



November 20, 1996

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety
United States Nuclear Regulatory commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Subject: Response to NRC Notice of Violation

Dear Ms. Pederson:

I am responding on behalf of Mr. Jon Wachs, President St. Joseph's Hospital, upon receipt of your October 22, 1996 letter to him. Your letter provided Notice of Violation to St. Joseph's Hospital based upon an inspection conducted on August 28 - 30, 1996.

Attached please find a document which briefly re-states each of the 5 violations cited in the Notice of Violation, and the corrective action(s) associated with each item. Also enclosed are attachments associated with the actions taken by St. Joseph's Hospital.

Please call me at (414) 447-2223 if you have any questions about our response.
Thank you.

Sincerely,

A handwritten signature in cursive script that reads 'Rick Hart'.

Rick Hart
Vice President Patient Services

RH:sah

Enc.

c: J. Wachs
W. Artner
R. Olson

9611220040 961120
PDR ADOCK 03003406
C PDR

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U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

11/20/96

REPLY TO A NOTICE OF VIOLATION

St. Joseph's Hospital
Milwaukee, WI
License No. 48-00537-03
Docket No. 030-03406

Gentlemen;

As discovered during the NRC inspection of August 28, 1996:

NRC Violation Statement:

1. Between May 25, 1994 and May 27, 1994, this licensee disposed of low level I-131 dry waste by release to the normal, non-radioactive trash, a method not authorized by 10 CFR 20.2001.

St. Joseph's Hospital Response:

This issue was reported to the NRC and resolved in 1994.

A report dated June 16, 1994 to B.J. Holt, Chief of Region III reported the results of the investigation by this Institution in 1994 and the safeguards put in place to prevent recurrence. No incident of this nature has occurred since that time. See attached.

NRC Violation Statement:

2. On August 28, 1996, Hospital security personnel opened a secured area to allow contractors to work on the fire sprinkler system. This is a violation of 10 CFR 20.1801 which requires that the licensee secure from unauthorized removal or access licensed materials that are stored in unrestricted areas. And, 10 CFR 20.1901 requires that the licensee control and maintain constant surveillance of licensed material that is in an unrestricted area and that is not in storage.

St. Joseph's Hospital Response:

This small room (W176) is used to store radioactive wastes. Because Security personnel had access to the room, the control of the room was not solely in the hands of Nuclear Medicine personnel. To regain sole control of this secured area, the lock was rekeyed for one key only on August 28, 1996. That key now is accessible to Nuclear Medicine personnel alone.

NRC Violation Statement:

3. On three instances, May 31, 1994, August 23, 1994, and on August 8, 1995 radioactive doses were administered in which the dose calibrator used to assay the doses had a linearity test that didn't test over the range of the dose assayed. This is in violation of 10

CFR 35.50 (b) (3) which requires, in part, that the licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 30 microcuries.

St. Joseph's Hospital Response:

A review of written protocols for linearity testing found that although, I-131 therapy dose directives were slowly increasing over time, the protocol hadn't changed to reflect this condition. The protocol was changed on August 28, 1996 to exceed the dose ranges currently in practice (copy attached).

NRC Violation Statement:

4. 10 CFR 20.1906 (b) and (c) require that each licensee monitor the external surfaces of a package labeled with radioactive white I, yellow II, or yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels unless the package contains quantities of radioactive material that are less than or equal to type A quantity, as defined in 10 CFR 71.4 and appendix A to Part 71.

St. Joseph's Hospital Response:

A review of posted procedure for the receipt of radioactive materials did indeed misguide individuals in the monitoring and wipe testing of incoming radioactive shipments. On August 28, 1996, those posted procedures were revised to require all DOT labeled packages to be monitored and all DOT labeled packages to be wipe tested except those shipments containing only Xe-133 gas within three hours of receipt or within three hours of the start of business if delivered after working hours. See attachment.

NRC Violation Statement:

5. 10 CFR 35.205 (e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases. During the inspection on August 28, 1996, the informational materials supplied by the trap manufacture was reviewed and found to be inadequate for proper procedure.

St. Joseph's Response:

A review of our NRC license states that the licensee would follow manufacture's instructions for the monitoring of Xe-133 gas trap effluent. Subsequently, the manufacturer was called and a copy of the instruction manual containing the protocol for gas trap monitoring was obtained. Our protocol for monitoring trap effluence does now include the introduction of Xe-133 gas into the system during testing. This protocol has been followed monthly since the inspection and demonstrates regulatory compliance.

CC: Regional Administrator,
Region III USNRC