GENESYS
REGIONAL MEDICAL CENTER
St. Joseph Campus

April 5, 1994

Mr. Michael Weber
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532

SUBJECT: Reply to a Notice of Violation
License No. 21-01103-04
Docket No. 030-02003

Dear Mr. Weber:

This correspondence is in reponse to the telephone call to Dr. Carnakanti Prasad on March 30, 1994 requesting clarification on the "Reason for Violation" for each of the violations noted in the survey of April 26 through May 4, 1993.

A. Violation: 10 CFR 35.410 requires that a licensee provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy. This instruction must describe, in part, the size and appearance of the brachytherapy sources.

Reason for Violation: The Registered Nurse who cared for the brachytherapy patient on April 20 and 21, 1993 was a part time, third shift employee Nurse who missed the most recent Radiation Inservice Class provided by the Radiation Safety Officer.

Corrective Steps Taken & Results Achieved: Extensive corrective action has been taken including radiation inservice to all nursing personnel on all three shifts on the Oncology Unit, 1 Main, 4 Main and 5 Main with Brachytherapy and I-131 therapy procedures performed.

Corrective Steps to Avoid Further Violations: As a part of the annual refresher course and new employee orientation, all nursing personnel will read Policy #110 - "Patients Receiving Radionuclide Therapy (Brachytherapy)", view an educational videotape on radiation safety concerning brachytherapy procedures; and, nursing employees assigned to 1 Main, 4 Main or 5 Main will be given additional instruction for care of patients receiving brachytherapy.

Date of Full Compliance: 5/93

B. Violation: 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures.

Reason for Violation: At the time of hire, the Radiation Safety Officer was not made aware of employment and specific employment date of nuclear medicine technologist. Following his employment, inservice classes were given to all staff on an informal basis; however, documentation was not made of individual employee attendance.

Corrective Steps Taken & Results Achieved: Annual refresher training has been provided reviewing appropriate policies and procedures including a Quality Management Program review to the Nuclear Medicine Technologists.

Corrective Steps to Avoid Further Violations: Annual refresher training is being provided reviewing appropriate policies and procedures including a Quality Management Program as of 5/5/93. Documentation of attendance is required by virtue of employee signature and Social Security number. As a part of the annual refresher course and new employee orientation, all nursing personnel will read Policy #110 - "Patients Receiving Radionuclide Therapy (Brachytherapy)", view an educational videotape on radiation safety concerning brachytherapy procedures; and, nursing employees assigned to 1 Main, 4 Main or 5 Main will be given additional instruction for care of patients receiving brachytherapy.

Date of Full Compliance: 5/93

C. Violation: 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Reason for Violation: The physician who administered Iodine-131 on August 5 and 12, 1991, left immediately for vacation and was not available for thyroid burden measurement.

Corrective Steps Taken & Results Achieved: Thyroid burden measurements are being performed by the RSO and/or an RSO designate on all personnel involved in the procedure on the date procedure is performed (without any exception).

Corrective Steps to Avoid Further Violation: Thyroid burden measurements are being performed by the RSO and/or an RSO designate on all personnel involved in the procedure on the date procedure is performed (without any exception).

Date of Full Compliance: 5/93

D. Violation: 10 CFR 35.50(d) requires, in part, that a licensee repair or replace a dose calibrator if the accuracy error exceeds ten percent.

Reason for Violation: Upon recognition of the dose calibrator accuracy error, the calibrator was replaced; however, the licensee did not document the date of replacement.

Corrective Steps Taken & Results Achieved: Repair or replacement of the dose calibrator will be properly performed according to 10 CFR 35.70(a)(Section 10) and date of performing the test will be documented to assure compliance.

Corrective Steps to Avoid Further Violation: Repair or replacement of the dose calibrator will be properly performed according to 10 CFR 35.70(a)(Section 10) and date of performing the test will be documented to assure compliance.

Date of Full Compliance: 5/93

E. Violation: 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Reason for Violation: The consulting physicist from MPC and the Radiation Safety Officer were not aware of the existence of the Cardiac Stress Room in the Cardiac Cath Lab.

Corrective Steps Taken & Results Achieved: A survey of the cardiac stress room with a radiation detection device was performed 5/5/93 and will continue to be performed to be in compliance.

Corrective Steps to Avoid Further Violation: Survey of the cardiac stress room with a radiation detection device will be performed to be in compliance.

Date of Full Compliance: 5/5/93

F. Violation: 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Reason for Violation: The consulting physicist from MPC and the Radiation Safety Officer were not aware of the existence of the Cardiac Stress Room in the Cardiac Cath Lab.

Corrective Steps Taken & Results Achieved: A survey of the cardiac stress room for removable contamination was conducted and will be routinely performed.

Corrective Steps to Avoid Further Violation: A survey of the cardiac stress room for removable contamination will be conducted once each week to be in compliance.

Date of Full Compliance: 7/93

If I can be of further assistance, please feel free to contact me at 810/762-8599.

Sincerely,

Homer W. Read
Assistant to the
President

HWR/cmn

Enclosure

cc: Carnakanti Prasad, Ph.D.
Joseph Kyle
Mark Gentle

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