

APPENDIX E

INDUSTRIAL/ACADEMIC/RESEARCH INSPECTION FIELD NOTES

Region III

Inspection Report No. 96001

License No. 34-19089-01

Licensee (Name & Address):

Docket No. 030-16055

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, OH 44110

Licensee Contact Robert Meschter

Telephone No. 216-692-32370

Last Amendment No. 41

Date of Amendment April 4, 1996

Priority B-1

Program Code 03211

Date of Last Inspection 11/3/95

☐ Announced
☐ Routine
☐ Initial

☒ Unannounced
☐ Special
☐ Reinspection

Next Inspection Date ☒ Normal ☐ Reduced ☐ Extended

Summary of Findings and Action:

- ☐ No violations cited, Clear 591 issued
☐ Violation(s), 591 issued
☒ Violation(s), Regional letter issued
☐ Follow-up on Previous Violations

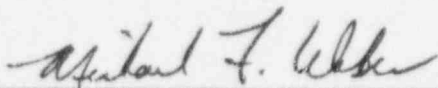
Were non-cited violations identified during this inspection?

☐ Y ☒ N

Was proprietary information reviewed by or received by the inspector?

☐ Y ☒ N

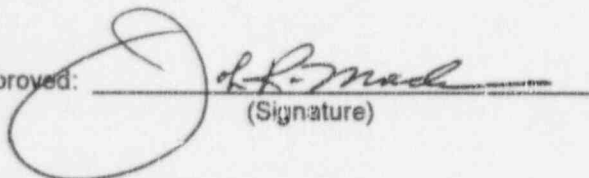
Inspector:


(Signature)

Date

5/15/96

Approved:


(Signature)

Date

5/20/96

1. INSPECTION HISTORY () N/A - Initial inspection

- A. Violations were identified during any of the last two inspections or two years, whichever is longer (X) Y () N

1. NCV - 12/4/95 ltr. - Failure to complete excavation of areas around facility by 7/7/95.
2. Violation - 11/29/94 ltr. - Failure to conduct an emergency exercise.
3. Violation - 7/26/90 ltr. - Failure to complete physical inventory.

- B. Response letter(s) or 591(s) dated: N/A

- C. Open violations from previous inspections:

1. Violation - 11/29/94 ltr. - Failure to conduct an emergency exercise.
2. Violation - 7/26/90 ltr. - Failure to complete physical inventory.

- D. Explain any previous violation(s) not corrected or repeated:

See DFI issued 9/27/95.

2. ORGANIZATION AND SCOPE OF PROGRAM

- A. Organizational Structure

*David Cesar - Vice President
*+Robert Meschter - RSO
+Steven Haddock - Isotope Handler
+Christopher Reed - Isotope Technician

+ Individuals contacted during inspection

* Individuals present at exit meeting

1. Meets license requirements [L/C] (X) Y () N
2. Multiple authorized locations of use and/or laboratories (X) Y () N
3. Briefly describe scope of activities, including types and quantities of use involving byproduct material, frequency of use, staff size, etc.

Current status: For the past three months or so, the three AMS workers at the London Rd. facility have spent most of their time dealing with the accumulation of water in the facility's underdrain system. Currently, five of the seven 3000 gallon plastic storage tanks residing in the warehouse area are filled with water. Lately, AMS has been filling 3-4 tank volumes per week, and discharging at the same rate. The discharges are delayed by at least four days, since the water must first be tested by both AMS and NEORS.

Regarding the use of licensed materials, AMS performed "beam-off" tests (see NCRP Report No. 33) with teletherapy heads and sources on the following dates in 1995: 3/2, 5/23, 4/9, 6/29, 7/26, 9/18, and 10/6. No tests have been performed in 1996. These tests are performed in the cage area. AMS received Co-60 sources on the following dates: 9/15/95, 10/6/95, and 3/18/96. AMS shipped Co-60 sources on the following dates: 9/20/95 (1427 Ci to NPI), and 10/18/95 (2449 Ci to Guatemala). The hot cell was not used for these transfers. Two additional sources are ready to be returned to NPI (pending AMS purchasing additional sources from NPI).

