

Dcd

April 3, 1997

Otto Cox
Chief Executive Officer
St. Elizabeth Hospital
1506 South Oneida Street
Appleton, WI 54915

SUBJECT: NRC INSPECTION AND NOTICE OF VIOLATION

Dear Mr. Cox:

This refers to the inspection finding identified by the NRC during an inspection conducted on June 25, 1996, at the St. Elizabeth Hospital facility regarding the minimal time a thyroid burden measurement must be taken after administration of an iodine therapy over 30 millicuries. This also refers to numerous conversations with members of your staff through March 19, 1997 concerning the issues surrounding this finding. At the conclusion of our review, our findings were discussed with Mr. Stanley Reed on March 19, 1997.

St. Elizabeth Hospital, in its license application, committed to use radiation safety procedures described in Appendix P of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," during the use of iodine therapy over 30 millicuries. Appendix P procedures indicate that the thyroid burden will be measured on personnel 1 day after the patient dosage administration. St. Elizabeth Hospital subsequently changed its bioassay procedure to require the thyroid burden to be measured immediately to within 72 hours after administration of the iodine therapy dosage. The licensee made this change through the Radiation Safety Committee as a ministerial change, pursuant to 10 CFR 35.31.

Section 35.31(a) authorizes a licensee to make minor changes in radiation safety procedures that are not potentially important to safety. Such changes include editing of procedures for clarity or personnel/telephone number updates, replacement of equipment, reassignment of tasks among employees, etc. A change in the frequency of measuring the thyroid burden of personnel present for the administration of an iodine therapy dosage is potentially important to safety, and would not meet the qualifications of a ministerial change. If you would like to change the frequency of measuring the thyroid burden, you should submit an amendment request, for approval by Region III.

Regarding the frequency of measuring the thyroid burden, Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," states that thyroid burdens should be measured at least 6 hours after exposure to allow for distribution of a major part of the

9704080165 970403
PDR ADOCK 03003466
C PDR



1007

iodine to the thyroid, but within 72 hours. The reference for this recommendation is the National Council on Radiation Protection and Measurements Report No. 55, "Protection of the Thyroid Gland in the Event of Release of Radioiodine." If St. Elizabeth Hospital intends to pursue an amendment request for authorization to immediately measure the thyroid burden, it should provide additional information that would demonstrate that measuring thyroid burdens prior to 6 hours after exposure is sufficient to allow for distribution of a major part of the iodine to the thyroid, and thereby adequate to determine uptake within the thyroid.

Consequently, based on the results of the inspection and further review of this finding, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice). A written response is required.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

Original signed by
Gary L. Shear for

Roy J. Caniano, Acting Director
Division of Nuclear Materials Safety

License No. 48-10219-01
Docket No. 030-03466

Enclosure: Notice of Violation

bcc w/encl: PUBLIC
H. Clayton, EICS

DOCUMENT NAME: G:\INSPRPTS\MTLS\030\03003466.971

To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	DNMS/RIII	<input checked="" type="checkbox"/>	DNMS/RIII	<input type="checkbox"/>	DNMS/RIII	<input checked="" type="checkbox"/>				
NAME	LaFranzo:jaw		Madera <i>LM</i>		Caniano <i>BLG</i>					
DATE	03/ 31 /97		03/ 02 /97		03/ 03 /97					

4 OFFICIAL RECORD COPY