U.S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 92-01

EA 92-242

License No. 53-00458-04

Docket No. 030-03537

Licensee: Department of the Army
Commander, Tripler Army Medical Center
Tripler AMC, Hawaii 96859-5000

Inspection Conducted: November 4, 5, 18, 25, and December 3, 1992

Inspector: Kent M. Prendergast, Radiation Specialist — Date Signed: 12/21/92

Approved: G. P. Yuhas — Date Signed: 12/21/92
Gregory P. Yuhas, Chief
Radioactive Materials Safety Branch

Areas Inspected: This was a routine unannounced radiation safety inspection. The areas examined included: organization; internal audits; training; material receipt, use and transfer; dose calibrator measurements; radiation surveys; personnel monitoring; leak tests and physical inventories; waste disposal; survey instruments and calibration; posting and labeling; independent measurements; and followup on a licensee report regarding lost brachytherapy seeds.

Results: One apparent violation for failure to perform adequate inventories of brachytherapy sources was identified (Section 16). Other areas examined appeared satisfactory and good radiation safety practices were noted. The inspector also observed improved cooperation and coordination between radiation oncology and health physics.

DETAILS

1. Persons Contacted:

*Colonel C. Jones, Deputy Commander of Clinical Services

*Major M. Young, Chief, Radiation Oncology

*Lt. Colonel C. Delaplain, Chief, Nuclear Medicine Service

*Major Daniel Fram, Radiation Oncology Physician

Donald Tolbert PH.D, Radiation Oncology

Lt. Colonel D. Berndt, Radiopharmacist

*Major Everett Gayle, Nuclear Medicine Staff Physician

*Captain John Mercier, Radiation Safety Officer

W. Waffird, Health Physics Staff

Major S. Shanahan, Head Nurse Ward 61 (Implant Therapy)

Major C. Stevenson, Head Nurse Ward 6 B-2 (Radiopharmaceutical Therapy)

* indicates presence at the exit interview

2. Organization

Tripler AMC's Commanding Officer is a Brigadier General and a medical doctor. Licensed activities are administered by the licensee's Radioisotope/Radiation Control Committee (R/RCC), which is chaired by the Deputy Commander - Clinical Services (DCCS). The Nuclear Medicine and Radiation Therapy Services are under the Department of Radiology. The Radioimmunoassay (RIA) Laboratory and the Blood Irradiator are under the Department of Pathology.

The Health Physics Office is staffed by the Radiation Safety Officer, and three health physics technologists. The license was amended on May 20, 1992, authorizing Captain John Mercier as the Radiation Safety Officer (RSO). The RSO reports to the Chief of Preventive Medicine for administrative matters and to the DCCS for matters related to radiation safety.

The R/RCC is staffed by the Chairman, RSO, and representatives from nursing, hospital administration, and authorized users from each type of use permitted under the license. The R/RCC meeting minutes were examined and the minutes documented that quarterly meetings were held and reviews required by 10 CFR 35.22(b) were satisfactorily accomplished.

No apparent violations or deviations were identified in this program area.

3. Audits

The licensee has an extensive audit program for all areas of radioactive material use. Management audits are conducted annually and audit findings are discussed during the R/RCC meetings. Audits are also performed by the Health Physics Department semi-annually. The audits used extensive checklists. Records of the latest audit performed by the Health Physics Department on September 25, 1992, were examined and the audit appeared comprehensive. The licensee appears to have a good audit program to ensure compliance with the NRC license and regulations.

No apparent violations or deviations were identified in this program area.

4. Training

The inspector evaluated the licensee's training program for radiation workers and ancillary personnel whose duties may require them to enter a restricted area. The licensee has an extensive training program providing initial and annual refresher training to about 350 individuals. The training included personnel in housekeeping, security, nursing, x-ray, laboratory, nd health physics. The training covered the general radiation protection requirements described in 10 CFR 19.12. Specialized radiation safety training is also provided to nursing and housekeeping personnel for radiation therapy involving implants and radiopharmaceuticals. The inspector reviewed selected training records for housekeeping and nursing personnel and the records were satisfactory.

