

Advanced Medical Systems, Inc.

1020 London Road
Cleveland, Ohio 44110
(216) 692-3270
(216) 692-3269

October 24, 1996

Mr. Kevin Null
Nuclear Materials Licensing, Region III
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

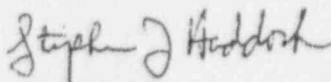
Re: Request for extension to Document Control Number 01585

Dear Mr. Kevin Null,

On October 24, 1996 the Advanced Medical Systems response to your September 24, 1996 request for additional information was due.

For a variety of reasons, AMS is unable to meet this commitment and is requesting a 30 day extension. You may expect to receive our responses on or before the November 24, 1996. Please call me at 216-692-3270 if you have any questions.

Sincerely,



Stephen J. Haddock
R.S.O.

cc: E. Svigel
D. Miller
C. Berger
C. Reed

NOV 04 1996

159
RECEIVED
NOV 04 1996
REGION III

9702110074 970129
PDR FOIA
ENGLISH96-444 PDR

pm 10-30-96

9702110074

AMS MEETING

WHAT: Closed meeting with AMS to discuss AMS' proposal to secure funds for the packaging and shipment of Co-60 sealed and bulk sources (and possibly wastes) for disposal at Barnwell.

WHEN: May 7, 1996, 1:00 p.m. CT.

WHERE: Conf. Room A.

WHO: AMS
David Cesar - Vice President
Dwight Miller - Attorney
Carol Berger - Health Physicist

NMSS
Don Cool-NMSS
Marian Zobler-OGC
Lou Bykowski-NMSS (phone)
Steve Lewis-OGC (phone)

RIII

DETAILS: AMS is negotiating with Chem-Nuclear to ship its Co-60 sealed and bulk sources (possibly including the loose waste, but definitely excluding the material in the front, stuck plug) to Barnwell for disposal.

AMS plans to present NRC a copy of the contract at the meeting. According to AMS, if it obtains NRC's approval to release funds, it will approach its bank re: its letter of credit.

AMS hopes to have all sealed and bulk Co-60 (except the material in the front plug) out of its facility within three months.

AMS' estimate for the packaging and disposal of the material is \$404,000.

C/Sb

AMS BRIEFING

4/26/96

I. DFI

A. Reduction of Inventory

1. Offsite transfer of sealed and unsealed byproduct material - ongoing (4 NPI sources, ~5k Ci), upcoming meeting about transfer of bulk and sealed sources
2. Offsite disposal of wastes - 3 to 5 years (why not ship w/ the sources?)

B. Performance of Inventory

1. Removal of the stuck plug of the front storage well - 3 to 5 years
2. Completion of the physical inventory - 3 to 5 years

C. Emergency Exercise - immediately after EP is approved (AMS' response to deficiency letter is currently being reviewed by NMSS).

D. Decommissioning/decontamination of the WHUT room - SAFSTOR (acceptable?). RIII received AMS' response to our deficiency letter on 4/17/96. RIII will send TAR to NMSS.

E. Decontamination of facility - no action. To be addressed in 7/15/96 "Update to Strategic Plan"

II. STRUCTURAL INTEGRITY REPORT

AMS is scheduling an independent evaluation of the facility's structural integrity. NRC will receive the report of the evaluation before 6/12/96.

III. WATER ISSUES

A. Currently, one 20,000 gallon frac tank contains insoluble Co-60 (this tank contains water from old under drains), another may or may not (NRC will take samples next week during inspection).

B. NMSS and OGC will decide if AMS' release of tanked ground water is a discharge to the sewer (solubility requirement) or an effluent release (no solubility requirement).

IV. INSPECTION

J. Madera and M. Weber will perform a routine, unannounced inspection next week.

NRC'S DFI / AMS' STRATEGIC PLAN

I. DFI - 9/27/95

- A. Reduction of Inventory
 - 1. Offsite transfer of sealed byproduct material
 - 2. Offsite disposal of wastes
 - 3. Offsite transfer of unsealed byproduct material
- B. Inventory
 - 1. Removal of the stuck plug of the front storage well
 - 2. Completion of the physical inventory
- C. Emergency Exercise
- D. Decommissioning/decontamination of the WHUT room
- E. Decontamination
 - 1. Decontamination of the hot cell
 - 2. Decontamination of the basement
 - 3. Decontamination of the Isotope Shop
 - 4. Decontamination of the Isotope Warehouse
 - 5. Decontamination of the HEPA filter room
 - 6. Decontamination of other contaminated areas

