad-scope medical license issued to the Medical Sciences Campus in San Juan. It was initially issued January 3, 1978, and was last renewed in entirety on June 14, 1989. This license authorizes medical diagnostic and therapeutic procedures as well as research and instrument calibrations at the Medical Science Campus, the Neurobiology Laboratory, and the Caribbean Primate Centers at Sabana Seca and Cayo Santiago Field Stations. No materials are currently being used at the primate centers. Only limited research using licensed material is being performed at the Neurobiology Laboratory.

B. Program Scope and Licensee Organization (87100)

The nuclear medicine program performs an average of 750 to 800 diagnostic procedures per month. The licensee had routinely performed ventilation studies using xenon-133; however, they discontinued its use approximately three months before the inspection due to problems with the equipment. They also performed 24 outpatient iodine therapies and eight inpatient iodine therapies during the first six months of 1991. All iodine-131 doses were in liquid form, except that capsules were used for uptake studies. The Chief of the Nuclear Medicine Division is also head of the Radiological Sciences Department and is the principal authorized user. There were two other doctors also using materials for human use.

The radiation therapy program performed approximately one brachytherapy procedure per month using cesium-137 sealed sources.

The licensee had approximately 44 active authorized users performing nonhuman research activities involving licensed material. The Committee had authorized 146 requests for nonhuman use of licensed material. (Some researchers had more than one authorization.)

The Radiation Safety Officer (RSO) was appointed to his position in September 1990. He has been employed full time in this capacity. He had a master's degree in Radiological Health and twenty-five years of experience. The Radiation Safety staff also included two full-time health physics technicians. The staff performed many functions including monitoring packages upon receipt, inventories of material, monthly audits

of all the laboratories, distribution and collection of personnel monitoring devices, leak testing of sealed sources and calibration of the survey equipment.

C. Radiation Safety Committee (87100)

The Chief of the Radiological Sciences Department served as the Chairman of the Radiation Safety Committee (RSC). Other members of the committee included heads of the Radiotherapy Division and Physics Division, researchers from the Physiology, Biochemistry and Pharmacology Departments, and representatives from nursing, security, administration, nuclear medicine, and the Radiation Safety Officer (RSO).

An inspector reviewed the minutes of the RSC meetings for the period from December 1989 through May 1991. The review of the minutes indicated that the committee was reviewing radiation dosimetry reports, applications for use of licensed material, results of radiation safety audits, annual review of the radiation safety program, and unusual events involving the use of licensed materials. The committee did not approve any new uses of licensed material for research for approximately six months due to their storage and waste disposal problems.

10 CFR 35.22(a) requires, in part, that the RSC meet at least quarterly and, in order to conduct business, the RSC is to establish a quorum which must include the management's representative. During review of the minutes the inspector noted that the committee did not meet during the first quarters of 1990 and 1991, and that a quorum was not established prior to conducting business at the meetings held on December 19, 1990, April 3, 1991, and May 22, 1991, in that no management representative was present. Failure of the Radiation Safety Committee to meet at least quarterly and to establish a quorum in order to conduct business were identified as apparent violations of 10 CFR 35.22(a).

10 CFR 35.22(a)(5) also requires, in part, that copies of the meeting minutes be promptly provided to each member of the RSC. In discussions with licensee representatives the inspector determined that copies of minutes of the meetings were not provided to the RSC members. Failure of the Radiation Safety Committee to provide copies of meeting minutes to its members was identified as an apparent violation of 10 CFR 35.22(a)(5).

Condition 20 of the license requires, in part, that the licensee conduct its program in accordance with the licensee's application dated August 29, 1988. Attachment 8.2 of the licensee's application requires each research candidate to submit evidence of training and experience equivalent to 40 hours of academic radiation disciplines. Documentation of training and experience of researchers which was submitted with the applications to use material did not demonstrate that the requirements established in the license were met in that there was no indication that individuals received the 40 hours of basic academic training but rather indicated only experience. Failure to assure that specified training and experience requirements were submitted prior to authorizing individuals for nonhuman uses of licensed material was identified as an apparent violation of License Condition 20 of License No. 52-01946-07.

Condition 12 of the license requires that licensed material for nonhuman use be used by, or under the supervision of, individuals designated by the RSC. During a discussion with a researcher in Room 617A of the Medical Sciences Building, the inspector determined that the researcher was using sulfur-35 for nonhuman use and was not authorized by, or working under, an individual authorized by the RSC. Failure to assure that licensed material for nonhuman use was used only by, or under the supervision of, individuals designated by the RSC was identified as an apparent violation of Condition 12 of License No. 52-01946-07.

