ENCLOSURE

NOTICE OF VIOLATION

The Radiology Institute Imaging Center
Hato Rey, Puerto Rico

Docket No. 030-30394
License No. 52-24969-01

During an NRC inspection conducted February 17-18, 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:

A. 10 CFR 35.32(a)(1) requires, in part, that the licensee's Quality Management Program include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries (Ci) of either sodium iodide I-125 or I-131. Pursuant to 10 CFR 35.2, "written directive" means, in part, an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of quantities greater than 30 Ci of either sodium iodide I-125 or I-131 which specifies the dosage to be administered.

Section 1.1, Part I, of the licensee's Quality Management Program submitted to the NRC on January 29, 1992, requires that there be signed and dated written directives prior to the administration of dosages greater than 30 Ci of either I-125 or I-131.

Contrary to the above, on April 6, 1992 and December 15, 1993, the licensee administered to patients dosages of 48.5 and 5000 Ci of sodium iodide I-131, respectively, without a written directive.

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

B. 10 CFR 35.32(b)(1) requires, in part, that the licensee's Quality Management Program be reviewed to verify compliance with all aspects of the program at intervals no greater than 12 months.

Contrary to the above, the licensee did not review its Quality Management Program to verify compliance with all aspects of the program between the time it was implemented in January 1992 and April 12, 1993, an interval in excess of 17 months.

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

C. 10 CFR 35.220 requires, in part, that the licensee possess portable radiation detection survey instrumentation capable of detecting dose rates over the range of 0.1 millirem per hour to 1000 millirems per hour.

Contrary to the above, during approximately two weeks each year since 1992, the licensee used its Monitor-4 survey instrument to demonstrate compliance with 10 CFR Part 35, and the instrument was not capable of detecting dose rates between 50 millirems per hour and 1000 millirems per hour.

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

D. Condition 15 of License No. 52-24969-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations and procedures contained in the license application dated January 27, 1988.

1. Attachment 9.1.1 of the license application dated January 27, 1988 specifies the areas where licensed materials were to be used.

   Contrary to the above, as of February 18, 1994, the licensee had been using licensed materials (Technetium -99m) in a cardiology laboratory, a location in the building not specified in the license application.

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

2. Item 10.4 of the license application dated January 27, 1988 requires that the licensee establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.

   Item 12 of the model safety rules published in Appendix I to Regulatory Guide 10.8 states, in part, "With a radiation detection survey meter, survey the generator storage, kit preparation and injection areas daily for contamination."

   Contrary to the above, as of February 17, 1994, the licensee was not surveying with a radiation detection survey meter the generator storage and kit preparation areas daily for contamination.

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

Pursuant to the provisions of 10 CFR 2.201, The Radiology Institute Imaging Center is hereby required to submit a written statement or explanation to the Regional Administrator, Region II, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, 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.

Dated at Atlanta, Georgia
This 1ST day of March, 1994