As discussed in AMS' 1/15/96 Strategic Plan, AMS' hot cell is operational for use in the decontamination of old sources.

- B. Radiation Safety Committee required [L/C] (X) Y () N
1. RSC fulfills license requirements [L/C] (X) Y () N
 2. Records maintained [L/C] (X) Y () N

D. Cesar - chair, R. Meschter - sec., S. Haddock, C. Berger - members. RSC meetings are held every quarter.

- C. Radiation Safety Officer
1. Authorized on license [L/C] (X) Y () N
 2. Fulfills duties as RSO (X) Y () N
- D. Use by authorized individuals [L/C] (X) Y () N

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- A. Instructions to workers/students per [10 CFR 19.12] (X) Y () N
- B. Training program required [L/C] (X) Y () N

1. If so, briefly describe training program:

Annual refresher training (general radiation protection) and annual respiratory protection training are required, as a minimum.

2. Training program implemented (X) Y () N
 3. Periodic training program required (X) Y () N
 4. Periodic training program implemented (X) Y () N
 5. Records maintained (X) Y () N
- C. Individuals understanding of procedures and Regulations is adequate (X) Y () N
1. Current operating procedures (X) Y () N
 2. Emergency procedures (X) Y () N
 3. Use of survey instrumentation (X) Y () N
- D. Revised Part 20 - Workers cognizant of requirements for:
1. Radiation Safety Program [20.1101] (X) Y () N
 2. Annual dose limits [20.1301, 1302] (X) Y () N
 3. New forms 4 and 5 (X) Y () N
 4. 10% monitoring threshold [20.1502] (X) Y () N
 5. Dose limits to embryo/fetus and declared pregnant worker [20.1208] (X) Y () N
 6. Grave Danger Posting [20.1902] (X) N/A
 7. Procedures for opening packages [20.1906] (X) Y () N
 8. Sewer disposal limits [20.2003] (X) Y () N

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

- A. Audits are required [L/C] () Y (X) N

- B. Audits or inspections are conducted () Y (X) N

"Formal" audits are not conducted; however, the RSO indicated that, as a normal part of his work, he audits the records continually to make sure that the required surveys, checks, etc., are done.

- C. Content and implementation of the radiation protection program reviewed annually by the licensee [20.1101(c)] (X) Y () N

- D. Records maintained [20.2102] (X) Y () N

RSC minutes

5. FACILITIES

- A. Facilities as described in license application [L/C] (X) Y () N

- B. Describe any Self-contained dry-source-storage irradiators [Part 36] and/or survey instrument calibrators (model, radionuclide, activity, use, etc.) (X) N/A

6. MATERIALS

- A. Isotope, chemical form, quantity and use as authorized [L/C] (X) Y () N

- B. Licensed materials secured to prevent unauthorized removal or access [20.1801, 1802] (X) Y () N

Security - In the past six months or so, AMS has upgraded its security system by installing motion detectors and sirens in the office and loading dock areas, adding additional metal intrusion bars on the garage door, adding additional door interlocks, etc. The security system is serviced and monitored by ADT.

- C. Leak tests and Inventories [L/C]
1. Performed as required (X) Y () N
 2. Adequate analysis methodology and sensitivity (X) N/A
 3. Records maintained [L/C] (X) Y () N

Inventory - AMS uses a computerized decay-corrected inventory based on information from the last physical inventory which was completed (with the exception of the stuck front plug) in 1993.

7. RADIATION SURVEYS

- A. Instruments and equipment:
1. Appropriate operable survey instrumentation possessed and readily accessible [L/C] (X) Y () N
 2. Calibrated as required [20.1501, L/C] (X) Y () N

Survey instruments are calibrated every six months by GTS Instrument Services, Pittsburgh, PA.

