U. S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 88-01

Docket No. 030-11006 License No. 53-16421-01

EA No. 88-257

Licensee: Honolulu Medical Group
550 South Beretania Street
Honolulu, Hawaii 96813

Inspection at: Honolulu Medical Group, Honolulu, Hawaii

Inspection Conducted: September 16, 1988

Inspector: P. R. Zurakowski 10/7/88
P. R. Zurakowski, Radiation Specialist Date Signed

Approved by: R. D. Thomas 10/13/88
R. D. Thomas, Chief Date Signed
Nuclear Materials Safety Section

Summary:

Inspection of September 16, 1988 (Report No. 30-11006/88-01)

Areas Inspected: This was a routine unannounced inspection which was conducted to examine and assess the overall effectiveness of the radiation safety program. The areas examined included: organization; internal audits; training and qualifications of personnel; radiation protection procedures; use of materials; storage of materials; instruments; receipt and transfer of materials; personnel radiation protection; effluent controls and waste disposal; and required postings. The period reviewed was from the date of the last inspection on August 1, 1986 to the present.

Because the Chief of Nuclear Medicine, who is also the Radiation Safety Officer (RSO), was not present during the inspection, additional inspection effort was conducted with the RSO over the phone on September 30. and October 11, 1988.

Results: Eight apparent violations were identified during the inspection. The apparent violations are summarized as follows:

A. The Radiation Safety Committee had not been meeting on a quarterly basis during the first half of 1988. See Section 2.

B. Leak tests of sealed sources had not been conducted on a semiannual basis. See Section [illegible] (Repetitive Violation)

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C. The licensee's dose calibrator had not been tested for accuracy on an annual basis. See Section 9.

D. The Radiation Safety Committee with the assistance of the Radiation Safety Officer, had not reviewed the radiation safety program on an annual basis. See Section 3. (Repetitive Violation)

E. Records of waste disposal had not been adequately maintained. See Section 13.

F. Training had not been provided to the janitorial or nursing staff who work with or near licensed material. See Section 4.

G. During the absence of the licensee's one authorized user, procedures utilizing licensed material were performed by a technologist at the request of physicians not named in the license or on any other license as authorized users. See Section 5.

H. Radiation dose rate trigger levels had not been established for use with required radiation surveys. See Section 8.

DETAILS

1. Persons Contacted

*Mr. Ronald Haranda, Medical Group Administrator
*Mr. Rick Smith, Nuclear Medicine Technologist
*Mr. Darran Yamada, Environmental Health Specialist, State of Hawaii
Dr. Richard Littenberg, Medical Director; Chief of Nuclear Medicine; RSO
(contacted by phone on September 30, and October 11, 1988)

*Present at the exit conference.

2. Organization

The licensee has a small Nuclear Medicine program staffed by only two persons, an authorized physician and a Nuclear Medicine Technologist. There is a RSO and a Radiation Safety Committee (RSC) which oversees the radiation safety program.

The RSC is required by 10 CFR 35.22(a)(2) to meet on a quarterly basis. The licensee could not recall if meetings were held during the first and second quarters of 1988. A review of the RSC meeting minutes by the inspector revealed no evidence that RSC meetings had been held during the first and second quarters of 1988. This was identified as an apparent violation.

When the licensee's one authorized user left on vacation three days prior to the inspection, he asked a visiting nuclear medicine physician from a nearby hospital to act in his place for approximately two weeks.

During telephone discussions on September 30 and October 11, 1988, the RSO stated that the licensee's Professional Practice Committee and RSC both reviewed and approved the visiting physician's qualifications to perform procedures for which he had been authorized under another NRC license.

The RSO stated that records documenting the visiting physician's approval would be made available for examination at the enforcement conference.

One apparent violation was identified.

3. Internal Audits

License Condition 18 of Amendment No. 4 required audits under the ALARA program in accordance with Regulatory Guide 10.8, Revision 1. Specifically, two of the audits required are the following:

Audit	Frequency
Management review of programs	annually
RSO review of program	annually

During a records review on September 16, 1988, the inspector was unable to locate documentation indicating that the required audit was performed for 1986. The licensee was unable to recall if the 1986 audit had been performed.

The inspector reviewed an annual audit conducted by the licensee's consultant for 1987 and found it to be in accordance with 10 CFR 35.22.

Failure to perform the 1986 audit was identified as an apparent violation. A similar violation was identified during the last inspection conducted on August 1, 1986.

One apparent violation was identified.