II. AMS' Response ("Strategic Plan - Revision 0") - 10/11/95

- A. High Priority Actions
 - 1. Complete the remediation report
 - 2. License renewal application
 - 3. Emergency plan
 - 4. Decommissioning funding plan
- B. Intermediate Priority Actions
 - 1. Recover hot cell capabilities
 - 2. Return NPI sources
 - 3. Identify a market for remaining bulk material
 - 4. Train first responders in emergency plan provisions
 - 5. Stage emergency exercise and perform critique
- C. Lower Priority Actions
 - 1. Remove plug in the hot cell
 - 2. Decontaminate the hot cell
 - 3. Complete/confirm the physical inventory and transfer/ship remaining sources
 - 4. Disposition of solid waste at the facility
 - 5. Disposition of treated water in collapsible storage tanks
- D. On-going Actions
 - 1. Audit/Assessment of Radiation Protection Program
 - 2. Upgrade of Standard Operating Procedures
 - 3. Housekeeping Improvements
 - 4. Community Relations
 - 5. Reconnection of Sewer System to London Road Interceptor

III. NRC Response 12/6/95

- A. Change to High Priority Actions:
 - 1. Recover hot cell capabilities
 - 2. Return NPI sources
 - 3. Identify a market for remaining bulk material
 - 4. Train first responders in emergency plan provisions
 - 5. Stage emergency exercise and perform critique
 - 6. Disposition of solid waste at the facility
- B. Do the Following:
 - 1. Request amendment to LC 14 (inventory)
 - 2. Address decontamination/decommissioning of WHUT Room
 - 3. Address decontamination of facility
 - 4. Respond to structural integrity report

IV. AMS' Response ("Strategic Plan - Revision 1") - 1/15/96

- A. High Priority Actions
 - 1. Complete the remediation report - **ongoing**
 - 2. License renewal application - **ongoing**
 - 3. Emergency plan - **ongoing**
 - 4. Decommissioning funding plan - **ongoing**
 - 5. Train first responders in emergency plan provisions - **within 60 days of NRC approval of emergency plan**
 - 6. Stage emergency exercise and perform critique - **within 60 days of completion of training**
- B. Intermediate Priority Actions
 - 1. Recover hot cell capabilities - **done**
 - 2. Return 34 NPI sources - **two sources returned since 10/11/95**
 - 3. Identify a market for remaining bulk material - **initiated discussions**
- C. Lower Priority Actions
 - 1. Remove plug in the hot cell
 - 2. Decontaminate the hot cell
 - 3. Complete/confirm the physical inventory and transfer/ship remaining sources
 - 4. Disposition of solid waste at the facility
 - 5. Disposition of treated water in collapsible storage tanks

V. AMS' Response ("Strategic Plan - Revision 2") - 4/8/96

- A. High Priority Actions
 - 1. Complete the remediation report - **ongoing**
 - 2. License renewal application - **ongoing**
 - 3. Emergency plan - **ongoing**
 - 4. Decommissioning funding plan - **ongoing**
 - 5. Train first responders in emergency plan provisions - **within 60 days of NRC approval of emergency plan**
 - 6. Stage emergency exercise and perform critique - **within 60 days of completion of training**
- B. Intermediate Priority Actions
 - 1. Recover hot cell capabilities - **done**
 - 2. Return 34 NPI sources - **four sources returned since 9/27/95 (~5000 Ci)**
 - 3. Identify a market for remaining bulk material - **solicitations of interest distributed**

- C. Lower Priority Actions
1. Remove plug in the hot cell
 2. Decontaminate the hot cell
 3. Complete/confirm the physical inventory and transfer/ship remaining sources
 4. Disposition of solid waste at the facility
 5. Disposition of treated water in collapsible storage tanks

VI. AMS' Response to Structural Integrity Report - 4/9/96

AMS is scheduling an independent evaluation of the facility's structural integrity. NRC will receive the report of the evaluation before 6/12/96.

VII. AMS' Response to 12/6/95 Letter - 4/24/96

- A. Change to High Priority Actions:
1. Recover hot cell capabilities - **done**
 2. Return NPI sources - **concur (7/15/96 update will show this)**
 3. Identify a market for remaining bulk material - **concur (7/15/96 update will show this)**
 4. Train first responders in emergency plan provisions - **concur**
 5. Stage emergency exercise and perform critique - **concur**
 6. Disposition of solid waste at the facility - **keep low priority**
- B. Do the Following:
1. Request amendment to LC 14 (inventory) - **depends on timeliness of renewal**
 2. Address decontamination/decommissioning of WHUT Room - **SAFSTOR**
 3. Address decontamination of facility - **will be done in 7/15/96 update**
 4. Respond to structural integrity report - **responded in 4/9/96 letter (see above)**

