U. S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 94-01

Docket No. 030-01213

License No. 04-00181-04

Licensee: Veterans Administration Medical Center
Wadsworth Medical Center
Wilshire and Sawtelle Boulevards
Los Angeles, California 90073

Inspection at: Address Above

Inspector: Kent M. Prendergast
Kent M. Prendergast Radiation Specialist — Date Signed: 3/14/94

Approved by: G. P. Yuhas
Gregory P. Yuhas, Chief, Radioactive Materials Safety Branch — Date Signed: 3/14/94

Inspection Summary:

Special Inspection on February 2-3, 1994 (Report No. 030-01213/94-01)

Areas Examined: This special, unannounced inspection was conducted to examine the circumstances surrounding the licensee's discovery of five iridium 192 seeds on December 27, 1993. The licensee reported to the NRC on January 21, 1994, that the Associate Radiation Safety Officer (ARSO) had discovered five iridium 192 brachytherapy seeds containing about 2.5 millicuries (mCi) in a ribbon on the floor of the Brachytherapy Storage Room. The inspector also examined the licensee's records of brachytherapy source use, personnel monitoring, and organization, interviewed individuals involved in the Brachytherapy Program, and visited the brachytherapy source vendor.

Results: The brachytherapy seeds found on the Storage Room floor were from Shipment Number 8101, last used on October 1, 1993. There were no indications that patients or members of the hospital staff received any measurable exposure as a result of the inadequate control of the five brachytherapy seeds. There was no conclusive evidence that the five unshielded sources were ever outside the Brachytherapy Storage Room. While the event was considered an isolated incident, there were several factors that contributed to the lost seeds: (1) the Source Custodian's (SC) failure to inventory the sources and supervise brachytherapy activities; (2) limited oversight of brachytherapy activities by the Radiation Safety Office; and (3) incomplete records of source use. Three violations of NRC requirements were identified. The violations involved the failure to inventory the sources and the failure to maintain adequate records of source use and surveys. (See Section 5)

DETAILS

1. Persons Contacted

Licensee Personnel

*M. Bays, Associate, Director
*B. Herron, Assistant Director
*B. Krutoff, Teletherapy Physicist
D. Venkataran, Dosimetrist
*J. Basinski, Radiation Safety Officer
L. St. Royal M.D., Radiation Oncologist
*R. Nusbaum, Alternate Radiation Safety Officer

Others

Craig Haywood, Asst. Physicist
David Gallardo M.D., Physician
Troy Hedger, Physicist, Alpha Omega Services Inc.
Bruce Hedger, Physicist, Alpha Omega Services Inc.
Gregory Yuhas, Chief, Radioactive Materials Safety Branch, NRC Region V

* Present during exit briefing

2. Background and Purpose of Inspection

On January 21, 1994, the Veterans Administration Medical Center, Los Angeles, California (VALA) reported by telephone to the NRC Operations Center that on December 20, 1993, the ARSO had discovered five iridium 192 brachytherapy seeds in a ribbon lying on the floor of the Brachytherapy Storage Room. According to the report, each seed contained about 0.5 millicuries or 2.5 mCi total. The radiation dose rate was approximately 1 mr/hr at one meter from the ribbon. The licensee's brachytherapy records indicate that the last iridium brachytherapy was performed on October 1, 1993, and that all seeds were returned to the manufacturer, Alpha Omega Services. According to the RSO, routine licensee surveys and an NRC inspection of the brachytherapy storage area on December 8, 1993, did not indicate the presence of any iridium sources in the storage location. In its report, the licensee stated that it was continuing to investigate this incident.

This special inspection was conducted to evaluate the circumstances involving the discovery of the five iridium seeds, to examine VALA's Radiation Safety Program regarding the use of iridium 192 seeds, and to determine compliance with NRC requirements. The licensee was previously inspected by NRC Region V on December 8, 1993. During that inspection one violation involving the licensee's failure to properly document the transport of iridium 192 seeds (shipment number 8101) to Alpha Omega was identified. The specific violation included the failure to correctly document the activity of the seeds, list an the emergency response phone number, and provide the proper shipping name and UN Number. The NRC inspector recommended further oversight by the RSO for this area during the December 8, 1993, inspection.

3. Organization

The licensee has a very active Radiation Oncology Program with most radiation therapy treatments performed using a cobalt 60 teletherapy unit (under the Teletherapy License Number 04-00181-12), or a linear accelerator (not regulated by the NRC). The licensee treats two to four patients a year using brachytherapy techniques (sealed sources). Records of brachytherapy source use indicate that there were two brachytherapies performed in 1993.

