

October 29, 1980

St. Lawrence Hospital
Sisters of Mercy
Attn: Mr. Kim Peters
Vice President
Professional Services
1210 West Saginaw Street
Lansing, MI 48914

License No. 21-15462-01

Gentlemen:

This refers to the investigation conducted by Messrs. C. H. Weil and W. J. Adam of this office on August 15, 1980, concerning activities at St. Lawrence Hospital, authorized by NRC Byproduct Material License No. 21-15462-01, and to the discussion of our findings with you on August 15 and 18, 1980.

This investigation was conducted to determine the circumstances surrounding the reported misadministration of 8.5 millicuries of iodine-131 to a patient.

The enclosed copy of our investigation report identifies areas examined during the investigation. Within these areas, the investigation consisted of a selective examination of procedures and representative records, observations, and interviews with personnel.

During this investigation, certain of your activities appeared to be in non-compliance with NRC requirements, as described in the enclosed Appendix A.

This notice is sent to you pursuant to the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Section 2.201 requires you to submit to this office within twenty days of your receipt of this notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Be sure to address each of these items in your response.

As a result of this investigation, a matter of concern to us is the apparent lack of involvement on the part of hospital management in the implementation of management controls in the ordering and administration of radiopharmaceuticals. By letter, dated May 2, 1979, we advised all medical licensees of

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our concerns in allowing hospital personnel to place excessive reliance on oral communication with respect to ordering and using radiopharmaceuticals. It appears that St. Lawrence Hospital did not implement the procedures recommended in the May 2, 1979, letter. The failure to implement these procedures was a contributing factor in the misadministration which occurred on August 13, 1980. Therefore, in addition to replying to the specific items on noncompliance, your response should describe the changes you have made in the management controls relating to the ordering and use of radiopharmaceuticals which will prevent a recurrence.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC's Public Document Room, except as follows. If the enclosures contain information that you or your contractors believe to be proprietary, you must apply in writing to this office, within twenty days of your receipt of this letter, to withhold such information from public disclosure. The application must include a full statement of the reasons for which the information is considered proprietary, and should be prepared so that proprietary information identified in the application is contained in an enclosure to the application.

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

Sincerely,

James G. Keppler
Director

Enclosures:

- 1. Appendix A, Notice of Violation
- 2. IE Investigation Report No. 030-09151/80-01
- 3. Letter, dated May 2, 1979, to all Medical Licensees

cc w/Enclosures:

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