UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

P.O. BOX 5067 SAN JUAN, PUERTO RICO 00936

DEPARTAMENT OF RADIOLOGICAL SCIENCES

NUCLEAR MEDICINE DIVISION

September 4, 1990

Mr. Stewart D. Ebneter
Regional Administrator
Office of Enforcement
U.S. Nuclear Regulatory Commission
Office of Governmental and Public Affairs
Region II
101 Marietta Street, N.W.
Atlanta, GA 30323

Enclosed you will find the "Reply to a Notice of Violation. Please feel free to contact us if you have any further information.

Cordially yours,

Frieda Silva de Roldán, MD
Director

FSR/vac

Enclosure

P.D. The original document will be send today Federal Express.

Copy sent to OE 9/6

UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MEDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

OFICINA DEL RECTOR
OFFICE OF THE CHANCELLOR

August 30, 1990

Stewart D. Ebneter
Regional Administrator
Office of Enforcement
U.S. Nuclear Regulatory Commission
Office of Governmental and Public Affairs
Region II
101 Marietta Street, N.W.
Atlanta, GA 30323

Docket NOS 030-13584
030-31462

License No. 52-01946-07
52-01946-09

Re: Reply to a Notice of Violation

Dear Mr. Ebneter:

According to the provisions of 10CFR.2.201, the University of Puerto Rico Medical Sciences Campus is required to submit a written explanation to the Nuclear Regulatory Commission regarding the alleged violations stated in your Notice of Violation of July 18, 1990.

A detailed explanation of the alleged violations and the corrective measures taken are:

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I. Violations of License 52-01946-07 (Broad Scope)

A. 1. Violation is admitted.

2. The reason for these violations were as follow:

April 13, 1989

The previous Radiation Safety Officer resigned on April 10, 1989 and the new RSO was appointed on April 11, 1989. The implant was performed without notifying the newly appointed RSO due to a lag in the communique notifying the Radiotherapy personnel of the appointment.

October 11, 1989

The RSO was not notified by the Radiotherapy personnel of this implant. This was due to inadequate performance on the part of the Radiotherapy personnel.

January 4, 1990

The Campus was on Christmas recess. The Radiation Safety Office technician (Mr. José Robles) was on vacation. The Radiotherapy personnel did not notify the RSO even though he was on call. This was due to inadequate performance on the part of the Radiotherapy personnel.

3. Corrective steps

a) Concerning these violations a meeting was held on April 10, 1990 with Mr. Onelio Núñez, Dean of Administration, Dr. Petra Burke, Acting Dean of Medicine, Dr. Victor Marcial, Director of Radiotherapy, Dr. Frieda Silva, Director of Nuclear Medicine and Chair of the Radiological Sciences Department and the Radiation Safety Committee, Mr. José A. San Inocencio, Assitant Dean of Administration, Mrs. Ida Nilsa Guzmán, Associate Dean of Administration and Dr. Heriberto Torres, Campus RSO. Dr. Marcial was notified that these violations were unacceptable, and a corrective action plan was drafted to prevent recurrence.

b) These violations (particularly 10/11/89 and 1/4/90) were isolated cases. The previous record on implant surveys has been satisfactory.

c) The following written procedures have been established to prevent further violations.

- The Radiation Safety Office will be notified at least 2 days in advance of any planned implant therapy by the Radiotherapy Division.

- When the patient is admitted to the hospital, the nursing supervisor will notify the Radiation Safety Office within 4 hours of admission.

- The physicist in charge of performing the dose calculation, will notify, in writing, the Radiation Safety Office before the implant is performed.

- The Radiation Safety Office will perform the survey after implanting the material and will record the date when source(s) will be removed.

- Violation of this procedure will be submitted to disciplinary sanctions, that may result in the termination of employment of the personnel involved.

4. Corrective steps for prevention of future violations.

- Refer to 1A3.c

5. Compliance: September 4, 1990

B. 1. Violation is admitted.

2. Reason for violation: The RSO was not notified by the Radiotherapy Personnel of the removal of the implant. This was due to the inadequate performance of the Radiotherapy personnel.

