APPENDIX

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

NRC Inspection Report: 30-10133/89-01 License: 49-15978-01

Docket: 30-10133

Licensee: Ivinson Memorial Hospital
255 North 30th Street
Laramie, Wyoming 82070

Inspection At: Ivinson Memorial Hospital
255 North 30th Street
Laramie, Wyoming 82070

Inspector: Wesley L. Holley 12/1/89
W. L. Holley, Radiation Specialist, Nuclear Materials Inspection Section Date

Approved: Charles L. Cain 12/1/89
Charles L. Cain, Chief, Nuclear Materials Inspection Section Date

Inspection Summary

Inspection Conducted October 26, 1989 (Report 30-10133/89-01)

Areas Inspected: Routine, unannounced inspection of institutional nuclear medicine activities including organization and management; training; procedures, materials, facilities, and instruments; receipt of radioactive material and personnel radiation protection; use of dose calibrator; and radioactive waste disposal.

Results: The inspection revealed lack of management control of the radiation safety program which resulted in the repetition of several violations identified during the previous inspection of September 10, 1986. The failure of management to review and evaluate these activities and facilities is indicative of a program in need of significant improvement. Additionally, the effectiveness of the roles of the radiation safety officer (RSO) and the radiation safety committee (RSC) need to be reviewed by the licensee.

Seven Violations were identified including three repeated from the previous inspection in 1986.

In the area of management and training, three violations were identified. These included failure to hold a quarterly RSC meeting, a repeat violation (Section 5); failure of the RSC, in conjunction with the RSO, to perform an annual program review (Section 5); and failure to present annual radiation protection training to ancillary personnel (Section 6).

In the area of equipment and tests, three violations were identified. These included failure to perform sealed source leak tests at required intervals, a repeat violation (Section 7); failure to perform calibration of a portable survey instrument (Section 7); and failure to properly perform dose calibrator checks and tests, a repeat violation (section 9).

Finally, in the area of waste management one violation was identified: failure to perform surveys of used Tc generators prior to returning them to the supplier and failure to maintain records of waste disposals and surveys (Section 10).

DETAILS

1. Persons Contacted

*Thomas Nord, Chief Executive Officer
*Robert M. Knight, M.D., Radiation Safety Officer
*Joe Hadley, Director of Radiology
L. J. Guthman, Director of Quality Care Resources
*Scot Caviness, Nuclear Medicine Technician

*Denotes those present at the exit interview.

2. Followup on Previous Inspection Findings

(Open) (30-10133/86-01) Violation of License Condition 17: Failure to perform dose calibrator annual accuracy tests. The inspector reviewed the dose calibrator annual accuracy test records for this inspection period, September 10, 1986, through October 26, 1989, and found an annual accuracy test had not been performed for 1988.

(Open) (30-10133/86-01) Violation of License Condition 17: Failure of the Radiation Safety Committee (RSC) to meet on a quarterly schedule. The inspector reviewed the RSC quarterly meeting records and determined that a meeting had been omitted during this inspection period, September 10, 1986, through October 26, 1989.

(Open) (30-10133/86-01) Violation of 10 CFR 35.14(e)(1)(i): Failure to perform leak tests of sealed sources on the required schedule. The inspector determined that some of the leak tests had not been performed for this inspection period, September 10, 1986, through October 26, 1989.

(Closed) (30-10133/86-01) Violation of 10 CFR 71.5 (49 CFR 173.415(a)): Failure to properly maintain Type A package performance test records. The inspector reviewed these records and found them to be adequate.

3. Licensee's Program - Overview

This licensee is authorized to use radiopharmaceuticals for uptake, dilution, and excretion studies, and to use radiopharmaceuticals, generators, and reagent kits for imaging and localization studies according to 10 CFR 35.100 and 35.200, respectively. Also, the licensee is authorized to use byproduct material identified in 10 CFR 31.11 for *in vitro* studies. The licensee has had two physicians/authorized users for the 10 CFR 35.100 and 35.200 activities. One of these individuals has served in the capacity of Radiation Safety Officer (RSO). The licensee also has had two other physicians as authorized users for 10 CFR 31.11 activities, but during this inspection period, September 10, 1986, through October 26, 1989, no work had been performed in this area. The licensee has had only one nuclear medicine technician, who essentially had full responsibility of the nuclear medicine safety program. The licensee's nuclear medicine department has received a 1660 mCi Mo-99/Tc-99m generator weekly and has performed approximately 35 diagnostic procedures per month using Tc-99m. The licensee had not experienced any misadministrations during this inspection period. Also, Appendix O of Regulatory Guide 10.8, Revision 1, (1980) is the Model ALARA program the licensee has committed to follow.