The inspector visited the two nursing wards where implants and radiation therapy are routinely performed and observed that nursing procedures require specific training prior to entering the rooms where therapy patients are treated. Discussions with nursing personnel at these stations indicated the nurses were familiar with the concepts of radiation safety and had received the required training to perform their responsibilities in a safe manner.

The inspector examined training records for individuals authorized to use the blood irradiator. The records indicate that all users had received initial training provided by the manufacturer or subsequent training by the Health Physics Office. A review of test scores indicated the individuals understood the radiation safety precautions and operation of the machine.

The licensee appears to have a good training program. No violations or deviations were identified in this program area.

5. Use of Licensed Material

a. Nuclear Medicine and Radiopharmaceutical Therapy

The licensee's Nuclear Medicine Department includes a thyroid counting area, a large diagnostic area utilizing seven cameras, a xenon room, a radiopharmacy, and dose preparation and injection areas. The facility workload averages 20-30 patients daily. The licensee performs about two thyroid therapies per week using less than thirty millicuries of iodine 131 and about fifteen thyroid ablations per year. The licensee has set up one room on the nursing ward where all the thyroid therapies that require hospitalization are performed. The inspector examined the licensee's procedures for such therapies and reviewed a number of charts. The nursing staff was familiar with the safety precautions for such therapies. The procedure used numerous checklists and included redundant checks to insure the correct patient receives the correct dose. Safety precautions were posted in the patients charts and noted to be posted on the door of the room. The precautions addressed necessary steps for visitor control, contamination control, patient control, and special instructions. The safety precautions and radiation surveys appeared to meet the requirements in 10 CFR Part 35. Records of bioassays for individuals involved in the preparation or administration of iodine 131 were examined and considered satisfactory.

The inspector observed nuclear medicine personnel at work and noted good health physics practices. Syringe and vial shields were routinely used and labeling was appropriate. The inspector conducted surveys in nuclear medicine and the results agreed with the licensee's and confirmed good contamination control. Xenon 133 gas storage and administration areas appear to be adequately controlled. Records documented that the operation of the xenon collection system was checked monthly and that the xenon room ventilation rates are checked every six months. The room ventilation rates indicated the room remained at negative pressure. The licensee's emergency procedures and clearance times for a spill of xenon 133 were properly posted.

b. Brachytherapy

The inspector visited the licensee's Radiation Oncology Department and had discussions with the medical physicist and nursing personnel. The licensee uses one private room on the ward that is maintained permanently for brachytherapy. The room was posted with safety precautions to be taken for patients with therapeutic implants. Prior to entering the room, nursing personnel are required to have had appropriate training and be on the approved list. An NRC Form 3 was posted at the nursing station and personnel appeared knowledgeable in safety precautions for radiation implants. A review of selected brachytherapy records indicated that the safety precautions provided met the requirements contained in 35.410 and

35.415. Records of surveys documented that appropriate surveys were performed in accordance with 35.406 following implant and removal of brachytherapy sources. The discussions indicated that there is improved cooperation and coordination between radiation oncology and health physics. The inspector also noted that health physics personnel provide support and assistance for all brachytherapy implants and removals.

c. Blood Irradiator

The licensee's blood irradiator was examined and the entrance to the machine was appropriately posted and locked. A special key was required in order to operate the machine. Records of training were available to document that satisfactory training had been accomplished. Only individuals who had completed the training and were on the approved list had access to the key to operate the machine. A survey of the machine indicated low radiation levels at the surface of the machine. Radiation levels, measured by the inspector, during operation ranged from mostly less than 1 millirem per hour to 6.5 millirem per hour at the surface of the drawer where samples are placed for irradiation. Emergency procedures were appropriately posted.