D. Radiation Safety Training (87100)

The licensee's application dated August 29, 1988, requires the licensee to provide annual radiation safety training for ancillary personnel (housekeeping, security, nursing and students) in addition to training prior to assuming duties with, or in the vicinity of, licensed materials. Through interviews with licensee representatives and reviews of radiation safety training records, the inspector determined that the licensee had provided semiannual radiation safety training, however, the licensee was not maintaining radiation safety training records for students and personnel. The RSO stated that based on the way the radiation safety training was currently provided, he could not be sure that all personnel including students, housekeeping, nurses, security, etc., had received initial training prior to working with, or in the vicinity of, radioactive materials and had attended annual refresher lectures. However, the licensee's procedure did not specify that training records should

be maintained. During informal discussions between the inspector and ancillary personnel, it appeared that they had a basic understanding of radiation safety principles.

No violations were identified.

E. Personnel Radiation Protection (83822)

A review of records by an inspector indicated that the licensee had issued between 200 and 300 personnel monitoring devices per month to individuals using radioactive materials and radiation-producing machines. Individuals working in nuclear medicine and with brachytherapy sources were issued both whole body and ring badges. Individuals working with phosphorus-32 were issued ring badges, and all other individuals working with licensed material were issued whole body badges. Badges were also issued to security, nursing and other personnel working in the vicinity of radioactive materials. The RSO was responsible for issuing the badges and for reviewing the dosimetry results. All reports reviewed by an inspector between March 1990 and March 1991 were signed by the RSO. A review of records indicated that there were no NRC radiation dose limits exceeded by individuals using radioactive materials.

10 CFR 20.201(b) requires that the licensee make or cause to be made 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 conditions. During the review of dosimetry records, the inspector noted that in April and May 1990, the dosimetry processor notified the licensee that a total of four badges were unreadable. The RSO indicated that the licensee did not investigate and estimate a possible exposure for these individuals. The inspector reviewed the individuals' exposure records and noted that these individuals' annual doses had been less than 50 millirems. Failure to evaluate the radiation dose received by individuals whose personnel dosimetry badges were non-readable by the dosimetry processor was identified as an apparent violation of 10 CFR 20.201(b).

Volatile forms of iodine-125 and iodine-131 were not being used in research; however, therapeutic doses of

volatile iodine-131 were being administered to patients. In accordance with Attachment 9.4 of the licensee's application dated August 29, 1988, all persons handling more than one millicurie of radioiodine must have their thyroid measured the following day. A review of thyroid bioassay records by an inspector indicated that all individuals involved in the dosing of the patients were receiving bioassays in accordance with the requirements of the license and Regulatory Guide 8.20, "Applications of Bioassays for I-125 and I-131," and no uptakes were in excess of the recommended action limits.

F. Receipt and Transfer of Radioactive Materials (87100)

Attachment 10.6 of the licensee's application dated August 29, 1988, requires all shipments of radioactive materials to be ordered with the approval of the RSO and received in Rooms R-133 or R-179 of the Biomedical Building at MSC. Radiopharmaceuticals were received in Room R-133 in the Nuclear Medicine area and were initially surveyed by the radiation safety staff. A review of records from January 1, 1991 to June 17, 1991, indicated that all packages containing radioactive materials received at the Medical Sciences Campus were properly surveyed upon receipt; however, it was determined through discussions with the RSO that at least one shipment of materials received on April 27, 1990, and used at the Neurobiology Laboratory had been delivered directly to that laboratory and not to the Medical Sciences Campus. Failure to receive all packages containing radioactive materials, not associated with Nuclear Medicine, at the Health Physics Office (Room R-179) at the Medical Sciences Campus was identified as an apparent violation of Condition 20 of License No. 52-01946-07.

G. Facilities and Equipment (87100)

During the inspection, the inspectors visited research facilities, nuclear medicine areas, storage areas and hospital rooms where brachytherapy sources were used or stored, and three waste storage areas on the Medical Sciences Campus. These visits included a selective examination of procedures, interviews with personnel, direct observations of activities, posting and labeling requirements, and security of the facilities by the inspectors. In the Nuclear Medicine area, the inspector observed that, in response to a violation identified during a previous NRC inspection, a mechanical device had been installed to prevent the door of the Hot Laboratory from being left open. Also, a combination lock had been placed on this door.

