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SARATOGA COMMUNITY HOSPITAL

15000 Gratiot Avenue
Detroit, Michigan 48205-1999
(313) 245-1200

May 26, 1994

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

SUBJECT: Reply to Notice Violation

In response to your attached letter of May 05, 1994, please be assured that Saratoga Community Hospital has taken the 1993 safety inspection issues very seriously as evidenced by our corrective action plan and our appearance at the enforcement conference of April 22, 1993.

We agree that the 1993 safety inspection issues required action, and we agree with the main reasons that caused the deficiencies outlined in your letter of May 05, 1994.

The most important fact is that all of the issues were resolved quickly once they were brought to your attention. More importantly, we have checks and balances in place to assure continuing compliance into the future. The most recent NRC inspection of February 24, 1994 confirmed our compliance.

As requested, we are hereby complying with the documentation requirements by enclosing our responses.

We agree that a sudden departure of the radiation technologist and a lapse in management oversight were the main reasons for the deficiencies in early 1993.

We also have enclosed our remittance in the amount of $2,500 as requested.

Please feel free to contact Mr. John Rowe, Administrative Director of Radiology/Nuclear Medicine, at (313) 245-1319, if you require further information.

Sincerely,

MICHAEL F. BREEN
Executive Director

cc: Radiation Safety Committee
John Rowe, MS. RT (R)
James Switzer, M.D.
Frank Bologna, M.A.
Radiation Physics Services, Inc.

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REPLY TO A NOTICE OF VIOLATION

(NRC Inspection Conducted from March 22, 1993 through April 6, 1993)

NRC Inspection Findings	Admission/Denied	Identified Reasons for Violation	Corrective Steps Taken With Results	Future Corrective Steps To Be Taken	Date When Full Compliance Was Achieved
A.1. On March 22, 1993, a Nuclear Medicine Technologist was not instructed in specified radiation safety topics before assuming duties with radioactive materials. Moreover, as of April 06, 1993, and since at least February 19, 1991, the annual refresher training did not include many of the specified topics, such as applicable regulations and license conditions.	Admission	A.1(a) Lack of direct supervision insistence on proper radiation safety training due largely to a perceived emergency situation caused by the immediate vacancy of the regular Nuclear Medicine Technologist.	A.1(a) The acting, newly hired, and all subsequent Nuclear Medicine Technologists who are currently or expect to assume duties as a Nuclear Medicine Technologist at Saratoga Community Hospital are instructed in specific radiation safety topics as part of a required orientation. All Nuclear Medicine Technologists (current and contingent) since April 06, 1993 have been properly orientated.	A.1(a) Annual refresher training is to be maintained. A check-off list of training topics with the appropriate date and signatures documenting training will be maintained. Annual review of the training topics will be conducted by the Radiation Safety Committee.	May 01, 1993
		A.1(b) Failure of the direct supervisor and Radiation Safety Officer to ensure appropriate annual Radiation Safety refresher training.	A.1(b) Annual refresher training is required and documented. The training topics have been developed by a qualified Medical Radiation Physicist and is reviewed annually to assure that it is in compliance with current standards. All Nuclear Medicine Technologists (current and contingent) are receiving proper annual refresher training.	A.1(b) Same as above	
A.2. Between March 16, 1993 and March 22, 1993, a Nuclear Medicine Technologist did not wear personal monitoring devices while in areas where radioactive materials were used or stored.	Admission	A.2. The newly hired Certified Nuclear Medicine Technologist had not yet received her new badges and spare radiation monitoring devices were not issued to her in the interim.	A.2. Proper radiation monitoring devices are issued and are required to be worn while on active duty in areas where radioactive materials are used or stored. Spare radiation monitoring devices are in reserve in the event that the initial devices are misplaced and/or unable to be used. Compliance is monitored by the Administrative Director and Radiation Safety Officer. All Nuclear Medicine Technologists wear the proper radiation monitoring devices.	A.2. Spare radiation monitoring devices are kept on hand. Compliance that the devices are being properly worn will be maintained by the Administrative Director of Nuclear Medicine.	May 01, 1993
A.3. During the weeks of September 7-11, 1992, November 23-27, 1992 and February 9 - March 15, 1993, the licensee did not survey any packages and packages containing radioactive materials were received during these time intervals.	Admission	A.3. Failure of the acting Nuclear Medicine Technologist to perform and document proper radiation surveys of packages containing radioactive materials. Further failure of Administration to note the lack of proper documentation.	A.3. All packages containing radioactive materials are now properly surveyed, and the results are documented appropriately. Since March 15, 1993, all appropriate packages have been surveyed.	A.3. Monitoring of survey documentation will be done by the Administrative Director of Nuclear Medicine, the Medical Radiation Physicist, and the Radiation Safety Officer. Annual refresher training will be maintained.	May 01, 1993

