APPENDIX

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-19652/88-01 License: 49-21004-01

Docket: 30-19652

Licensee: Riverton Me al Hospital - Health Trust, Inc.
2100 W. Su.. .t Drive
P.O. 1280
Riverton, Wyoming 82501

Inspection At: Riverton, Wyoming

Inspection Conducted: March 24, 1988

Inspectors: Larry Ricketson — 4-8-88
L. T. Ricketson, P.E., Radiation Specialist — Date

Dale A. Powers — 4/8/88
Dr. D. A. Powers, Chief, Nuclear Materials Inspection Section — Date

Approved: Dale A. Powers — 4/8/88
Dr. D. A. Powers, Chief, Nuclear Materials Inspection Section — Date

Inspection Summary

Inspection Conducted March 24, 1988 (Report 30-19652/88-01)

Areas Inspected: A special, unannounced inspection was performed. Included in the inspection was a review of the radiation protection program, licensed program requirements, and corrective actions involving previous violations.

Findings: The following apparent violations were identified:

1. Performance of a therapy procedure by an unauthorized individual. (Section 6)

2. Failure of the Radiation Safety Committee to meet quarterly. (Section 8)

3. Failure to test the dose calibrator for geometry dependance. (Section 10)

4. Failure to instruct workers. (Section 9)

5. Failure to amend the license to reflect a change in the name of the facility. (Section 5)

6. Failure to perform a physical inventory of sealed sources. (Section 11)

7. Failure to make a record of a diagnostic misadministration. (Section 7)

8. Failure to secure a copy of a radioactive materials license on which a visiting physician was named. (Section 6)

9. Failure to include all required information on records of radiopharmaceutical administrations. (Section 12)

DETAILS

1. Persons Contacted

*Bruce Birchell, Administrator
Thomas McCallum, M.D., Radiation Safety Officer
*Walter Landl, Jr., Supervisor, Nuclear Medicine Department
Annette Baker, Technologist

*Denotes attendance at the exit meeting.

2. Reason for Special Inspection

On September 30 and October 1, 1986, the NRC performed an inspection of the licensee and identified nine apparent violations. An enforcement conference was held November 4, 1986, and a Notice of Violation and Proposed Imposition of Civil Penalties was issued January 21, 1987. An Order Imposing Civil Monetary Penalty was issued June 11, 1987. A special inspection was performed to verify that corrective actions were taken as outlined in the licensee's letter of February 12, 1987.

At the time of the current inspection the licensee's nuclear medicine program was found to be active, performing approximately 15 procedures per month.

3. Followup on Previous Inspection Findings (September 30 through October 1, 1986)

(Open) Violation of License Condition 11 (now License Condition 12) - Unauthorized user of licensed materials - Of the seven individuals listed on the license as authorized users, only one was found to be practicing at the facility. This individual was found to have performed a procedure for which he was not authorized. (See Section 6)

(Open) Violation of License Condition 12.B (now 10 CFR 35.27) - Visiting physicians were not specifically named as users on other licenses. There is no indication that this violation has recurred; however, a related item was identified as an apparent violation. (See Section 6)

(Closed) Violation of 10 CFR 35.14(b)(4)(ii) - Failure to properly test each elution of technetium 99m to determine the concentration of molybdenum-99 present. Interviews and demonstrations confirm that individuals presently employed have received the proper training. This action has prevented the recurrence of this item.

(Closed) Violation of License Condition 15 - Failure to follow operating procedures and wear personnel monitoring devices - Observations indicate that the licensee's corrective actions have prevented recurrence of this item.

(Open) Violation of License Condition 15 (now 10 CFR 35.50) - Failure to follow operating procedures and perform quarterly linearity tests on dose calibrators - Records indicate that the licensee's corrective actions have prevented the recurrence of this item; however, a related item was identified as an apparent violation. (See Section 10)

(Open) Violation of License Condition 15 (now 10 CFR 35.22) - Failure of the Radiation Safety Committee to meet quarterly - This item was identified as having recurred. (See Section 8)

(Closed) Violation of 10 CFR 35.14(e)(1)(i) - Failure to leak test sealed sources - Records indicate that the licensee's corrective actions have prevented recurrence of this item.