10 CFR 20.207(a) requires licensed materials stored in unrestricted areas be secured against unauthorized removal from the place of storage. During a tour of Room 607A of the Medical Services Building, the inspectors observed a container of 250 microcuries of sulfur-35 in an unlocked refrigerator in an unrestricted, unattended area. Failure to secure licensed material in an unrestricted area against unauthorized removal from the place of storage was identified as an apparent violation of 10 CFR 20.207(a). Similar violations were identified in NRC inspection reports issued on July 19, 1990 and June 14, 1989.

Attachment 11 of the licensee's application dated August 29, 1988, states that radioactive waste will be placed in a clearly identified receptacle appropriately marked with a radiation tag or label. During the visits to Room B-316, the inspectors observed that phosphorus-32 waste had been placed in a receptacle of biological waste which was not labeled with radiological warning signs. In addition, in Room B-316, there was a container of pipette tips contaminated with phosphorus-32, which was unlabeled. Failure to place radioactive waste in a receptacle marked with a standard radiation tag or label was identified as an apparent violation of Condition 20 of License No. 52-01946-07.

The licensee had a concrete vault under the Health Physics office where several sources were stored and instrument calibrations were performed. 10 CFR 20.203(f) requires that containers of licensed material bear a durable, clearly visible label identifying the radioactive contents. The inspector observed a lead container in the source storage area. Radiation surveys were performed by the inspector. Radiation levels of approximately 35 mR/hr at contact with the lead shield were measured. The RSO indicated that the container contained an unknown long-lived gamma-emitting source of unknown strength. No identification information was found on the container. The RSO indicated that the source had been left at the facility by researchers with the U.S. Atomic Energy Commission. The licensee had not identified the contents. Based on the radiation levels on the container and the origin of the material, the inspector determined that the container held greater than 10 CFR 20, Appendix C, quantities of licensed material. Failure to label the source container in the source storage vault was identified as an example of an apparent violation of 10 CFR 20.203(f).

H. Audits and Surveys (87100)

The inspectors reviewed nuclear medicine records, including dose calibrator constancy, accuracy, linearity, and geometric dependence for the past year. The records indicated that the tests were being performed and recorded appropriately. Also, the RSO was reviewing and signing the records. Records also indicated that the generator elutions were tested for molybdenum-99 "breakthrough," daily and weekly surveys were being performed and recorded appropriately, and all radiopharmaceuticals were assayed in the dose calibrator prior to dosing the patient. A review of radiopharmaceutical therapy and brachytherapy records for the period of April 1990 through May 1991 also indicated that required surveys immediately after dosing patients, before releasing patients and before the room was released for unrestricted use were being performed and recorded.

10 CFR 35.205 requires, in part, that the ventilation rates in areas where radioactive gases are used be measured each six months. A review of records by an inspector indicated that the air flow rates were being measured every six months for the fume hood where gases and volatile materials were being stored and in the camera room where xenon-133 gas was used.

10 CFR 35.59(b)(2) requires the licensee to test sealed sources for leakage at intervals not to exceed six months. 10 CFR 35.59(d) requires that the licensee maintain a record of leak tests for five years. A review of sealed source leak test records from April 1990 through April 1991 indicated that leak tests have been performed on all sealed sources, except two calibration sources in nuclear medicine at intervals not to exceed six months. The sources which were not leak tested were a 150 microcurie barium-133 source and a 150 microcurie cesium-137 source. Failure to leak test all sealed sources that require leak testing was identified as an apparent violation of 10 CFR 35.59(b)(2). This is similar to a violation identified in an NRC inspection report dated July 19, 1990. Although sixteen cesium-137 sources received in the fall of 1990 were leak tested, the inspector determined through a review of records and interviews with licensee representatives that no records were maintained on their leak test results. Failure to maintain a record of the leak test results for sixteen cesium-137 sources was identified as an apparent violation of 10 CFR 35.59(d).

10 CFR 35.59(g) requires the licensee to maintain inventory records of quarterly physical inventories of sealed sources which include the model and serial numbers of each source. A review of sealed source physical inventory records from April 1990 through April 1991 performed by the inspectors indicated that quarterly inventories were being performed for all sealed sources; however, the records did not contain the model numbers of each source and the serial numbers. Failure to record all required information on inventory records was identified as an apparent violation of 10 CFR 35.59(g).

