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WARREN GENERAL HOSPITAL

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February 1, 1994

REPLY TO A NOTICE OF VIOLATION

B. J. Holt, Chief
Nuclear Materials Inspection
Section 1
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

License No. 43-12685-01
Docket No. 030-02831

Dear Mr. Holt:

In response to your letter of January 10, 1994 and the enclosed Notice of Violation, we are submitting the following reply.

The violation which occurred on October 26, 1992 resulted from an error by an employee of Warren General Hospital. For the test in question the technologist administering the radiopharmaceutical failed to provide the authorized user with a written directive to be signed and dated prior to the administration of 5 millicuries of sodium iodide I-131. Although all other applicable procedures contained in the Quality Management Program - verification of written order, double verification of identity of patient, verification of dose and route of administration, and verification of dose by calibration - were properly carried out, the technologist failed to follow the procedure which calls for any dosage of 30 microcuries or greater of sodium iodide I-131 to be considered therapeutic and to be signed off by the authorized user.

To correct this violation two actions have been taken. First, the aforementioned procedure in our Quality Management Program was reviewed in conjunction with our consulting physicist (Nuclear Medicine Consultants) and determined to be satisfactory. Second, Ms. Sharon Long of Nuclear Medicine Consultants provided an inservice program in October 1993, attended by all technologists, to review this specific violation and to reiterate the correct procedure.

Since the date of the violation there have been no further dosages of sodium iodide I-131 of 30 microcuries or greater administered to patients. It is our belief that the actions taken in response to the cited violation have been and will continue to be sufficient to avoid further violations.

Sincerely,

Kevin R. Andrews

Kevin R. Andrews
Chief Executive Officer

Charles Curtiss

Charles Curtiss, D.O.
Radiation Safety Officer

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