(Open) Violation of 10 CFR 35.14(f)(2) (now 35.59(g)) - Failure to physically inventory sealed sources at least quarterly - Records indicate that this item has recurred. (See Section 11)

(Open) Violation of License Condition 1 - Failure to modify the license to reflect a change in the name of the facility. This item was found to have recurred. (See Section 5)

4. Program Areas Inspected

The following program areas were inspected. The inspection included interviews with cognizant individuals, observation of activities, independent measurements, and record reviews. The depth and scope of these activities were consistent with past findings and with the current status of the facility.

Except as noted, the inspection revealed no violations, deviations, deficiencies, unresolved items, or open items. Notations after a specific inspection item identify the following: I = item not inspected or only partially inspected, V = violation, D = deviation, H = deficiency, U = unresolved item, and O = open item.

Inspection Procedure	Program Area and Inspection Requirements
83822	Radiation Protection
	02.01 - Procedures - V
	02.02 - Instruments and Equipment
	02.03 - Exposure Controls
	02.04 - Posting, Labeling, and Control
	02.05 - Surveys
	02.06 - Notifications and Reports
87100	Program Requirements
	02.01 - Program Administration - V

02.02 - Authorized Materials, Uses, and Users - V

02.03 - Facilities and Equipment

02.04 - Radiation Protection

02.05 - Radioactive Effluents and Waste Disposal

02.06 - Confirmatory Measurements

5. Program Administration

License Condition 1 lists the name of the facility. Representatives of the licensee stated that the name of the facility had been changed about September 1987 to Riverton Memorial Hospital - Health Trust, Inc. It was later confirmed by Region IV counsel that there was no improper transfer of the license from one corporation to another, but rather only a name change had occurred. The licensee failed to obtain or request a license amendment to specify the name change.

This was identified by the NRC inspectors as an apparent repeat violation of License Condition 1.

6. Authorized Materials, Uses, and Users

License Condition 12 lists the individual users and states the specific uses of licensed materials for which they are authorized. Records indicate that on August 28, 1987, a patient received a therapy dose of 15 millicuries of I-131. The radiologist who performed the procedure was not authorized to use licensed material for therapy.

This radiologist, who is also the Radiation Safety Officer, stated that he had not read the license and did not know that he was not authorized to do therapy. The Confirmation of Action Letter from Region IV dated March 29, 1988, confirmed that the licensee will submit, prior to April 29, 1988, the qualifications of the subject physician in regard to the conduct of therapy procedures.

The administration of a therapy dose was identified by the NRC inspectors as an apparent violation of License Condition 12.

10 CFR 35.27(a) allows a licensee to permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days if certain requirements are fulfilled.
10 CFR 35.27(a)(2) requires that the licensee have a copy of a license issued by the Commission or an Agreement State that identifies the visiting authorized user by name as an authorized user.

Licensee representatives stated that a visiting physician had been employed and nuclear medicine procedures were performed at those times under his oversight. From records, the licensee's representatives were able to give the dates of use as February 9 and 11, 1988, and March 7 and 8, 1988. The representatives were unable to produce a copy of the license on which the visiting physician appeared.

The failure to secure a copy of the requisite license was identified by the NRC inspectors as an apparent violation of 10 CFR 35.27(a)(2). The inspectors later verified that the physician was listed on License No. 49-18276-01 as an authorized user for the type of procedures performed.

7. Misadministrations

10 CFR 35.2 defines a diagnostic misadministration as a dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent. 10 CFR 35.33(c) requires that when a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, and retain the record as directed by 10 CFR 35.33(d).

