NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Veterans Administration Medical Center
Albany, New York

Docket No. 030-10026
License No. 31-02755-05
EA 90-209

During an NRC inspection conducted on November 20-21, 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 the associated civil penalty are set forth below:

A. 10 CFR 20.207(a) requires that licensed material stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials in an unrestricted area and not in storage be 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 radioactive materials.

Contrary to the above, on August 3, 1990, a shipment of radioactive material (1 millicurie of tritium) was left unsecured in an unrestricted area (window sill in the hallway) and was not under the constant surveillance or immediate control of the licensee.

B. 10 CFR 35.315(a)(8) requires, in part, that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, the licensee shall measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage.

Contrary to the above, the licensee did not, within three days after the administration of the dosage, measure the thyroid burden of an individual who prepared and administered a radiopharmaceutical therapy dosage of iodine-131 on July 13, 1990; and the patient who received this dosage was hospitalized for compliance with 10 CFR 35.75.

C. 10 CFR 35.22(b)(6) requires that the Radiation Safety Committee review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

Contrary to the above, as of November 21, 1990, the Radiation Safety Committee, with the assistance of the Radiation Safety Officer, did not perform an annual review of the radiation safety program for 1989.



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D. 10 CFR 35.205(c) requires, in part, that before receiving, using or storing a radioactive gas, licensees calculate the amount of time needed after a spill to reduce the concentration in the room to the limit listed in 10 CFR Part 20, Appendix B.

Contrary to the above, as of November 21, 1990, no calculation was performed of the time needed after a spill of xenon-133 to reduce the concentration in the imaging room (Room 626D) to the applicable limit.

E. 10 CFR 20.303 describes requirements for the disposal of radioactive materials by release into the sanitary sewerage system. 10 CFR 20.401(c)(3) requires that each licensee maintain records of disposals made under 10 CFR 20.303.

Contrary to the above, as of November 21, 1990, adequate records were not maintained, as required under 10 CFR 20.401, of disposals in 1988 and 1989 of radioactive material released into the sanitary sewerage system. For 1988, the records were disorganized and confusing in that one record indicated that 24,014.9 microcuries were disposed while another record indicated that 971.4 microcuries were disposed. For 1989, no records were maintained.

F. 10 CFR 35.70(d) requires that a licensee shall establish radiation dose rate trigger levels for area surveys required by paragraphs (a) and (b) of 10 CFR 35.70.

Contrary to the above, as of November 21, 1990, the licensee did not establish radiation dose rate trigger levels for the area surveys required under 10 CFR 35.70.

G. 10 CFR 35.59(b)(2) requires, in part, that each sealed source or brachytherapy source be tested for leakage at intervals not to exceed 6 months or at intervals approved by the Commission or an Agreement State.

Contrary to the above, as of November 21, 1990, sealed sources (containing licensed material) were not tested for leakage from October 14, 1989 to November 21, 1990, an interval which exceeded 6 months, and no other interval was approved.

H. 10 CFR 35.205(e) requires, in part, that licensees measure the ventilation rates available in areas of use of radioactive gases each 6 months.

Contrary to the above, as of November 21, 1990, the ventilation rates available in Room 609D had not been measured during the last 12 months and, during that period, radioactive xenon gas was used in that room.

I. 10 CFR 35.315(a)(7) requires that, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, the licensee must survey the patient's room and private sanitary

facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room and that the room not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

Contrary to the above, on July 16, 1990, a radiopharmaceutical therapy patient's room was reassigned before a survey was performed to ensure that removable contamination was less than 200 disintegrations per minute per 100 square centimeters, and the patient was hospitalized for compliance with 10 CFR 35.75.

J. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting any portion of a restricted area shall be instructed in the health protection problems associated with exposure to radioactive materials or radiation, in precautions and procedures to minimize exposure, and in the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation or radioactive materials.

Contrary to the above, as of November 21, 1990, the licensee did not adequately instruct individuals working in or frequenting any portion of a restricted area in the health problems associated with exposure to radioactive materials, in precautions and procedures to minimize exposure and the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radioactive materials. For example, some research laboratory personnel did not know that contamination surveys were required after they performed experiments with radioactive material and others were unaware of the requirement to maintain accurate radioactive material inventories and waste disposal records.

