

APPENDIX A

NOTICE OF VIOLATION

Saints Memorial Medical Center, Inc.  
Lowell, Massachusetts 01854

Docket No. 030-01883  
License No. 20-06296-01

During an NRC inspection conducted on October 15 and 20, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

10 CFR 35.13(a) requires that a licensee apply for and must receive a license amendment before it receives or uses byproduct material for a clinical procedure permitted under 10 CFR Part 35 but not permitted by the license issued pursuant to 10 CFR Part 35.

Contrary to the above, as of January 29, 1993, the licensee received and used byproduct material for thyroid ablation therapy, a clinical procedure permitted under 10 CFR Part 35 but not permitted by the licensee's license issued to the licensee pursuant to 10 CFR Part 35; and, as of that date, the licensee had not applied for license amendment authorizing the performance of this procedure.

Specifically, on January 29, 1993 a patient received approximately 28 millicuries of Iodine-131 for treatment of thyroid carcinoma. License No. 20-06296-01 authorizes the use of byproduct material for the diagnosis and treatment of hyperthyroidism and treatment of cardiac dysfunction.

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

Pursuant to the provisions of 10 CFR 2.201, Saints Memorial Medical Center, Inc. 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 I, 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 for Information may be issued to show cause 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.

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