Matson

ST JOSEPH
Hospital & Health Center
205 West 20th Street
Lorain, Ohio 44052-3794
(216) 233-1000

December 17, 1993

US Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: Reply to a Notice of Violation

Dear Sirs:

Enclosed is our Reply to a Notice of Violation addressed to us in your letter of November 26, 1993, following the NRC inspection of our licenses and our quality management program at our facility September 30, 1993.

We would like to commend your staff members (Ms. Evelyn Matson, Ms. Sally Merchant, Mr. William Reichhold and Mr. Stephen Lu, NRC Consultant from Lawrence Livermore) for their professionalism shown during the inspection. It was particularly enlightening for them to express the positive aspects of our programs as well as pointing to the areas needing improvements.

We have addressed each violation for our licenses (34-04474-01 and 34-04474-02) as indicated in your letter (Nov 26, 1993) and we feel we are now in full compliance in correcting all violations. Corrective measures were instituted within several days following the NRC inspection exit conference of September 30, 1993.

Thank you for your time and for adding strengths to our programs here at St Joseph Hospital and Health Center. Please address any additional questions or concerns to David L. Hykes, M.S., our Radiation Safety Officer and Teletherapy Physicist at 216-233-1044.

Sincerely

Brian Lockwood
President and CEO

David L. Hykes
RSO and Physicist

Enclosure: Reply to a
Notice of Violation

DEC 27 1993

REPLY TO A NOTICE OF VIOLATION

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1. Removeable contamination must be less than 200 dpm per cm squared post radiopharmaceutical therapy using a radiation detection survey instrument before assigning the room to another patient. Only two patients were treated during 1992/1993. A portable GM survey meter and a portable Victoreen Panoramic survey meter were used to detect any radiation levels above background. All areas above background were wiped clean and rechecked with the meters before the rooms were released.

   Corrective steps have included discussion of the violation with appropriate staff to alert them to the problem and the establishment of a new procedure to detect removable contamination from wipes of the room using our thyroid uptake probe to count the wipes. This has been established and will be instituted on the next I-131 therapy patient.

   The above corrective steps will be periodically reinforced with verbal communications between our staff and our medical physicist and all information will be reviewed by our physicist before the room is released as a means to prevent further occurrences.

   We are now in full compliance in correcting this violation.

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2. A written directive must be obtained prior to the administration of sodium iodide (I-125 or I-131) on quantities greater than 30 uCi. This directive must include the specific patient, the isotope and form, the dose, and it must be signed and dated by an authorized user. A 5 uCi dose of I-131 for a whole body scan was given without this written directive.

   Corrective measures have included specific inservices to the nuclear medicine technologists in reviewing the QM program and the need to obtain a written directive from an authorized user. Several individual users have been informed as well. All authorized users will be notified in a meeting on December 20th, 1993 (monthly meeting of all radiologists) and the QM program will be outlined for them at that time and the need for their authorized written directive will be emphasized.

   Corrective measures to prevent further violations will include periodic verbal reminders to all individuals involved as to the need for the appropriate written directive. In addition a memo will be issued to all nuclear medicine technologists and authorized users outlining the QM program requirements before January 1, 1994.

   We are in full compliance in correcting this violation.

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3 (a). A written directive indicating the radiopharmaceutical for therapy, its chemical form, and the dose to be administered must be signed and dated by the authorized user. On at least six occasions the physician wrote only the dose and the specific product name (METASTRON) rather than the isotope and form.

Corrective actions included inservices to appropriate personnel to write strontium-89 chloride or Sr-89 chloride instead of metastron.

To prevent further violations, the physicist or his designee will review all cases prior to injection of the strontium-89 chloride. This was corrected immediately following the NRC exit conference with our staff on September 30, 1993. Constant verbal reminders are given by the physicist to the authorized users. This will also be addressed in a full memo to appropriate personnel before January 1, 1994.

We are in full compliance in correcting this violation.

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3 (b). A written directive must include the full signature of the authorized user. One authorized user was initialing the written directives rather than providing a full signature.

This was corrected immediately following the NRC exit conference of September 30, 1993 through inservices with the authorized users by the physicist. In addition all charts are reviewed weekly by the physicist and specific inservices have been provided to all technologist or therapists indicating what was required in a written directive including a full signature. Treatments can not be given by the therapists without a full written directive except as stated in our QM program for verbal directives which must be written within 24 hours.

A memo indicating the necessary information for a written directive will be issued before January 1, 1994 to all authorized users and all technologist/therapists and constant verbal reminders will be used to prevent further violations.

We are in full compliance in correcting this violation.

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3 (c). A written directive for a brachytherapy implant must include the total dose or total exposure time. On one occasion (August 9, 1993) a written directive did not include a total dose or total exposure time. The violation occurred because of the clinical status of the patient in that the authorized user was not sure the patient could tolerate the implant procedure for an extended period of time. Dose was to be determined depending on the length of time the patient could tolerate the treatment up to 30 hours (verbal).

Corrective steps were taken immediately following the NRC exit conference of September 30, 1993. This included specific inservices from the physicist to all authorized users of brachytherapy restating the QM program requirement and the NRC requirements. All technologists/therapists were inserviced as well. No initiation of implant preparation can occur without a full written directive which includes the total dose or the total time as well as all other items mandated in the written directive which must also be signed and dated by the authorized user.

Corrective measures to prevent further violations include will include a memo issued from the physicist to all therapists and authorized users before January 1, 1994 reinforcing the need for a proper written directive and the necessary information to be contained in this directive. Periodic verbal reminders will be used to reinforce this information. In addition, a new mandatory prescription form will be developed for a very specific written directive format for all brachytherapy patients which will be signed and dated prior to loading each implant. This form should be completed by January 1, 1994.

We are currently in full compliance in correcting this violation.