No violations or deviations were identified in this program area.

6. Storage of Licensed Materials

Waste storage areas for RIA laboratories and nuclear medicine were inspected and found to be well maintained. Radiation warning signs were appropriately posted and the areas were properly secured. Records were available to document that appropriate surveys had been performed. The inspector performed radiation surveys and no anomalous exposure or contamination levels were encountered.

No violations or deviations were identified in this program area.

7. Material Receipt and Transfer

Packages containing radioactive materials are received by authorized individuals from nuclear medicine, radiation therapy, and the RIA laboratories. Opening procedures have been established and followed pursuant to 10 CFR 20.205(d). Records indicate that incoming packages are wiped and surveyed in accordance with 10 CFR 20.205. There were no transfers of radioactive materials to other facilities.

No violations or deviations were identified in this program area.

8. Dose Calibrator Measurements

The inspector reviewed the licensee's dose calibrator records for compliance with 10 CFR Part 35. Dose calibrator constancy, accuracy, linearity, and geometry measurements were performed by the

radiopharmacist at the required frequencies to meet 10 CFR 35.50. There were no instances where the linearity error exceeded five percent in records observed since the last inspection. The radiopharmacist prepares and routinely checks the activity of each radiopharmaceutical dosage in a dose calibrator before administration. It was also observed that the licensee's dose calibrator is computerized and that the required measurements and tests must be performed each day (e.g., moly-breakthrough and constancy) prior to using the dose calibrator. The program will not allow the calibrator to be used without performing the required tests and obtaining satisfactory results. Records were maintained and the signature of the RSO was observed on the linearity, accuracy and geometry dependence tests.

No violations or deviations were identified in this program area.

9. Survey Instruments and Calibration

The licensee maintains an ample supply of calibrated and operable survey meters. Appropriate survey instruments were available in all the facilities visited during this inspection. The instruments were randomly checked and appeared operational and within their calibration period. The inspector observed that survey instruments were checked with a dedicated check source as required by 10 CFR 35.51(c). Records were available to document calibration was performed in accordance with 10 CFR 35.51.

No violations or deviations were identified in this program area.

10. Radiation Surveys

Daily and weekly surveys required by 10 CFR 35.70 are conducted by nuclear medicine personnel. Trigger levels have been established for radiation and contamination surveys. The records documented that satisfactory surveys have been conducted and that corrective action was taken when trigger levels were exceeded. The Health Physics Office also conducts routine surveys to verify the adequacy of surveys being performed in nuclear medicine, radiation therapy, and RIA laboratories. The survey records examined were complete and included the date, the survey meter used, the area surveyed, trigger levels, survey results in mr/hr or disintegrations per minute per 100 square centimeters, and the name or initials of the individual who performed the survey. Records of surveys performed in nuclear medicine, radiation therapy, RIA laboratories, and waste storage were examined and considered satisfactory.

The licensee appears to have a good survey program. No violations or deviations were identified in this program area.

11. Personnel Monitoring

Tripler AMC uses the U.S. Army NVLAP approved dosimetry program to provide TLD's that are exchanged monthly. The RSO reviews the dosimetry

reports monthly and the reports are discussed during the quarterly meetings of the R/RCC. The maximum quarterly exposure since the last inspection was 87 mrem whole body, and 370 mrem finger. The records were complete and contained the information listed on the NRC-5 form. Records of nursing personnel involved with radiation therapy were also examined and exposures were noted to be low, mostly minimal. Based upon the records, the licensee practices ALARA.

No violations or deviations were identified in this program area.

12. Waste Disposal

The inspector visited two RIA laboratories where microcurie quantities of radioactive materials were disposed to the sanitary sewer. Records were available to document the receipt, use, and disposal of small amounts of radioactive liquid to the sewer. The records are also forwarded to the Health Physics Office to insure Part 20 limits are maintained. Solid wastes from these laboratories (iodine 125) are stored for decay five half lives before disposal to the normal trash, as permitted by their license. There has been no disposal of solid waste from these laboratories for many years.