4. Compliance History

During the NRC inspection conducted in 1978, the inspector identified two items of noncompliance: (1) the RSC had not formally met quarterly, and (2) receipt of package surveys had not been performed. The licensee responded in a letter dated June 13, 1978, and presented procedures to correct these violations. A 1981 inspection resulted in two items of noncompliance: (1) the licensee did not possess a portable survey meter capable of measuring exposure rates up to 100 mR/h, and (2) the licensee had not performed required quarterly linearity tests and geometrical variation tests on the dose calibrator. The licensee responded to this inspection in a letter dated August 1, 1981, informing the NRC of the purchase of a new survey meter and the development of new procedures for the dose calibrator linearity and geometrical variation tests.

Section 2, above, lists the four violations identified during the 1986 inspection. The licensee described corrective actions in a letter dated January 1, 1987.

In reviewing the apparent violations of the current inspection with those of previous inspections, continuing recurrence of violations associated with the RSC and dose calibrator are evident for the last 10 years. An increase in the number of violations in the last two inspections has also been noted.

5. Organization and Management Controls

The licensee's organization has been small and noncomplex. It has consisted of a nuclear medicine technician (NMT) reporting to the director of radiology who has reported to the chief executive officer (CEO). The RSO has been outside this line of organization and has reported to the CEO administratively. The inspector determined that virtually all of the radiation safety program of the nuclear medicine department had been delegated by the RSO to the nuclear medicine technician. The RSO has been one of the physicians listed as an authorized user, and the technician has been a certified NMT. Both of the positions have been occupied with individuals different from those of the previous inspection (30-10133/86-01). The RSC consisted of the RSO, NMT, director of radiology, and a representative of the nursing staff; therefore, the membership was found to be in compliance with 10 CFR 35.22.

The inspector determined that, although the RSC had met on all other required occasions, they had not met during the second quarter of 1988. This was identified as an apparent violation of 10 CFR 35.22(a)(2). This is an apparent repeat violation from the previous NRC inspection. Also, the inspector determined that an annual review of the licensee's nuclear medicine radiation safety program had been performed during 1987, but had not been performed during 1988 by the RSC with assistance from the RSO. This was identified as an apparent violation of 10 CFR 35.22(b)(6). During this inspection period, September 10, 1986, through October 26, 1989, the inspector noted that the licensee had not had a visiting authorized user and had only made a few minor changes in the radiation safety procedures which complied with 10 CFR 35.27 and 10 CFR 35.31, respectively.

Two apparent violations were identified.

6. Training

In Item 12 attached to the license application dated August 6, 1985, which is listed in License Condition 14.A, the licensee had committed to conduct in-house radiation safety training annually to ancillary personnel who work in the vicinity of radioactive materials. Also, new employees are to be given training as soon as possible after their date of hire. This instruction is to include information pertaining to radiation safety, ALARA, and the potential hazards associated appropriately to their respective duties.

The inspector determined that the NMT had presented radiation safety retraining to housekeeping personnel in April 1989. Except for this training, the licensee had not presented any radiation safety training to ancillary personnel including security and nursing staff since the previous inspection, conducted September 10, 1986. This was identified as an apparent violation of License Condition 14.A which references the licensee's application

One apparent violation was identified.

7. Procedures, Materials, Facilities, and Instruments

The inspector reviewed various radiation safety and diagnostic written procedures. These appeared to be adequate. These procedures had been used by the nuclear medicine department and were readily available. In reviewing operating procedures and observing the performance of two procedures, the inspector determined that vials containing radiopharmaceuticals had been contained in radiation shields which were properly labeled and syringe shields were utilized properly in accordance with 10 CFR 35.61 and 10 CFR 35.60, respectively. The facilities and equipment were arranged in an efficient, safe manner in that the hot lab was adjacent to the diagnostic procedure administration area and they were connected by a doorway. These areas were appropriately posted in accordance with 10 CFR 19.11. The records of various surveys of these areas required by 10 CFR 35.70 were examined by the inspector and determined to be adequate. Only properly authorized material (Tc-99m) was found in use by the licensee. However, the inspector determined that only three leak tests were performed on sealed sources since the previous inspection. This was identified as an apparent violation of 10 CFR 35.59(b) which requires that sealed sources be leak tested on a 6-month schedule. These were Cs-137 (143 μCi) and Ba-133 (241 μCi) sources utilized in the dose calibrator checks and tests. This is an apparent repeat violation from the previous NRC inspection.

