NOTICE OF VIOLATION

McLaren Regional Medical Center
Flint, Michigan

License No. 21-04171-04
Docket No. 030-02048

During an NRC inspection conducted on November 17, 1997, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

> 10 CFR 35.32(a) requires, in part, that the licensee 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.
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> Pursuant to 10 CFR 35.32(a)(4), the quality management program must include written policies and procedures to meet the specific objective that each administration is in accordance with a written directive, which is defined in 10 CFR 35.2.
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> The licensee's radiopharmaceutical quality management program dated August 1, 1994, requires that the technologist verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive and the actual dose calibrator assay shall be verified with the dosage listed on the written directive.
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> Contrary to the above, the licensee's quality management program failed to ensure that the specific details of the administration were verified in accordance with the written directive. Specifically, on November 10, 1997, a technologist and physician administered 4.6 millicuries (170 MBq) of sodium iodide I-131 to a patient, and failed to verify that the dosage was in accordance with the prescribed dosage of 8 millicuries (296 MBq) as noted on the written directive by the authorized user.
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> This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, McLaren Regional Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. 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 action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 15th day of December 1997