The VALA Brachytherapy Program is conducted under the Radiation Oncology Program. The radiation safety activities associated with brachytherapy treatments are the responsibility of the Source Custodian (SC). The SC is responsible for maintaining an inventory of all brachytherapy sources, performing quarterly inventories, surveying the Brachytherapy Storage Room quarterly, and providing radiation safety support during brachytherapy. The SC is a medical physicist who routinely works in the Radiation Therapy Department under the Teletherapy License. However, the inspector noted that the brachytherapy sources are listed under the licensee's Broad Scope Nuclear Medicine License rather than the Teletherapy License. Based upon interviews with the RSO and individuals involved in brachytherapy, there was little oversight of brachytherapy activities by the Radiation Safety Office. It appears that the RSO's oversight of the brachytherapy program has been limited to monthly surveys of the Brachytherapy Storage Room and the semiannual leak tests of brachytherapy sources. The Radiation Safety Office was not involved in any of the activities associated with the September 29, 1993, brachytherapy source implant or the October 1, 1993, source removal. Further, the SC apparently was not an active participant in the source implant other than to perform a survey after the implant on September 29, 1993, and the SC was not present in the patient's room during the source removal conducted on October 1, 1993.

The RSO's failure to more tightly oversee brachytherapy activities, while not a violation, is one of the factors that contributed to the incident and is considered a program weakness that requires management attention.

4. Personnel Monitoring

The licensee's personnel radiation monitoring records were reviewed for the period from September 1993 through December 1993. The licensee assigns film badges to all personnel in the Radiotherapy Department. Individuals such as nurses and physicians who do not routinely wear a film badge are given a temporary badge, and the licensee maintains the exposure history for the individuals who wore the temporary badges. The badges are processed monthly by Landauer and the exposure reports are reviewed monthly by the physicist. A review of the personnel monitoring records for September 1, 1993 to December 31, 1993, indicated that personnel in the Radiation Therapy Department received very low exposures during this period. The highest exposure during the period was noted to be 20 millirem. During the review, two problems regarding exposure records were identified:

(1) the resident physician who had performed the brachytherapy treatment had lost his film badge in September 1993, but the loss was not recorded in his records, and the record indicated that his exposure for September 1993 was minimal. Licensee personnel stated that they had estimated his exposure. The Medical Physicist in charge of dosimetry stated they must have lost both the record of the lost film badge and the estimate of dose.

(2) One physician received 10 millirem on his badge during October 1993 but his record indicated minimal dose. According to the medical physicist, they had mistakenly failed to note that the physician had been assigned a temporary badge. The licensee corrected both of these mistakes during this inspection.

Although no violations of NRC requirements or unusual personnel doses were noted, the mistakes in the film badge records indicate a need for increased attention to detail and management oversight of this program area.

5. Lost seeds

The circumstances surrounding the discovery of five iridium seeds were reviewed in detail during the inspection. The inspectors examined the licensee's report regarding the iridium seeds (letter to NRC dated January 25, 1994); examined the patient's treatment chart; examined records of exposure; and interviewed radiation safety personnel involved in the source implant and removal, and individuals who provided care for the patient. The NRC inspectors also visited the source manufacturer to discuss its procedures for shipping and receipt of iridium 192 seeds.

a. On September 27, 1993, according to shipping records, Alpha Omega delivered 75 iridium 192 seeds to VALA. The seeds measured .289 mg/RA Eq/ per seed on September 27, 1993. The shipment was composed of 15 ribbons containing five seeds per ribbon (75 seeds) for a total activity of 37 mCi. The quantity of seeds delivered to VALA was confirmed by an autoradiograph viewed at the Alpha Omega facility. VALA records of receipt indicate that 75 seeds were signed for on September 27, 1993. The SC stated that a physical inventory of the seeds was not performed at the time the shipment was placed in the Brachytherapy Storage Room.

b. On September 29, 1993, according to records of brachytherapy use, 75 seeds were removed, still in the vendor's container, from the Storage Room and taken to Room 5665, where 10 ribbons (50 seeds) were implanted into a patient by a resident physician under the supervision of one of the authorized users. According to those interviewed, the resident physician and the authorized user were very careful in their procedures to ensure that each ribbon contained five seeds and that the ribbons were properly sealed in their catheters to preclude any inadvertent removal. Following the implant, the SC helped survey the room and place caution signs in the chart and on the door. According to these records, 25 sources

were placed in storage following the procedure and a survey was performed of the patient and surrounding areas. However, the records did not specifically indicate who removed the sources from the Storage Room, who returned them to the Storage Room, and who performed the survey. According to those interviewed, the iridium sources were removed from the Storage Room by the two physicians (mentioned above) and an assistant physicist, and returned by the same team. The inspectors interviewed the participants of the implant regarding their actions involving the unused iridium sources, but none of the individuals involved were able to recall whether anyone removed the unused ribbons from the perimeter of the vendor's container and placed them in the center hole of the vendor's container. The SC stated that his initial on the procedure record did not mean that he performed the required step, but only that he had requested the action and believed that it had been taken.