AMS TANKS 164 & 695

April 1996

Tank	Source	Sample Type	Concentration	Error	MDA
164	NEORSD	Filtered Water	6.1	2.7	5.0
164	NEORSD	Filter	37.1	12.4	9.5
695	NEORSD	Filtered Water	4.8	2.3	4.8
695	NEORSD	Filter	2.7	1.8	2.6
164	AMS	Unfiltered Water	0.6	7.5	19
164	AMS	Filter	0.2	4.2	11
695	AMS	Unfiltered Water	0.1	4.9	15
695	AMS	Filter	-3.0	2.2	9.3
164	NEORSD split	Unfiltered Water	30	10	5.9
164	NEORSD split	Filter	7.7	3.0	4.2
695	NEORSD split	Unfiltered Water	0.7	4.0	16
695	NEORSD split	Filter	-0.16	0.54	5.5

- Notes: (1) All measurements are in picoCuries per liter (pCi/l).
- (2) The NEORSD samples were analyzed by NEORSD's lab, Outreach Laboratories.
- (3) The AMS and NEORSD split samples were analyzed by AMS' lab, Lockheed Laboratories.
- (4) The NEORSD and NEORSD split samples were taken at varying depths, after the water had been mixed for approx. three days.
- (5) The AMS samples were taken from the top of the tank, after the water had been mixed for approx. seven days.

RIII OUTSTANDING ACTIONS - AMS
4/24/96

- EP - RIII received AMS' revised Emergency Plan - 9/28/95
 - RIII mailed deficiency letter - 2/28/96
 - RIII rec'd AMS' response - 3/26/96
 - RIII sent AMS' response to NMSS for review - 3/27/96
 - Current status: RIII waiting for NMSS' response - 3/27/96
- DFP - RIII received AMS' "Conceptual Decommissioning Plan" - 10/30/95
 - RIII mailed deficiency letter - 3/20/96
 - RIII rec'd response - 4/17/96
 - Current Status: RIII evaluating response
- Renewal Application - RIII received AMS' application - 11/3/95
 - RIII mailed "preliminary deficiency letter" asking for rad protection procedures referenced (but not included) in renewal package - 12/5/95
 - RIII rec'd letters dated 12/28/96, 1/5/96, 2/13/96, 3/13/96 with ALL requested procedures
 - Current Status: RIII evaluating submittal
- English letter re: tank 880 - NRC promised full results in 2/26/96 ltr
 - Current status: RIII waiting for OK from NMSS - 4/17/96
- English letter to Madera re: tanks 164 and 695 - 4/18/96
 - Current status: RIII waiting for OK from OGC and NMSS - 4/23/96
- Meschter letter to Wright re: counting procedures - 4/19/96
 - Current status: RIII writing response
- English letter to Wright re: tanks 164 and 695 - 4/19/96
 - Current status: RIII writing response

RIII "COMPLETED" ITEMS

- Meschter letter re: release of tank 880
 - Current status: RIII mailed letter - 4/17/96
- AMS letter dated 10/17/95 re: grouting of 4" line, etc., received 10/26/95
 - Current status: RIII mailed Amendment No. 41 - 4/16/96
- Meschter letter re: tank 880 - NRC promised full results in 2/22/96 ltr
 - Current status: RIII mailed letter - 3/19/96
- Ohio DOH letter dated 1/30/96 re: LLW (dirt from excavation project) at AMS
 - Current status: RIII mailed response letter - 3/18/96
- NRC structural integrity inspection
 - RIII rec'd report from NMSS - 12/22/95
 - RIII mailed letter w/ report - 3/12/96
 - Current Status: RIII rec'd response on 4/9/96. AMS will evaluate facility, complete report by 6/12/96.
- NEORSD faxes dated 1/31/96, 2/1,5,7,12/96 re: AMS tanks 877, 222 & 880
 - Current status: RIII mailed response letter - 2/26/96
- TAR re: AMS' analysis procedures
 - Current status: RIII sent to NMSS - 2/23/96
- NEORSD letter dated 12/21/95 to EDO re: Inspection Report 95005
 - Current status: RIII mailed response letter - 2/1/96
- Surveillance Plan - RIII received Plan - 9/5/95
 - Current Status: RIII amended license (to include Plan) - 1/16/96
- Financial Assurance (\$1.8M) - received by RIII in 1/95
 - Current status: RIII mailed letter - 1/8/96
- NEORSD letter dated 11/13/95 re: grouting of 4" line, etc., rec'd 11/17/95
 - Current status: RIII mailed response letter - 12/20/95

- NEORSD letter dated 11/14/95 re: 3000 gallon discharge, received 11/17/95
 - Current status: RIII mailed response letter - 12/14/95
- English response - RIII received English's letter - 10/9/95
 - Current status: RIII mailed response letter - 12/13/95
- *• DFI letter - RIII received AMS' response - 10/19/95
 - Current status: RIII mailed response letter - 12/6/95
- Inspection Report covering 4/3/95-11/3/95 inspection
 - Current status: RIII mailed report - 12/4/95
- Kalstrom response - RIII received Kalstrom's letters - 8/23/95 and 9/29/95
 - Current status: RIII mailed response letter - 11/20/95
- * still an open item

INSPECTION PLAN

Licensee: AMS
1020 London Rd.
Cleveland, OH

License No: 34-19089-01

Inspection Dates: April 29-30, 1996

Inspectors: J. Madera and M. Weber, accompanied by Frank Talbot, Ohio Dept. Of Health

Purpose of Inspection: The inspection will be a routine, unannounced inspection and will include the areas described below.