3. Calibration records maintained [20.2103(a)] (X) Y () N

B. Briefly describe area survey requirements [20.1501(a), L/C]:

Various alarms (gamma alarms, air monitors, equipment and security alarms, etc.) are checked daily. Controlled areas are surveyed semimonthly. Restricted areas are surveyed monthly.

C. Performed as required [20.1501(a), L/C] (X) Y () N

1. Contamination found () Y (X) N
2. Corrective action taken and documented () Y () N

D. Records maintained [20.2103, L/C] (X) Y () N

E. Protection of members of the public

1. Licensee made adequate surveys to demonstrate either (1) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (2) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [20.1301(a)(1), 1302(b)] (X) Y () N
2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] (X) Y () N
3. Records maintained [20.2103, 2107] (X) Y () N

8. RADIOACTIVE WASTE () N/A

A. Disposal () N/A

1. Decay-in-storage (X) N/A
2. Special procedures performed as required [L/C] (X) Y () N

AMS has discharged onto its parking lot approx. 100,000 gallons of water from its new underdrain system since last fall. Prior to discharge, the water is tested by AMS and NEORS. By Court Order, the Co-60 concentration must be < 100 pCi/l. The Co-60 must also be soluble in water per 10 CFR 20.2003.

3. Liquid scintillation (LS) media and animal carcasses per [20.2005] (X) N/A
4. Improper/unauthorized disposals [20.2001] () Y (X) N
5. Records maintained [20.2103(a), 2108, L/C] (X) Y () N

B. Effluents () N/A

1. Release into sanitary sewer [20.2003] (X) Y () N
 - a. Material is readily soluble or readily dispersible [20.2003(a)(1)] (X) Y () N
 - b. Monthly average release concentrations do not exceed Appendix B values [20.2003] (X) Y () N
 - c. No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year [20.2003] (X) Y () N
 - d. Procedures to ensure representative sampling and analysis properly implemented [20.1501(a)(2), L/C] (X) Y () N

See comments above in Item 8.A.

2. Release to septic tanks [20.2003] () Y (X) N
3. Waste incinerated () Y (X) N
4. Control of effluents and ashes [20.1201, 1301, 1501, 2001, L/C] (See also IP 87102, RG 8.37) (X) Y () N

a. Compliance with air emissions requirements in Part 20:

Licensee has demonstrated compliance with air emission requirements in 10 CFR Part 20 (X) Y () N

Basis for compliance determination (circle one or more; provide basis below)

- (1) Measured concentrations of radionuclides in air effluents are below Appendix B, Table 2 concentrations (and external dose < 50 mrem/yr)
- (2) Bounding calculations show that air effluents could not exceed Appendix B, Table 2 concentrations (and external dose < 50 mrem/yr)
- ☒ (3) Dose modeling shows that dose equivalent to the individual likely to receive the highest dose does not exceed 10 mrem/yr
- (4) Licensee does not possess sufficient radioactive material to exceed Part 20 requirements

b. Description of effluent monitoring program

1. Monitoring system hardware equipment adequate (X) Y () N
2. Equipment calibrated as appropriate (X) Y () N
3. Air samples/sampling technique (charcoal, HEPA, etc.) analyzed with appropriate equipment (X) Y () N

Water - As discussed above in Item 8.A.2, prior to discharge, the water from the new underdrain system is tested by AMS and NEORS. AMS counts its samples on an in-house gamma spectroscopy system. If Co-60 is detected above the limits discussed above, AMS has the samples analyzed by its contract laboratory.

Air - Air from the hot cell, etc., is continually monitored. The monitoring system consists of a vacuum pump which pulls air through a filter, and a radiation detection instrument which counts the filter. If the counts from the filter exceed a threshold, an alarm sounds, and various exhaust and supply fans are stopped. This system is checked monthly. In the case of an electrical power failure, this system is powered by a natural gas burning emergency generator.