The following problems were identified in the licensee's records regarding the September 29 - October 1, 1993, brachytherapy treatment: (1) The licensee's records did not indicate the initials of the individual who actually returned the unused seeds to storage or who performed the survey after the implant. (2) The records indicated that 25 iridium sources were returned to the Storage Room on September 29, 1993, but according to those interviewed, there was no count or inventory of the unused sources that were returned to the Storage Room. The licensee's failure to inventory the sources upon return to the Storage Room contributed to a lack of information as to when the sources were actually lost. The licensee's failure to maintain records containing the initials of the individual who returned the sources to storage following the implant is considered a violation of 35.406(b)(3) (94-01-01).

c. On October 1, 1993, a resident physician under the supervision of the authorized user, with the help of a dosimetrist from the Therapy Department, moved the tool cart, a backup pig, and the Alpha Omega storage container assumed to contain the 25 unused iridium 192 seeds from the Brachytherapy Storage Room to Room 5665. According to the authorized user, the resident physician and the dosimetrist carefully removed 10 ribbons from the patient in Room 5665. The SC was not present in the patient's room for the source removal, according to the authorized user. The dosimetrist stated that after removing the ribbons from the patient, the ribbons were checked to ensure that they contained five seeds per ribbon. The resident physician stated he was sure that ten ribbons were removed and that the ribbons were placed in the lead storage container supplied by Alpha Omega. No one recalled ever placing one of the ribbons in the backup pig. Following the procedure, the dosimetrist obtained a survey meter and surveyed the patient and the room. The assistant and the physicians then reportedly returned the cart and the vendor's container to the Brachytherapy Storage Room. After returning the cart, the dosimetrist placed the vendor's container into the shipping container and closed the lid. The assistant

stated that he did not count the seeds returned to the Storage Room. According to the resident physician, the patient and Room 5665 were surveyed and that the radiation warning signs were removed. The resident was sure there were no lead storage pigs left in Room 5665. The resident physician stated that he did not recall placing the unused ribbons in either the central cylinder of the Alpha Omega container or the central cylinder of any other pig. Although 25 seeds were supposedly removed from the Storage Room, the records only indicate that 50 seeds were removed from the patient and put in the container with the unused ribbons and that 75 seeds were returned to the Storage Room. A survey of the patient was performed. The record of the patient survey indicated background radiation levels at one meter.

The following violations were identified during the review of the October 1, 1993, records. The October 1, 1993, implant removal records indicate neither the number of sources removed from storage, which is another example of a violation of 35.406(b)(1), nor the initials of the person who returned the iridium sources to the storage room as required by 35.406(b)(3). Also, the record of the patient survey did not indicate the type of survey instrument or the name of the individual performing the survey as required by 10 CFR 35.404 (94-01-02). Further, according to those interviewed, there was no inventory of the iridium sources when they were returned to storage to ensure that all of the iridium sources had been accounted for as required by 10 CFR 35.406(a) (94-01-03).

d. On October 21, 1993, the Source Custodian (SC) supposedly shipped seventy five seeds (29.6 mCi) in container B-11 from VALA to Alpha Omega Services, Inc. According to those interviewed, no inventory was performed on the sources prior to shipment and no one was able to recall placing the unused ribbons in the central cylinder of the Alpha Omega storage pig. According to the SC, the unused ribbons are normally cut and the unused seeds are placed in the center hole of the storage pig.

   The failure to inventory the sources prior to shipping contributed to the lack of knowledge regarding when the five missing seeds became separated from the shipment. The failure to inventory and the (the lack of detailed knowledge as to the handling of the seeds) in preparation for shipping to the manufacturer is a further indication that increased oversight is required.

e. On October 25, 1993, the ARSO performed a routine monthly survey of the source storage area. The survey indicated that the highest exposure rate observed in the room was 0.5 mr/hr at the L shield. The records also indicated that the area in front of the safe on the floor was wiped for contamination. During this survey all readings were considered normal. A similar survey was performed on November 25, 1993, which also indicated normal readings. The ARSO was convinced he would have detected the 5 seeds had they been stored in the backup pigs.

f. On December 8, 1993, the licensee was inspected by the NRC. As part of this inspection the NRC inspector surveyed the source storage room with a Ludlum Model 3 calibrated September 14, 1993. The survey was performed using a thin window G-M pancake probe. The survey included all areas within the storage room and all containers that may be used to store radioactive materials. The containers stored in one shielded area where a number of uranium trimmer bars were located were removed by the RSO to check in an area with lower background to obtain more sensitivity. These storage pigs were taken to the entrance of the storage room by the RSO where they were surveyed on the most sensitive scale. There was no activity detected on the surface or in any of the storage pigs. The NRC inspector also surveyed the adjacent storage room and all readings were background. During this inspection, there were no abnormal readings encountered in the room or the containers. All sources in the storage room were also inventoried and accounted for. The VALA RSO also performed surveys of the storage room with a TBM-3 survey meter and no abnormal survey meter readings were encountered.

