U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-16055/94001(DRSS)

License No. 34-19089-01 Priority I Category B

Docket No. 030-16055

Licensee: Advanced Medical Systems, Inc. (AMS)
1020 London Road
Cleveland, OH 44110

Inspection At: Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio

Site Inspection Conducted: February 22 and 25, 1994

In Office Inspection Conducted: March 10 and 11, 1994

Inspector: Wayne Slawinski — 4-13-94
Wayne Slawinski, Senior Radiation Specialist — Date

Reviewed By: John R. Madera — 4-13-94
John R. Madera, Chief Materials Licensing Section — Date

Approved By: Roy J. Caniano — 4-13-94
Roy J. Caniano, Chief Nuclear Materials Safety Branch — Date

Inspection Summary

Inspection during the period February 22 - March 11, 1994 (Report No. 030-16055/94001(DRSS))

Areas Inspected: Special, announced, limited scope inspection to review the circumstances surrounding a licensee reported whole body occupational exposure in excess of regulatory limits. The inspection also included a review of licensee and contractor activities associated with the leak testing and subsequent transfer of several cesium-137 sealed sources to an Agreement State licensee in April 1993.

Results: A breakdown in certain administrative aspects of the licensee's radiation protection program and isolated instances of inadequate radiation safety officer oversight were identified. The problems caused or contributed to five occupational whole body radiation exposures in excess of regulatory quarterly limits. Four violations of regulatory requirements were identified (Sections 3 and 4).

DETAILS

1. Persons Contacted

Licensee Personnel

Steve Haddock, Isotope Technician
*Mark Loeser, Radiation Safety Officer (RSO)
*Sherry Stein, Director of Regulatory Affairs

Licensee Contractor Personnel

+ Angus Hinson, Manager, Corporate Environmental Health/Safety and Quality Assurance, Alaron Corporation
+ Mary Shepherd, Vice President, J. L. Shepherd & Associates
+ Jonathan Wallace, Radiation Safety Officer, Alaron Corporation

* Denotes those present at the exit interview on March 1, 1994.
+ Denotes telephone contacts only.

2. Purpose and Scope of Inspection

This was a special, limited scope inspection to review a licensee reported whole body overexposure to a contract worker involved in decontamination activities at its facility during the fourth quarter of 1993. The inspection also included a review of activities related to the leak testing and transfer of cesium-137 sealed sources to an Agreement State licensee in April 1993.

The inspection consisted of interviews of licensee and contractor personnel and reviews of applicable records and licensee procedures.

3. Summary of Overexposure

On November 19, 1993, the licensee notified NRC Region III of a whole body occupational dose in excess of 10 CFR 20.101(b) quarterly limits to a contract worker involved in decontamination and equipment installation activities at its London Road facility. A cumulative whole body dose of 3.075 rem was incurred by the worker during the period October 5, 1993 - November 11, 1993. The accumulated dose was based on vendor evaluated thermoluminescent dosimeter (TLD) data and licensee electronic dosimeter (alarming dosimeter) readings. An electronic dosimeter value was used as the dose of record, in part, because the worker failed to wear his assigned TLD on one occasion while conducting hot cell decontamination work. The overexposure was discovered by the licensee's RSO on November 17, 1993, during a review of work logs and TLD/electronic dosimeter records.

In addition to the 3.075 rem whole body overexposure to one worker, the inspection identified four other contract worker whole body exposures in excess of applicable 10 CFR 20.101(a), 1.25 rem whole body limits. The four other workers each received whole body exposures between 1.53 and 2.17 rem, while involved in hot cell cleanup and equipment installation activities during the fourth quarter of 1993. The licensee did not have Form NRC-4, or equivalent information, completed for any of these five workers.

The licensee's written report of the whole body exposure in excess of 10 CFR 20.101(b) limits (3.075 rem exposure) is provided as an attachment. This report satisfies 10 CFR 20.405 requirements for the 3.075 rem overexposure. However, as of April 8, 1994, the licensee failed to submit a report pursuant to 10 CFR 20.405, regarding the four whole body occupational exposures in excess of 10 CFR 20.101(a) limits (greater than 1.25 rem/quarter). The licensee was advised during the inspection on February 25, 1994 and exit meeting on March 1, 1994 that four other exposures in excess of applicable regulatory limits was identified.

