"REPLY TO A NOTICE OF VIOLATION"

03019652

49-21004-01

June 23, 1988

Director, Office of Enforcement,
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sirs:

Please find enclosed information pursuant to a reply to a notice of violation letter dated June 3, 1988.

The information contained within this letter corresponds alphabetically to the noted violations as indicated during the NRC inspection of this facility dated March 24, 1988.

Violation A

A physician at this facility did indeed order and administer a therapeutic dose of Iodine-131 in the amount of 15 millicuries. The physician in question was unsure as to his authorized uses and possession limits at this facility. This physician has since been advised as to all authorized possession limits and uses. A license amendment request has been submitted to the NRC requesting additional authorization for this physician concerning the use of I-131 for hyperthyroidism and cardiac dysfunction. In the future strict attention will be given to authorized amounts and uses of radioactive materials at this facility.

Violation B

Technical personnel working within the nuclear department in the past had inadvertently not been given all instructions as required by 10 CFR 19.12. This was an oversight on the part of the Radiation Safety Officer as well as radiation safety committee and administration of this facility. All new employees now frequenting the nuclear department will be given appropriate instructions as required by the regulations. The appropriate instructions will be given by either the Radiation Safety Officer and/or the visiting Radiation Safety auditors. Documentation attesting to these instructions will be maintained on file for future review.

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Violation C

The radiation safety committee had not met in a substantial period of time beginning October 1, 1986 through March 24, 1988. This was due to an oversight on the part of the radiation safety committee and management. Starting immediately radiation safety committee meetings will be held on a quarterly basis. These meetings will be scheduled in order to coincide with the quarterly radiation safety audits performed by an independent party. The independent party will attend these meetings. Minutes from the radiation safety committee meetings will be made available to all personnel involved. Minutes from the RSC meetings will be maintained on file for future review.

Violation D

Several physicians listed on our radioactive materials license were inadvertently maintained on the license after their performance of duties were discontinued. These physicians were allowed to remain on this license due to the fact that we were unsure as to whether or not these physicians would be frequenting this facility as authorized users for a substantial period of time subsequent to May of 1987. In the future any physician no longer performing duties pertaining to radioactive materials at this facility will be deleted from the radioactive materials license as soon as possible. This will be accomplished by requesting deletion in writing to the Regional Office of the Nuclear Regulatory Commission. Also as mandated by the modification of our radioactive materials license as specified by the Nuclear Regulatory Commission, the Regional NRC office would be notified by telephone as soon as we ascertain that any employee is to terminate employment at this facility when involved in nuclear medicine activities.

Violation E

A quarterly sealed source inventory was missed during the period covering September 24, 1987 and March 24, 1988. This was due mainly to a change in personnel within the nuclear department who were unaware of this requirement. In the future the sealed source inventories will be conducted on a quarterly basis. This will be performed by our Radiation Safety Auditors. Records of quarterly inventories will be maintained on file and reviewed by the Radiation Safety Officer.

Violation F

A visiting physician did perform procedures within the nuclear department, a copy of the physician's radioactive materials license was not obtained prior to his temporary employment. In the urgency of locating and securing an authorized user for procedures at this facility, a copy of the physician's license was not obtained. In the future a license indicating an authorized physician will be acquired and approved by the radiation safety committee prior to that physicians' performing nuclear medicine procedures at this facility. All documentation will be maintained on file for future review.

Violation G

Personnel involved in the nuclear medicine department were unaware of conditions set forth by 10 CFR 35.2. This regulation has subsequently been reviewed at this facility. In the future all record keeping as mandated by 10 CFR 35.33 Paragraph C will be reviewed by the Radiation Safety Officer and documented. These records will be maintained as direct by 10 CFR 35.33 Paragraph D.

Violation H

It is apparent that record keeping requirements pursuant to 10 CFR 35.53 (C) were incomplete. This requirement has subsequently been reviewed by personnel at this facility. In the future all required documentation concerning radiopharmaceutical doses to patients as described in 10 CFR 35.53 (C) (2) and 10 CFR 35.53 (C) (3) as well as 35.53 (C) (5) will be maintained on file for review.

The modifications to our radioactive materials license as set forth by the nuclear regulatory commission have also been implemented. An independent medical physics consulting firm has been secured. Attached, please find the evaluations that will be reviewed on a quarterly basis by the consulting firm. I also would like to indicate that our Radiation Safety Officer has recently attended a Radiation Safety Officer's Training Course. This course was provided by Nuclear Medicine Associates, a medical physics consulting group. Topics covered during the Radiation Safety Officers Course included applicable portions of 10 CFR Parts 19, 20, 30, 31 and 35, license applications, NRC inspections, NRC enforcements policies and levels of violations, radiation safety committee meeting requirements, items required in order to satisfy ALARA commitments, film badge reports, personnel dosimetry, records and record keeping necessitated by both the NRC and State Regulatory Agencies. We now feel our Radiation Safety Officer has an adequate background in order to help comply with regulatory requirements.

I hope this information meets with your approval. Please feel free to contact me if any questions arise. Upon receipt of your reply if all information meets with your approval. An initial Radiation Safety Audit will be scheduled as soon as possible. Thank you.

Sincerely,

Bruce K. Birchell

Bruce K. Birchell, Administrator,
Riverton Memorial Hospital/Health Trust, Inc.

cc: Regional Administrator
U.S. Nuclear Regulatory Commission
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