1. Organization
 - a. Management control (RSC: Cesar-chair, Meschter-sec, members-Haddock, Svigel, Berger)
 - b. RSC mtgs. (quarterly)
2. Program
 - a. Walk through
 - b. Progress of dirt building (bldg. is built; when will dirt be placed inside?)
 - c. Status of Strategic Plan/DFI commitments (see attachment)
3. Daily, Weekly, Monthly Surveillances - Record Review
 - a. Daily (ISP-5)
 - b. Weekly (ISP-2A, 2B, 2C)
 - c. Semi-monthly (ISP-6A)
4. Facilities and Equipment
 - a. Postings (inside & outside building)
 - b. Security upgrades
 - c. Survey instruments (in calibration?)
 - d. Gamma spec. system (confirmatory measurement?)
5. Personnel Radiation Protection
 - a. Personnel monitoring - review records
 - b. ALARA program and implementation
 - c. Airborne potential
 - d. Bioassay program
6. Receipt and Transfer (DOT)
 - a. Procedures for opening packages (Part 20 followed?)
 - b. Transfer
 - c. Records
7. Independent Measurements
 - a. Outside, near contaminated dirt
 - b. Outside, along south wall
 - c. Outside, vicinity of 1995 construction projects
 - d. Inside, throughout
8. Emergency Response
 - a. General condition of pump house
 - b. Is there a phone in the pump house?
9. Allegation re: Use of Licensed Materials
 - a. Review shipping papers for NPI source returns
 - b. Review "beam off test" records
 - c. What else are they doing? Any service?
10. Obtain samples from Tank 695 at varying depths
11. Exit Meeting

Reviewed By: John R. Madera, Chief
Materials Licensing Branch

Date

Approved By: Cynthia D. Pederson, Director
Division of Nuclear Materials
Safety

Date



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

May 8, 1996

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

Dear Mr. English:

In my February 26, 1996 letter, I indicated that NRC would provide you with the complete results from our analysis of water samples from Advanced Medical Systems, Inc.'s (AMS) Tank 880, since our analysis was still in progress at that time. These water samples were obtained by an NRC inspector at the AMS facility on February 13, 1996. Based on our preliminary analysis of these samples, on February 16, 1996, we had informed AMS that insoluble cobalt-60 (Co-60) had been detected in a water sample from Tank 880, and therefore, a discharge of Tank 880 would be an apparent violation of 10 CFR 20.2003.

On February 26, 1996, before our analysis was complete, we were informed by AMS that it planned to filter the water in Tank 880 with a one micron filter, decontaminate the tank, refill the tank with the filtered water, upgrade and add additional mixing pumps in the tank to ensure both horizontal and vertical mixing, and then test the water at the top and bottom of the tank. On March 4 and 5, 1996, we received AMS' draft results of its contract laboratory's analysis of water samples from Tank 880. Based on these results, we concluded that the discharge of Tank 880 would not be in violation of 10 CFR 20.2003. Subsequently, on March 8, 1996, AMS discharged Tank 880.

As discussed in a letter dated April 17, 1996, to AMS, the basis for our position regarding the March 4 and 5, 1996 results was as follows. The March 4, 1996, results (Enclosure 2) indicated that the concentration of Co-60 in the water did not exceed the limits of 10 CFR Part 20, Appendix B, for releases to the sanitary sewer. With respect to 10 CFR 20.2003, the results of the analysis of the top filter indicated that insoluble Co-60 may have been present. We did, however, question the accuracy of the measurement since the error, 1.7 picoCuries per liter (pCi/l), reported by AMS' contract laboratory for this filter exceeded the minimum detectable activity (MDA) of 1.6 pCi/l for the particular measurement. By facsimile dated March 5, 1996 (Enclosure 3), AMS provided us with the results of a recount of the top filter. This sample was recounted at AMS' request. These results indicated that there was no detectable, insoluble Co-60 on the filter. The error for this analysis, 0.34 pCi/l, was less than the MDA of 3.7 pCi/l and is, therefore, more analytically acceptable. Taking this additional information into consideration, we concluded that discharge of Tank 880 did not violate 10 CFR 20.2003.