10 CFR 20.405(a) requires, in part, that within 30 days, each licensee make a written report to the Commission concerning each exposure to radiation in excess of any applicable limit in Part 20 or in the NRC License. The licensee's failure to make a written report to the Commission of each exposure to radiation in excess of 10 CFR 20.101 limits within 30 days of its occurrence, is a violation of 10 CFR 20.405(a)(1)(i).

The NRC's evaluation of the worker exposures in excess of 10 CFR 20.101 limits, is provided in Section 4.

One violation of regulatory requirements was identified.

4. Evaluation of Overexposures

a. Oversight & Responsibility

In mid-1993, the licensee initiated efforts to dislodge a floor plug in the hot cell of its London Road facility. Removal of the plug is necessary so the licensee can gain access to the radioactive material stored within the plug and complete its initial physical inventory of radioactive material. Condition 14 of License No. 34-19089-01 requires that a physical inventory be conducted by June 1, 1993. Until the front plug is removed and the inventory completed, the licensee continues to be in violation of the inventory requirement.

Initial plug removal efforts were conducted by the licensee remotely, without physical entry into the hot cell, due to the cell's hazardous radiological environment. These efforts were unsuccessful. More extensive efforts to remove the stuck plug were initiated in October 1993, involving personnel entry into the

cell to perform decontamination work and install/repair equipment necessary to support the removal project. The licensee was assisted in these latter efforts by an NRC licensed contractor, who supplied ten health physics/decontamination technicians to conduct the work in the hot cell.

Subsequent to this inspection, the licensee claimed that the front plug removal project that began in approximately October 1993 was conducted under the contractor's NRC license and not the AMS license. AMS claimed that overall project management, oversight and responsibility was the contractors. Notwithstanding these claims, the NRC has determined that AMS had ultimate responsibility for the project because: (1) the contractors NRC license prohibited temporary job site work at customer facilities otherwise licensed by the NRC; and (2) no contractual agreement was developed and approved by the NRC, superseding or overriding the contractors temporary job site license restriction.

Although the contractor provided a site project supervisor for daily oversight of its personnel, AMS was responsible for overall project supervision and oversight under the terms and conditions of its NRC License No. 34-19089-01.

b. External Exposure Controls & Monitoring

The hot cell was remotely decontaminated to improve its radiological condition prior to personnel entry into the cell for additional decontamination, installation of temporary shielding and other equipment to supplement the plug removal project. Upon completion of remote decontamination, direct radiation levels in the cell ranged from 12-100 rad/hour. These levels were reduced to 5-10 rad/hour after further decontamination and installation of temporary shielding.

Personnel exposures while working in the hot cell were controlled through direct RSO oversight, stay time limitations based on measured radiation levels and use of alarming dosimetry.

Radiation work permits (RWPs) were developed for various phases of the project, stipulating the specific radiological control and monitoring requirements for the task. For example, RWP No. 93-26 and No. 93-30 were developed for hot cell decontamination and cell hoist installation activities respectively, each requiring the use of various personnel exposure monitoring devices consisting of whole body TLD/film badges, finger ring TLDs, self reading pocket dosimeters and alarming dosimeters.

According to the licensee, each hot cell worker was equipped with and required to wear self reading pocket dosimeters and TLDs to monitor wrist and ankle exposure and a TLD and alarming dosimeter to monitor whole body dose. TLDs were supplied and analyzed by a National Voluntary Laboratory Accreditation Program (NVLAP)

approved dosimetry processor, pursuant to 10 CFR 20.202(c). Whole body and extremity TLDs were exchanged and processed by the vendor on weekly and monthly cycles, respectively.

Hot cell entries were made on a near daily basis by the contract workers throughout October and early November 1993. During hot cell activities, the contractor's Project Supervisor was typically positioned at the ingress to the hot cell to monitor worker entry and departure. The AMS RSO was normally stationed in the cell control area so as to directly observe hot cell activities through the cell window. This oversight, however, was not always sufficient to ensure worker adherence to RWP requirements.

