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:

- 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
- 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.

- 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 'ledical 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).

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

Condition .5 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.

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).

 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.
 - 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).

 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).

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 28H day of August 1991