C/S8

9605160319 1211

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

Original signed by Cynthia D. Pederson

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

See Attached Distribution

To receive a copy of this document, indicate in the box: C = Copy without attachment/enclosure E = Copy with attachment/enclosure N = No copy

OFFICE	RIII	C RIII	C RIII	C RIII	C RIII
NAME	MWeber:dp	JMadera	DCool	MZobler	CPederson
DATE	05/3/96	05/7/96	05/1/96	05/1/96	05/8/96

via e-mail

4/19/96

via e-mail

4/22/96

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AMS File

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John Madera (JRM4)
Kevin Null (KGN)
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Marian Zobler (MLZ)
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Jon DeCicco (JXD1)
Jim Caldwell (JLC1)
Fred Combs (FCC)
Donald Cool (DAC)
Steve Crockett (SFC)
Geoffrey Wright (GCW)

ENCLOSURE 1

Results of NRC's Analysis of Water and Filters from Tank 880

(Samples obtained by NRC on 2/17/96)

Water Samples

Top or Bottom	Sample Number	Filtered or Unfiltered	Count Time (hours)	Activity (pCi/l)	MDA (pCi/l)
bottom	1	unfiltered	17.4	176 ± 13	19
bottom	1	filtered	26.8	30.6 ± 6.3	13
bottom	2	unfiltered	15.8	162 ± 16	24
bottom	2	filtered	56.9	14.0 ± 5.5	12
bottom	3	unfiltered	25.9	80.5 ± 8.2	15
top	1	unfiltered	2.6	< MDA	53
top	2	unfiltered	17.2	< MDA	22
top	3	unfiltered	24.8	< MDA	18
top	4	unfiltered	23.5	< MDA	16

Filter Samples

Top or Bottom	Sample Number	Count Time (hours)	Activity (pCi)	MDA (pCi)
bottom	1	24.4	17.2 ± 1.2	1.5
bottom	2	24.6	20.6 ± 1.3	1.6
top	1	14.4	< MDA	2.1
top	2	15.7	< MDA	1.7
top	3	11.0	< MDA	2.3
top	4	22.6	< MDA	1.7

NOTES:

(1) MDA stands for minimum detectable activity.



Advanced Medical Systems, Inc.

1020 London Rd
Cleveland, Ohio 44110
216-692-3270

FAX(216) 692-3269

FAX MESSAGE

FROM: Bob Meschter

TO: Mike Weger

FAX NUMBER:

DATE: 3-4-96

PAGE 1 OF 5

MESSAGE:

Attached FYI - sample
RESULTS FROM TRAK 880
we intend to dump this TRAK
3-7-96

TANK 550 FILTER

LOCKHEED ANALYTICAL SERVICES

RAD DATA REPORT (r#01)

TEM, Inc.

(PROJECT FAST TAT GAMMA SPEC)

Client Sample ID: W022996-001 TOP

LAL Sample ID: L6539-1

Date Collected: 29-FEB-96

Date Received: 01-MAR-96

Matrix: water

Login Number: L6539

Co-60

GAMMA SPEC LAL-0043_3435B

2.3

1.7

1.6

DC1/L

DRAFT

TANK 890 FILTER

LUCKHEED ANALYTICAL SERVICES

RAD DATA REPORT (r#01)

LEM, Inc.

(PROJECT PASS TAI GAMMA SPEC)

Client Sample ID: W022996-002 BOTTOM

LAL Sample ID: L6539-2

Date Collected: 29-FEB-96

Date Received: 01-MAR-96

Matrix: water

Login Number: L6539

Co-60

GAMMA SPEC LAL-0063_L6538

-0.8

2.0

8.0

DCI/L

DRAFT

TAM SSO WATER

LOCKHEED ANALYTICAL SERVICES

RAD DATA REPORT (r001)

LEM, Inc.

(Project FAST TAT GAMMA SPEC)

Client Sample ID: W022006-001 TOP

Date Collected: 29-FEB-96

Matrix: Water

LAL Sample ID: L6539-4

Date Received: 01-MAR-96

Login Number: L6539

Co-60

01-MAR-96 GAMMA SPEC LAL-W063_56357

3.5

7.6

18.

pCi/L

DRAFT

PAV 980 WATER

IBM, INC.

Login number: 66539

DRAFT

ENCLOSURE 3

LOCKHEED MARTIN



Lockheed Analytical Services
975 Kelly Johnson Drive
Las Vegas, NV 89119

(702)361-3955 ext. 289
fax (702)361-3137

FAX TRANSMITTAL COVER

DATE: March 5, 1996

NUMBER OF PAGES (including cover) 3

FROM: Karen Germann

TO: Mr. Robert Meschter

PHONE #: (216) 692-3270

FAX #: (216) 692-3269

COMMENTS: Draft data

Bob -

We realized there was a calculation error on the other filter sample (L6539-2) here are the revised results.

The sample L6557-1 is the reanalysis that you requested this morning.

I will be out of the office tomorrow morning. If you have further questions call

Russ Stimmel or Terry Romanko.

Thanks -
Karen

LOCKHEED ANALYTICAL SERVICES

RAD DATA REPORT (rad01)

IER, Inc.