3. Corrective steps

a) The RSO will be notified of the date and time of the implant removal. The RSO will perform the appropiate surveys.

b) Violation of this procedure will be submitted to disciplinary sanctions that may result in the termination of employment of the personnel involved.

4. Corrective steps to prevent future violations

- Refer to 1B3b

5. Compliance: September 4, 1990

C. 1. Violation is admitted.

2. Reason for violation: The Nuclear Medicine Technologist in charge of the Hot Laboratory left the door opened and the area unattended. Lack of air conditioning in the room contributed to this behavior.

3. Corrective steps

All Nuclear Medicine Technologist were informed of the violation and the serious implication of these actions.

Written reprimands will be issued if the violation is detected by the Nuclear Medicine Physicist. Violations will be submitted to disciplinary sanctions that may result in termination of employment.

4. Corrective steps to prevent future violations

In addition to the corrective actions taken previously, the following steps were taken:

a) A central air conditioning unit was installed inside the room.

b) A mechanical device was installed in the door to prevent it from being left open.

c) A glass viewing section was installed in the door to look inside without the need to open it.

5. Compliance already achieved

D. 1. Violation is admitted.

2. Reason for violation: The RSO did not perform the leak tests when required. There was inadequate supervision of the RSO personnel. There was lack of a written working plan for the year.

3. Corrective steps

a) The leak test for all sealed sources were done on April 19, 1990. All of them showed less than 0.005 mCi of removable contamination.

b) An annual working plan was prepared by the RSO stating all activities to be done during the year.

4. Corrective steps to prevent future violations
- An annual work plan will be prepared by the RSO. The plan will be submitted for approval to the Campus Radiological Safety Committee. Proper implementation of the plan will be the responsability of the RSO and his Office.

5. Compliance already achieved.

E. 1. Violation is admitted.

2. Reason for violation: The RSO did not perform the quarterly inventory, instead he performed a biannual inventory.

3. Corrective steps

a) The physical inventory is now in compliance with 10CFR35.59 (g).

b) From April 2, 1990 to present, the inventory has been conducted every 3 months as required by the regulations.

4. Corrective steps to prevent future violations
- The physical inventory is included in the annual working plan.

- The Radiological Safety Committee will perform a quarterly review of the activities presented in the annual working plan.

5. Compliance already achieved.

F. 1. Violation is admitted.

2. Reason for violation: No written records of the surveys were kept in the Radiological Safety Office or elsewhere. The ambient dose measurements were performed biannualy during the physical inventories.

3. Corrective action

The ambient dose measurements are performed during the quarterly physical inventories. Record of this measurement is kept in the same document used for the physical inventories.

4. Corrective steps to prevent future violations
   - The ambient dose measurements is part of the annual working plan of the RSO. It will be reviewed by the Radiological Safety Committee on a quarterly basis.

5. Compliance already achieved.

G. 1. Violation is admitted.

2. Reason for violation: The Radiation Safety Office failed perform fume hood air velocity measurements.

3. Corrective actions

a) The air velocity measurement at different points on the chemical hood at the Nuclear Medicine hot room were performed by the Radiation Safety Office on August 31, 1990.

4. Corrective steps to prevent future violations

   - The air flow measurement at the Nuclear Medicine hot room will be performed every six months or more frequently if needed. Results will be presented to the Radiation Safety Committee by the RSO.

5. Compliance September 4, 1990.

H. 1. Violation is admitted.

2. Reason for violation: The RSO failed periorm air flow measurements at the Nuclear Medicine Laboratory.

3. Corrective actions

a) The air flow measuremnts for Xe-133 were performed by the Radiation Safety Office on August 31, 1990.

4. Corrective steps to prevent future violations

- The measurements will be performed together with all other necessary test, as scheduled in the annual work plan. Measurements will be performed every six months, or more frequently if needed. This activities will be reviewed in the Radiation Safety Committee meetings.

I. 1. Violation is admitted.

2. Reason for violation: The Campus RSO resigned April 10, 1990. The Radiotherapy personnel opened the packages without notifying the newly appointed RSO. This was due to lack of communication.

3. Corrective actions

a) Radiotherapy staff was instructed on the importance of complying with the requirements of the license. Violation of this procedure will be submitted to disciplinary sanctions that may result in the termination of employment of the personnel involved.

