NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Veterans Administration Medical Center
Brooklyn, New York

Docket Nos. 030-02623
030-11781
070-03042
License Nos. 31-02892-03
31-02892-05
SNM-1969
EA 89-190

During an NRC inspection conducted between July 19-21, 1989 and continued in the Region I office between August 12, 1989 and August 21, 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 civil penalties 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 penalties are set forth below:

I. License Condition 15 of NRC License 31-02892-05 requires, in part, that licensed radioactive material be possessed and used in accordance with the statements, representations, procedures and enclosures to the licensee's application dated June 30, 1981.

Item 1 of the emergency procedure which was included with this application requires that in the event the teletherapy unit source drawer fails to return to the safe shielded position, the patient is to be removed from the treatment room.

Contrary to the above, while a patient was undergoing teletherapy on October 25, 1988, the teletherapy unit source drawer failed to return to the safe shielded position because of a timer failure, and the patient was not removed from the treatment room.

This is a Severity Level III violation (Supplement VI)

Civil Penalty - $2,500

II. A. 10 CFR 35.13(c) requires that a licensee apply for and receive a license amendment before it changes its Radiation Safety Officer.

Contrary to the above, the Radiation Safety Officer was changed in May 1988; however, the licensee did not apply for or receive a license amendment until June 1989.

B. 10 CFR 35.21(a) requires, in part, that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are performed in accordance with approved procedures and regulatory requirements, in the daily operation of the licensee's byproduct

safety program. Further, 10 CFR 35.21(b)(2) requires, in part, that the RSO implement written policy and procedures for performing periodic radiation surveys; training personnel who work in areas where byproduct material is used; and keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

Contrary to the above, as of July 21, 1989, the Radiation Safety Officer (RSO) did not ensure that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. For example, the RSO was not assigned the responsibility for ensuring, nor did he ensure, that the radiation safety activities in the teletherapy and nuclear cardiac pacemaker radiation safety programs were performed in accordance with the written policy and procedures required and did not keep any copies of records, reports, licenses or amendments associated with the teletherapy and nuclear cardiac imaging programs.

C. 10 CFR 35.22(a)(1) requires, in part, that membership in the Radiation Safety Committee include an authorized user of each type of use permitted by the license.

Contrary to the above, as of July 21, 1989, membership in the Radiation Safety Committee did not include an authorized user of some of the types of use permitted by the license. Specifically, the membership in the Radiation Safety Committee did not include an authorized user from the teletherapy program or the nuclear cardiac pacemaker program.

D. 10 CFR 19.12 requires, in part, that all individuals working in or frequenting a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and function of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of July 19, 1989, two individuals who worked in the research department, a restricted area, had not been instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purposes and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

E. 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.

Contrary to the above, as of July 21, 1989, necessary and reasonable surveys were not performed to assure compliance with 10 CFR 20.101(a), which establishes the maximum permissible radiation exposure limits to the whole body of individuals working in restricted areas. Specifically, no evaluation was made of the radiation exposure to the whole body of a teletherapy physician who worked in a restricted area and whose radiation dosimetry results were unavailable because the dosimeter was either damaged or the returned to the vendor too late for processing during eight of twelve months in 1988.

F. License Condition 16 of NRC License 31-02892-03 requires that licensed radioactive material be possessed and used in accordance with the statements, representations, and procedures contained in the radioactive material license application dated June 20, 1985.

1. Item 15 of the application dated June 20, 1985 states, in part, that radioactive materials will be handled in accordance with the general rules for the safe use of radioactive material described in Appendix G of Regulatory Guide (Reg. Guide) 10.8, "Guide for the Preparation of Applications for Medical Programs".

   Item 1 of Appendix G requires that all personnel wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used. Item 7 of Appendix G requires that all personnel wear personal radiation monitoring devices (film badge or thermoluminescent dosimeter) at all times when in areas where radioactive materials are used or stored.

   Contrary to the above, on July 19, 1989, two individuals who used radioactive material in a research area did not wear laboratory coats or personal radiation monitoring devices.

2. Item 14 of the application dated June 20, 1985 requires that packages containing radioactive material be opened in accordance with the procedures described in Appendix F of Reg. Guide 10.8

   Item 2.f of Appendix F of Reg. Guide 10.8 requires that a wipe sample of the external surface of the source container be assayed and the amount of removable radioactivity recorded.

   Contrary to the above, as of July 19, 1989, packages containing radioactive material were not opened in accordance with the procedures described in Appendix F of Reg. Guide 10.8. Specifically, on days when the Radiation Safety Officer was not

present, although wipe samples of the external surfaces of the source containers were collected, the samples were not assayed for the amount of removable radioactivity.

3. Item 17 of the application dated June 20, 1985 requires that area radiation surveys be performed in accordance with the procedures described in Appendix I of Reg. Guide 10.8. Item 1 of Appendix I requires that all radiopharmaceutical elution, preparation, and injection areas be surveyed daily with an appropriately low-range radiation survey meter.

   Contrary to the above as of July 19, 1989, daily radiation surveys were not made of certain radiopharmaceutical elution, preparation, and injection areas, in that:

   a. daily radiation measurements were made only of refuse containers in the nuclear medicine area and not of the preparation & injection areas; and

   b. radiation surveys were not made of radiopharmaceutical elution, preparation, and injection areas on weekends when radioactive materials were used in the nuclear medicine area.