(Project FAST TAT GAMMA SPEC)

Client Sample ID: W022996-002 BOTTOM

Date Collected: 29-FEB-96

Matrix: Water

LAL Sample ID: L6539-2

Date Received: 01-MAR-96

Login Number: L6539

Cs-60

01-MAR-96 GAMMA SPEC LAL-0063_36358

-0.3

1.2

3.3

dci/L

Mar-06-96 07:26A
03-05-96 13:37

LOCKHEED ANALYTICAL SERVICES + 2166923269

NO. 302 P.04
002

LOCKHEED ANALYTICAL SERVICES

RAD DATA REPORT (rs01)

TEM, Inc.

(Project FAST TAT GAMMA SPEC)

Client Sample ID: W022996-001-TOP

LAL Sample ID: L6557-1

Date Collected: 29-FEB-96

Date Received: 05-MAR-96

Matrix: Water

Login Number: L6557

Co-60

05-MAR-96 GAMMA SPEC 1AL-0063_34477

-0.34

0.34

3.7

pCi/L

DRAFT



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

May 13, 1996

96-15
030-16055

MEMORANDUM TO: Cynthia D. Pederson, Director
Division of Nuclear Material Safety, Region III

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS *DKL*

SUBJECT: SAMPLING AND COUNTING PROCEDURES USED BY
ADVANCED MEDICAL SYSTEMS (AMS) *34-1987-11*

I am responding to your TAR dated February 22, 1996, regarding the methods used by AMS to sample water from its ground water storage tanks. Our understanding of the TAR identified two broad issues to be addressed:

1. The detection sensitivity that would be considered acceptable in showing compliance with regulations applicable to discharges to sanitary sewer systems.
2. The appropriate methods of sampling the storage tanks to show compliance with sewer discharge regulations.

Although these two issues are connected, they will be addressed separately for convenience and clarity.

1. Showing compliance with the sewer discharge regulations in 10 CFR § 20.2003 usually requires that licensees perform measurements to quantify the concentrations of radioactive materials in the discharge water. Frequently it also requires showing the absence of insoluble materials in that water. Due to technical factors, it is not possible to show the complete absence of insoluble materials in the discharge, and it is therefore necessary to establish a level of measurement sensitivity that would be deemed adequate to satisfy the regulatory requirements. This sensitivity is expressed in terms of the lower limit of detection (LLD) or, as it is frequently called in the industry, the minimum detectable activity (MDA).

NRC has traditionally adopted the industry practice of considering as adequate an MDA that is readily achievable using standard measurement practices and equipment, together with ordinary precautions in performing the measurements. The above practice is subject to the additional industry accepted constraint that the acceptable MDA not be higher than 10% of the applicable limit, unless that value is not readily achievable.

In the case of sewer discharges of water containing ^{60}Co , this practice implies that an MDA of no higher than 300 picocuries/liter (pCi/L) would be considered acceptable. However, for ^{60}Co , MDA values far lower than 300 pCi/L

Contact: Sami Sherbini
(301) 415-7902

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are easily achievable with even the simplest of detection equipment, and we expect licensees to operate at these lower values. The MDA value that is readily achievable varies depending on many factors, such as local background levels, and should be established on a case-by-case basis and justified by the licensee. In the case of AMS, we suggest that the licensee be requested to propose a reasonable measurement protocol, establish the MDA for that protocol, and submit the details to NRC for approval.

For purposes of showing compliance with the prohibition on discharges of insoluble, non-biological material, we believe the MDA used in reactor environmental technical specifications for ^{60}Co may be an appropriate value to use as a reference in this case. This value is 15 pCi/L, and should be readily achievable by AMS. However, we caution that this is not a generic position, and each case that may arise in the future will be evaluated separately. In the case of AMS, the final acceptable MDA may be somewhat higher or lower than 15 pCi/L, depending on the details of the licensee's proposed sampling and counting protocol and what, in our evaluation, constitutes a reasonable attempt for achieving an appropriate sensitivity. The MDA of 15 pCi/L would be applicable both to measurements of total activity in the water sample, as well as any measurements to determine the content of insoluble activity in that sample.

In addition, you should be aware that NRC, in cooperation with EPA, will be conducting a comprehensive survey to include sampling of effluents (ash, sludge, etc.) at sewage treatment plants across the country to determine the effects of reconcentration. Information obtained from this survey will be used to determine if rulemaking is required. However, in the interim, we are considering alternatives to address the current rule language regarding release of insoluble radioactive material. Alternatives include issuing guidance in the form of an Information Notice or requesting the Office of Nuclear Regulatory Research to initiate rulemaking in this limited area.