Attachment 10.12 of the licensee's application dated August 29, 1988, requires the licensee to survey each laboratory on a monthly basis and to keep records which include actions taken in cases of excessive dose rates or contamination and followup survey information. Through discussions with licensee representatives and reviews of records, the inspector determined that the radiation safety staff performed surveys of each laboratory on a monthly basis which included surveys for radiation levels and smears for contamination. However, corrective actions and resurvey results for research areas where the radiation or contamination levels exceed the licensee's action levels were not documented. Failure to record actions taken in cases where radiation or contamination levels found during surveys of research laboratories exceeded the action levels and failure to record follow-up survey information was identified as an apparent violation of Condition 20 of License No. 52-01946-07.

10 CFR 35.70(b) requires the licensee to survey radiopharmaceutical waste storage areas weekly. Through discussions with licensee representatives and reviews of records, the inspector determined that the licensee was not performing weekly surveys of radiopharmaceutical waste storage areas. Failure to perform required weekly surveys of radiopharmaceutical waste storage areas was identified as an apparent violation of 10 CFR 35.70(b).

I. Radioactive Waste Storage and Disposal (84850)

Through a review of the licensee's radioactive waste disposal procedures and discussions with licensee representatives, the inspector determined that the licensee stores all solid and most liquid waste in three storage locations (a room located on the roof of the Medical Sciences Building, a separate waste storage building located near the nuclear medicine laboratory,

and a room off the stairwell in the Library building). The stored waste included nuclear medicine waste.

The room located on the roof was full of waste. The room was properly secured, and radiation levels inside and out were within permissible limits.

10 CFR 20.203(f) requires that containers of licensed material bear a durable, clearly visible label identifying the radioactive contents. The separate waste storage building was approaching capacity. It contained a variety of waste ranging from nuclear medicine short-lived isotopes to unknown materials which had been stored for 20 to 30 years. Som of the short-lived isotopes had decayed to background levels but were still being stored. The condition of the containers and bags was deteriorating. There were unlabeled containers of waste, the contents of which were unknown to the licensee. Radioactive material labels on other containers had deteriorated due to age and were no longer legible. Failure to label containers located in the radioactive waste building as required was identified as another example of an apparent violation of 10 CFR 20.203(f).

The inspectors observed evidence of liquid run-off around the door of the waste storage building onto the ground outside the building. Based on this observation and the poor condition of some of the containers inside the building, the licensee representative stated that the licensee would collect and analyze soil samples from the area of the apparent run-off to ensure that radioactive material had not been inadvertently released from the storage building.

The inspector observed that the room off the stairwell of the library building had poor ventilation. Even though no evidence of spills was found, the concentration of toluene fumes from liquid scintillation vials was high enough for the licensee to be concerned about the possibility of an explosion. The licensee representative stated that immediate action would be taken to evaluate the hazard in the room and to take corrective action.

The licensee attributed much of the waste accumulation to their inability to dispose of the materials by incineration for over two years. The licensee reported that the physical improvements to the incinerator had been recently completed. Requests to various local and federal authorities, including NRC, were being prepared requesting authority to operate the incinerator. No estimated date of submission of requests was available.

III. License No. 52-01946-09

A. Licensed Program (87100)

License No. 52-01946-09 is a medical teletherapy license initially issued in March 1990 to the Medical Sciences Campus but superceded an earlier license (52-01946-08) for the same material and purpose. It was last renewed in June 1990. This license authorizes the treatment of humans using cobalt-60 in a teletherapy unit located on the first floor of the Biomedical Building.

B. Program Scope and Licensee Organization (87100)

The Radiotherapy Department treats approximately fifteen patients per day. Two of the four authorized users were routinely performing licensed activities. In addition, there were two physicians performing licensed activities on a part-time basis under the direct supervision of the authorized users. The licensee's Radiation Safety Committee (RSC) can designate authorized users; however, the RSC chairperson indicated that the RSC preferred to have authorized users specifically listed on the license.

The Chief of the Physics Division of the Radiological Sciences Department supervises two dosimetrists and several teletherapy machine operators. There had not been any changes in the dosimetry and teletherapy machine operations staff since the last inspection.

C. Radiation Protection (83822)

A review of records by an inspector indicated that occupational exposures associated with these licensed activities were well within the regulatory limits. During a facility tour, licensee personnel were observed wearing the required dosimetry devices. It was also noted that the required postings, labeling and administrative controls were in place to help prevent accidental radiation exposures. Emergency procedures were conspicuously posted near the teletherapy machine console. Members of the technical staff interviewed during the inspection were knowledgeable of basic radiation safety and operating and emergency procedures.

Radiation levels measured by the inspector in unrestricted areas surrounding the treatment room with the machine on were well within regulatory limits.

No violations were identified.