4. Corrective steps to prevent future violations
- The established procedure will be published and distributed to all Radiotherapy personnel and staff. It will included a statement regarding the penalty for violating the procedure.

5. Full compliance already achieved.

J. 1. Violation is admitted.

2. Reason for violation: The new RSO failed to performed the annual review of the Radiation Safety Program with the Committee.

3. Corrective actions

a) The revision of 1989 was performed on May 1990, and the 1990 revision will be presented on the first meeting on 1991.

4. Corrective steps to prevent future violations
- The review of the program is part of the annual working plan. The Radiation Safety Committee, on its first quarterly meeting will include as part of its agenda the revision of the program presented by the RSO.

5. Full compliance already achieved.

K. 1. Violation is admitted.

2. Reason for violation: All the required test were performed by the Nuclear Medicine Physicist, and the RSO failed to sign the records.

3. Corrective action

a) All records were reviewed and signed by the RSO as required by 10CFR35.

4. The Nuclear Medicine Physicist will notify the RSO in writting when the test are performed. The RSO will review and sign all the records required for the dose calibrator. He shall report to the Radiation Safety Committee on the status of the testing and the records.

5. Full compliance already achieved.

II. Violations of License No. 52-01946-09

A. 1. Violation is admitted.

2. Reason for violation: The spot checks were adequately performed by the Assistant Physicist, the Radiotherapy Physicist failed to review them as required.

3. Corrective action

a) All spot checks from April to date were reviewed by the Radiotherapy Physicist.

4. Corrective steps to prevent future violations

- Dr. Heriberto Torres, will only have the duties of Radiotherapy Physicist, as soon as the new RSO is certified by NRC. An ammendment to the license, will be submitted with the documentation of the newly appointed RSO. He will continue on the position until a final full time appointment is made.

5. Full compliance already achieved.

B. 1. Violation is admitted.

2. Reason for violation: The teletherapy physicist failed to perform the required calibration.

3. Corrective action

a) Full calibration was performed by the the teletherapy on April 6, 1990.

4. Corrective steps to prevent future violations

- Dr. Heriberto Torres will continue as Radiotherapy Physicist until a full time appointment is made.

5. Full compliance already achieved.

C. 1. Violations is admitted.

2. Reason for violation: The teletherapy physicist and his staff failed to perform the leak test of the teletherapy unit.

3. Corrective actions

a) The leak test were performed on April 19, 1990 and it was satisfactory.

4. Corrective steps to prevent future violations

- The teletherapy physicist and his staff will perform the test every 6 months and report the results to the RSO. The RSO will report to the Radiation Safety Committee.

5. Full compliance already achieved.

We hereby request that the proposed civil penalties be decreased or eliminated due to the fact that the alleged violations were corrected, and the University of Puerto Rico has taken the necessary steps to avoid future violations.

In your evaluation of our response to the Notice of Violation, please consider, that the University of Puerto Rico is a non-profit organization dedicated to higher education. In particular, the University of Puerto Rico Medical Sciences Campus provides the services for medically indigent patients which would otherwise not receive these services anywhere else in Puerto Rico.

The University of Puerto Rico in its commitment to public health, teaching and research has a vital interest in mantaining to its fullest extent this license. Therefore, it has committed itself to a comprehensive action plan, that will prevent the occurrence of these type of incidents.

Cordially yours,

Manuel Marina, MD
Acting Chancellor
Medical Sciences Campus

I hereby certify that the above information is true to the extent of my knowledge.

