ENCLOSURE

NOTICE OF VIOLATION

University of Puerto Rico
Rio Piedras, Puerto Rico

Docket No. 030-13584
License No. 52-01946-07

During an NRC inspection conducted on March 9 and 13, 1992, 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, the violations are listed below:

A. Condition 20 of License No. 52-01946-07 requires, in part, that the licensee conduct its program in accordance with the statements, representations and procedures described in the licensee's application dated August 29, 1988, and licensee's letter dated January 14, 1991.

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 standard radiation 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 regular trash.

   Contrary to the above, on March 9, 1992, iodine 125 waste located in Room A-639 of the licensee's research facility was contained in an untagged and unlabeled plastic bag along with non-radioactive waste.

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

2. Attachment 9.1 of the licensee's application designates laboratories A-617A, R-632, R-633, R-643, R-646, R-663, R-678, R-688, and R-689, as authorized places of use and as temporary storage locations for licensed material on the sixth floor of the licensee's research facility. Licensee's letter dated January 14, 1991, designates a room located in the basement of the main building for storage of waste associated with research activities.

Contrary to the above:

a. As of March 9, 1992, the licensee was storing iodine 125 waste in Room A-639 on the sixth floor of the licensee's research facility, an unauthorized place for use or temporary storage of this licensed material.

b. As of March 9, 1992, the licensee had been storing phosphorus 32 waste in Room B-330, an unauthorized waste storage area.

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

3. Attachment 10.4, Subparts B.6 and B.7 of the licensee's application states that containers in which radioactive materials are being stored or transported shall be appropriately marked with labels or decals identifying the nuclide, the activity within the container, the date of the activity estimate, and the initials of the responsible custodian.

Contrary to the above, on March 9, 1992, the labels on sealed waste packages containing carbon 14, sulphur 35 and tritium in Room A-643, the labels on sealed waste packages containing phosphorus 32 in Room B-330, and the labels on a sealed waste plastic bag containing tritium in Room A-617, did not identify the activities within the containers, the dates of the activity estimates and the initials of the responsible custodian.

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

B. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on October 11 and 17, 1991, the licensee did not survey with a radiation detection instrument at the end of the day the nuclear medicine laboratory, an area where radiopharmaceuticals were routinely prepared for use and administered.

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

C. 10 CFR 35.70(d) requires that a licensee establish radiation dose trigger levels for the daily and weekly surveys conducted in areas where radiopharmaceuticals are routinely prepared for use or administered and areas where radiopharmaceuticals or radiopharmaceutical waste is stored, and that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

Contrary to the above, on September 12, October 4 and 24, and November 2, 1991, licensee personnel, while performing surveys of the nuclear medicine laboratory, obtained survey results which exceeded the licensee's established trigger levels but failed to notify and the Radiation Safety Officer.

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

D. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above:

1. The licensee's dose calibrator linearity test performed on July 22, 1991, covered only the range between 138 millicuries and 14 microcuries while the highest dosage that the licensee administered to a patient was 146 millicuries.

2. The licensee's dose calibrator linearity tests performed on October 30, 1991 and January 27, 1992, covered the ranges only down to 12 and 11 microcuries, respectively.

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

E. 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 December 10, 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, as of December 10, 1991, the licensee's personnel dosimetry processor had notified the licensee that there were unreadable dosimetry badges during the month of September 1991, and the licensee had not made the necessary surveys to evaluate the radiation dose received by the individuals who used those badges.

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

F. 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 access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on December 9, 1991, licensed materials located in Rooms A-639 and A-645 of the Medical Sciences Building, unrestricted areas, were not secured against unauthorized removal and were not tended under constant surveillance and immediate control of the licensee.

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

G. 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 December 10, 1991, the Radiation Safety Committee had not provided each member with a copy of the minutes of the meetings held in October and November 1991.

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

Pursuant to the provisions of 10 CFR 2.201, the University of Puerto Rico is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region II, within 30 days from the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of

Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Atlanta, Georgia
this 31st day of July 1992