2. Sampling the water storage tanks at AMS should be performed in such a manner that the results of the water sample analysis can be used to provide a reliable estimate of the radioactive contents of the tank. This is normally achieved by thoroughly mixing the contents before obtaining the sample, but other sampling techniques may be justified in special circumstances. For example, stratified sampling is often performed in waste storage tanks, without first mixing the contents of the tank. Although the results in this case are more difficult to interpret, and the sampling is much more difficult to perform, it is an acceptable sampling method if conducted properly.

If AMS is able to thoroughly mix the contents of the tank prior to sampling, then we suggest that they be encouraged to do so, thereby ensuring easy interpretation of the results. However, if the licensee wishes to adopt an alternative method, they should be permitted to do so, provided the method, together with the calculations necessary to identify and quantify the contents

of the tank, are technically justified and approved by the NRC. AMS may also be permitted to show compliance with the discharge concentration requirements, as well as the prohibition on discharge of insoluble materials, by measuring the total (soluble and insoluble) concentration of ^{60}Co in the water. Samples that show no detectable activity above background using this method, together with procedures that achieve an acceptable MDA, as discussed above, need not be separately checked for insoluble material content.

We reviewed the AMS procedure you provided with your TAR, Procedure RSP-019, "Assessment of radioactivity in water samples", and found that it was incomplete and contained several apparent technical errors. We suggest that AMS be requested to develop detailed procedures describing the methods they will use to obtain water samples, the methods they will use to analyze those samples, and the decision logic that they will use to determine if the water in the tank may be discharged. The revised procedures should be reviewed by NMSS before approving routine tank discharges from AMS to ensure their adequacy and also to ensure that the methods selected are technically correct.

Attached, please find a proposed letter to send from RIII to AMS specifically requesting the above identified information necessary for us to make an evaluation on future planned discharges.

We believe that this addresses the questions you raised in your TAR with respect to the issues at AMS. Please call the technical contact indicated above if you need further clarifications or assistance.

ATTACHMENT

Robert Meschter, R.S.O.
Advanced Medical Systems, Inc.
1020 London Road,
Cleveland, Ohio 44110

Dear Mr. Meschter,

We have reviewed your practices and procedures for sampling and discharging the waste storage tanks that you use to collect water from the footer drain system on your site, and we have concluded that we need additional information for us to complete our review. Detailed written procedures should be prepared describing the manner in which samples are to be obtained, the methods of sample analysis, the methods to be used to determine insoluble material content, and the logic to be used to determine if the water meets the requirements for discharge from the tank. AMS Procedure RSP-019, "Assessment of Radioactivity in Water Samples" was incomplete and contained several technical errors. A complete, revised procedure needs to be submitted to the NRC for review and approval.

You should also provide written details of the sampling and measurement protocol that are not appropriately included in your procedures. This document should provide the justifications for the value of the Minimum Detectable Activity (MDA) you select for your measurements, including sufficient detail to permit a determination that the selected methods of measurement, including detector type, shielding, background levels, counting times, and other factors represent reasonably achievable performance. These procedures and technical document should be submitted to the NRC for review and approval prior to implementation on a routine basis.

When preparing the above documents, you should address in sufficient detail at least the following issues:

- All tanks must be sampled before discharge of the water to the North East Ohio Regional Sewer District (NEORS), or to any location that would ultimately discharge to that sewer district. You may choose any sampling protocol that is suitable to your specific conditions, but we encourage you to consider thorough mixing of the tank before sampling to facilitate interpretation of the analysis results. In any case, sampling should be performed in such a manner that the sample would enable you to reliably identify and quantify the contents of the tank with a reasonable degree of accuracy. The details of the sampling protocol, such as mixing methods and time, sample size and shape (e.g. cylindrical bottle, Marinelli beaker, etc.), points of sample withdrawal from the tanks, and so on should be included in your sampling procedures.
- Water samples must be analyzed for their content of licensed material, which in your case is limited to ^{60}Co . The analysis should be conducted in such a manner as to consistently achieve a sensitivity, expressed in terms of the MDA, that is similar to that achievable using standard measurement techniques for this type of sample throughout the industry.

The chosen analysis methods should include taking appropriate precautions during the measurements, such as providing adequate shielding, ensuring a low background counting location, counting for an appropriately long period of time, using good counting geometries, taking sufficiently large water samples, and so on.

Your procedures or technical document should include detailed descriptions of the detectors to be used, the background that would be considered compatible with counting this type of sample, counting geometry, counting time, methods of MDA determination, level of activity that is to be considered indistinguishable from background, logic to be used in deciding if the tank may or may not be discharged, and so on.