D. Facilities and Equipment (87100)

An inspector verified proper operation of the treatment room door interlocks, beam condition indicator lights, patient viewing systems and the permanent room monitor, which was equipped with a backup power supply. The licensee possessed a calibrated dosimetry system, and appropriate, operable and calibrated survey instruments. A review of records indicated that the room monitor had been checked daily for proper operation.

During the inspection it was noted that the licensee had possessed and used the same source since 1984, and the source strength has been reduced by more than 60% of its original activity through radioactive decay. Consequently, patient treatment times have increased by this factor, thus increasing the possibility of irradiating other-than-intended tissues due to patient movement during irradiation. The licensee's management acknowledges that, within one year, the output of the cobalt-60 source would be so low as to not be useful for performing therapy. However, the licensee had not made a decision on purchasing a new source or terminating the licensed activities. The licensee limits the use of the teletherapy machine to treatments of head or neck tumors and a few uterine or prostate cancers.

No violations were identified.

E. Quality Assurance (87100)

10 CFR 35.632 specifies the required teletherapy unit full calibration frequency, the required procedures to be followed when performing the full calibrations of teletherapy unit outputs and the items to be evaluated when performing the calibrations.

Through reviews of teletherapy unit calibration records and discussions with licensee representatives, the inspector verified that the licensee utilized the required procedures for performing full calibrations, and that the calibrations were performed annually as required. Accounting for decay, the difference between the outputs determined during the 1990 and 1991 calibrations was minimal (within 0.6%), and the measured outputs correlated well with the most recent vendor's source certification dated in 1986.

The full calibration also included: (1) coincidence of

radiation field and field light localizer, (2) uniformity of radiation field and beam angle dependence, (3) timer constancy and linearity, (4) machine on-off error, and (5) accuracy of the measuring/localization device.

The inspection team also verified that the licensee corrects for decay the teletherapy machine's output on a monthly basis to ensure an accurate patient irradiation time.

Licensee representatives indicated that there had been no misadministrations during the past year and that there was an unwritten internal quality assurance program intended to prevent misadministrations. The program consisted of double verification of irradiation time calculations and final treatment plans. In addition, the licensee requested that each patient bring in a photograph to be attached to their treatment log, but approximately 40% of the logs reviewed did not have photos attached. In these cases the licensee used social security numbers, telephone numbers and addresses to assure positive patient identification prior to treatments. At the time of the inspection, the licensee had not considered formalizing the Quality Assurance program to prevent teletherapy misadministrations, in that the procedures were not written or approved by the RSC.

The inspector verified that the licensee performed spot checks on the teletherapy system on a monthly basis. Since the previous inspection, the licensee's teletherapy physicist had been reviewing the spot check results within the required fifteen days of the date of the spot check. The checks included all required information.

No violations were identified.

IV. License No. 52-01986-04

A. Licensed Program (87100)

License No. 52-01986-04 covers licensed activities at the College of Natural Sciences in Rio Piedras. This license was initially issued on March 18, 1969, and was most recently renewed on September 25, 1990. This license authorizes the use of specified types and quantities of radioactive materials for laboratory research and teaching in the areas of cell biology, microbial ecology, immunology, and biochemistry in the college's Biology and Chemistry Departments.

B. Program Scope and Licensee Organization (81700)

The licensee had nine authorized users, including the Radiation Safety Officer (RSO), conducting nonhuman use experiments and overseeing student use of licensed materials within their laboratories.

The RSO was appointed to his position in June 1990. The licensee relies on the Radiation Safety Technician (RST) to monitor day-to-day activities under the license such as: verifying that researchers completed and maintained required records of receipt of radioactive material and laboratory surveys; provide radiation safety training to research assistants, technicians, students who worked with radioactive material, and ancillary personnel; ensure that radiation survey meters were calibrated; distribute and collect personnel monitoring devices; maintain dosimetry records; review orders for radioactive material; maintain records of disposal; and maintain material inventory records to ensure that authorized limits were not exceeded.

Based on discussions with the licensee personnel and on inspection findings discussed below, the inspectors noted that the RST's recent change in duties has adversely affected the RST's ability to adequately perform tasks assigned to him under the license. At the time of the inspection, the RST was performing radiation safety functions mostly on his own time.

C. Radiation Safety Committee (RSC) (87100)

The RSO serves as Chairman of the RSC. Other members of the committee include the Chairman of the Biology Department and other researchers from the biology and chemistry departments. A review of the RSC's minutes indicated that the committee was reviewing radiation dosimetry reports, applications for the use of licensed material, results of radiation safety audits, and the annual review of the radiation safety program. The committee had also noted that additional space need to be found for the storage of radioactive waste and that, as a result of his recent promotion, a replacement for the present RST needed to be identified.