Radioactive material from Radiation Oncology that is no longer used is returned to the manufacturer. Records were available to document Department of Transportation requirements are followed.

Waste from nuclear medicine including radiopharmaceutical therapy is held for ten half lives, labels and radiation markings removed, surveyed, and disposed in the hospital normal trash. Records examined were satisfactory and met the requirements of 10 CFR 35.92.

No apparent violations or deviations were identified in this program. area.

13. Sealed Source Inventory and Leak Testing

The licensee possesses a number of small sealed calibration and reference sources in nuclear medicine and numerous brachytherapy sources in radiation oncology. Leak tests are performed semiannually and inventories are conducted quarterly. Records examined indicated compliance with 10 CFR 35.59 and the NRC license.

The inspector also performed a partial inventory of sources in the Radiation Oncology Source Storage Room and the sources inventoried were as described in the inventory list. All sources requested on the inventory list were accounted for and the activity of the sources was as permitted by the NRC license.

No apparent violations or deviations were identified in this program area.

14. Posting and Labeling

The licensee maintains current copies of the NRC License, Operating and Emergency Procedures, and 10 CFR Parts 19 and 20. An NRC Form-3 and notice indicating where these documents could be viewed was posted in all areas visited where radioactive materials are used and/or stored. Posting and labeling of containers and radiation warning signs for storage areas and rooms where materials are used was in compliance with 10 CFR 20.203.

No apparent violations or deviations were identified in this program area.

15. Independent Measurements

The inspector conducted radiation surveys using a Ludlum Model 3 survey meter, calibrated on May 27, 1992. The surveys included; the Nuclear Medicine Department and Nuclear Pharmacy, the Radiation Oncology Source Storage Room, the Blood Irradiator Room, and three rooms where medical waste is stored for decay. The surveys indicated there were no abnormal radiation or contamination levels in any of the areas visited.

No apparent violations or deviations were identified in this program area.

16. Notification of Lost Brachytherapy Seeds

a. Chronology

* December 27, 1988, 144 iridium 192 seeds were received by the medical physicist containing 88 millicuries of iridium 192.

* January 11, 1989, 70 seeds were inserted into a patient.

* January 13, 1989, 70 seeds were removed from the patient and returned to the source storage room.

* August 16, 1989, a complete inventory of all seeds was performed. One hundred and forty four seeds were accounted for based on statements by the previous RSO.

* June 25, 1992, a special inventory of the iridium 192 seeds was performed. During the inventory, 91 of the original 144 seeds were present and 53 seeds were unaccounted for. On July 21, 1992, 39 more seeds were accounted for. The licensee was unable to account for 14 seeds.

* June 25-July 27, 1992, the licensee conducted an investigation to determine the disposition of the missing seeds.

* July 2, 1992, the newly appointed RSO notified the NRC regarding the missing seeds by telephone.

* July 10, 20, and 21, 1992, the iridium storage pig was determined to be defective. The pig was cut open and shavings analyzed resulting in 39 more seeds being accounted for. The licensee has accounted for 130 of the original 144 seeds. Fourteen seeds remain missing.

* July 27, 1992, 130 seeds were returned to Alpha Omega.

* July 28, 1992, a report was submitted to NRC documenting the results of the licensee's investigation.

b. Licensee Investigation

The licensee notified the NRC on July 2, 1992, that following a special inventory of brachytherapy sources, 14 iridium 192 seeds were unaccounted for. The licensee submitted a report on July 28, 1992, documenting their investigation of the missing sources. Their investigation included; an examination of records of receipt, use, inventories, surveys, dosimetry records, and statements by personnel in health physics and radiation oncology during the period between December 1988 and June 1992. The licensee was unable to determine the disposition of the missing seeds. The following were noted:

The brachytherapy seeds were received on December 27, 1988, and used on a patient on January 11, 1989. The seeds were removed from the patient on January 13, 1989, and were returned to source storage.

