NOTICE OF VIOLATION

Lowell General Hospital
Lowell, Massachusetts

Docket No. 030-01811
License No. 20-00506-03

During an NRC inspection conducted on October 28 and 29, 1996, a violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, the violations are listed below:

A. 10 CFR 35.404(a) requires that, immediately after removing the last temporary implant source from a patient, the licensee make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed, and that the licensee not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

Contrary to the above, the licensee removed the last temporary implant source from a patient, and the licensee did not perform a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources had been removed. Specifically, on November 7, 1995, the licensee removed the last iridium-192 temporary implant source from a patient, but did not perform a radiation survey of the patient to confirm that all sources had been removed.

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

B. 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 August 12, 1996, the licensee administered to a patient 156.5 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 physicist who helped administer this dosage.

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

C. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for calibration of survey meters are described in the application dated November 24, 1993, and were approved by License Condition No. 15.

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The application dated November 24, 1993 states in Item No. 9.2 that the licensee will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2. In particular, the apparent source activity or the exposure rate at a given distance from the calibration source must be traceable by documented measurements to a standard certified within 5 per cent by the National Institute of Standards and Technology. Further, the source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of calibration of survey meters sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.

Contrary to the above, on October 29, 1996, the licensee, through its Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the survey meter was calibrated with a Tc-99m source whose apparent source activity or exposure rate at a given distance was not traceable by documented measurements to a standard certified by the National Institute of Standards and Technology and which was of insufficient strength to give an exposure rate of about 30 mR/hr at 100 cm.

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

Pursuant to the provisions of 10 CFR 2.201, Lowell General Hospital, 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. 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.