C. Waste Management () N/A

1. Waste compacted [L/C] () Y (X) N
2. Storage area(s) () N/A
 - a. Protection from elements and fire [L/C] (X) Y () N
 - b. Control of waste maintained [20.1801] (X) Y () N
 - c. Containers properly labeled and area properly posted [20.1902, 1904] (X) Y () N
 - d. Package integrity maintained [L/C] (X) Y () N

AMS has constructed a large, wooden frame on the back parking lot which will be used to hold the dirt from the 1995 excavation project. The frame will be lined (top & bottom) with plastic sheets.

3. Packaging, Control and Tracking [App. F.III]
[20.2006(d)]:

- | | | |
|----|---|-------------|
| a. | Not packaged for disposal in cardboard or fiberboard boxes [61.56(a)] | (X) Y () N |
| b. | Liquid wastes solidified, i.e., less than 1% freestanding liquid, and void spaces minimized [61.56(a), (b)] | () Y (X) N |

The water in the WHUT room has not yet been solidified, although AMS is looking at this option.

- | | | |
|----|--|-------------|
| c. | Does not generate harmful vapors [61.56] | (X) Y () N |
| d. | Structurally stable (will maintain its physical dimensions and form under expected disposal conditions) [61.56(b)] | (X) Y () N |
| e. | Packages properly labeled [App. F.III.A.2] | (X) Y () N |
| f. | Licensee conducts a QC program to ensure compliance with [61.55, 56] and includes management evaluation of audits [App. F.III.A.3] | (X) Y () N |
| g. | Shipments not acknowledged within 20 days after transfer are investigated and reported [App. F.III.A.8] | (X) N/A |

4. Transfers to land disposal facilities (X) N/A

- | | | |
|----|---|-------------|
| D. | Records of surveys and material accountability are maintained [20.2103, 2108] | (X) Y () N |
|----|---|-------------|

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- | | | |
|----|---|---------|
| A. | Describe how packages are received and by whom: | () N/A |
|----|---|---------|

Sources are transported in source exchangers. The dose rate of the package is first checked (compared with the TI) by AMS workers, and then wipe tests are done on the package and truck bed.

- | | | |
|----|---|-------------|
| B. | Written package opening procedures established and followed [20.1906(e)] | (X) Y () N |
| C. | All incoming packages with DOT labels <u>wiped</u> , unless exempted (gases and special form) [20.1906(b)(1)] | (X) Y () N |
| D. | Incoming packages surveyed per [20.1906(b)(2)] | (X) Y () N |
| E. | Monitoring in (C) and (D) above, performed within time specified [20.1906(c)] | (X) Y () N |
| F. | Transfer(s) between licensees performed per [30.41] | (X) Y () N |
| G. | All sources surveyed before shipment and transfer [20.1501(a), 49 CFR 173.475(l), L/C] | (X) Y () N |
| H. | Records of surveys and receipt/transfer maintained [20.2103(a), 30.51] | (X) Y () N |

- I. Transfers within licensee's authorized users or locations performed as required [L/C] (X) N/A
- J. Arrangements made for packages containing quantities of radioactive material in excess of Type A quantity [20.1906(a)] (X) Y () N
- K. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] (X) Y () N
10. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-189) () N/A
- A. Licensee shipments are:
- (X) delivered to common carriers
() transported in licensee's own private vehicle
() both
() no shipments since last inspection
- B. HAZMAT training [172.700-704] (X) Y () N
- C. Packages () N/A
1. Authorized packages used [173.415, 416(b)] (X) Y () N
2. Performance Test records on file () N/A
- a. Special Form Sources [173.476(a)] (X) Y () N
- b. DOT-7A packages [173.415(a)] (X) Y () N
3. COCs on file with NRC for Type B [71.12(c)(1)] (X) Y () N
4. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class [172.403, 173.441] (X) Y () N
5. Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee) [172.301, 306, 310, 312, 324] (X) Y () N
6. Closed and sealed during transport [173.475(f)] (X) Y () N
- D. Shipping Papers () N/A
1. Prepared and used [172.200(a)] (X) Y () N
2. Proper (Shipping name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and chemical form, Activity, Category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable)) [172.200-204] (X) Y () N
3. Readily accessible during transport [177.718(e)] (X) Y () N
- E. Vehicles () N/A
1. Placarded [172.504] (X) Y () N
2. Cargo blocked and braced [177.842(d)] (X) Y () N
3. Proper over packs (shipping name, UN Number, labeled, statement indicating that inner package complies with specification packaging) [173.25] (X) Y () N
- F. Any incidents reported to DOT [171.15, 16] (X) N/A