An examination by the current RSO of x-rays taken subsequent to the source removal procedure eliminated the possibility that the seeds had inadvertently remained in the patient.

There were no abnormal exposures observed in survey records or dosimetry records.

The licensee determined that a defective storage pig contributed to the problem of the missing seeds. The design of the pig allowed for sources to be stuck within the inner spaces of the pig. The failure to return the sources to the manufacturer following their use resulted in the deterioration of the plastic catheters that held the seeds, due to the constant exposure to radiation. When the catheters deteriorated, more seeds were released into the interior spaces of the storage pig. After cutting open the storage pig and analyzing the shavings, 130 seeds were accounted for. Fourteen seeds remain missing.

The licensee was unable to determine any information that indicated the missing seeds ever left the restricted area while their activity could be detected.

The licensee determined the best corrective action to prevent recurrence of this problem is to return the iridium 192 seeds to the

manufacturer promptly, following their use. If the iridium sources are present at the time of quarterly inventories, each individual source will be sighted and accounted for.

The Radioisotope/Radiation Control Committee reviewed and accepted the RSO's investigation and conclusions during the quarterly committee meeting held on August 11, 1992.

c. NRC Evaluation

The NRC inspector examined the licensee's report, held discussions with the previous RSO and medical physicist, reviewed records of inventories, surveys, and dosimetry and noted the following.

Based upon records and statements by personnel, the only procedure involving the seeds in question was performed on a patient during January 11-13, 1989. A review, by the inspector of the patient's x-rays and reports dated March 22, 1989, and March 6, 1990, confirmed there were no iridium 192 seeds inadvertently left in the patient. Dosimetry records for health physics and radiation oncology personnel did not reveal any anomalous exposures. Routine room surveys were normal and indicated no seeds remained in the room.

The previous RSO stated during discussions with the inspector that he performed a complete inventory and accounted for each seed on August 16, 1989. However, the licensee's subsequent quarterly inventories required by 10 CFR 35.59(g) were conducted, but did not detect the loss of the 14 seeds. Records indicated that inventories were performed on a quarterly frequency from 1989 to June 1992, however the routine inventory merely consisted of looking into the pig and noting that sources were present. The routine inventory did not include a physical sighting and count of each individual source as required by 10 CFR 35.59(g). The failure to account for each brachytherapy source during quarterly inventories is a violation of 10 CFR 35.59(g) (92-01-01).

The inspector calculated the combined activity of the 14 missing seeds to be about one millicurie on August 16, 1989, at the time of the last complete inventory. The 14 seeds, although they had decayed about three half lives, still represented a safety hazard during this period due to their high surface exposure rate which is about 4.8 Rem/hour/millicurie at one centimeter, based on the gamma constant for iridium 192. Using this number and the inverse square calculation the 14 seeds would measure about five millirem per hour at one foot. However, in June of 1992, the seeds had decayed about 17 half lives and would be undetectable with routine survey instrumentation. The inspector's review of all licensee records pertaining to the seeds disposition indicated no seeds left the restricted area.

The licensee's investigation, although unable to determine the location or disposition of the 14 missing seeds, appears

adequate. The licensee's corrective action also appears adequate and should preclude any further problems in this area. The inspector also noted that the individuals responsible for the missing seeds are no longer present at Tripler AMC. At the time of the inspection there appeared to be good cooperation between health physics and radiation oncology.

One violation of NRC requirements was identified in this area.

17. Exit Interview

On November 5, 1992, an exit interview was held with the individuals identified in Section 1 of this report. The inspector discussed the scope and the initial findings of the inspection. The inspector acknowledged improvements in the Radiation Safety Program and noted increased cooperation and coordination between radiation oncology and health physics. On December 3, 1992, the licensee was informed of the results of the NRC deliberations regarding the violation described in the Notice accompanying this report.