4. Item 17 of the application dated June 20, 1985 requires that area radiation surveys be performed in accordance with the procedures described in Appendix I of Reg. Guide 10.8. Item 4.b. of Appendix I provides that weekly and monthly surveys be conducted which cnsist of a series of wipe tests to measure cmtamination levels. The method for performing wipe tests are to be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Item 6 of Appendix I requires thatareas be cleaned if the contamination level exceeds 200 dpm/100 cm^2.

   Contrary to the above, as of June 19, 1989, the weekly area radiation surveys were not performed in the nuclear medicine area in accordance with the procedures described in Appendix I, in that on days when the Radiation Safety Officer was absent the results of area radioactive contamination sample analyses were not converted from counts per minute to disintegrations per minute nor were the results compared to the appropriate action level (200 dpm/100 cm^2) to determine if the area was required to be cleaned.

G. 10 CFR 35.59 (c)(3) requires that a wipe sample taken from a sealed source being tested for leakage in accordance with Section 35.59 be measured so that the leakage test can detect the presence of 0.005 microcurie of radioactive material on the sample.

Contrary to the above, as of July 19, 1989, although the wipe tests of the sealed sources were obtained and measured, the results of the test were recorded in cpm, and therefore, could not be compared to the 0.005 microcurie action level requirement of 10 CFR 35.59(e) to determine if the source should be removed from service and stored.

H. 10 CFR 35.632(a)(3) requires, in part, a full calibration measurement be performed on each teletherapy unit at intervals not to exceed one year. 10 CFR 35.632(g) requires that a record be maintained of the full calibration of each teletherapy unit source for the duration of use of the teletherapy unit source. The record must include, among other things: the manufacturer's name, the model number and serial number of both the teletherapy unit and the source; the model numbers and serial numbers of the instruments used to calibrate the unit; a determination of the coincidence of the radiation field and the field indicated by the light beam indicating device; an assessment of timer linearity and constancy; the calculated on - off error; the estimated accuracy of each distance measuring or localization device; and the signature of the teletherapy physicist.

Contrary to the above, as of August 21, 1989, records of the annual full calibrations of the teletherapy unit for September 1987, May 1988, and March 1989 did not include some of the information required by 10 CFR 35.632(g). Specifically, the records did not include:

1. the manufacturer's name, the model number and serial number of both the teletherapy unit and the source;

2. the model numbers and serial numbers of the instruments used to calibrate the unit;

3. a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

4. an assessment of timer linearity and constancy;

5. the calculated on - off error;

6. the estimated accuracy of each distance measuring or localization device; and

7. the signature of the teletherapy physicist.

This is a repeat violation.

I. 10 CFR 65.634(a) and (d) require that safety and output spot checks be performed once in each calendar month for each teletherapy unit used for medical use. 10 CFR 35.634(f) requires that a record be maintained of each monthly output and safety spot check performed

of the teletherapy system. The record must include, among other things: the manufacturer's name, the model number and serial number of both the teletherapy unit and the source; the model numbers and serial numbers of the instruments used to measure the output of the teletherapy unit; determination of the coincidence of the radiation field and the field indicated by the light beam indicating device; the calculated on - off error; the difference between the measured output and the anticipated output; notations indicating the operability of each entrance door interlock; each electrical and mechanical stop; each beam condition indicator light; the viewing system; and the signature of the person performing the monthly spot check.

Contrary to the above, as of August 21, 1989, records of teletherapy system monthly output and safety spot checks performed between January 1988 and July 1989 (a period of 18 months) did not include the following information:

1. the manufacturer's name, the model number and serial number of both the teletherapy unit and the source;

2. the model numbers and serial numbers of the instruments used to measure the output of the teletherapy unit;

3. a determination of the coincidence of the radiation field and the field indicated by the light beam indicating device;

4. the calculated on - off error;

5. the difference between the measured output and the anticipated output;

6. notations indicating the operability of each entrance door interlock;

7. each electrical and mechanical stop;

8. each beam condition indicator light;

9. the viewing system; and

10. the signature of the person performing the monthly spot check.

This is a repeat violation.

J. 10 CFR 35.615(d)(3) requires that the permanent radiation monitor installed in each teletherapy room be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

Contrary to the above, as of July 21, 1989, the permanent radiation monitor in the teletherapy room was not checked with a dedicated check source for proper operation any day before the teletherapy unit was used for treatment of patients.

K. 10 CFR 35.647(a) requires that each teletherapy unit be fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

Contrary to the above, as of July 21, 1989, the teletherapy unit was not fully inspected and serviced at five year intervals to assure proper functioning of the source exposure mechanism. The last full inspection and servicing of the teletherapy unit was performed during a source replacement on September 8, 1982.

These violations have been classified in the aggregate as a Severity Level III problem (Supplement VI)

Civil Penalty - $6,250 (assessed equally among the 14 violations)

Pursuant to the provisions of 10 CFR 2.201, Veterans Administration Medical Center (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 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 penalties 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 penalties 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 penalty 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 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 penalties should not be imposed. In addition to protesting the civil penalties, 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, 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 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 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 28TH day of November 1989