11. PERSONNEL RADIATION PROTECTION

- A. Licensee performed exposure evaluation [20.1501] (X) Y () N
- B. Licensee incorporated ALARA considerations in the Radiation Protection Program [20.1101(b)] (X) Y () N
- C. External Dosimetry () N/A
1. Licensee monitors workers [20.1502(a), L/C] (X) Y () N
 2. External exposures account for contributions from airborne activity [20.1203] (X) Y () N
 3. Supplier Landauer Frequency Monthly
 4. Supplier is NVLAP-approved [20.1501(c)] (X) Y () N
 5. Dosimeters exchanged at required frequency [L/C] (X) Y () N
- D. Internal Dosimetry () N/A
1. Licensee monitors workers [20.1502(b), L/C] (X) Y () N
 2. Briefly describe licensee's program for monitoring and controlling internal exposures

Air samplers are used when workers enter a contaminated area. In addition, annual whole body counts or bioassays (urine tests) are performed. However, for one of the AMS workers, the last whole body count was performed on 10/24/94. According to the RSO as well as the worker involved, the bioassay was missed due to an oversight. As soon as this error was detected, the worker ordered the urine bioassay kit and updated the "To Do" list on AMS' computer. The safety significance of this apparent violation is mitigated by the following facts: (1) all of the annual bioassay results for the other workers for the past two years were less than the MDA, and (2) the personnel air monitoring results for 1994, 1995 and 1996 did not reveal any abnormal readings.

3. Air sampling performed (X) Y () N
 4. Monitoring/controlling program implemented (X) Y () N
 5. Respiratory protection equipment [20.1703, L/C] (X) Y () N
- E. Reports () N/A
1. Reviewed by RSO and workers Frequency monthly
 2. Inspector reviewed personnel monitoring records for period 1/1/94 to 3/31/96
 3. Prior dose determined for individuals likely to receive doses [20.2104] (X) Y () N
 4. Maximum exposures TEDE

1994 - 0.98 rem TEDE

1995 - 0.66 rem TEDE, 6.12 rem extremity

The majority of the 1995 extremity dose was received during the decontamination of the basement where a "pellet" was found with a contact reading of 50 rem/hr. The pellet was placed in a waste drum, behind the shielding wall in the basement. During this decontamination work, the workers used whole body TLDs, pocket dosimeters, and ankle badges.

1996 - 140 mrem whole body year-to-date (3/31/96)
- 321 mrem extremity year-to-date (4/4/96)

5. Maximum CDE Organs see above
6. Maximum CEDE see above

6. Maximum CEDE see above
7. Licensee sums internal and external [20.1202] (X) Y () N
8. TEDEs and TODEs within limits [20.1201] (X) Y () N
9. NRC Forms or equivalent [20.2104(d), 2106(c)]
- a. NRC-4 (X) Y () N Complete: (X) Y () N
- b. NRC-5 (X) Y () N Complete: (X) Y () N
10. Worker declared her pregnancy in writing during inspection period (review records) (X) N/A
- If yes, licensee in compliance with [20.1208] () Y () N
- and records maintained [20.2106(e)] () Y () N
- F. Who performed PSEs at this facility (number of people involved and doses received) [20.1206, 2104, 2105, 2204] (X) N/A
- G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, L/C] (X) Y () N

12. NRC INDEPENDENT MEASUREMENTS

- A. Survey instrument Serial No. Last calibration
- Ludlum Model 19 micro R meter 30761 11/17/95
- B. Inspectors' measurements were compared to licensee's (X) Y () N

- C. Describe the type, location, and results of measurements:

The following are NRC measurements:

Inside building:

