

IE-07
PUBLIC

FEB 3 1994

St. Mary Hospital
ATTN: Colleen Mahoney
Vice President
2222 Lake Drive
Milwaukee, WI 53201

License No. 48-01828-01
Docket No. 030-03422

Dear Ms. Mahoney:

This refers to the routine safety inspection conducted by Thomas Young of this office on November 15, 1993, through January 28, 1994 of activities authorized by NRC Byproduct Material License No. 48-01828-01, and to the discussion of our findings with you and your staff on January 28, 1994.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

In addition to the above areas, the inspector examined actions described in your letter dated April 22, 1991, regarding violations found during our April 2, 1991 inspection. We have no further questions regarding these matters.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

In addition to the violations indicated in the enclosed notice, other violations were identified for failure to: (1) place in the nuclear medicine policy and procedure manual a copy of the manufacturer's radiation safety instructions for the therapeutic use of strontium-89, (2) retain records of radiation safety instruction for all personnel caring for the patient receiving iodine-131 therapy and hospitalized for compliance with § 35.75, (3) record the time of survey and the survey instrument used to make the survey of the patient and the area at the time of administration of the iodine-131 therapeutic dosage for each patient hospitalized for compliance with § 35.75, (4) implement Regulatory Guide 10.8, Appendix P, with regard to records for bioassay of iodine-131 in the thyroid of individuals who administer therapeutic dosages in excess of 30 millicuries, (5) retain a record of contaminated items that were removed from the iodine-131 therapy patient rooms for decay in storage. These violations are not being cited because they are categorized as Severity Level V violations, and you committed to correcting the violations within a reasonable period of time, and the other remaining criteria specified in Section VII.B. of the NRC Enforcement Policy, 10 CFR Part 2, Appendix C were satisfied.

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However, we are concerned about the number and types of violations identified during this inspection. In the aggregate, the violations are indicative of the lack of management involvement to ensure oversight and supervision of licensed activities and effective communication between the Radiation Safety Officer, the authorized users, the members of the Radiation Safety Committee, and the senior hospital management. Although corrective actions have been implemented for the violations, the causal factors must be carefully evaluated to prevent programmatic deficiencies that may lead to future violations.

A management meeting has been scheduled for Friday, February 4, 1994, at 1:30 p.m. The meeting will be conducted by telephone. We request that you and other key representatives of your radiation safety program participate in the meeting, including your Radiation Safety Officer and the Chairman of the Radiation Safety Committee. You should be prepared to discuss your plans to strengthen management involvement and oversight of licensed activities.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards

Enclosure: Notice
of Violation

cc w/enclosure:
J.K. Chan, Ph.D.
Radiation Safety Officer

bcc w/enclosure:
PUBLIC

yes
RIII
Young
2/2/94

yes
RIII
HoTT
2/2/94

yes
RIII
-cm for
Caniano
2/2/94

yes
RIII
Axelson

yes
RIII
DeFayetta
2/3/94