

Hobart, Indiana 46342 (219) 942-0551

St. Mary Medical Center

October 2, 1990

George M. McCann, Chief Nuclear Materials Safety - Section 1 United States Nuclear Regulatory Commission Region III 799 Roosevelt Road Glen Ellyn, Illinois 60137

Dear Mr. McCann:

Re: License No. 13-03459-03 Docket No. 030-31379

This letter is in response to your notice of violation letter we received dated September 13, 1990, concerning your inspection of our Nuclear Medicine facility at St. Mary's Medical Center - Hobart on August 29, 1990.

I have reviewed your letter in which you listed three areas with activities which appeared to be in violation with our NRC license requirements. I would like to respond to these violations and indicate, (1) the corrective action taken and the results achieved, (2) the corrective action taken to avoid further violations and (3) the date when full compliance will be achieved.

CORRECTIVE ACTION TAKEN AND RESULTS ACHIEVED:

VIOLATION:

- The linearity tests performed quarterly on 1. the dose calibrator is supposed to be performed over the range from the highest dose that will be administered to the patient down to 10 microcuries. The last linearity test performed in July of 1990 started with the highest activity but only went down to 165 microcuries. The technologist started the procedure too late in the week and did not come in on the weekend to finish the procedure. I have discussed the procedure with the technologists and we will begin using the "Calicheck System" to eliminate this problem so the test can be completed within about 1 hours time.
- The linearity test mentioned above did not

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> have the Radiation Safety Officers signature. In addition, results of daily constancy checks on the dose calibrator were not recorded and maintained for 10 occasions between March and August 1990, when radiopharmaceuticals were administered. Radiation Safety Officer reviewed the procedure and signed the portion of the test that was completed. The other occasions usually occurred during weekends when the technologists were called in for Stats and did not check the dose calibrator as indicated in our license. The technologist was informed that there must be a dose calibrator constancy check performed each day the dose calibrator is used to measure patient doses, even if the tests occur on weekends.

There were 7 occasions when daily survey results were not recorded and maintained between March and August 1990, when radioactive drugs were administered. These seven occasions appeared to correlate with most of the occasions as indicated above, when the technologists were called in for Stats on weekends. The technologists were informed that any time procedures are performed in the department a daily survey must be performed, even on weekends.

As indicated above, all of the department technologists, the Radiation Safety Officer and the Chairman of the Radiation Safety Committee have been informed of the violations.

CORRECTIVE ACTION TAKEN TO AVOID FURTHER VIOLATIONS:

Since we are the license holder and are responsible for all items listed in the license, we have developed a list of tests and report forms that are required to be performed, the necessary signatures and when the procedures have to be completed or signed. The list actually requires the results to be submitted in advance of the actual due date so if there are problems they can be redone before they are officially required to be completed. We have also worked out a list to make sure the appropriate signatures are on the respective documents. Dr. Torabi has been provided a specific mailbox at each facility and a list when each of the documents are due. He then also has a check system to make sure his signature is present on these reports and documents.

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DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED:

The appropriate documents have been reviewed and signed. The "Calicheck System" is being used this month to perform the linearity, and the Senior Technologist will check daily to make sure appropriate dose calibrator checks and surveys have been completed as necessary.

I hope the above information is satisfactory. If you require additional information or if you have any questions pertaining to the information submitted, please give me a call at (219) 947-6011.

Sincerely,

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Vice President, Operations

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