Manuel Marina, MD
Acting Chancellor
Medical Sciences Campus

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

AUG 2 8 1991

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

EA 91-089

University of Puerto Rico
ATTN: Dr. Jose M. Saldana
President
General Post Office Box 364984
San Juan, Puerto Rico 00936-4984

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - $6,250 (INSPECTION REPORT NOS. 52-01946-07/91-01, 52-01946-09/91-01, 52-01986-04/91-01, 52-01986-01/91-01, 52-10510-04/91-01, AND 52-19434-02/91-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Ms. C. Connell, Mr. H. Bermudez, Mr. J. Ennis, and Mr. L. Franklin on June 17-21, 1991, at the University of Puerto Rico facilities located on the Medical Sciences Campus, College of Natural Sciences Campus, Mayaguez Campus, and the Agricultural Experiment Station, in Puerto Rico. The inspection included a review of the organization and administration of each licensed program, radiation safety aspects of each program, radiation safety training of personnel, and radioactive waste storage and disposal. In addition, the inspection placed special emphasis on the review of management control and oversight of licensed activities. The report documenting this inspection was sent to you by letter dated July 23, 1991. As a result of this inspection, multiple failures to comply with NRC requirements were identified. An enforcement conference was held on July 26, 1991, with Dr. Saldana and other members of your staff in the Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of this conference was sent to you by letter dated August 14, 1991.

The violations in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) were identified by the NRC during the inspection of the broad scope NRC license program at the Medical Sciences Campus and include failures to: secure licensed material against unauthorized removal, conduct leak tests of sealed sources at the required intervals, properly evaluate dosimetry data, survey radiopharmaceutical waste storage areas, properly label radioactive material containers, adhere to Radiation Safety Committee meeting requirements, properly maintain sealed source inventory

records, and maintain leak test records for sealed sources. Additional details regarding the violations are described in the previously issued NRC inspection report referred to above.

We are concerned with the results of the inspection of the University's Medical Sciences Campus broad license, particularly the research program. A similar concern was made known to you previously as a result of an NRC inspection conducted in April 1990 which resulted in the imposition of a civil penalty of $12,500 for violations associated with both your broad license, specifically the nuclear medicine program operated under that license, and the teletherapy license. The 11 violations that were cited against your broad license resulted in a civil penalty of $6,250. In our letter of July 19, 1990, which transmitted the Notice of Violation and Proposed Imposition of Civil Penalties, you were informed then of the NRC's concern about your inadequate management oversight and control and your apparent inability to assure lasting effectiveness of corrective actions. In addition, you were advised that repetitious violations were of particular concern and could not be tolerated. During this inspection, however, there were violations cited that were similar to previously cited violations.

It is apparent that the root causes of your continuing poor performance are inadequate management oversight, your staff's lack of understanding of the regulatory requirements associated with your broad license, and your failure to assure that corrective actions to resolve violations in one area of your broad license (nuclear medicine) were applied to other areas such as research. Effective management oversight and control is extremely important because of the wide range of authority associated with your broad license. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), the violations in Section I are classified in the aggregate as a Severity Level III problem.

To emphasize again the need for stronger management oversight, more effective control of your licensed radiation programs, and effective implementation of corrective actions throughout the entire program so as to ensure that problems and potential violations are self-identified, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $6,250 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. The escalation and mitigation factors in the Enforcement Policy were considered. The base civil penalty has been increased by 50 percent because the violations were identified by the NRC. Neither escalation nor mitigation was warranted for corrective action to prevent recurrence because, even though immediate corrective actions were taken for some of the violations, adequate long term corrective action to address the root cause issues had not been formulated and implemented at the time of the enforcement conference (for example, actions to assure adequate understanding of the regulatory requirements associated with your broad license). Additional escalation of 100 percent was warranted

because of your poor past enforcement history. It is apparent that the corrective actions implemented in response to the enforcement action, EA 90-076, which was issued on July 19, 1990, have not been effective in preventing non-compliance with the regulations as identified in Inspection Report 52-01946-07/91-01. None of the other factors warranted further adjustment of the civil penalty. Therefore, based on the above, the base civil penalty has been increased by 150 percent.

As discussed during the enforcement conference, the NRC expects the University of Puerto Rico to bring its programs into full compliance. During the enforcement conference it was evident that the University is committed to long term program improvement and that you now recognize the importance of focusing management attention and resources on these problems. It is particularly noteworthy that Dr. Saldana has decided to appoint a high level official from his immediate staff to provide the day-to-day management oversight and control of licensed programs throughout the University system and that this individual will report directly to Dr. Saldana. Also, Dr. Saldana's personal assurance that there is full institutional commitment to the resolution of the problems should have both an immediate and far reaching positive effect on your efforts to achieve and maintain compliance.