The NRC inspectors identified from record reviews that on October 14, 1987, a child, age 9, was given a dose of 17.4 millicuries of technetium-99m for a bone scan. When questioned about the size of the dosage, licensee representatives, including the Radiation Safety Officer, stated that this error could be primarily attributed to not taking into account the age of the patient (using the licensee's Webster's Rule for converting adult doses to children's doses). Licensee representatives stated that the dose (as given in their procedures) for a bone scan was 10 to 15 millicuries. Taking the patient's age into account, a dose of approximately 9.4 millicuries maximum should have been administered. The Radiation Safety Officer offered that the misadministration was the result of the technologist being inadequately trained. The technologist acknowledged that she had prepared the dose, although the Radiation Safety Officer administered the injection.

Although the licensee failed to follow their procedure for bone scan dosage administrations, a violation is not warranted because the subject procedure is not an NRC requirement by regulation or license condition.

Because the licensee had not prepared a report concerning the incident, the NRC inspectors identified this as an apparent violation of 10 CFR 35.33(c).

8. Radiation Safety Committee

10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly.

Through a review of the meeting minutes, the inspectors were able to establish that the Radiation Safety Committee had met only once, on October 6, 1987, since the last inspection.

This was identified by the NRC inspectors as an apparent repeat violation of 10 CFR 35.22(a)(2).

9. Training and Instruction

10 CFR 19.12 requires that all individuals working in or frequenting any portion of a restricted area shall be instructed in the health protection problems associated with exposure to radioactive materials, in precautions to minimize such exposure, and in the purposes and functions of protective devices employed. This regulation requires that individuals be instructed in, and instructed to observe, the applicable provisions of Commission regulations and licenses, and shall be instructed in their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or any condition which may lead to unnecessary exposure to radiation or radioactive materials.

The only nuclear medicine technologist available for interview stated that she had been working at the hospital for about 6 months and had not been trained in accordance with the above regulation. Licensee representatives acknowledged that instruction of this nature had not been supplied by the licensee.

This was identified by the NRC inspectors as an apparent violation of 10 CFR 19.12.

10. Instrumentation

10 CFR 35.50(a) requires that a medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator. 10 CFR 35.50(b)(4) requires that the licensee test the dose calibrator for geometry dependence upon installation. A record of this calibration shall be kept for the duration of the use of the dose calibrator.

Representatives of the licensee could not produce a record for verification that the above test had been performed on their dose calibrator, nor could they personally attest to the fact that such a test had ever been performed.

The NRC inspectors identified this is an apparent violation of 10 CFR 35.50(b)(4).

11. Inventories

10 CFR 35.59(g) requires that a licensee in possession of a sealed source shall conduct a quarterly physical inventory of all such sources in its possession.

The NRC inspectors found that the licensee had three sealed sources which were used in checking the dose calibrator. Records indicate that inventories were performed quarterly from October 9, 1986, to September 24, 1987; however, none have been performed since the latter date.

The NRC inspectors identified this as an apparent repeat violation of 10 CFR 35.59(g).

12. Records

10 CFR 35.53(c) requires that a licensee, after measuring the activity of each radiopharmaceutical dosage, retain a record of the measurements including certain information. 10 CFR 35.53(c)(2) requires that the record include the patient's name. 10 CFR 35.53(c)(3) requires that the record include the prescribed dosage and the activity of the dosage at the time of measurement. 10 CFR 35.53(c)(5) requires that the record show the initials of the individual who made the record.

Records of administrations did not include the prescribed dosage as well as the measured dosage. Records reviewed were from the period of May 1987 through March 1988. The record of a bone scan performed on October 9, 1987, did not include the name of the patient. The record of a bone scan performed on October 14, 1987, did not include initials of the individual who made the record.

The NRC inspectors identified these as multiple examples of apparent violations of 10 CFR 35.53(c).

13. Exit Meeting

The NRC inspectors met with the hospital administrator and the Nuclear Medicine Department supervisor and summarized the scope and findings of the inspection as presented in this report.