Border of cage area - 120 uR/hr
 Bladders - 5 uR/hr
 Water storage tanks - 5 uR/hr
 Boundary of LLW storage room - 60 uR/hr
 Back entrance to Isotope Shop - 100 uR/hr
 Boundary of HLW storage room - 150 uR/hr
 Hot cell window - 50 uR/hr
 Isotope Shop window - 220 uR/hr
 Warehouse - 10 uR/hr
 Border of restricted area at loading dock - 100 uR/hr
 Border of restricted area at loading dock near sump pump - 200 uR/hr

Outside building:

Contaminated dirt boundary - 60 uR/hr
 Border of restricted area outside Isotope Shop - 120 uR/hr
 South area - 60 uR/hr
 Southeast area - 150 uR/hr
 Near entrance - 20 uR/hr
 London Rd. - 15 uR/hr
 Mandalay & London Rd. - 10 uR/hr
 Atlas parking lot near grape vines - 15 uR/hr

The following are AMS measurements (from recent survey records):

First floor doorway outside shielded work room - 0.2 mR/hr
 Change room entrance to ISA - 2 mR/hr

Second floor center of office area - 1 mR/hr
 WHUT room door - 50 k dpm/100 cm²
 North end of HEPA room - 1 R/hr
 West side of back basement - 1 R/hr
 HLW storage room center - 4 R/hr
 Outside of building - < 0.02 mR/hr

13. NOTIFICATION AND REPORTS

() N/A

- A. Licensee in compliance with [19.13, 30.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20) (X) Y () N
- B. Licensee in compliance with [20.2201, 30.50] (theft or loss) (X) None
- C. Licensee in compliance with [20.2202, 30.50] (incidents) (X) Y () N
- D. Licensee in compliance with [20.2203, 30.50] (overexposures and high radiation levels) (X) None
- E. Licensee aware of NRC Ops Center phone number (X) Y () N

14. POSTING AND LABELING

- A. NRC-3 "Notice to Workers" is posted [19.11] (X) Y () N
- B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted or a notice indicating where documents can be examined is posted [19.11, 21.6] (X) Y () N
- C. Other posting and labeling per [20.1902, 1904] and the licensee is not exempted by [20.1903, 1905] (X) Y () N

15. RECORD KEEPING FOR DECOMMISSIONING

- A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] (X) Y () N
- B. Records include all information outlined in [30.35(g)] (X) Y () N

16. BULLETINS AND INFORMATION NOTICES

- A. Bulletins, Information Notices, NMSS Newsletters, etc., received by the Licensee (X) Y () N
- B. Licensee took appropriate action in response to Bulletins, Generic Letters, etc. (X) Y () N

17. SPECIAL LICENSE CONDITIONS OR ISSUES

() N/A

A. Special license conditions or issues to be reviewed:

Emergency Plan - The inspectors checked the general condition of the pump house (the offsite emergency response control center). The pump house contains a large emergency kit (containing survey meters, batteries, PDRs, a respirator, signs, clothing, money, rope, first aid equipment, etc.), a working phone (installed last Oct.), and various alarms. The alarms are monitored by ADT and become activated if the pumps run (this would occur if the sprinkler system at AMS failed to operate) or if the pumps have been tampered with.

B. Evaluation:

No problems were identified.

18. CONTINUATION OF REPORT ITEMS

() N/A

Sampling of frac tank 695 - The inspectors took six 0.5 liter water samples at varying depths. The water in the tanks had been recirculating for approximately 72 hours. In the Region III laboratory, each water sample was tested for solubility. As shown in the following table, Co-60 was not detected on the filters.

TANK	SOURCE OF SAMPLE	SAMPLE TYPE	RESULT	MDA (pCi)
695 top	NRC	Filter	<MDA	1.6
695 top	NRC	Filter	<MDA	1.6
695 middle	NRC	Filter	<MDA	2.4
695 middle	NRC	Filter	<MDA	1.6
695 bottom	NRC	Filter	<MDA	2.0
695 bottom	NRC	Filter	<MDA	1.9

19. VIOLATIONS, NCVs, AND OTHER ISSUES

() N/A

Note: Briefly state (1) the requirement and (2) how and when the licensee violated the requirement. For non-cited violations, indicate why the violation was not cited.

