UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

December 20, 1999

EA 99-289

Ms. Diane M. Radloff
Vice President Patient Care Services
St. John Hospital and Medical Center
22101 Moross Road
Detroit, MI 48236-2172

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report 030-02028/99001(DNMS))

Dear Ms. Radloff:

This refers to the inspection conducted on October 19 through 23, 1999, at St. John Hospital and Medical Center (St. John) in Detroit, Michigan. The purpose of the inspection was to review the circumstances surrounding a reported radiopharmaceutical misadministration. During the inspection, apparent violations of NRC requirements were identified and were documented in the NRC inspection report sent to you by our letter dated December 1, 1999. In that letter we indicated that NRC had sufficient information to proceed with the enforcement action, however, you were given an opportunity to discuss the apparent violations at a predecisional enforcement conference or address the apparent violations in writing. During a telephone conversation between Dr. W. Nikesch of your staff and Mr. G. Wright of my staff on December 7, 1999, St. John declined a conference and declined to provide additional written correspondence.

Based on the information developed during the inspection and the information provided in your report of misadministration dated October 29, 1999, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice).

Violation A of the Notice is indicative of a weakness in the implementation of the St. John quality management program (QMP). At the request of the authorized user, orders were placed for iodine-131 therapy doses of 250 and 300 millicuries to be administered to two patients. On September 7, 1999, before the completion of the written directives, the acting pharmacy technologist unpacked the two iodine I-131 vials, measured each dose in the dose calibrator (264 and 296.7 millicuries), and printed out the labels with the information regarding the doses and the patients names. Later, the authorized user prescribed a treatment dose of 200 millicuries for patient A and 300 millicuries for patient B. The administering technologist took the written directives for both patients and proceeded to the nuclear pharmacy with patient A. Both doses were re-assayed and the amounts posted on the written directive forms. At that point, the administering technologist failed to compare the ordered dose with the written directive to assure that patient A would receive the proper dose of 200 millicuries. In addition, the second party verification was not performed. As a result of these failures, patient A

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received a 32 percent overdose. NRC regulations and licensee policies are in place to ensure physician's prescriptions are administered as written. Failure to adhere to these regulations and policies can result in serious consequences to patients. It is imperative that the utmost care and attention to detail are used when dealing with radioactive material. Therefore, violation A of the Notice is classified in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III violation.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for *Corrective Action* is warranted based on the following corrective actions planned or taken: (1) the two technologists involved were prohibited from administering therapy doses until the licensee was satisfied that they had a complete understanding of and could correctly implement the QMP; (2) all individuals involved with the therapy program have received retraining on the QMP including the form revisions; and (3) the written directive form has been modified to clarify the methods of dose verification to be used.

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of the Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

Violation B of the Notice addresses the release of two patients who had received a therapeutic quantity of a radiopharmaceutical without determining whether the exposure to any other individual would likely exceed 5 millisieverts (0.5 rem). This violation is classified as a Severity Level IV.

The NRC has concluded that information regarding the reasons for the violations, and the corrective actions taken and planned to correct the violation and prevent recurrence are already adequately addressed in our inspection report and in your letter dated October 29, 1999. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosed Notice, and your response if you choose to respond, will be placed in the NRC Public Document Room.

Sincerely,

J. E. Dyer
Regional Administrator

Docket No. 030-02028
License No. 21-03210-01

Enclosure: Notice of Violation

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