

NOTICE OF VIOLATION  
AND  
PROPOSED IMPOSITION OF CIVIL PENALTY

Oakland General Hospital  
Madison Heights, Michigan

Docket No. 030-02101  
License No. 21-11494-01  
EA 94-009

During an NRC inspection conducted on December 20 and 21, 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:

I. Violation Assessed a Civil Penalty

10 CFR 35.32(a) requires, in part, that each licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the specific objectives that: (1) prior to administration, a written directive is prepared for any brachytherapy radiation dose; (2) prior to each administration, the patient's identity is verified by more than one method; (3) final plans of treatment and related calculations for brachytherapy are in accordance with the written directive; (4) each administration is in accordance with the written directive; and (5) any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Contrary to the above, between January 27, 1992, and December 27, 1993, the licensee did not establish and maintain a written quality management program to provide high confidence that byproduct material would be administered as directed by the authorized user. Furthermore, during the same period, the licensee administered brachytherapy radiation doses to six patients without a written quality management program.

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

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 35.27(a)(2) provides, in part, that a licensee may permit any visiting user to use licensed material for medical use under the terms and conditions of the licensee's license for sixty days each year if the licensee has a copy of a license issued by the Commission or Agreement State or a permit issued by a Commission or Agreement State broad licensee that identifies the visiting authorized user by name as an authorized user for medical use.

Contrary to the above, from September 14, 1993, through

December 21, 1993, the licensee permitted a visiting authorized user to use licensed material for medical use under the terms and conditions of the licensee's license, and the licensee did not have a copy of a license issued by the Commission or an Agreement State or a permit issued by a Commission or Agreement State broad licensee that identified the visiting user by name as an authorized user for medical use.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 35.22(b)(6) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review annually, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

Contrary to the above, from December 1991 through December 1993, the licensee's Radiation Safety Committee did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Oakland 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 or a demand for information may be issued as to 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 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 violation

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 responses 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 60532-4351.

Dated at Lisle, Illinois  
this 2nd day of February 1994