The violations in Section II of the enclosed Notice were identified by the NRC during the inspection performed at the College of Natural Sciences, Rio Piedras, and include failure to: check packages for contamination before opening, perform and record surveys, and verify that forms for receiving and handling radioactive material were completed properly.

The violations in Section III of the enclosed Notice were identified by the NRC during the inspection performed at the University's Agricultural Experiment Station, Rio Piedras, and include failure to: perform inventories to account for all sources, properly secure licensed material, and properly post a licensed material storage area.

The violations in Section IV of the enclosed Notice were identified by the NRC during the inspection performed at the University's Mayaguez campus, and include failure to: perform annual audits of the radiation safety program, perform inventories of licensed material, perform monthly surveys, conduct a Radiation Survey Committee meeting during fiscal year 1989, and post required documents and notices at the Marine Sciences Laboratory.

Although the violations in Sections II through IV were categorized at either Severity Level IV or V and were not assessed a civil penalty, they represent a lapse in attention to detail which, if continued in the long term, could lead to more serious violations and escalated enforcement action. It is apparent that the root cause of several of these violations is inadequate training, a recurrent problem that was noted throughout the inspection. We do recognize that there has been some improvement as indicated by the inspection results in the medical teletherapy license program. During the inspection in April 1990, violations associated with that program also resulted in a civil penalty. No violations associated with that program were identified during the June 1991 inspection.

During the inspection at the College of Natural Sciences in Rio Piedras, the inspectors noted that records of routine contamination wipe surveys were being recorded in counts per minute (cpm) instead of disintegrations per minute (dpm), and that licensee personnel did not know the efficiency of the counting equipment used to count the wipe test samples. This resulted in licensee personnel not knowing whether they were exceeding their wipe test action level, which is 100 dpm per 100 square centimeters. To preclude further occurrence of this type of potentially significant problem, you should include in your response to this letter actions taken or planned to assure that the efficiency of the counting equipment is known for all contamination wipe surveys performed in connection with licensed activities under all of the University's NRC licenses, and that the results of the wipe test surveys are recorded in dpm per 100 square centimeters, which is the unit of measurement for wipe test action levels. This issue was discussed during the exit interview and identified as an apparent violation; however no violation is being issued.

Lastly, but of no less significance, the NRC is particularly concerned about the public health and safety implications associated with your lack of aggressive action to resolve your radioactive waste storage and disposal problem. Therefore, in addition to the information that you submitted in your letter of August 6, 1991, we are requesting the specific written information identified below.

We emphasize that a license to use NRC regulated material is a privilege granted by the NRC, and any further recurrence of violations or problems in managing your licensed activities may result in escalated enforcement action, such as higher civil penalties or modification, suspension, or revocation of your licenses.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In addition to this response, we request that you develop and submit to NRC within 60 days of the date of this letter:

1.a. A Radiation Safety Improvement Plan, suitable for incorporation into the terms and conditions of your licenses, that addresses those actions necessary to ensure timely and lasting improvement in the radiation safety program, improvements needed in procedures and practices to achieve and maintain compliance with NRC requirements and license conditions, and periodic internal or external audits that you plan to implement to assess your program effectiveness.

1.b. A schedule for completion of all actions described in the plan, including interim milestones for the more complex actions.

2.a. A description of actions that you have taken or plan to take to ensure that radioactive waste at the University of Puerto Rico is properly identified, packaged, labeled, and stored; and that it is secured against unauthorized removal and disposed of in accordance with regulatory requirements.

2.b. A schedule for accomplishing the actions that you describe.

NRC needs this information in order to have assurance that, in the future: 1) your licensed activities will be conducted in accordance with regulatory requirements and 2) the existing radioactive waste disposal problem at the University of Puerto Rico will be resolved in a timely manner and in accordance with regulatory requirements. If you do not intend to develop and submit to NRC the information requested in Paragraphs 1 and 2 above, you are required, pursuant to Section 182 of the Atomic Energy Act of 1954 as amended, to provide in writing, under oath or affirmation, your reasons as to why you should not be required to develop and submit the requested information.

