NOTICE OF VIOLATION

Providence Hospital
Southfield, MI

License No. 21-02802-03
Docket No. 030-02022

During an NRC inspection conducted on January 30 through February 8, 1995, 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 35.315(a)(4) requires, in part, that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, a licensee promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20.

   Contrary to the above, on many occasions since approximately February 13, 1992, the licensee administered dosages of iodine-131 to patients for radiopharmaceutical therapy which require hospitalization for compliance with 10 CFR 35.75, and the licensee did not adequately measure the dose rates in contiguous restricted and unrestricted areas, specifically the adjacent room.

   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 many occasions since approximately February 13, 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).

3. 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 July 7, 1994, and December 30, 1994, the licensee administered to a patient approximately 60 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.

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

4. 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 approximately January 1, 1993, the licensee did not survey for removable contamination once each week the Novi facility's nuclear medicine department, an area where radiopharmaceuticals are routinely prepared for use, administered, or stored.

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

5. 10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the names of the individuals permitted to handle the sources, (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage, (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

Contrary to the above, since approximately February 13, 1992, the licensee's record of brachytherapy source usage did not include: (1) the number and activity of the sources in storage after the removal, and (2) the number and activity of sources in storage after the return.

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

Pursuant to the provisions of 10 CFR 2.201, Providence 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 a demand

fo 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.

Dated at Lisle, Illinois
this 13 day of February 1995