No violations were identified.

D. Radiation Safety Training (87100)

Condition 15 of the license requires the licensee to conduct its program in accordance with the licensee's application received November 9, 1989, and letter dated July 24, 1990, in which the licensee states that radiation safety training will be provided to research assistants, technicians and students. A radiation safety training program had been established and implemented. All personnel interviewed by the inspectors exhibited an awareness of radiation safety principles. However, based on the violations identified in the areas of receipt requirements for radioactive material and surveys, additional training of students and researchers is needed.

No violations were identified.

E. Personnel Radiation Protection (81700)

The licensee instituted the use of personnel monitoring devices (wrist TLDs) at the beginning of 1991 for personnel working with phosphorus-32, with TLD exchange occurring quarterly. Previously, no personnel dosimetry was provided. Through interviews with the RST and a review of records, the inspector determined that TLDs are issued to approximately fifty people. The first exposure report had been received by the licensee, and all TLDs showed no measurable exposure.

The licensee had one fume hood in which iodine-125 was used and stored. The inspectors verified that the face velocity was 100 feet per minute with the sash in the operating position.

No violations were identified.

F. Audits and Surveys (81700)

Procedure 10 of Item 10 of the licensee's application states, in part, that contamination surveys, consisting of a series of wipe tests, will be conducted at the end of each experiment using radioactive materials. Additionally, all survey results, including negative results, are to be recorded. The licensee established in this application an action level for contamination of 100 disintegrations per minute (dpm) per 100 square centimeters (cm^2).

The licensee's application also provides that contamination wipes shall be performed on packages of radioactive materials received by researchers.

The licensee's letter dated July 24, 1990, states that the RST will verify that the researchers complete receiving and handling forms.

A review of survey records from August 1990 until June 1991 performed by the inspectors found that the results of all surveys (including negative results) were not being recorded for the laboratory in Room JGD-216, that contamination wipes were not taken on packages of radioactive materials received or on laboratory surfaces at the end of experiments using radioactive materials in Room JGD-217, and that results of contamination wipes were not evaluated in a manner that would permit the licensee to determine whether the action level of 100 dpm/100 cm^2 was exceeded. Through interviews with personnel and a review of records by the inspectors, it was determined that laboratory personnel performing contamination wipes did not know the efficiencies of their counting equipment and were recording the results in counts per minute (cpm). Reviews of records by the inspectors indicated the required records, as described above, were not properly completed by the researcher and these deficiencies were not detected and corrected by the RST.

Failure to perform contamination surveys of packages of radioactive materials upon receipt, to perform adequate contamination surveys, to perform surveys at the end of experiments, to record the results of all surveys performed, and to ensure that researchers were properly completing forms for receiving and handling radioactive materials were identified as apparent violations of Condition 15 of License No. 52-01986-04.

G. Receipt and Transfer of Radioactive Material (87100)

The licensee's application received November 9, 1989, states that radioactive materials will be delivered directly to the requesting laboratory and requires that the RST be notified of such receipts. By reviewing records of receipt, the inspectors found that, on numerous occasions, the RST was not being notified of all receipts of radioactive materials to the laboratories in Rooms JGD-107 and JGD-216. Failure to notify the RST of all receipts of radioactive material was identified as an apparent violation of Condition 15 of License No. 52-01986-04.

H. Waste Disposal (84850)

Liquid wastes containing carbon-14 or hydrogen-3 (tritium) were diluted and then disposed of through designated sinks in accordance with regulatory

requirements. The licensee had calculated that if they disposed of all materials for which they were licensed, they would not exceed the limits in 10 CFR 20, Appendix B, Table 1, Column 2. Other radioactive waste containing phosphorus-32 or iodine-125 was stored in the laboratories for at least ten half-lives, surveyed, and then disposed as ordinary trash in accordance with License Condition 13.

The inspectors observed that some laboratories were beginning to have problems finding sufficient space to store their radioactive waste. The Radiation Safety Committee was aware of this situation and was attempting to find additional storage space.

No violations were identified.

V. License No. 52-01986-01

A. Licensed Program (87100)

License No. 52-01986-01 was initally issued to the university's Agricultural Experiment Station in Rio Piedras on February 13, 1957, and most recently renewed on May 22, 1989. The license authorizes the storage of certain carbon-14 tagged material (plant material and pesticides), use of hydrogen-3 and nickel-63 detector cells in gas chromatographs for sample analysis, and use of portable moisture/density gauges containing cesium-137 and/or americium-241.