The inspector determined that the licensee possessed two portable survey instruments, Atomic Products Corporation, Model 069-701, Serial No. 279 and Xetex, Model 305B, Serial No. 8355. These instruments had been continuously in use for this inspection period and were operable at the time of this inspection. They had been calibrated according to the procedure prescribed in 10 CFR 35.51 by Western Radiation Consultants, Ft. Collins, Colorado, annually for 1987, 1988, and 1989. However, the Atomic Products Corporation instrument had not been calibrated during 1988. This was identified as an apparent violation of 10 CFR 35.51(a) which requires survey instruments to be calibrated annually.

Two apparent violations were identified.

8. Receipt of Radioactive Material and Personnel Radiation Protection

The inspector reviewed incoming package receipt procedures, package receipt surveys, and associated records. These were found to be as required. The licensed material had been received from suppliers and used according to 10 CFR 35.49(a).

The inspector reviewed the personnel dosimetry program and determined the vendor's personnel dosimetry report to be equivalent to Form NRC-5 and adequate for NRC requirements. For this inspection period, September 10, 1986, through October 26, 1989, the maximum quarterly whole body and extremity dose equivalents received by nuclear medicine personnel were 230 mrem and 200 mrem, respectively. It was noted that the nuclear medicine personnel were wearing whole body and extremity dosimetry at the time of this inspection.

No apparent violations or deviations were identified.

9. Use of Dose Calibrator

The inspector determined that the licensee had used a Nuclear Pharmacy Model AccuCal 2002 dose calibrator and had committed in License Condition 14.A to follow the procedures specified in Regulatory Guide (RG) 10.8, Revision 1, (1980) concerning the dose calibrator checks, tests, and records. It was noted that the molybdenum break-through tests had been performed in accordance with 10 CFR 35.204 and the measurement of radiopharmaceutical dosages as specified in 10 CFR 35.53 had been properly performed. In reviewing the licensee's dose calibrator activities concerning the use, possession, calibration, and checks, the inspector determined most of these activities had been performed in compliance with 10 CFR 35.50. However, further review of the dose calibrator checks and test procedures and the records for these activities determined that the dose calibrator daily constancy checks had not been performed properly with the correct procedure to monitor the checks for greater than ±5 percent deviation from the correct value as specified in RG 10.8. The licensee's procedure was simply a listing of the daily constancy readings with no procedures to determine the percent difference. The inspector determined that the dose calibrator quarterly linearity tests were not properly performed in accordance with RG 10.8 because an incorrect procedure was followed which had not allowed for the determination of greater than 5 percent deviation from the correct value, if it occurred. Also, the inspector determined that the dose calibrator annual accuracy test/calibration had not been performed during 1988. This latter occurrence is also a repeat violation from the previous inspection. These incorrect procedures were identified as an apparent violation of License Condition 14.A which commits the licensee to follow the procedures in RG 10.8, for all dose calibrator tests and checks as mentioned above.

One apparent violation was identified.

10. Radioactive Waste Disposal

The inspector reviewed the licensee's radioactive waste disposal program and determined that the waste had been decayed in storage for at least 10 half lives ($T\frac{1}{2}$) then surveyed and released to trash. Also, the licensee shipped the decayed Mo-99/Tc-99m generator ($\geq 10\ T\frac{1}{2}$) back to the vendor. These had been shipped in DOT-7A packages provided by the vendor.

The inspector determined that records had not been maintained for disposal of the decayed trash and for the surveys of the disposed trash during this inspection period. Also, during the inspection interview, the inspector determined that the licensee had not performed radiation surveys of the decayed generators before returning them to the vendor. These occurrences were identified as an an apparent violation of 10 CFR 35.92.

One apparent violation was identified.

11. Exit Meeting

The inspector met with the licensee's representatives denoted in Section 1 on October 26, 1989, and summarized the scope, findings, and concerns of the inspection, specifically, the apparent lack of management control of the radiation safety program. The Commission's enforcement policy as specified in 10 CFR 2, Appendix C, was briefly discussed.

PROPOSED ENFORCEMENT CONFERENCE AGENDA

IVINSON MEMORIAL HOSPITAL

DECEMBER 15, 1989

2 P.M.

I.	INTRODUCTION AND PURPOSE OF MEETING	A. B. BEACH
II.	NRC DISCUSSION OF APPARENT VIOLATIONS	C. L. CAIN W. L. HOLLEY
III.	LICENSEE COMMENTS AND RESPONSE	THOMAS NORD
IV.	ENFORCEMENT POLICY	G. F. SANBORN
V.	CLOSING COMMENTS	A. B. BEACH