License Condition No. 19 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including any enclosures. A referenced letter, dated December 4, 1986, transmitted a revised Isotope Facility Safety Procedures Manual (ISP-1). Chapter 3.4 of ISP-1, Hot Cell Entry and Action Levels, requires that a job specific RWP be used for each hot cell entry. Chapter 7.2 of ISP-1, Personnel Monitoring, requires that all personnel entering controlled areas wear approved film badges.

The RWPs for the hot cell decontamination and hoist installation project which took place in the fourth quarter of 1993 (RWP No. 93-26 and No. 93-30), required that TLD/film badges be used to monitor whole body exposures.

Although monitored by the contractor's project supervisor and AMS RSO, contract workers did not always wear required TLD/film badges while conducting decontamination and hoist installation activities in the hot cell, a controlled area. Specifically, on the afternoon of October 7, 1993, a contract worker performed decontamination work in the hot cell and failed to wear his assigned whole body TLD dosimetry device. The failure to wear required personnel monitoring devices is a violation of License Condition No. 19.

The workers failure to wear assigned dosimetry was identified after the individual exited the hot cell and removed his protective clothing. Apparently, the worker's TLD was inadvertently left clipped to a different pair of trousers, worn during hot cell work earlier that day. Neither the worker, project supervisor or RSO identified the problem prior to the workers hot cell entry that afternoon. The alarming dosimeter worn by the individual during the afternoons hot cell work on October 7 measured a dose of 285 mrem. This value was assigned as the workers whole body dose that afternoon and added to the doses measured by the TLD worn by the worker during all other hot cell activities that calendar quarter.

Administrative dose limits for contractor personnel were originally established at 2 rem/quarter and later increased to 2.8 rem when the project's scope was expanded due to hot cell hoist failure and subsequent replacement. During early phases of the project in October 1993, alarming dosimeter alarm thresholds were set so workers would not exceed one-half the administrative dose limits. However, during later phases of the project in November 1993, alarm dosimeter set-points were established so as not to exceed the allowable administrative dose.

License Condition No. 19 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including any enclosures. A referenced letter, dated December 4, 1986, transmitted a revised Isotope Facility Safety Procedures Manual (ISP-1), which includes procedure ISP-14, Entering The Hot Cell.

Item 5.15 of ISP-14 requires that alarming dosimeters be set to alarm at an accumulated dose equal to ½ (2400 mrem minus the total dose for the quarter).

Notwithstanding the above procedure, on several occasions during the fourth quarter hot cell decontamination and hoist installation project, alarming dosimeters worn by individuals while working in the hot cell were set at alarm thresholds exceeding the value calculated using the ISP-14 equation. For example, on November 11, 1993, a hot cell worker's alarming dosimeter was set to alarm at about 600 mrem rather than 110 mrem calculated using the required equation.

According to the licensee, had alarming dosimeters been set to alarm at ISP-14 dictated values, workers would have been unable to conduct meaningful work in the cell during latter phases of the project because stay times would have been severely restricted. The RSO assumed that the alarming dosimeter alarm threshold dictated by ISP-14 could be altered as deemed necessary.

The licensee was aware that one worker failed to wear his TLD during a cell entry on October 7, 1993 and received a dose of 285 mrem as measured by electronic dosimetry; however, the RSO failed to account for this dose later in the project when establishing the alarming dosimeter set-points for this worker. The worker made multiple hot cell entries from October 5 - November 10, 1993. The RSC tracked the workers cumulative dose through TLD processing records and daily alarming dosimeter logs. Prior to the workers cell entry on November 11, the licensee assumed the individuals cumulative quarterly whole body dose was 2180 mrem, rather than the actual 2465 mrem. Consequently, the RSO believed the workers quarterly accumulated whole body dose was over 600 mrem shy of the 2800 mrem administrative dose limit. As a result, the worker was allowed to conduct hot cell activities on November 11 until his dosimeter alarmed at its preset 600 mrem

threshold. It was later discovered that the licensee failed to account for the 285 mrem exposure received on the afternoon of October 7, and that the worker's cumulative dose exceeded the 3 mrem quarterly limit of 10 CFR 20.101(b).

