GENESYS
REGIONAL MEDICAL CENTER
St. Joseph Campus

March 16, 1994

Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

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

Dear Sir:

Relative to the NRC inspection of Genesys Regional Medical Center - St. Joseph Campus from April 26 through May 4, 1993 and subsequent violations, please find response of said violations below:

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: On April 20 and 21, 1993, licensee personnel cared for a patient undergoing implant therapy without providing required radiation safety instruction to the individual concerning the size and appearance of the brachytherapy source.

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

Rec'd w/ck # 185405 for 3,750.00.

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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: In 1991, a nuclear medicine technologist was not instructed in radiation safety topics before assuming duties with radioactive materials. Moreover, since approximately December 14, 1990, many nuclear medicine technologists and radiation oncology nurses were not instructed in radiation safety topics during annual refresher radiation safety training.

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: On August 5 and 12, 1991, the licensee administered to a patient approximately 200 millicuries of Iodine-131, a dosage which requires hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the individuals who helped prepare or administer this dosage until August 22 and 23, 1991, respectively, periods in excess of three days.

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: As of March 30, 1992, the licensee did not repair or replace a dose calibrator with an accuracy error of 11.95 percent, an error exceeding ten percent.

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: Since at least December 14, 1990, the licensee did not survey with a radiation detection instrument at the end of the day the cardiac stress room, an area where radiopharmaceuticals are routinely administered.

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: Since at least December 14, 1990, the licensee did not survey for removable contamination once each week the cardiac stress room, an area where radiopharmaceuticals are routinely administered.

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

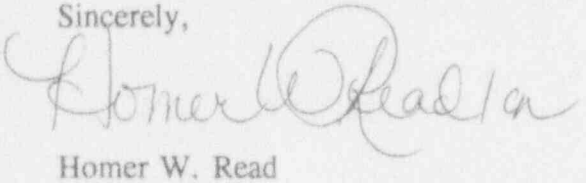
Corrective Steps to Avoid Further Violation: A survey of the cardiac stress room for removable contamination will be conducted once each week to be in compliance.

Date of Full Compliance: 7/93

Please find enclosed at this time our Check No. 185905, made payable to the Treasurer of the United States, representing the civil penalty for the above violations in the amount of $3,750.

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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