

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Genesys Regional Medical Center
Flint, Michigan

License No. 21-01103-04
Docket No. 030-02003
EA 94-014

During an NRC inspection conducted from April 26 through May 4, 1993, 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, 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 35.410 requires that a licensee provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy. This instruction must describe, in part, the size and appearance of the brachytherapy sources.

Contrary to the above, on April 20 and 21, 1993, licensee personnel cared for a patient undergoing implant therapy and the licensee had not provided the required radiation safety instruction to those individuals concerning the size and appearance of the brachytherapy sources. (01013)

- B. 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 are described in the application dated June 21, 1990, and letters dated August 28, 1989, (with attachments), September 29, 1990, October 9, 1990, October 10, 1990, October 26, 1990, April 15, 1991, June 26, 1991, August 9, 1991, and were approved by License Condition No. 10.

Item 8 of the letter dated August 28, 1989 requires, in part, that initial and annual refresher radiation safety training be provided to all radiation workers.

Contrary to the above, in 1991, a nuclear medicine technologist was not instructed in radiation safety topics before assuming duties with radioactive materials. Moreover, since approximately December 14, 1990, many nuclear medicine technologists and radiation oncology nurses were not instructed in radiation safety topics during annual refresher radiation safety training. (01023)

- C. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Contrary to the above, on August 5 and 12, 1991, the licensee

administered to a patient approximately 200 millicuries of iodine-131, a dosage which requires hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the individuals who helped prepare or administer this dosage until August 22 and 23, 1991, respectively, periods in excess of three days. (01033)

This is a repeat violation.

- D. 10 CFR 35.50(d) requires, in part, that a licensee repair or replace a dose calibrator if the accuracy error exceeds ten percent.

Contrary to the above, on as of March 30, 1992, the licensee did not repair or replace a dose calibrator with an accuracy error of 11.95 percent, an error exceeding ten percent. (01043)

- E. 10 CFR 35.70(a) requires that a licensee 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 at least December 14, 1990, the licensee did not survey with a radiation detection instrument at the end of the day the cardiac stress room, an area where radiopharmaceuticals are routinely administered. (01053)

- F. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, since at least December 14, 1990, the licensee did not survey for removable contamination once each week the cardiac stress room, an area where radiopharmaceuticals are routinely administered. (01063)

This is a Severity Level III problem (Supplement VI).
Civil Penalty - \$3,750.

Pursuant to the provisions of 10 CFR 2.201, Genesys Regional 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 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 will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information 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 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 VI.B.2 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 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, 801 Warrenville Road, Lisle, Illinois 60532.

Dated at Lisle, Illinois
this 15th day of February 1994