Contract worker TLD and alarming dosimeter results were reviewed by the inspector for the fourth quarter of 1993. Of the ten contract workers, four incurred cumulative whole body exposures between 1.53 and 2.17 rem and one, as discussed above, a dose of 3.075 rem. For the latter exposure, TLD results accounted for 2790 mrem and alarm dosimeter data for 285 mrem.

10 CFR 20.101(a) requires that the licensee limit the whole body radiation dose of an individual in a restricted area to one and one quarter rem per calendar quarter, except as provided by 10 CFR 20.101(b). 10 CFR 20.101(b) allows a licensee to permit an individual in a restricted area to receive a whole body radiation dose of three rem per calendar quarter provided specified conditions are met.

As described above, the licensee did not limit the whole body radiation dose of individuals working in its hot cell, a restricted area, to one and one quarter rem per calendar quarter and the conditions of 10 CFR 20.101(b) were not met.

Specifically, five contract workers each received whole body doses between 1.53 and 3.075 rems during the fourth calendar quarter of 1993.

The licensee requested Form NRC-4 information from the contractor and assumed the data it received was complete, the conditions of 20.101(b) were satisfied, and the applicable regulatory whole body quarterly dose limit for each contract worker was 3 rem. However, the licensee failed to verify that contractor supplied information satisfied 10 CFR 20.101(b) and 20.102(b) requirements for determination of prior dose for each contract worker. Although the licensee had 1993 exposure information for all ten contract workers and partial historical occupational exposure information for certain workers prior to 1993, the licensee failed to maintain complete Form NRC-4 or equivalent data, signed by each individual, showing each period of time after the individual attained the age of 18 in which occupational radiation dose was received. The licensee also failed, in several instances, to calculate on Form NRC-4, or equivalent, the previously accumulated occupational dose received by each individual and the additional dose allowed under 20.101(b), as required by 20.102(b)(1) and (b)(2).

c. Causes

The root and contributing causes of the five occupational exposures in excess of regulatory limits as determined during the inspection are described below.

The licensee's radiation protection program has been chronically understaffed for several years. This necessitates that the RSO fulfill all health physics responsibilities, most administrative radiation prctection duties and certain management oversight roles. As a result, program oversight problems continue to occur. Pressure to initiate the front plug removal project and enable completion of a physical inventory was also a contributor to the problems identified during this inspection. Specific examples contributing to the exposure control problem are as follows:

(1) Inadequate contractor oversight of its personnel.

(2) Inadequate RSO oversight of daily activities.

(3) Establishment of alarming dosimeter alarm set-points and administrative dose limits too close to the regulatory exposure limit.

(4) Inadequate review of worker occupational exposure data.

Examples (1) and (2) appear to be isolated instances since no other worker oversight problems were reported to have occurred during the plug removal project. As a result of example No. 3, little margin for worker dose uncertainty existed. This appears to have been a poor health physics decision.

Three violations of regulatory requirements were identified.

5. Sealed Source Leak Testing

The inspector reviewed licensee and contractor activities associated with the leak testing and transfer of several cesium-137 sealed sources to the contractor's agreement state facility in California. Details are provided below.

In April 1993, the AMS RSO and a representative from J. L. Shepherd & Associates, a California Agreement State licensee, jointly prepared four cesium-137 sealed sources for shipment from the AMS facility to J. L. Shepherd's facility in California. The cesium sources ranged in activity from 105 to 1156 curies, were stored in the "source garden" of the AMS facility and had not been used or leak tested for up to approximately 25 years.

AMS is required by License Condition No. 12 to test sealed sources for leakage before any use or transfer to another person, unless they have been leak tested within 6 months before the date of use or transfer. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which one might expect contamination to accumulate. The removable contamination leak test limit is 0.005 microcuries.