B. Program Scope and Licensee Organization (87100)

The licensee's program was of limited scope. One authorized user maintained custody of the carbon-14 tagged plant material, another performed sample analysis on the gas chromatographs and maintained custody of the carbon-14 tagged pesticides, and a third, who is also the Radiation Safety Officer (RSO), was authorized to use the moisture/density gauges. The RSO was appointed to that position in 1988.

C. Inventory and Leak Testing (87100)

The inspectors were informed that a number of unneeded gas chromatograph detector cells containing tritium were on hand and that the licensee was considering returning the excess detector cells to the manufacturer.

Condition 17 to License 52-01986-01 requires that the licensee conduct a physical inventory every six months to account for all sources and/or devices received and

possessed under the license. Records of such inventories are required to be maintained for two years from the date of the inventory.

The authorized user who had custody of the gas chromatograph detector cells informed the inspector that no inventories of these sources had been conducted since the previous NRC inspection in October 1990, in which the licensee was cited for violating the same requirement. Failure to conduct physical inventories of all sources and/or devices possessed under the license was identified as an apparent violation of Condition 17 to License 52-01986-01.

The nickel-63 detector cell not in storage was being leak tested every three years, as required.

D. Security (83822)

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

The inspectors observed that vials of carbon-14 tagged pesticides were stored in an unsecured refrigerator located in an uncontrolled breezeway. The researcher estimated that the refrigerator contained in excess of a millicurie of carbon-14. Failure to secure licensed materials in an unrestricted area against unauthorized removal was identified as an apparent violation of 10 CFR 20.207(a).

E. Posting and Labeling (83822)

10 CFR 20.203(e) requires that each area or room in which licensed material is used or stored and which contains any radioactive material in amounts exceeding 10 times the quantity of such material specified in Appendix C of 10 CFR 20 be conspicuously posted with a sign bearing the radioactive caution symbol and the words "Caution Radioactive Material." The Appendix C quantity of carbon-14 is 0.1 millicuries.

During the inspection, the inspector observed that the refrigerator containing more than one millicurie of carbon-14 and was not posted with a "Caution Radioactive Material" sign. Failure to conspicuously post the refrigerator containing greater than the

specified amount of licensed material was identified as an apparent violation of 10 CFR 20.203(e).

The researcher informed the inspector that some of the carbon-14 tagged pesticides had been held in storage since 1958 and that the project for which the samples were acquired was completed several years ago. There were no plans to either use or dispose of the material.

The inspectors noted that the labels on a number of the vials containing carbon-14 tagged pesticides were deteriorating due to age. Two labels were no longer totally legible. The researcher believed that the vials contain less than 0.1 millicuries each, therefore, were not required to be labeled with a "Caution Radioactive Material" label in accordance with 10 CFR 20.203(f).

VI. License No. 52-10510-04

A. Licensed Program (87100)

License No. 52-10510-04 is a broad-scope research and development license issued to the Mayaguez Campus. It was initially issued August 15, 1978, and was most recently renewed June 12, 1989. This license authorizes research, educational experiments, instrument calibrations and use of gas chromatographs at the Mayaguez Campus and at the Marine Sciences Laboratory on Magueyes Island. It also authorizes the use of portable moisture-density gauges at temporary jobsites.

B. Program Scope and Licensee Organization (87100)

At the time the license was initially issued, the licensee anticipated a large research program; however, a review by inspectors of the research activities during subsequent inspections indicated that licensed activities have been minimal and not within the scope of this type of license.

During this inspection, materials in use on the Mayaguez Campus included microcurie quantities of iodine-125 in the Chemistry Department and microcurie quantities of sulfur-35 and hydrogen-3 in the Biology Department. In addition a gas chromatograph, which used a nickel-63 foil, was used at the Marine Sciences Laboratory at Magueyes Island. These were the only materials in use under this broad-scope license.

C. Radiation Safety Committee (87100)

Condition 12 of the license requires that licensed materials used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee (RSC). A review of records by the inspector indicated that research protocols were submitted to the RSC and that approvals were on file for current research on campus. Condition 20 of the license requires the licensee, in part, to conduct its program in accordance the application dated August 20, 1983, and letter dated April 11, 1986, which requires the RSC to meet no less than once a fiscal year, and that the RSC perform an annual audit of the radiation safety program. However, through discussions with licensee representatives, the inspector determined that no meeting of the RSC was held during fiscal year 1989, and that the RSC did not conduct audits of the radiation safety program during 1989 and 1990. Failure of the Radiation Safety Committee to meet at least once each fiscal year and to perform annual audits of the radiation safety program were identified as apparent violations of Condition 20 of License No. 52-10510-04.