Violation: LC 23 (tie down of 3/27/91 letter) - Failure to perform annual bioassay for AMS worker (See Item 11.D, above)

20. DEBRIEF WITH LICENSING STAFF

Inspection findings discussed with licensing staff

(X) Y () N

Items discussed: Complete inspection

21. EPA REFERRAL FORM

EPA referral form for air effluents sent to appropriate
EPA regional office per IP 87102

(X) Y () N

22. PERFORMANCE EVALUATION FACTORS

Licensee (name & location)

Inspectors: J. Madera, M. Weber

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, OH 44110

Inspection Dates: 4/29-30/96

- | | | |
|----|---|-------------|
| A. | Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight | () Y (X) N |
| B. | RSO too busy with other assignments | () Y (X) N |
| C. | Insufficient staffing | () Y (X) N |
| D. | Radiation Safety Committee fails to meet or functions inadequately | () Y (X) N |
| E. | Inadequate consulting services or inadequate audits | () Y (X) N |

Remarks (consider above assessment and/or other pertinent PEFs):

Regional follow-up on above PEFs citations:

END

May 22, 1996

Lawrence K. English
Assistant General Counsel
Northeast Ohio Regional
Sewer District
3826 Euclid Avenue
Cleveland, Ohio 44115-2504

Dear Mr. English:

I am writing in response to the March 7, 1996 telephone conversation between you and members of my staff, regarding the use of the Advanced Medical Systems, Inc. (AMS) facility located at 1020 London Road, Cleveland, Ohio. In the conversation, you indicated that AMS was not currently performing licensed activities at the facility, and that AMS had not performed licensed activities there for the past few years.

In response to your statement, on April 29 and 30, 1996, during a routine, unannounced safety inspection at AMS, two NRC inspectors interviewed AMS workers and reviewed AMS' records regarding the performance of licensed activities at the 1020 London Road facility. The interviews and record review revealed that, during 1995 and 1996, licensed activities were performed at the 1020 London Road facility. Specifically, during 1995, AMS workers used licensed materials to perform "beam-off" tests of teletherapy heads on seven occasions. No such tests have been performed in 1996. During 1995, AMS received shipments of cobalt-60 sources on two occasions, and shipped cobalt-60 sources offsite on two occasions. During 1996, AMS received a Co-60 source on one occasion. In addition, in 1996, AMS workers packaged and prepared two Co-60 sources for future shipment offsite.

In summary, during 1995 and 1996, licensed activities have been performed at AMS' facility located at 1020 London Rd., Cleveland, Ohio.

Please do not hesitate to contact me should you have any further questions regarding AMS.

Sincerely,

Geoffrey C. Wright, Acting Deputy Director
Division of Nuclear Materials Safety

Docket No. 030-16055
License No. 34-19089-01

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C. Jones, NMSS
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Jim Caldwell (JLC1)
Fred Combs (FCC)
Donald Cool (DAC)
Steve Crockett (SFC)
Geoffrey Wright (GCW)

May 23, 1996

Mr. David Cesar, Vice President
Advanced Medical Systems, Inc.
121 North Eagle Street
Geneva, Ohio 44041

Dear Mr. Cesar:

During our May 7, 1996 meeting, you described a proposal to dispose of the majority of your bulk and sealed cobalt-60, and contaminated waste. We support your initiative to remove the majority of the bulk and sealed cobalt-60 material and contaminated waste from the Advanced Medical Systems, Inc. (AMS) London Road site. However, we have questions regarding how you intend to fund this initiative in that active licensees, such as AMS, that decommission portions of their facilities, typically do so using funds from sources other than those set aside in decommissioning financial assurance instruments. Nevertheless, we are open to any proposal that will improve the radiological conditions at the London Road facility and facilitate eventual decommissioning.