The cesium-137 sources were removed from the source garden and loaded into both AMS and Shepherd shipment containers (teletherapy unit heads) and dry smears were taken of those head surfaces which came in contact with the source, including the source rotor assembly. The rotor assembly is a surface on which contamination would accumulate should the source be leaking.

Smears were analyzed in the licensee's well counting system and showed no leakage in excess of regulatory limits. Inspector review of the licensee's smear analysis methods, equipment, leak test records and shipping documents disclosed no problems. Compliance with License Condition No. 12 leak test requirements appears to have been achieved.

The packages were shipped to the Shepherd facility with Shepherd acting as the consignor under their agreement state license. Upon receipt, Shepherd wipe tested the shipment heads and identified smearable contamination levels of up to 10,000 dpm (0.0045 microcurie) on the back of one of the source wheel rotor assemblies which housed the 105 curie source. The cesium-137 source itself contained in the shipment head, however, was not leak tested. The amount of removable contamination identified by the smear was slightly less than the regulatory sealed source leak test limit of 0.005 microcurie and consequently was not a reportable incident. Subsequent wipe tests of the shipment head by J. L. Shepherd identified lesser levels of removable contamination.

Both Shepherd and AMS speculate that the contamination identified upon package receipt was due to minor residual contamination within the source rotor assembly itself and was not the result of a leaking cesium-137 source. This appear to be a plausible explanation since portions of the shipment head (and source housing/rotor assembly) were decontaminated by AMS prior to their use to satisfy DOT shipping requirements. Consequently, it appears likely that some residual contamination not completely removed during head decontamination was present on the rotor assembly and/or interior surface of the shipment head where the source resides, and was detected during subsequent smear tests. There is no evidence to suggest, at this time, that the cesium-137 source leaked in excess of regulatory limits or that the exterior surfaces of the shipment package exhibited contamination in excess of DOT limits during transport.

As of March 11, 1994, the 105 curie cesium-137 source remains housed in the suspect head assembly and stored in a restricted area of the J. L. Shepherd facility. Shepherd plans to remove the cesium-137 source from its head assembly in the near future and conduct a source leak test at that time. Shepherd agreed to contact NRC Region III if actual source leakage was detected.

No violation of regulatory requirements was identified.

6. Exit Meeting

The inspector met with the licensee's RSO at the conclusion of the site inspection on February 25, 1994, and summarized the scope and findings of the inspection. On March 1, 1994, the inspector and a NRC Region III management representative met with those denoted in Section 1, to further discuss the inspection findings and their applicability to the NRC Enforcement Policy delineated in 10 CFR Part 2, Appendix C. During the latter meeting, one of the licensee's representatives indicated that the front plug removal project and related hot cell decontamination activities were conducted under the contractors NRC license and not the AMS license. The licensee contended that project oversight and any problems occurring during the project were the responsibility of the contractor. The NRC representatives acknowledged the comment and indicated that this matter would be reviewed further.

Attachment: As stated

Advanced Medical Systems, Inc.
121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 FAX (216) 466-0186

LICENSE FILE
Attachment

December 7, 1993

34-19089-01

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555

RE: ESTIMATED OVEREXPOSURE TO PERSONNEL REPORT
IN ACCORDANCE WITH 10 CFR 20.405
Advanced Medical Systems, Inc., USNRC License 34-19089-01

Dear Sirs:

For the past month-and-a-half, we have been involved in an attempt to dislodge a floor plug located within the AMS London Road facility hot cell. Since the inception of this project, we have consulted with and contracted Alaron Corporation.

Alaron Corporation has contracted a variety of junior H.P. techs and decon techs for the implementation of this project's objectives. A total of nine personnel have been contracted by Alaron Corporation.

