DCD

November 19, 1996

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

SUBJECT: NOTICE OF VIOLATION DATED AUGUST 20, 1996

Dear Mr. Cox:

This acknowledges receipt of your letter dated September 3, 1996, in response to our letter dated August 20, 1996 transmitting a Notice of Violation.

We acknowledge the error in the Notice of Violation which states, in part, each dose calibrator shall be tested for linearity between the highest dosage administered to 10 microcuries. 10 CFR 35.50(b)(3), revised as of January 1, 1996, states, in part, each dose calibrator shall be tested for linearity between the highest dosage administered to 30 microcuries (1.1 MBq). Unless otherwise stated in your license, you are required to perform linearity tests at the frequency and between the ranges indicated in the most recent revision of 10 CFR 35 which, at this time, is the revision stated above.

We disagree with the statement in your letter that a linearity test using 200 millicuries instead of 40 millicuries will provide little if any additional safety or equipment performance assessment. The intent of the dose calibrator linearity test is to assess the capability of the dose calibrator to indicate the correct activity over the range of use of that calibrator. If the linearity of your particular dose calibrator is not determined for the entire range of use, i.e., the linearity test is performed using 40 millicuries of technetium-99m, but doses are administered up to 200 millicuries, then this test will not assess the capability of the dose calibrator to indicate correct activity over the entire range of use. The radioisotope used in the linearity test is not a crucial factor since the annually required accuracy test verifies the accuracy of radionuclides with different photon energies and ensures that the activity is within a few percent of a given calibrated reference source. Technetium-99m is most frequently used for the linearity test because of its availability and short half-life.

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Notwithstanding the above, we have reviewed your corrective actions, which appear to be adequate, and have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,

Original signed by Cynthia D. Pederson

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

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

bcc: J. Madera
bcc w/ltr dtd 09/03/96: Public IE07
B. Burgess, EICS

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DATE	11/15/96	11/18/96	11/[illegible]/96			

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St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

September 3, 1996

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 20555-0001

License No. 48-10219-01
Docket No. 030-03466
Re: Reply to Notice of Violation

Dear Nuclear Regulatory Commission:

On June 25, 1996, a routine NRC inspection stated that our linearity test for the dose calibrator did not comply with 10 CFR 35.50(b)(3). The Notice of Violation states that the linearity test be tested between the highest dosage and 10 microcuries. According to my current 10 CFR 1/1/96 edition the linearity test should be tested to a lower level of 30 microcuries although prior regulations identified the 10 microcurie level. Does this regulation change require licensees to make a formal change in their program? The violation also states we tested the range of 39.4 mCi to 21 microcuries on April 15, 1995 although we tested to a lower level of 7.5 microcuries.

In our linearity tests prior to the inspection we had tested the range from about 40 millicuries to below 10 microcuries which corresponds to our diagnostic range of activities. In December of 1993 we started using occasional therapeutic doses of I-131 which exceed 30 millicuries. Since we receive I-131 in unit dose form and do not change the volume or activity we interpreted the regulation to not apply for this type of occurrence. We were concerned that a linearity test with Tc-99m at a high activity would not correlate with the different energy spectrum of I-131. Using I-131 as a linearity isotope for decay is not practical due to cost and its relatively long half life. Our dose calibrator activity for I-131 did correlate well with the stated activity supplied by the original distributor and we feel that our measured doses are in the appropriate prescribed activity range. It appears that the intent of a linearity test is to verify that a dose calibrator demonstrates small accuracy changes from low activities to high activities which would allow low activity calibration sources to be used for equipment assessment. In using calibrated I-131 unit doses which are independently assayed and then verified by the end user this provides a redundancy and appropriate safety. A linearity test using 200 millicuries instead of 40 millicuries will provide little if any additional safety or equipment performance assessment.

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 • FAX (414) 738-2040

This correspondence is to indicate that we f[illegible] our interpretation was reasonable. However, since it is simple to increase our linearity i[illegible]l dose level to about 200 millicuries of technetium-99m we started using the 200 millicurie level as of the next scheduled linearity test (July 1996). This information was conveyed to the inspector at the time of the inspection. Please contact Stanley A. Reed (414-738-2190) if there are any questions concerning this response.

Respectfully submitted,

Otto L. Cox

Otto Cox, President/Chief Executive Officer

Stanley A. Reed

Stanley A. Reed, MS, Medical Physicist