NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

North Detroit General Hospital
Detroit, Michigan

Docket No. 030-12467
License No. 21-10578-02
EA 90-160

During an NRC inspection conducted August 15 through September 7, 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:

A. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for personnel monitoring are described in the application dated July 10, 1989, and were approved by License Condition No. 14.

The application dated July 10, 1989, states in Item 9.4, "Personnel Monitoring Program," Subitem 2, that all individuals who are occupationally exposed to radiation on a regular basis and may receive greater than one-tenth the quarterly permissible limits will be issued a film or TLD whole body monitor. Item 9.4, Subitem 3, further requires that all individuals who handle radioactive material on a regular basis be issued a film or TLD finger monitor.

Contrary to the above, during the period July 19 - 27, 1990, the licensee did not provide a whole body monitor or a finger monitor to an individual who handled radioactive material on a regular basis and who could have received an occupational exposure to radiation in excess of one-tenth of the quarterly permissible limit.

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 materials 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 radiation and radioactive materials.

Contrary to the above, on August 15, 1990, licensed materials consisting of sealed dose calibrator reference sources and unit doses of radiopharmaceuticals, located in an unrestricted area of the nuclear medicine department, were not secured against unauthorized removal, and were not under constant surveillance and immediate control of the licensee.

C. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for safe use of radiopharmaceuticals are described in the application dated July 10, 1989, and were approved by License Condition No. 14.

The application dated July 10, 1989, Item 10.4, "Rules for the Safe Use of Radiopharmaceuticals," Subitem 5, prohibits eating, drinking, smoking, or the application of cosmetics in any area where radioactive material is used or stored.

Contrary to the above:

1. On August 15, 1990, as observed by the NRC inspectors, a cup containing water was left on a desk in the area where radioactive material is used; and a technologist admitted drinking in the area where radioactive material is used on that date and on other dates.

2. On one occasion between July 19-27, 1990, as observed by a licensee employee, a temporary contractor nuclear medicine technologist was smoking in areas where radioactive materials are used or stored.

D. 10 CFR 35.70(a) requires licensees to survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, since the date of the previous inspection, November 29, 1989, the licensee did not perform the required survey of the area where radioapharmaceuticals were routinely prepared for use or administered at the end of each day of use.

E. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for calibration of the dose calibrator are described in the application dated July 10, 1989, and were approved by License Condition No. 14.

The application dated July 10, 1989, Item 9.3, "Calibration of Dose Calibrator", requires, in part, that the constancy testing be performed using a long-lived reference source, that the net readings of the reference source be compared to the calculated values for the source, and that the Radiation Safety Officer be notified and the unit be repaired or replaced if the constancy error exceeds ten percent.

Contrary to the above, from February 20 through August 30, 1990, the dose calibrator constancy error exceeded ten percent, when compared to the calculated values for the licensee's 155 microcurie cesium-137 reference source, and the Radiation Safety Officer was not notified nor was the unit repaired or replaced.

F. 10 CFR 35.50(b)(3) and (c) require, in part, that each dose calibrator be tested for linearity upon installation and, as appropriate, following repair.

10 CFR 35.50(e) requires, in part, that records of dose calibrator linearity tests be maintained for three years unless directed otherwise.

Contrary to the above, the licensee did not maintain a record of the test for dose calibrator linearity which was performed following the repair and reinstallation of the dose calibrator on or about February 20, 1990.

G. 10 CFR 35.53(a) and (b) require, in pertinent part, that the licensee measure the activity of each radiopharmaceutical dosage before medical use.

10 CFR 35.53(c) requires, in part, that records of the measurement of radiopharmaceutical dosages contain:

1. Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

2. Patient's name, and identification number if one has been assigned;

3. Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

4. Date and time of the measurement; and

5. Initials of the individual who made the record.

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for keeping records of unit dosage use are described in the application dated July 10, 1989, and were approved by License Condition No. 14.

The application dated July 10, 1989, Item 10.8, "Unit Dose Records", requires that unit dose records contain the following data in addition to that required by 10 CFR 35.53(c):

1. Date of receipt
2. Activity as recorded on the packing slip
3. Supplier
4. Time and date of administration
5. Measured activity
6. Method of disposal

Contrary to the above:

1. From July 19 through 27, 1990, 30 unit doses were used for nuclear medicine patients. Records were not maintained for 15 of these unit doses, and the records for the remaining 15 unit doses did not contain the time and date of administration, the measured activity, or the patient's name.

2. On July 30 and 31, 1990, the records for 14 unit dose studies were incomplete in that: none included the initials of the individual making the record; none showed the method of disposal after use; 12 doses lacked the time of measurement; and 2 doses lacked a corresponding radiopharmacy dose slip.

H. 10 CFR 30.51(a) requires, in pertinent part, that each licensee keep records showing the receipt of byproduct material.

Contrary to the above, from July 19 through 31, 1990, the licensee did not keep records showing the receipt of byproduct material for 28 unit doses of radiopharmaceuticals.

I. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for training personnel who work with or in the vicinity of radioactive material are described in the application dated July 10, 1989 and were approved by License Condition No. 14.

The application dated July 10, 1989, Item 8.1, "Personnel Training Program," requires, in part, that all radiation workers and ancillary personnel whose duties require them to work in the vicinity of radioactive material receive instruction in certain topics and at specified frequency:

- Before assuming duties with, or in the vicinity of radioactive materials.
- During annual refresher training.
- Whenever there is a significant change in duties, regulations, or in the terms of the license.

Item 8.1 further requires that the instruction include; among other topics:

- Applicable regulations and license conditions.
- Appropriate radiation safety procedures.
- The licensee's in-house work rules.

Contrary to the above, since the date of the previous inspection, November 29, 1989, the licensee failed to train three radiation workers in appropriate radiation safety procedures, in-house work rules, and applicable regulations and license conditions.

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

Cumulative Civil Penalty - $2,500 (assessed equally among the nine violations)

Pursuant to the provisions of 10 CFR 2.201, the North Detroit General Hospital (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (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, 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 is 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 actions 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 under 10 CFR 2.201, the Licensee may pay the civil penalty 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 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 in whole or in part, 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. 2282c.

The response noted above (Reply to 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 III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 29th day of October 1990