NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Veterans Administration Medical Center
New York, New York 10010

Docket No. 030-02611
License No. 31-00032-04
EA 89-165

During an NRC inspection conducted on July 20, 1989, 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 (1989) (Enforcement Policy), 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:

A. 10 CFR 20.201(b) requires, in part, that each licensee make such surveys as may be necessary to comply with the regulations of 10 CFR Part 20. 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, surveys were not made to assure compliance with 10 CFR 20.101, which establishes maximum permissible radiation exposure limits for the whole body and the extremities of individuals working in restricted areas, as evidenced by the following examples:

1. as of July 20, 1989, no evaluation of the whole body and extremity radiation exposures had been made for numerous individuals working in the nuclear medicine and research services (restricted areas) and for whom radiation dosimetry results were not available.

2. on July 20, 1989, a nuclear medicine technologist was not wearing a ring badge dosimeter while performing radioactive material package receipt surveys, and this dosimeter was needed to perform appropriate surveys to assure compliance with 10 CFR 20.101.

3. as of July 20, 1989, research personnel working with up to 5 millicuries of phosphorus-32 had not been issued ring badge dosimeters, and these dosimeters were needed to perform appropriate surveys to assure compliance with 10 CFR 20.101.

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 licensed materials in an unrestricted area and not in storage be under 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 July 20, 1989, licensed materials were present in rooms 16047-W and 16013F-W, which were not locked (unrestricted areas), and these materials were not secured against unauthorized removal nor were they under the constant surveillance and immediate control of the licensee. These rooms were unrestricted areas since they were accessible to non-radiation workers and members of the general public, as evidenced by the fact that the inspector was able to enter these areas unchallenged.

C. Condition 11.A of License No. 31-00032-04 states that licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee.

Contrary to the above, as of July 20, 1989, users of licensed material were not designated by the Medical Isotopes Committee (Radiation Safety Committee). The authorized users of licensed radioactive material were designated by the Chief of the Nuclear Medicine Service and the Chairman of the Medical Isotopes Committee without review and approval by the Medical Isotopes Committee.

D. Condition 19 of License No. 31-00032-04 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated August 15, 1986, letters dated October 31, 1983, March 12, 1981, November 21, 1980, December 27, 1978, and application dated April 7, 1978.

1. Item 7.6, Page 8 of the application dated April 7, 1978, states that the Medical Isotopes Committee shall review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license.

   Contrary to the above, between December 16, 1987 and July 20, 1989, the Medical Isotopes Committee did not perform a review of the entire radiation safety program to determine that all activities were being conducted safely and in accordance with NRC regulations and the conditions of the license.

2. Item 7, Page 9 of the application dated April 7, 1978, states that the Medical Isotopes Committee shall meet as often as necessary to conduct its business, but not less than once in each calendar quarter.

   Contrary to the above, the Medical Isotopes Committee did not meet during the fourth calendar quarter of 1988 and the first two calendar quarters of 1989.

3. Item 14, page 34 of the application dated April 7, 1978 states that packages containing radioactive material will be opened in accordance with the procedures described in Appendix F of the NRC "Guide for the Preparation of Applications for Medical Programs" dated November 1, 1977 (NUREG-0338, Rev. 1).

   Items 2 and 3, respectively, of Appendix F of NUREG-0338 require, in part, the measurement of radiation exposure rate at three feet from the surface of the package and at the surface of the package. Additionally, Item 4 of Appendix F requires that protective gloves be worn when opening packages containing radioactive material.

   Contrary to the above, on July 20, 1989, packages containing radioactive material were not opened in accordance with the procedures described in Appendix F of NUREG-0338, Revision 1, in that: 1) radiation measurements were not made at three feet from the surface of the package and at the surface of the package, and 2) the inspector observed a nuclear medicine technologist who was not wearing protective gloves opening packages containing radioactive material.

   The failure to measure the radiation exposure rate at three feet from the surface of the package is a repeat violation.

4. Item 15.11, page 36 of the application dated April 7, 1978, requires that each patient dose be assayed prior to administration and that no dose differing by more than ± ten percent from the prescribed dose be used.

   Contrary to the above, as of July 20, 1989, radiopharmaceutical doses were not assayed prior to administration to assure that no dose varied by more than ± ten percent from the prescribed dose.

5. Item 4 of the letter dated December 27, 1978, states that the procedures described in Appendix D, Section 2 of NUREG-0338 will be used for the calibration of the dose calibrator. Item I of Appendix D, Section 2, requires, in part, that the test for instrument constancy be performed before each daily use of the instrument.

   Contrary to the above, as of July 20, 1989, dose calibrator constancy was not tested before each daily use of the instrument; rather, it was only tested after all radiopharmaceuticals had been assayed.

6. Item 4 of the letter dated December 27, 1978, states that the procedures described in Appendix D, Section 2 of NUREG-0338 Rev. 1 will be used for the calibration of the dose calibrator. Item E of Appendix D, Section 2, requires, in part, that dose calibrator linearity be ascertained over the entire range of activities employed.

Contrary to the above, as of July 20, 1989, dose calibrator linearity was not ascertained over the entire range of activities employed. Specifically, although the range of use of the instrument was between 100 millicuries and 100 microcuries, dose calibrator linearity was tested only between 110 millicuries and 5 millicuries.

7. Item 15.15, page 36 of the application dated April 7, 1978, requires that generator, kit preparation, and injection areas be surveyed for contamination after each procedure or at the end of each day.

   Contrary to the above, as of July 20, 1989, kit preparation and injection areas were not surveyed for contamination after each procedure nor at the end of each day.

8. Item 15.4, page 35 of the application dated April 7, 1978, states that eating, storing, or preparation of food is forbidden in a laboratory or rooms where work with unsealed radioactive sources is taking place or where contamination may exist.

   Contrary to the above, on July 20, 1989, food (and associated utensils) were stored in Room 1029-W and Room 16013F-W, both of which were areas where radioactive materials were stored or used and where the potential for contamination existed.

   This is a repeat violation.

9. Item 7.6.4, page 17 of the radiation safety manual submitted as part of the application dated August 15, 1986, requires that laboratory areas where radioactive materials are used be surveyed at least once per calendar month.

   Contrary to the above, as of July 20, 1989, research laboratory areas where radioactive materials are used were not surveyed at least once per calendar month.

10. Items 4 and 5 of the letter dated November 20, 1980, state that, prior to disposal, waste will be monitored with a low level survey meter and that records of surveys will be maintained.

    Contrary to the above, as of July 20, 1989, records were not maintained of surveys performed on radioactive waste prior to disposal.

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

Civil Penalty - $2500 (assessed equally among the 13 violations).

Pursuant to the provisions 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 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 alleged violation, (2) the reasons for the violation if admitted, (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, 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, or money order 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, 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, 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 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, DC 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
WILLIAM T. RUSSELL
William T. Russell
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 13th day of October 1989