The license application dated August 9, 1983, requires that procurement requests for radioactive materials be approved by the Radiation Protection Officer (RPO). During the entrance interview, the RPO received a telephone call from a researcher who informed her that the researcher (an authorized user) had violated their procedures in the RPO's absence by ordering and receiving 250 microcuries of sulfur-35 without having the order approved by the RPO. The researcher's protocol had RSC approval. The licensee immediately informed the inspector, and in order to prevent recurrence, the licensee indicated that a training session on procurement procedures was to be given. The inspector determined that this was a non-cited violation in accordance with the NRC Enforcement Policy, 10 CFR 2, Appendix C, Section V.G.1.

D. Surveys and Inventories (87100)

The application dated August 9, 1983, requires that, in areas using small quantities of radioactive materials, surveys (direct and smears) be performed on a monthly basis. The inspector reviewed areas of use and survey records and found that, since January 1989, no monthly survey had been performed. Through interviews with licensee personnel, the inspector determined that use of materials occurred frequently between January 1989 and June 1991 in both the Chemistry and Biology Departments. Failure to perform required surveys of

laboratories on a monthly basis was identified as an apparent violation of Condition 20 of License No. 52-10510-04.

The licensee's application dated August 9, 1983, also requires that inventories be performed by the RPO at a six-month intervals. A review of inventory records by the inspector indicated that between January 1989 and June 1991, only one inventory was performed in April 1990. Failure to perform inventories every six months was identified as an apparent violation of Condition 20 of License No. 52-10510-04.

E. Facilities and Equipment (87100)

The inspectors performed independent radiation surveys of laboratories in the Chemistry Department on the Mayaguez campus and at the Marine Sciences Laboratory. No radiation levels above regulatory limits were detected. Two users of licensed material in the Chemistry Laboratory were interviewed and appeared knowledgeable on radiation safety matters and the licensee's policies.

10 CFR 19.11 requires that the licensee post current copies of Part 19, Part 20, the license, the license conditions, documents incorporated into the license, license amendments and procedures, or a notice describing the documents and where they can be found, and a "Notice to Employees." During the inspection, the inspector noted that the postings required by 10 CFR 19.11 were present at the Mayaguez Campus. At the Marine Sciences Laboratory, the postings required by 10 CFR 19.11(a) and (b) were not present. Failure to post the required documents and notices was identified as an apparent violation of 10 CFR 19.11(a) and (b).

VII. License No. 52-19434-02

A. Licensed Program (87100)

License No. 52-19434-02 is a specific license issued on March 9, 1982, for storage only of hydrogen-3 and cesium-137 and for the use of a nickel-63 foil in a gas chromatograph for sample analysis at the Caribbean National Forest, Luquillo Forest, El Verde Research Station. The licensee was most recently renewed on December 24, 1990.

B. Radiation Protection (83822)

The licensed hydrogen-3 and cesium-137 are isotopes that were injected in two trees in 1968. The inspectors visited the site and confirmed that the area where the trees were located was isolated by means of a wire fence and radiation safety signs were posted. In addition, the inspectors found that the nickel-63 foilin the gas chromatograph had not been used since June 1989, and no material was present at the laboratory.

No violations were identified.

VIII. Exit Interview (30703)

The inspection scope and findings of this special inspection were summarized and discussed with the individuals indicated in Section I of this report. The team leader pointed out that this special inspection included an assessment of the overall effectiveness of management oversight of the programs and was prompted by the overall poor enforcement history of the University, particularly at the Medical Sciences Campus. In addition to the specific apparent violations discussed previously in this report, the team leader also identified a number of other issues which warrant University management attention, including the need to increase University management oversight and control over licensed activities, the University-wide problem with the storage and disposal of radioactive waste, the need for increased management involvement in the activities of the radiation safety committees, lack of full awareness of regulatory requirements by the appropriate University staff members, and the need for the development of an effective program to identify and correct violations of regulatory requirements.

The team leader also discussed the limited research being performed under the broad scope license issued to the Mayaguez Campus and the possible reduction in the scope of the license.

Licensee management acknowledged the inspectors' findings and did not provide any dissenting comments. The licensee did not identify as proprietary any information reviewed by the inspectors.