UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	Docket Nos. 030-13584 and 030-31462
UNIVERSITY OF PUERTO RICO	)	License Nos. 52-01946-07 and
San Juan, PR	)	52-01946-09(08)
	)	EA 90-076

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

University of Puerto Rico (Licensee) is the holder of Broad Medical and Teletherapy License Nos. 52-01946-07 and 52-01946-09(08) issued by the Nuclear Regulatory Commission (NRC or Commission) on January 3, 1978 and March 8, 1990, respectively. The licenses authorize the Licensee to use byproduct material in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on April 2-3, 1990. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated July 19, 1990. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalties proposed for the violations. The Licensee responded to the Notice by letter dated September 4, 1990. In its response, the Licensee admitted the violations but proposed that the civil penalties be decreased or eliminated.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalties proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay civil penalties in the amount of $12,500 within 30 days of the date of this Order, by check, draft, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C.

20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region II, 101 Marietta Strett N.W., Atlanta, Georgia 30323.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

Whether on the basis of the violations which were admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 19th day of October 1990

APPENDIX

EVALUATIONS AND CONCLUSIONS

On July 19, 1990, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued for violations identified during an NRC inspection. University of Puerto Rico responded to the Notice on September 4, 1990. In the response the licensee admitted the violations, but requested that the civil penalties be decreased or eliminated. The NRC's evaluation and conclusion regarding the licensee's requests are as follows:

Restatement of Violations

I. Violations of License No. 52-01946-07 (Broad License)

A. 10 CFR 35.415(a)(4) requires, in part, that for each patient receiving implant therapy, a licensee promptly, after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR 20.

Contrary to the above, on April 13, 1989, October 11, 1989, and January 4, 1990, the licensee did not conduct any surveys for dose rates in the contiguous restricted and unrestricted areas to demonstrate compliance with the requirements of 10 CFR 20 after implanting the material in a patient receiving implant therapy.

B. 10 CFR 35.404(a) requires, in part, that immediately after removing the last temporary implant therapy source from a patient, a licensee make a radiation survey of the patient to confirm that all sources have been removed.

Contrary to the above, on April 17, 1989, the licensee did not make any survey of an implant therapy patient immediately after the removal of iridium-192 temporary implant therapy sources to confirm that all the sources had been properly removed.

C. 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 licensed materials in an unrestricted area and 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 April 2, 1990, licensed materials located in the the radiopharmaceutical storage and preparation laboratory (hot lab) of the Nuclear Medicine Department, an unrestricted area,

was not secured against unauthorized removal and were not under the constant surveillance and immediate control of the licensee in that the laboratory was left open and unattended.

This is a repeat violation (Inspection 89-01).

D. 10 CFR 35.59(b)(2) requires that a licensee in possession of any sealed sources or brachytherapy sources test the sources for leakage at intervals not to exceed six months or other intervals approved by the Commission and described in the manufacturer's label or brochure that accompanies the sealed sources.

Contrary to the above, between June 1989 and April 3, 1990, an interval exceeding six months, the licensee did not test any sealed source or brachytherapy source in its possession for leakage and no other intervals for testing these sources had been approved by the Commission.

This a repeat violation (Inspection 87-01).

E. 10 CFR 35.59(g) requires, in part, that a licensee in possession of any sealed sources or brachytherapy sources shall conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, between December 12, 1988 and May 3, 1989 (the 1st quarter of 1989), and between May 3, 1989 and October 6, 1989 (the 3rd quarter of 1989), the licensee did not conduct quarterly physical inventories of any sealed sources and brachytherapy sources in its possession.

This is a repeat violation (Inspection 85-01).

F. 10 CFR 35.59(h) requires, in part, that a licensee in possession of any sealed sources or brachytherapy sources measure the ambient dose rates quarterly in all areas where such sources are stored.

Contrary to the above, between June 1989 and April 3, 1990 (the 3rd and 4th quarter of 1989, and 1st quarter of 1990), the licensee did not measure the ambient dose rates in any areas where sealed or brachytherapy sources are stored.

G. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the regulations 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. When appropriate, such an evaluation includes physical survey of the location of materials and equipment, and measurements

of levels of radiation and concentrations of radioactive material present.

10 CFR 20.103(b)(1) requires, in part, that a licensee, as a precautionary procedure, use process or other engineering controls to limit concentrations of radioactive material in air to the extent practicable.

Contrary to the above, between January 1989 and April 3, 1990, the licensee's surveys made to verify compliance with the requirements of 10 CFR 20.103(b)(1) were inadequate in that air flow rates in fume hoods used as process and engineering controls for the handling and storage of multiple dose vials containing millicurie quantities of iodine-131 were not being measured and evaluated.

This is a repeat violation (Inspection 87-01).

H. 10 CFR 35.205(e) requires that a licensee measure the ventilation rates available in areas of radioactive gas use each six months.

Contrary to the above, between January 1989 and April 3, 1990, the licensee did not measure the ventilation rates available in the room where xenon-133 gas was used.

