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DEC 30 1993

Nuclear Medicine Center
ATTN: Rajashri S. Manoli, M.D.
Radiation Safety Officer
10425 West North Avenue
Wauwatosa, WI 53226

License No. 48-24325-01
Docket No. 030-18480

Dear Dr. Manoli:

This refers to the telephone conversation between you and W.P. Reichhold of my staff concerning your responses to our Notice of Violation (NOV) dated October 5, 1993.

We have reviewed your response letters dated October 18, 1993, and November 4, 1993, and have no further questions regarding Item 3. However, your responses did not adequately address Items 1 and 2 in the NOV.

Your responses to Item 1 failed to include written policies and procedures for implementing your Quality Management (QM) Program.

A QM program is required for the administration of any therapeutic dosage of a radiopharmaceutical and for quantities of sodium iodide-131 and iodide-125 greater than 30 microcuries. Your QM program must include written policies and procedures to meet the following objectives:

1. A written policy to ensure an authorized user sign and date written directives before administration of any therapeutic dosage of a radiopharmaceutical, or any dosage of sodium iodide-131 or sodium iodide-125 in quantities greater than 30 microcuries.

2. A written procedure to ensure that before administering a radiopharmaceutical dosage, more than one method is used to identify the patient named in the written directive.

3. A written procedure to ensure that the specific details of the administration (such as radiopharmaceutical, dosage, and route of administration) is confirmed by the individual administering the dose, before the dosage is given.

4. A written procedure to instruct all workers to seek guidance if they do not understand how to carry out the written directive.

5. A written procedure to perform periodic reviews of the radiopharmaceutical QM program that includes the number of patient administrations that will be reviewed, all recordable events, and all misadministrations.

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Your response to Item 1 in the NOV must address all of the objectives listed above.

Your response to Item 2 in the NOV implies that you have determined the efficiency of your system used to analyze contamination smears to be 62.5 percent; however, you failed to indicate if the system is capable of detecting 2,000 disintegrations per minute as required. Please indicate if the instrument used to analyze smears is capable of detecting 2000 disintegrations per minute for the contaminant involved.

Please send your written response to the matters discussed above by January 7, 1994.

We will gladly discuss any questions you have concerning this letter. You may wish to discuss your response with Mr. Reichhold prior to submission. Mr. Reichhold can be reached at (708) 829-9839.

Sincerely,

B. J. Holt, Chief
Nuclear Materials Inspection
Section 1

bcc w/ltrs dtd 10/18/93
& 11/4/93:
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Reichhold/bt
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