

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Puerto Rico
San Juan, Puerto Rico

Docket Nos. 030-13584 and 030-31462
License Nos. 52-01946-07 and
52-01946-09(08)
EA 90-076

During the Nuclear Regulatory Commission (NRC) inspection conducted on April 2-3, 1990, 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, (1990), 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 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).

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. 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 violation, (2) the reasons for the violations if admitted, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps which 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 penalties 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 penalties 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 penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, 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 penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1990), 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 civil penalties.

Upon failure to pay any civil penalties due, which has been subsequently determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the the Act, 42 U.S.C 2282c.

The responses noted above (Reply to a Notice of Violation, letter with payment of civil penalties, 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, DC 20555, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II.

FOR THE NUCLEAR REGULATORY COMMISSION

Original Signed by:
Stewart D. Ebnetter

Stewart D. Ebnetter
Regional Administrator

Dated at Atlanta, Georgia
this 19th day of July 1990