This is a repeat violation (Inspection 87-01).

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.

Item 10.7, page 30, of the licensee's application dated August 29, 1988, states that packages containing radioactive material will be opened in accordance with the procedures described in Appendix L of Regulatory Guide 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs" (August 1987) (RG 10.8). Step 2.c of Appendix L requires that radiation dose rate measurements be made at one meter from the package and on contact with the package surface.

Contrary to the above, on April 11, 1989, no radiation survey measurements were made either at one meter from the package or at contact with the package, upon receipt of a package containing iridium-192 implant therapy sources.

This is a repeat violation (Inspection 85-01).

J. 10 CFR 35.22(b)(6) requires that to oversee the use of licensed materials, the Radiation Safety Committee must review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

Contrary to the above, an annual review of the radiation safety program was not performed by the Radiation Safety Committee and the Radiation Safety Officer for 1988. The last two reviews were performed in March 1990 (for 1989) and in April 1988 (for 1987).

K. 10 CFR 35.50(e)(2), (3), and (4) require that records of dose calibrator accuracy, linearity, and geometric dependence tests, include the signature of the Radiation Safety Officer.

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.

Item 9.3 of the application dated August 29, 1988, requires that the model procedures in Appendix C, RG 10.8, be followed for calibration of the dose calibrator. Procedure 8. of Appendix C requires that the RSO review and sign the records of all geometry, linearity, and accuracy tests.

Contrary to the above, between April 1989 and April 3, 1990, the Radiation Safety Officer did not review or sign the dose calibrator accuracy, linearity, and geometric dependence test records.

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 11 violations).

II. Violations of License Number 52-01946-09 (Teletherapy License)

A. 10 CFR 35.634(a) requires, in part, that a licensee authorized to use teletherapy units for medical use perform output spot checks on each teletherapy unit once in each calendar month. 10 CFR 35.634(c) requires, in part, that a licensee have the teletherapy physicist review the results of each spot check within 15 days.

Contrary to the above, between April 1989 and April 3, 1990, the licensee did not have the teletherapy physicist (Radiation Safety Officer) review the results of each spot check either within the 15 days required or at anytime during the 12-month period from April 1989 to the date of the inspection.

B. 10 CFR 35.632(a)(3) and (f) require, in part, that a licensee authorized to use a teletherapy unit for medical use perform full calibration measurements at intervals not to exceed one year and that these full calibration measurements be performed by the licensee's teletherapy physicist.

License Condition 11.B of License No. 52-01946-09 specifies the licensee's designated teletherapy physicist by name.

Contrary to the above, between April 1, 1987 and April 3, 1990, the designated teletherapy physicist did not perform the annual full calibration measurements of the teletherapy system documented for June 9, 1987, June 9, 1988 and June 9, 1989. Instead, these annual full calibrations were performed by an individual not meeting the qualifications of a teletherapy physicist and not designated by License No. 52-01946-09 to perform such measurements.

C. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of any sealed sources test the sources for leakage at intervals not to exceed six months or at other intervals approved by the Commission and described in the label or brochure that accompanies the sealed sources.

Contrary to the above, between June 1989 and April 3, 1990, an interval exceeding six months, the licensee did not test the teletherapy system sealed source in its possession for leakage and no other intervals for testing this source had been approved by the Commission.

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

Civil Penalty - $6,250 (assessed $1,500 for Violation A, $4,250 for Violation B and $500 for Violation C).

Summary of Licensee's Request for Mitigation

The licensee requests that the civil penalties be decreased or eliminated due to the fact that the alleged violations were corrected, and the licensee has taken the necessary steps to avoid future violations. The licensee asks that NRC's evaluation consider that the University is a non-profit organization dedicated to higher education and, in particular, the Medical Sciences Campus provides services for medically indigent patients who would otherwise not receive the services anywhere else in Puerto Rico.

NRC Evaluation of Licensee's Request for Mitigation

The correction of identified violations is always required and is not a basis for mitigation of a civil penalty unless the action taken is prompt and comprehensive. As stated in the NRC's July 19, 1990 letter, neither escalation nor mitigation of the base civil penalty for the violations in Section I or II of the Notice was warranted for the licensee's corrective action to prevent recurrence because, although it was considered comprehensive, it was not prompt.

The NRC acknowledges that the University is a non-profit organization that provides essential services for medically indigent patients. As stated in the NRC Enforcement Policy, it is not the NRC's intention that the economic impact of a civil penalty be such that it puts a licensee out of business or adversely affects a licensee's ability to safely conduct licensed activities. In fact, in developing the base civil penalties in Tables I.A, consideration

was given to the fact that some licensees, such as the University, are non-profit organizations.

NRC Conclusion

The staff concludes that the violations occurred as stated and that the licensee has not provided a sufficient basis for mitigation of the proposed civil penalties. Consequently the proposed civil penalties of $12,500 should be imposed.

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