NRC Inspection Findings	Admission/Denied	Identified Reasons for Violation	Corrective Steps Taken With Results	Future Corrective Steps To Be Taken	Date When Full Compliance Was Achieved
B. The licensee used a reusable collection system for radioactive Xenon-133 gas and did not check the operation of the collection system during the months of January and February, 1993.	Admission	B. Failure of the acting Nuclear Medicine Technologist to properly check and document the operation of the Xenon-133 gas collection system. Further failure of the Administration to note the lack of proper documentation.	B. Appropriate monthly checks on the Xenon-133 gas collection system are now performed and documented. The Nuclear Medicine Technologists are properly trained and are provided with the annual refresher training. The checks are complete and documented.	B. Monitoring of the documentation of the monthly checks on the Xenon-133 gas collection system will be conducted by the Administrative Director of Nuclear Medicine, the Medical Radiation Physicist, and the Radiation Safety Officer. Annual refresher training will be maintained.	May 01, 1993
C. Between December 16, 1992 and March 19, 1993, the licensee did not mathematically correct patient dosage readings for a dose calibrator linearity error greater than ten percent and the patient dosages were greater than ten microcuries.	Admission	C. Failure of the acting Nuclear Medicine Technologist to properly correct patient dosage readings and to document such calculations. Further failure of the Administration to note the lack of proper documentation.	C. Appropriate training relative to performing and mathematically correcting for dose calibrator linearity errors have been given. Annual refresher training is also given. Monitoring of such documentation is performed by the Administrative Director of Nuclear Medicine, the Radiation Safety Officer and the Medical Radiation Physicist. Corrections are being performed in the appropriate circumstances.	C. Annual refresher training will be maintained and documented. Compliance will be reviewed by the Administrative Director of Nuclear Medicine, the Medical Radiation Physicist, and the Radiation Safety Officer.	May 01, 1993
D. The licensee did not test its dose calibrator for linearity or geometry dependence at the time of installation, which occurred on March 22, 1993.	Admission	D. Failure of the licensee to have the dose calibrator properly tested upon installation.	D. A loaner dose calibrator was transferred to Saratoga Community Hospital and properly tested prior to use. A new dose calibrator was purchased and appropriately tested by a Medical Radiation Physicist.	D Proper dose calibrator acceptance testing will be performed on all new or loaned dose calibrators by a qualified Medical Radiation Physicist. Compliance will be reviewed by the Administrative Director of Nuclear Medicine, the Radiation Safety Officer and the Radiation Safety Committee.	May 01, 1993
E. During September 7-11, 1992, November 23-27, 1992, and February 9 - March 15, 1993, the licensee did not check the dose calibrator for consistency, and the dose calibrator was used to measure patient doses of radio-pharmaceuticals during these time intervals.	Admission	E. Failure of the acting Nuclear Medicine Technologist to properly check and document the dose calibrator for consistency. Further failure of the Administration to note the lack of proper documentation.	E. The Nuclear Medicine Technologists (current and contingent) have received appropriate training for checking the dose calibrator for consistency. Proper documentation of the checks are maintained. The dose calibrator is properly checked.	E. Annual refresher training will be maintained and documented. Compliance will be reviewed by the Administrative Director of Nuclear Medicine, the Medical Radiation Physicist, and the Radiation Safety Officer.	May 01, 1993
F. During the weeks of September 7-11, 1992, November 23-27, 1992 and February 9 - March 15, 1993, the licensee did not survey with a radiation detector instrument at the end of the day, areas where radio-pharmaceuticals were routinely prepared for use or administered.	Admission	F. Failure of the acting Nuclear Medicine Technologist to perform and document proper surveys at the end of the service day. Further, failure of the Administration to note the lack of proper documentation.	F. The Nuclear Medicine Technologists (current and contingent) have received training on appropriate radiation detection surveys including routine daily surveys. Proper documentation of all surveys are maintained.	F. Annual refresher training will be maintained and documented. Compliance will be reviewed by the Administrative Director of Nuclear Medicine, the Medical Radiation Physicist, and the Radiation Safety Officer.	May 01, 1993

NRC Inspection Findings	Admission/Denied	Identified Reasons for Violation	Corrective Steps Taken With Results	Future Corrective Steps To Be Taken	Date When Full Compliance Was Achieved
G. During the weeks of September 7-11, 1992, November 23-27, 1992, and February 9 through march 15, 1993, the licensee did not survey for removable contamination in areas where radio-pharmaceuticals were routinely prepared for use, administered or stored.	Admission	G. Failure of the acting Nuclear Medicine Technologist to perform and document proper surveys in areas were radio-pharmaceuticals were prepared. Further, failure of the Administration to note lack of documentation.	G. The Nuclear Medicine Technologists (current and contingent) have received training on appropriate radiation detection surveys including those surveys for areas where radio-pharmaceuticals are routinely prepared for use, administration, or stored. Documentation of such surveys are maintained.	G. Annual refresher training will be maintained and documented. Compliance will be reviewed by the Administrative Director of Nuclear Medicine, the Medical Radiation Physicist, and the Radiation Safety Officer.	May 01, 1993