



Sacred Heart Hospital

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February 26, 1994

Mr. Roy Caniano, Chief
Nuclear Materials Safety Branch
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

SUBJECT: A REPLY TO A NOTICE OF VIOLATION

Dear Mr. Caniano:

In response to your letter of February 1, 1994, and in reference to Notice of Violation, License No. 48-03116-01, Docket No. 030-03435, the following information is given.

Item Number One: Unlocked Hot Lab

1. We have no adequate reason for this violation.
2. We have corrected this violation by establishing a departmental policy requiring that the door to the "hot" lab be locked at all times when not in use.
3. Frequent checks by the RSO since the December 1, 1993 NRC inspection date has demonstrated that the locked door policy is being followed.
4. Full compliance has been achieved since the date of the NRC inspection on December 1, 1993.

Item Number Two: Quality Management Program

1. We have no adequate reason for this violation.
2. The Quality Management Program had been implemented and a copy of the program had been submitted to the NRC in 1993, however, this was later in the year after the January 27, 1993 compliance date had passed. We are in full compliance since the NRC inspection date of December 1, 1993.
3. Written policies and procedures to meet the specific objective that each byproduct administration is in accordance with a physician written directive have been developed. A physician signature is required before ordering the radioisotope and before administration to the patient. The RSO has written a departmental policy which will be administered through the Radiation Safety Committee. This policy will become part of the routine monthly QA procedures.

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4. Full compliance has been achieved since the date of the NRC inspection on December 1, 1993.

Item Number Three: Quality Management Program

1. We have no adequate reason for this violation. Although we had a written Quality Management Program in place, it was not explicitly followed.
2. The RSO has written a departmental policy which will be monitored by the Radiation Safety Committee and routine monthly QA procedures.
3. Under the RSO's surveillance no isotope is ordered without the written directive of the physician. A departmental policy directive has been written. Compliance will be monitored by the monthly QA process.
4. Full compliance has been achieved since the NRC inspection date of December 1, 1994.

Item Number Four: Instrument Check, Dedicated Check Source

1. We have no adequate reason for this violation.
2. A dedicated radioactive check source has been conveniently positioned in a conspicuous location to remind the Nuclear Medicine Technologist of the daily instrument check requirement. A departmental policy has been written and the procedure has been placed in the monthly QA process. The policy will be enforced by the Radiation Safety Committee.
3. Compliance with the new policy will be monitored by RSO to preclude future violations.
4. Full compliance has been achieved since the NRC inspection on December 1, 1993.

Item Number 5: Individual Patient Labels on Syringes and Shields

1. We have no adequate reason for this violation.
2. Individual patient gum labels will be generated by the Dupont/Pharma Nuclear Medicine Manager computer system. Each patient syringe or syringe shield will be labeled with such computer generated label.
3. The RSO has written a departmental policy to insure compliance. The policy will be monitored by the monthly QA process and enforced by the Radiation Safety Committee.
4. Full compliance was achieved since the NRC inspection on December 1, 1993.

Item Number Six: Thyroid Burden

1. We have no adequate reason for this violation.
2. The RSO has written a departmental policy to insure compliance. The policy will be monitored by the monthly QA process and enforced by the Radiation Safety Committee.
3. Same as 2 above.
4. Full compliance has been achieved since the NRC inspection on December 1, 1993.

Following the NRC inspection of December 1, 1993, Sacred Heart Hospital has taken a concerned and active role to correct the deficiencies as outlined in the exit conference with NRC compliance staff and our hospital management on December 1, 1993. We feel we have made appropriate improvements which have returned us to proper compliance with NRC regulations. Particular emphasis and attention will be directed to those non-compliance items which are of a repeat nature.

We wish to thank the NRC for their educative role and helpful attitude and we recommit our efforts to a safe and compliant Nuclear Medicine Department.

Sincerely,



Glenn G. Horejsi
Assistant Administrator

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