4. Training and Qualification of Personnel

A review of the training program indicated that the licensee was not in compliance with the training requirements specified in the license for the years 1986 and 1987. The license requires, in part, that ancillary personnel, including nurses and janitorial staff, who have close contact with licensed material shall:

A. Be instructed in department layout.
B. Be instructed in restricted areas.
C. Be instructed in Basic Radiation Protection.
D. Be instructed as to the location and/or posting of pertinent NRC regulations and guides.
E. Be instructed to his/her obligation to report any unsafe condition.
F. Be instructed as to an appropriate response to emergency situations.
G. Be informed of their right to examine personal radiation exposure dosimetry and bioassay results.
H. Be informed of any changes concerning the above.

During telephone discussions on September 30 and October 11, 1988, the RSO was asked if the required training had been given and records maintained. No specific confirming information concerning the training sessions or records of training was provided. Therefore, this item was identified as an apparent violation.

One apparent violation was identified.

5. Use of Materials

The licensee's operations authorized by this license are conducted by the Nuclear Medicine Laboratory. The program is rather small in scope and is conducted by one Nuclear Medicine Physician and one Nuclear Medicine Technologist. The license was rewritten in the new 10 CFR Part 35 format by Amendment No. 5 which was issued on August 13, 1987. License Condition 12 lists Richard L.Littenberg, M.D. as the authorized user.

Also, 10 CFR 35.11 states in part that medical use of byproduct material shall only be authorized in accordance with a specific license issued by the NRC.

During a telephone discussion on September 30, 1988, the RSO stated he was not aware that beginning on August 13, 1988, his program needed to be conducted under the applicable requirements of the new Part 35. It appears that some of the problems identified during this inspection can be traced to this misunderstanding. This includes the requirement that the RSC now meet quarterly rather then twice a year as formally authorized.

A records review of the uses of licensed materials on September 14 and 15, 1988 during the extended absence of the authorized user, indicated that four procedures utilizing licensed material on patients were conducted by the Nuclear Medicine Technologist. The technologist stated during the inspection of September 16, 1988 that he was asked to perform these procedures by physicians employed by the Honolulu Medical Group but not named in the NRC license. The technologist further stated that to his knowledge the visiting physician had not been involved in the decision to conduct the procedures. Subsequent telephone conversations were held regarding this matter between J. Montgomery of the NRC staff and Dr. Littenberg, RSO, on September 30 and October 11, 1988. No confirming information has been provided by the RSO that would indicate the procedures were authorized in accordance with license condition 12 and 10 CFR 35.11.

One apparent violation was identified.

6 Leak Testing

The licensee uses sealed sources in the calibration of their dose calibrator. One of these sources of 200 µCi Cs-137 activity was found to have been tested for leakage on 11/19/86 and again on 6/25/87, an interval greater then 7 months. A sealed I-125 source with an activity greater that 100 µCi in December of 1987 was tested for leakage on May 1st and December 1st, 1987 a period greater then 6 months. Sealed sources containing activity greater then 100 µCi are required to be leak tested at intervals not greater then 6 months. The lack of proper leak testing of sealed sources was identified as an apparent violation of 10 CFR 35.59. A similar leak test violation was identified during the last inspection conducted on August 1, 1986.

One apparent violation was identified.

7. Storage of Materials

The security of licensed material was examined during this inspection in the Nuclear Medicine Laboratory and associated radioisotope laboratory. The security measures and practices used to safeguard licensed material were found to be compatible with regulatory requirements and good health physics practices.

No apparent violations were identified.

8. Radiation Protection Procedures

10 CFR 35.70(d) requires in part that the licensee establish radiation dose rate trigger levels for required radiation surveys. 10 CFR 35.70(h) requires in part that the licensee retain records of the trigger levels for at least three years.

During a telephone discussion on September 30, 1988 the RSO was asked if they had established trigger levels in the radioisotopes laboratory in the event of spills or other mishaps in this area as recommended by their consultant during the audit of January 29, 1988. The RSO commented that he had discussed the consultant's memo with the Nuclear Medicine Technologist. However, he was not sure if these trigger or action levels had been established.

One apparent violation was identified.

9. Instrumentation

During the inspection of September 16, 1988 it was found that the licensee's survey meter and dose calibrator were operable and in calibration. The calibrations are currently being conducted by the licensee's consultant and all required records were maintained in accordance with regulatory requirements.

However, the records indicated the consultant had conducted the yearly dose calibrator accuracy check on January 29, 1988. Contrary to 10 CFR 35.50 this required test had not been conducted for the years 1986 and 1987. This was identified as an apparent violation.