After reviewing your responses, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D Ebneter

Stewart D. Ebneter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Puerto Rico — EA 91-089

Medical Sciences Campus San Juan, Puerto Rico	Docket No. 030-13584 License No. 52-01946-07
College of Natural Sciences Rio Piedras, Puerto Rico	Docket No. 030-01183 License No. 52-01986-04
Agricultural Experiment Station Rio Piedras, Puerto Rico	Docket No. 030-01182 License No. 52-01986-01
Mayaguez Campus Mayaguez, Puerto Rico	Docket No. 030-14313 License No. 52-10510-04

During an NRC inspection conducted on June 17 - 21, 1991 violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1991), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations of License Number 52-01946-07 (Broad License)
(Violations Assessed A Civil Penalty)

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

Contrary to the above, on June 18, 1991, licensed material consisting of 250 microcuries of sulfur 35 located in an unlocked refrigerator in Room 607A of the Medical Sciences Building, an unrestricted area, was not secured against unauthorized removal and was not tended under the constant surveillance and immediate control of the licensee.

This is a second repeat violation (Inspections 90-01 and 89-01).

B. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, sealed sources containing approximately 150 microcuries of cesium 137 and 150 microcuries of barium 133 with a leak test frequency not to exceed six months were not tested for leakage between April 3, 1990 and June 18, 1991, an interval exceeding six months.

This is a repeat violation (Inspection 90-01).

C. 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.

Contrary to the above, as of June 17, 1991, the licensee did not make surveys to assure compliance with 10 CFR 20.101(a) that limits the radiation exposure of individuals in a restricted area. Specifically, in April and May 1990, the licensee's personnel dosimetry processor notified the licensee that four dosimetry badges (three ring badges and one whole body badge) were non-readable, and the licensee did not make necessary surveys to evaluate the radiation dose received by the individuals who used those badges.

D. Condition 12.C. of License No. 52-01946-07 requires that licensed material for other than human use be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

Contrary to the above, on June 18, 1991, a researcher located in Room 617A of the Medical Sciences Building was using sulfur 35 for other than human use and was not designated by the Radiation Safety Committee to do so, nor was he using the licensed material under the supervision of an individual designated by the Radiation Safety Committee. The researcher ordered and received licensed material under his own name and was not, at that time, conducting his research under the supervision of an individual designated by the Radiation Safety Committee.

E. 10 CFR 35.70(b) requires the licensee to survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceutical waste is stored. 10 CFR 35.70(h) requires the licensee to retain a record of this survey with specific information for three years.

Contrary to the above, between April 3, 1990, and June 19, 1991, the licensee did not survey with a radiation detection survey instrument at least once each week in areas where radiopharmaceutical waste is stored.

F. 10 CFR 20.203(f) requires that, except as provided by 10 CFR 20.203(f)(3), each container of licensed material bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above:

1. On June 18, 1991, several containers of radioactive waste in the waste storage building did not bear durable, clearly visible labels identifying the radioactive contents and the containers were not excepted from such labeling; and

2. On June 19, 1991, a container of radioactive materials located in the sealed source storage vault below the Health Physics Office did not bear any label identifying the radioactive contents and the container was not excepted from such labeling.

G. 10 CFR 35.22(a)(2) requires the Radiation Safety Committee to meet at least quarterly.

Contrary to the above, the Radiation Safety Committee failed to meet from December 20, 1989 through April 4, 1990, and from December 19, 1990 through April 3, 1991, periods in excess of one calendar quarter.

H. 10 CFR 35.22(a)(3) requires the Radiation Safety Committee to establish a quorum in order to conduct business with at least one-half of the committee's membership present, including a management representative.

Contrary to the above, on December 19, 1990, April 3, 1991, and May 22, 1991, the Radiation Safety Committee met and conducted business without first establishing a quorum in that a representative of management was not present at those meetings.

I. Condition 20 of License No. 52-01946-07 requires that the licensee conduct its program in accordance with the statements, representations, and procedures described in the licensee's application dated August 29, 1988.

1. Attachment 11, Subparts 11.1, 11.1.2, and 11.1.6 of the licensee's application state that radioactive waste will be placed in clearly identified receptacles which are appropriately marked with the radiation standard tag or label and that under no circumstance will radioactive materials be discharged into waste baskets or other containers which would permit the contamination of the regular trash.

