NOTICE OF VIOLATION

Parma Community General Hospital Parma, Ohio License No. 34-08051-01 Docket No. 030-02774

During an NRC inspection conducted on April 18, 1994 with continuing NRC review through May 24, 1994, 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 violations are listed below:

1. 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 application dated March 15, 1993, and were approved by License Condition No. 14.

The application dated March 15, 1993, states in Item No. 10.4 that cosmetics are not to be applied in any area where radioactive material is stored or used.

Contrary to the above, as of April 18, 1994, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, hand lotion, a cosmetic, was routinely applied in the hot lab, an area where radioactive material is stored and used.

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

2. 10 CFR 35.315(a)(7) requires that, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, a licensee survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

Contrary to the above, on August 24, 1992, the licensee did not conduct a survey for removable contamination before assigning another patient to the room of a patient who had received radiopharmaceutical therapy and had been hospitalized for compliance with 10 CFR 35.75.

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

 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, during the weeks of April 2, 1993 to June 18, 1993, the licensee did not survey for removable contamination areas where radiopharmaceuticals are routinely prepared, administered, or stored.

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

With respect to Item 3., the inspection showed that actions had been taken to correct the identified violation and to prevent occurrence. Consequently, no reply to the violation is required and we have no further questions regarding this matter. With respect to Items 1. and 2., pursuant to the provisions of 10 CFR 2.201, Parma Community General Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission. Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) 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 demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

JUN 1 4 1994

Dated

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B. J. Helt, Chief Nuclear Materials Inspection Section 1