One apparent violation was identified.

10. Receipt and Transfer of Materials

Records of receipts and associated surveys were found to be maintained as required. No transfers of licensed material have been made by the licensee. The local radiopharmacy delivers unit doses to the Nuclear Medicine Laboratory Unused portions are held for decay in storage for future disposal as nonradioactive.

No apparent violation was identified.

11. Personnel Protection - External

A. Personnel monitoring records for the period from August 1986 to the time of the inspection were reviewed. The maximum quarterly whole body and extremity exposures observed in the records were 58 and 165 mrem respectively. Because the Nuclear Medicine Technologist handles the licensed material almost exclusively and gives the majority of the injections, his exposures are almost always the highest even though they are quite low. No records were observed to be missing. Lost or missing film badges have not been a problem in this program.

B. Personnel Protection - Internal

The licensee's procedures include, in part, that thyroid scans be conducted on medical personnel within 72 hours subsequent to their administering of therapeutic doses of Iodine-131. It was found that the licensee's consultant had identified a problem with the licensee's thyroid counting technique during the audit of January 29, 1988. The counting equipment used had not been evaluated properly to insure minimum detectability of 0.04 µCi. The licensee has arranged for the technologist, who is responsible for administering all therapeutic doses, to get scanned with a suitable calibrated unit at the Queens Medical Center. Since the audit, the technologist has conscientiously had the scan performed in a timely manner with a calibrated unit. Because the licensee discovered this problem and made prompt corrective action prior to the inspection a citation will not be issued.

No apparent violations were identified.

12. Radiation Surveys

Radiation and wipe surveys are required to be conducted in the Nuclear Medicine Laboratory and radioisotope laboratory. The licensee had been conducting the required surveys in a timely manner. Because of the small size of the licensee's program it was noted that these surveys consistently showed background readings or very low dose rates and wipe counts in the radioisotopes laboratory. However, it was noted by the inspector that the licensee had a spill of approximately 2 mCi of thallium-201 in the Cardiology Treadmill Room. The Treadmill Room is not part of the Nuclear Medicine Laboratory and the thallium-201, although used in 2 mCi doses 10 to 20 times a month, is accelerator produced material and is not under NRC jurisdiction. The lack of surveys in this room constitutes poor health physics practice. The licensee's RSO stated that the surveys would be conducted in the future.

No apparent violations were identified.

13. Effluent Controls, Waste Disposal

All radioactive waste having short half lives is held for decay for a minimum of ten half lives. It is then monitored and disposed of as nonradioactive waste if the radiation levels have reached background levels. Because of the small size of the program and the procurement of radiopharmaceuticals in unit doses, the waste is stored conveniently and securely in the radioisotopes laboratory in a small cabinet. This area was found to be properly secured and posted.

A review of the disposal records indicated that the licensee is not in full compliance with requirements of 10 CFR 35.92(b). Disposal records dated December 22, 1987 were deficient as follows:

A. The date that the byproduct material was placed into storage was not recorded.

B. The background dose rate was not recorded.

C. The survey instrument used for the survey measurements was not recorded.

One apparent violation was identified.

14. Posting of Notices

Posting in accordance with 10 CFR 19.11 was found to be acceptable.

During the telephone discussion on September 30, 1988 the RSO was asked if the Nuclear Medicine Laboratory was posted in accordance with 10 CFR 35.205(d) when the xenon apparatus was used for lung studies. The RSO indicated that the necessary calculations to show the air flow characteristics for the laboratory had been performed in conformance with regulatory requirements. However, he was not sure if the posting requirement had been fulfilled. This item is to be resolved.

No apparent violations were identified.

15. Transportation

The licensee has made no shipments of licensed material. All radiopharmaceuticals are delivered to the laboratory by a local radiopharmacy. The Nuclear Medicine Technologist stated that in the event of an incorrect shipment the radiopharmacy has agreed to pick up the shipment and transport it back to their own laboratory.

No apparent violations were identified.

16. Exit Interview

An exit interview was held with the Medical Group Administrator and the Nuclear Medicine Technologist at the conclusion of the inspection. The inspector discussed and summarized the scope and findings of the inspection and the apparent violations. The serious nature of unauthorized use of licensed material and the more restrictive nature of the new Part 35 were also discussed with the licensee.

17. Conclusions

Based upon the number and type of apparent violations identified during this inspection, two problem areas should be given more attention by the licensee: (1) increased management overview of the program, and (2) the RSO function should include more through audits of the complete program

The apparent violations identified during this inspection should have been identified by the licensee during routine audits.