g. On December 27, 1993, during the routine monthly survey of the source storage room, the ARSO noticed that the background radiation levels in the room adjoining the brachytherapy storage room were increased over normal levels. Using his survey meter the ARSO quickly determined the increased radiation levels were from five unshielded iridium seeds in one ribbon lying in plain view on the floor of the storage room. The seeds measured about 60 mr/hr at four inches using a Cutie Pie survey meter.

h. On January 6, 1994, following the licensee's investigation, the five extraneous seeds were returned to the supplier with instructions to accurately determine their activity. The supplier determined that the average activity of the seeds was 0.187 mCi per seed, which is consistent, accounting for decay, with Shipment Number 8101 which was used during the last therapy conducted on October 1, 1993. The color of the ribbon (red) was also consistent with Shipment Number 8101. The supplier checked its records for other users that may have been supplied with seeds of similar activity and color. According to the supplier, only two other users were shipped seeds of a similar activity, one in Cleveland, Ohio and one in Irvine, California. The Irvine ribbons contained eight seeds per ribbon, not five as had been used at VALA.

i. On February 1, 1994, Alpha Omega Services Inc. responded to VALA indicating that the seeds that had been returned to Alpha Omega on October 21, 1993, had been subjected to a spot check in which the batch first went thorough a physical count and were then weighed. The supplier reported that in both instances it appeared as though all seeds were accounted for.

j. On February 3, 1994, the NRC inspectors visited Alpha Omega Inc. to gather additional information regarding the five returned seeds. The VA RSO and ARSO accompanied the inspectors. During this visit,

Alpha Omega described its procedures for shipping and receipt, and provided the inspectors with an autoradiograph used to document that 75 iridium sources had been shipped to VALA. Alpha Omega's receipt procedures involve counting and weighing each shipment. However, the Alpha Omega RSO stated that it was possible, due to the number of shipments received, that the VALA shipment may not have been correctly counted. The inspectors also performed surveys with 1 mCi of iridium 192 placed in the backup pig that had been taken to Room 5665. Using a G-M survey meter, a reading of 4 mr/hr at the surface of the transport pig and 0.4 mr/hr at one foot were obtained by the NRC inspectors and the hospital RSO. Consequently, it seems likely that the seeds would have been detectable had they been present in a low background area in the source storage room. If the seeds were shielded in an area of high background radiation, such as in the shielded area where the uranium trimmer bars were located, the seeds may not have been detected.

Based on the findings of this inspection, the licensee lost control of five iridium 192 brachytherapy sources measuring about 2.5 millicuries, during the period from September 27 to December 27, 1993. It seems clear that all of the sources were removed from the patient. The sources were found in the licensee's Brachytherapy Storage Room, and neither dosimetry records nor other evidence indicates that personnel were exposed to the sources. The exact time the sources were lost could not be determined, because there were no complete inventories performed on the sources while they were in the licensee's possession. The factors that contributed to the loss appear to include: (1) the Source Custodian's failure to inventory and account for all iridium brachytherapy sources; (2) a lack of supervision and oversight of brachytherapy activities by the SC and the Radiation Safety Office; and (3) incomplete records regarding source use. Although not considered a contributing factor to the loss of control, the inspectors noted that a number of therapy personnel were aware of the location of the key to the Brachytherapy Storage Room. This created a problem in determining the number of individuals with access to the sources.

Three violations of NRC requirements were identified during the inspection of the events surrounding the discovery of five iridium seeds: (1) the failure to count the number of sources returned to the source storage room in accordance with 10 CFR 35.406(a); (2) the failure to maintain records of brachytherapy usage indicating the initials of the persons who withdrew the sources from the source storage room and returned them to it in accordance with 10 CFR 35.406(b); and (3) the failure to maintain records of surveys that included the type of survey instrument used and the initials of the individuals who performed the surveys in accordance with 10 CFR 35.404.

6. Exit Meeting

On February 3, 1994, an exit meeting was held with the persons noted in Section 1 of this report. The inspectors discussed the scope and initial findings of the overall inspection, including their conclusions regarding

the contributing factors for the loss of control of five iridium 192 seeds. The licensee was informed of the violations regarding their failure to inventory the seeds and maintain adequate records of brachytherapy source use. The licensee did not identify as proprietary any of the material provided to or reviewed by the inspectors during the inspection. Other items discussed during this meeting are described in Section 2 to 5 of this report.