Contrary to the above, on June 18, 1991, phosphorus 32 waste located in Room B-316 of the Medical Sciences Building was placed in a receptacle of biological waste, without any radiological warning signs, and was prepared to be disposed of as biological waste.

2. Attachment 10.6.A.3. of the licensee's application states that all shipments of radioactive materials are to be received in the Hot Lab (Room R-133 of the Biomedical Building) and in the Health Physics Laboratory (Room R-179 of the Biomedical Building) and inspected by the Health Physics Office staff prior to delivery to the user.

   Contrary to the above, as of June 19, 1991, packages containing radioactive materials had been delivered directly to the Neurobiology Laboratory and had not been initially received and surveyed by the Health Physics Office staff at the Central Medical Science Campus prior to delivery to the user.

3. Attachment 8.2 of the licensee's application states that candidates for use of radioactive materials in research should submit evidence of training and experience equivalent to 40 hours of academic radiation disciplines including specific subjects.

   Contrary to the above, on September 19, 1990, November 8, 1990 and November 30, 1990, candidates for use of licensed materials in research were approved without submitting evidence of training and experience equivalent to 40 hours of academic radiation disciplines.

4. Attachment 10.12 of the licensee's application states that the licensee will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2 (August 1987). Item 1.e. (Records) of Appendix N specifies that the licensee will keep records which include actions taken in the case of excessive dose rates or contamination and follow up survey information.

   Contrary to the above, as of June 18, 1991, records of surveys performed in the research laboratories did not indicate the actions taken and follow up survey information for cases involving excessive dose rates or contamination.

J. 10 CFR 35.22(a)(5) requires the Radiation Safety Committee to promptly provide each member with a copy of the meeting minutes.

   Contrary to the above, as of June 17, 1991, the Radiation Safety Committee was not providing copies of the meeting minutes to all committee members.

K. 10 CFR 35.59(g) requires the licensee to maintain inventory records of quarterly physical inventories for all sealed sources and requires those records to contain specified information including model number of each source and serial number if one has been assigned.

Contrary to the above, as of June 17, 1991, the licensee was not recording assigned source model numbers and serial numbers on its quarterly sealed source inventory records.

L. 10 CFR 35.59(d) requires the licensee to retain leak test records for five years which contain specified information for all sources tested.

Contrary to the above, as of June 17, 1991, records of leak tests were not maintained for the sixteen Cesium 137 sources received in August 1990.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplements IV and VI).

Cumulative Civil Penalty - $6,250 (assessed equally among the 15 violations).

II. Violations of License No. 52-01986-04 (College of Natural Sciences) (Violations Not Assessed A Civil Penalty)

Condition 15 of License No. 52-01986-04 requires that the licensee conduct its program in accordance with the statements, representations, and procedures described in the licensee's application received November 9, 1989, and letter dated July 24, 1990.

1. Procedure 5.c. of Item 10 of the licensee's application states that the surface of the source container will be checked for contamination using a cotton swab when initially opening packages containing radioactive material.

Contrary to the above, as of June 20, 1991, the surface of source containers received in Room JGD 217 were not being checked for contamination when initially opening packages containing material.

This is a Severity Level IV violation (Supplement VI).

2. Procedure 5.d. of Item 10 of the licensee's application states that the Radiation Safety Technician is to be notified upon receipt of material.

Contrary to the above, as of June 20, 1991, the Radiation Safety Technician had not been notified of all receipts of material in Rooms JGD 107 and JGD 216.

This is a Severity Level IV violation (Supplement VI).

3. Procedure 10 of Item 10 of the licensee's application states that laboratories using radioactive material will perform surveys at the end of the experiment and that a permanent record would be kept of all survey results, including negative results.

   (a) Contrary to the above, from February 1991 until June 20, 1991, required surveys were not performed in Room JGD 217 at the end of the experiments.

   This is a Severity Level IV violation (Supplement VI).

   (b) Contrary to the above, as of June 20, 1991, a permanent record of results of all surveys in Room JGD 216, including negative results, was not maintained.

