



SAINT LAWRENCE HOSPITAL

1210 West Saginaw

Lansing, Michigan 48914

(517) 372-3610

November 24, 1980

Mr. James G. Keppler
Director
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

License No. 21-15462-01

Dear Mr. Keppler:

This letter constitutes our formal reply to your letter of October 29, 1980 which contained the "Notice of Violation." The letter was received in my office on November 3, 1980.

As outlined in paragraph five of your letter, we are submitting the following in reply to the Notice:

1. In reference to item one of the Notice, all packages of radiolnuclides are monitored prior to opening in accordance with the quoted section of the July 14, 1976 application. Results are recorded in a log located in the department. The corrective action verifies the isotope strength compared to the ordered strength, and will avoid further noncompliance. It went into effect on September 29, 1980.
2. In reference to item two of the Notice, all packages of radionuclides are opened to verify the contents against the purchase order, and to inspect the integrity of the final source container. Results and any irregularities are recorded in a log located in the department. The corrective action verifies the contents of the package with the purchase order and the integrity of the final source container. It went into effect on September 29, 1980.
3. In reference to your request for a description of changes made in the management controls relating to the ordering and use of radiopharmaceuticals, the following actions were implemented on September 29, 1980. to avoid further noncompliance by reducing reliance on oral communications with respect to ordering as recommended in your May 2, 1979 letter.

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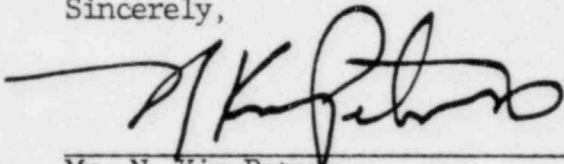
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3. Continued

- A. The Hospital's supplier has been notified that no therapeutic-level dosages are to be shipped, unless ordered specifically by a radiologist with the patient's name attached or typed on the prescription.
- B. Orders are placed by phone only with the supplier's nuclear pharmacist.
- C. The desired radioisotope activity is specified clearly defining the units of activity.
- D. The nuclear pharmacist is directed to refer to the chart to provide an accurate measurement of the capsule which the Hospital can expect to receive.
- E. The capsule strength quoted by the nuclear pharmacist is documented on the purchase order.
- F. The nuclear pharmacist is required to repeat the complete order to re-verify dosages and accuracy.
- G. Department manager verifies and signs each purchase order.

We believe that the implementation of these procedures have brought us into full compliance with your specified requirements as of this date. If you need clarification or additional information, please contact me directly.

Sincerely,



Mr. N. Kim Peters
Vice President
Professional Services

NKP/sfb

xc: Don Hutton
Paul Niland, MD
Mary Ann Grace
Frank Kueppers