K. License Condition 18 states, in part, that the license is based on the licensee's statements and representations in the application dated December 6, 1985.

1. The licensee's "General Rules for Safe Use of Radioactive Materials for Research Laboratories" described in Appendix 20 of the license application, dated December 6, 1985, require that individuals do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.

   Contrary to the above, on November 20, 1990, as observed by the NRC inspector, there was evidence of eating and drinking in five research laboratories (Rooms A607, A625, A629, B607 and B630) where radioactive material was stored or used. Specifically, the evidence involved soft drinks on radioactive material work counters, candy wrappers in trash cans, and a microwave oven which smelled like popcorn in a room designated as a radioactive material use area. Furthermore, a researcher confirmed that the microwave oven had been used for making popcorn.

2. The licensee's procedures described in Section 3.1.4.G. of the license application, dated December 5, 1985, require that authorized users notify the Radiation Safety Officer whenever there is a change in laboratory personnel or location.

   Contrary to the above, as of November 21, 1990, two authorized users did not notify the Radiation Safety Officer of changes in laboratory location. Specifically, a room designated as a research laboratory used for radioactive materials was converted into a general storage area, and another laboratory was no longer used for radioactive materials, but was still posted as a radioactive materials use area, and neither the RSO nor the RSC were notified of these changes.

3. The licensee's procedures described in Section 3.1.4.A. of the license application require authorized users to maintain on file, up-to-date records of the use, disposition, storage and disposal of all radionuclides including the amount of radioactivity, isotope, chemical form, volume or weight, date of analysis, company and location of isotope.

   Contrary to the above, as of November 21, 1990, up-to-date records of radioactive waste disposal were not maintained by the authorized user for radioactive waste generated in Room A607.,

L. 10 CFR 20.201(b) requires that each licensee make 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 mateirals under a specific set of conditions.

   Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.103 and 20.106, which, respectively, limit exposure of individuals to concentrations of radioactive materials in air in restricted areas, and limit radioactivity in releases to unrestricted areas. Specifically, as of November 21, 1990, xenon airborne concentrations in restricted areas (room 626D) and in releases to unrestricted areas were not calculated to demonstrate compliance with the requirements of 10 CFR 20.103 and 20.106.

M. 10 CFR 35.13(e) requires that a licensee shall apply for and must receive a license amendment before it adds to or changes the areas of use or address or addresses of use (of licensed material) identified in the application or in the license.

   Contrary to the above, as of November 21, 1990, the licensee changed the location of use of radioactive xenon gas from room 609D to 626D without applying for or receiving a license amendment.

N. 10 CFR 35.50(e)(3) requires that licensees retain records of quarterly dose calibrator linearity tests for 3 years unless directed otherwise and that the record include the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test and the signature of the Radiation Safety Officer.

Contrary to the above, as of November 21, 1990, records of quarterly linearity tests did not contain the serial number of the dose calibrator nor the signature of the Radiation Safety Officer.

O. 10 CFR 35.50(e)(1) requires that licensees retain records of daily constancy checks of dose calibrators for 3 years unless directed otherwise and that the records include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured and the initials of the individual who performed the test.

Contrary to the above, as of November 21, 1990, records of daily constancy checks did not include the model and serial number of the dose calibrator.

P. 10 CFR 35.50(e)(4) requires that licensees retain records of tests for dose calibrator geometrical dependence for 3 years unless directed otherwise and that the records include the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

Contrary to the above, as of November 21, 1990, the records of tests for geometrical dependence did not include the serial number of the dose calibrator nor the signature of the Radiation Safety Officer.

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

Cumulative Civil Penalty - $3,750 (assessed equally among the 18 violations)

Pursuant to the provision of 10 CFR 2.201, Veterans Administration Medical Center 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 the Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The 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 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 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 "Answer to a Notice of Violation" and may: (1) deny the violation(s) 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, 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 (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 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. 2282(c).

The responses to the Director, Office of Enforcement, noted above (Reply to a 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 I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

FOR THE NUCLEAR REGULATORY COMMISSION

Original Signed By:
Thomas T. Martin

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 29 day of January 1991