The original scope of this project, as stated above, was for the removal of a floor plug in the hot cell. However, due to equipment failures, the scope of the project needed to be expanded. Based on the original scope, we set an administrative exposure limit of 2000mR per person. When the project scope was expanded, the administrative exposure limit was expanded to 2800mR. This limit extension was evaluated and authorized by Alaron Corporation. One member of the Alaron Corporation crew received an actual exposure based on TLD reports of 2790mR for the fourth quarter of 1993. However, the AMS RSO, upon reviewing Alaron's logs, discovered that on one occasion, this one individual did not wear his TLD into a high radiation area. No one noticed that the TLD was missing until the individual exited the high radiation area one time. With this entry into the high rad area, the individual received an approximate exposure of 285mR. This exposure is difficult to exactly determine because there was an alarming dosimeter that was reading approximately 40% to 50% too high. There is no way of determining if this individual used this alarming dosimetry. Therefore, the maximum extent of this individual's exposure for the fourth quarter of 1993 was 3075mR.

The initial objective did not require entry into the hot cell with the exception of passing material into and out of the hot cell. When the project scope and administrative exposure limits were expanded, it was anticipated that the hot cell would need remote decon and personnel entry into the hot cell for decon and installation of temporary shielding. Upon completion of remote decon, the rad levels inside the hot cell ranged from 100R/Hr to 12R/Hr. Upon completion of the temporary shielding installation, the radiation levels in the work area were between 12R/Hr and 5R/Hr.

The causes of the overexposure are as follows:

The first cause was due to an oversight by the Alaron senior project personnel for not insuring that the individual was wearing his TLD when entering the high rad area.

The second cause was the individual himself. When this individual made his first entry of the day into the high rad area in the morning, this individual had his TLD on. Before the individual made a second entry of the day, he had changed clothes and left the TLD on the first set of clothes.

The final cause was that all senior personnel did not remember that the individual had forgotten his TLD over a month previously.

A chronology of events is as follows:

5 October 1993	Individual reported to site.
7 October 1993	Afternoon - TLD not worn into high radiation area.
20 October 1993	TLD exposure report was compared to dosimetry records for entries. No one realized the discrepancy between TLD and dosimetry records was due to the individual not wearing his TLD. As stated above, we had an alarming dosimeter that was reading approximately 40% to 50% too high. We all suspected the individual had worn this alarming dosimeter.

NOTE 1: Prior to each entry into the high rad area, an ALARA meeting was conducted. The ALARA review would determine who would enter the area, the level of exposure monitoring to be employed, and the alarming dosimeter setpoints to be set for each individual entering the high rad area. Per the RWP, the alarming dosimeter setpoint was to be set less than allowable dose determined during the ALARA meeting.

NOTE 2: When TLD exposure reports were received, they were compared to dosimetry records for daily entries. There were several individuals that had significant differences between the TLD and alarming dosimetry. Some differed by as much as 40% for the week. Exposure and MPC's were closely monitored for all individuals entering the high rad areas.

11 November 1993 The individual made his last entry into the high rad area. It was his last day on site due to approaching the administrative exposure limit. As AMS' RSO, I wanted to review the dosimetry records and Alaron's logs for this individual. It was at that time I saw the note that the individual had not worn his TLD over a month before.

12 November 1993 The TLD's were sent via Federal Express to Landauer, Inc. for reporting.

16 November 1993 Exposure reports confirmed the suspected overexposure.

17 November 1993 Consultation with AMS personnel and Alaron personnel was conducted.

18 November 1993 Region III notified.

Upon evaluation of this event with Alaron Corporation Project Management, and the exact cause determined, a discussion was held with all personnel. The importance of individual responsibility for exposure control was discussed and stressed. Additional administrative controls have been initiated to more closely monitor an individuals use of TLD's and dosimetry and tracking of any individual not wearing a TLD in a restricted area.

Sincerely,

M. W. Loeser 12/9/93

M. W. Loeser
Radiation Safety Officer

MWL:jmb
cc: USNRC, Region III

mA Eagle Street • Geneva, Ohio 44041
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December 7, 1993

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555

RE: ES ATED OVEREXPOSURE TO PERSONNEL REPORT
IN ACCORDANCE WITH 10 CFR 20.405
Advanced Medical Systems, Inc., USNRC License 34-19089-01

Information about the individual that received the estimated overexposure is as follows:

Name: [redacted]

SSN: [redacted]

DOB: [redacted]

4th Quarter 1993 Exposure	3075mR
Total 1993 Exposure	3075mR

MWL:jmb