During the May 7, 1996 meeting, you indicated there are time constraints on signing a contract for disposal of the material. To facilitate NRC's timely review of your proposal, we need the following information:

1. Other Sources of Funding for Proposed Removal and Disposal of Radiological Material

Confirm and demonstrate that AMS has exhausted all reasonable means to secure funding for the proposed radiological material removal and disposal aside from the current decommissioning financial assurance instrument.

2. Precise Source of Funding if Funds Set Aside for Decommissioning are Used

Provide details on the amount and precise source of funding AMS is proposing to use to fund the radiological material removal and disposal. If the source of funding could affect the existing letter of credit (e.g., funds which presently serve as collateral for the letter of credit), describe how the instrument will be affected.

3. Effect of Material Removal on Decommissioning Plan

Provide an estimate of the impact on the current decommissioning plan, including funding, that will result from the disposal of the material.

clb4

If AMS proceeds in accordance with its proposal, it will be required to take the following actions:

1. Revision to Decommissioning Plan and Cost Estimate

If AMS is able to remove and dispose of the bulk and sealed sources and contaminated waste as proposed, it must submit a revised "Conceptual Decommissioning Plan" for NRC approval (the original plan dated October 20, 1996, is still being reviewed). This plan must include a revised radiological material inventory, as well as revised plans and costs for decommissioning the facility.

2. SAFSTOR and DECON

The NRC has not made a decision as to whether AMS' use of the SAFSTOR approach to decommissioning originally proposed in its Conceptual Decommissioning Plan is acceptable. Accordingly, your revised Conceptual Decommissioning Plan and cost estimate(s) should address both prompt decommissioning (DECON) and delayed decommissioning (SAFSTOR).

3. Submittal of New Decommissioning Financial Assurance Instrument

If funds for the proposed materials removal and disposal are used such that the net value of the current letter of credit is reduced, AMS must submit a new letter of credit for NRC approval.

If AMS proceeds in accordance with its proposal, the matter of AMS' final decommissioning cost estimates will remain unresolved. That matter will be addressed separately.

In accordance with 10 CFR 2.790, a copy of this letter and your response will be placed in the NRC Public Document Room (PDR). If AMS finds it necessary in its response to provide any information that it considers being proprietary under section 2.790(a)(4), AMS will file an application for withholding in accordance with section 2.790(b) and will also file a non-proprietary version that can be placed in the PDR.

Sincerely,

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

Docket No. 030-16055
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May 22, 1996

Lawrence K. English
Assistant General Counsel
Northeast Ohio Regional
Sewer District
3826 Euclid Avenue
Cleveland, Ohio 44115-2504

Dear Mr. English:

I am writing in response to the March 7, 1996 telephone conversation between you and members of my staff, regarding the use of the Advanced Medical Systems, Inc. (AMS) facility located at 1020 London Road, Cleveland, Ohio. In the conversation, you indicated that AMS was not currently performing licensed activities at the facility, and that AMS had not performed licensed activities there for the past few years.

In response to your statement, on April 29 and 30, 1996, during a routine, unannounced safety inspection at AMS, two NRC inspectors interviewed AMS workers and reviewed AMS' records regarding the performance of licensed activities at the 1020 London Road facility. The interviews and record review revealed that, during 1995 and 1996, licensed activities were performed at the 1020 London Road facility. Specifically, during 1995, AMS workers used licensed materials to perform "beam-off" tests of teletherapy heads on seven occasions. No such tests have been performed in 1996. During 1995, AMS received shipments of cobalt-60 sources on two occasions, and shipped cobalt-60 sources offsite on two occasions. During 1996, AMS received a Co-60 source on one occasion. In addition, in 1996, AMS workers packaged and prepared two Co-60 sources for future shipment offsite.

In summary, during 1995 and 1996, licensed activities have been performed at AMS' facility located at 1020 London Rd., Cleveland, Ohio.

Please do not hesitate to contact me should you have any further questions regarding AMS.

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Division of Nuclear Materials Safety

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C/64

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