   This is a Severity Level V violation (Supplement VI).

4. The licensee's letter dated July 24, 1990, states that the Radiation Safety Technician will verify that the researchers complete forms for receiving and handling radioactive material in compliance with the standards and regulations established in the license.

   Contrary to the above, as of June 20, 1991, the licensee's Radiation Safety Technician was not verifying that the forms for receiving and handling radioactive material were completed properly. Specifically, the technician was not verifying that the forms demonstrated that packages were routinely surveyed for contamination prior to opening, that the technician was being notified of all material receipts and that laboratory surveys were being performed and recorded as required.

   This is a Severity Level V violation (Supplement VI).

III. Violations of License No. 52-01986-01 (Agricultural Experiment Station) (Violations Not Assessed a Civil Penalty)

A. Condition 17 of License No. 52-01986-01 requires the licensee to conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

   Contrary to the above, from October 17, 1990 until June 20, 1991, an interval in excess of 6 months, the licensee did not perform inventories to account for all sources and/or devices received and possessed.

   This is a repeat violation (Inspection 90-01).

   This is a Severity Level IV violation (Supplement VI).

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

Contrary to the above, on June 20, 1991, licensed material consisting of eleven vials of carbon 14 ranging from 50 microcuries to 386 microcuries per vial stored in an unlocked refrigerator in an open hallway, an unrestricted area, was not secured against unauthorized removal, and was not tended under the constant surveillance and immediate control of the licensee.

This is a Severity Level IV violation (Supplement IV).

C. 10 CFR 20.203(e) requires that rooms or areas in which specified amounts of licensed material are used or stored be conspicuously posted "Caution - Radioactive Material."

Contrary to the above, on June 20, 1991, a refrigerator which contained eleven vials of carbon 14 ranging from 50 to 386 microcuries per vial and which was located in an open hallway was not posted as required.

This is a Severity Level V violation (Supplement IV).

IV. Violations of License No. 52-10510-04 (Mayaguez Campus) (Violations Not Assessed A Civil Penalty)

A. Condition 20 of License No. 52-10510-04 requires that the licensee conduct its program in accordance with the statements, representations, and procedures described in the licensee's application dated August 9, 1983, which includes the licensee's Radiation Safety Regulations Manual, and letter dated April 11, 1986.

1. Section 2.2.7.7 of the Radiation Safety Regulations Manual requires that the Radiation Safety Committee perform an annual audit of the radiation safety program.

Contrary to the above, the Radiation Safety Committee failed to perform annual audits of the radiation safety program for the calendar years 1989 and 1990.

This is a Severity Level IV violation (Supplement VI).

2. Section 2.5 of Appendix 2 of the Radiation Safety Regulations Manual requires that the Radiation Protection Officer perform inventories of licensed material every six months.

   Contrary to the above, between January 1989 and March 1990 and between May 1990 and June 17, 1991, intervals which exceed six months, the Radiation Protection Officer failed to perform inventories of licensed material.

   This is a Severity Level IV violation (Supplement IV).

3. Section 4.3 of Appendix 4 of the Radiation Safety Regulations Manual require that laboratory areas where less than 100 microcuries of licensed material are used be surveyed monthly by each user.

   Contrary to the above, from January 1989 to June 17, 1991, monthly surveys had not been performed in Biology and Chemistry laboratories which frequently use licensed material in amounts less than 100 microcuries.

   This is a Severity Level IV violation (Supplement VI).

4. The licensee's letter dated April 11, 1986, states that the Radiation Safety Committee will meet no less than once each fiscal year.

   Contrary to the above, the Radiation Safety Committee failed to meet during the fiscal year 1989.

   This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees."

   Contrary to the above, on June 19, 1991, the licensee did not have posted any of the required documents or notices at the Marine Sciences Laboratory.

   This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, the University of Puerto Rico (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1991), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter

may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Suite 2900, 101 Marietta Street, N.W., Atlanta, Georgia 30323.

FOR THE NUCLEAR REGULATORY COMMISSION

Stewart D. Ebneter
Regional Administrator

Dated at Atlanta, Georgia
this 28th day of August 1991