- Samples that show no detectable activity above background using procedures that achieve the above-noted MDA need not be checked for insoluble material content. Samples that do show activity above background should be tested further for their content of insoluble licensed material, in your case ^{60}Co . This procedure would be considered acceptable provided the MDA used to measure the total activity in the sample is also adequate for purposes of determining the content of insoluble material in that sample. The details of subsequent treatment and testing, and the final disposition of the water, should be detailed in the technical or procedures.
- Acceptable methods for determining insoluble material content are described in NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20." Procedures to determine whether the detected activity differs from background should be based on a previously-established decision level. Use of the MDA as a decision level is not acceptable. NRC considers use of 5 percent probabilities for both Type I and Type II errors acceptable. Use of other error probabilities must be justified. Details of these methods should be included in the technical document, and their implementation should be included in the procedures.

Please call me at (708) 829-9800 if you have any further questions, or need clarifications on any of the above items.

Sincerely,

Cynthia Pederson, Director
Division of Nuclear Material Safety,
Region III

May 20, 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 your facsimile dated April 18, 1996, regarding the discharge of water at Advanced Medical Systems, Inc. (AMS). In your communication, you expressed concern about the presence of insoluble cobalt-60 in the water from AMS' underdrain system and manhole which had been pumped into storage Tanks 164 and 695.

Your facsimile lists the results of the solubility tests performed by your contract laboratory. For Tank 164, your laboratory measured a cobalt-60 activity of 37.1 ± 12.4 picoCuries (pCi) on the filter, with a minimum detectable activity (MDA) of 9.5 pCi. For Tank 695, your laboratory measured a cobalt-60 activity of 2.7 ± 1.8 pCi on the filter, with an MDA of 2.6 pCi. Since cobalt-60 was detected on these filters, Northeast Ohio Regional Sewer District (NEORSO) considers the cobalt-60 in Tanks 164 and 695 to be insoluble. Inasmuch as 10 CFR 20.2003 requires that licensed material which is discharged into a sanitary sewerage system be readily soluble in water, NEORSO requested that NRC prohibit AMS from discharging the water from these tanks.

On April 18, 1996, in response to NRC's request, AMS indicated that it would postpone the discharge of Tanks 164 and 695 until it had determined that the discharges would meet regulatory requirements.

By facsimile dated April 25, 1996, AMS indicated that its contract laboratory, Lockheed Analytical Services, had measured the cobalt-60 concentration and performed a solubility test of two water samples from each tank. Cobalt-60 was detected in a water sample and on a filter sample from Tank 164, but it was not detected in the samples from Tank 695 (see enclosure 1). AMS has indicated to NRC that it plans to filter the water in Tank 164.

In response to your April 18 facsimile, on April 29, 1996, two NRC inspectors went to AMS and took six 0.5 liter water samples at varying depths from Tank 695. The water in the tanks had been recirculating for approximately 72 hours. In the Region III laboratory, each water sample was tested for solubility. Cobalt-60 was not detected on these filters. The NRC analysis, therefore, did not reveal that the water in Tank 695 contained insoluble

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cobalt-60 (see enclosure 2). Thus, it does not appear that discharge of Tank 695 would be in violation of 10 CFR 20.2003. These results were transmitted to AMS on May 13, 1996. It is our understanding that as of May 20, 1996, AMS has not discharged Tank 695.

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

Sincerely,

Original signed by

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

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

Enclosures: 1. Results of AMS' analysis
2. Results of NRC's analysis

See Attached Distribution

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Enclosure 1

RESULTS OF AMS' ANALYSIS OF SAMPLES FROM TANKS 164 AND 695

TANK	SOURCE OF SAMPLE	SAMPLE TYPE	RESULT	MDA
164	NEORS/AMS split	Unfiltered Water	30 ± 10	5.9
164	AMS	Unfiltered Water	0.6 ± 7.5	19
164	NEORS/AMS split	Filter	7.7 ± 3.0	4.2
164	AMS	Filter	0.2 ± 4.2	11
695	NEORS/AMS split	Unfiltered Water	0.7 ± 4.6	16
695	AMS	Unfiltered Water	0.1 ± 4.9	15
695	NEORS/AMS split	Filter	-0.16 ± 0.54	5.5
695	AMS	Filter	-3.0 ± 2.2	9.3

Notes:

- (1) Measurements of water samples have units of picoCuries per liter (pCi/l). Measurements of filter samples have units of picoCuries (pCi).
- (2) MDA stands for minimum detectable activity.
- (3) The AMS and NEORS/AMS split samples were analyzed by AMS' contract laboratory, Lockheed Analytical Services.
- (4) The NEORS/AMS split samples were taken at varying depths, after the water had been mixed for approximately three days.
- (5) The AMS samples were taken from the top of the tank, after the water had been mixed for approximately seven days.

Enclosure 2

RESULTS OF NRC'S ANALYSIS OF SAMPLES FROM TANK 695

TANK	SOURCE OF SAMPLE	SAMPLE TYPE	RESULT	MDA
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

Notes:

- (1) Measurements of filter samples have units of picoCuries (pCi).
- (2) MDA stands for minimum detectable activity.
- (3) The NRC samples were taken at the depths shown, after the water had been mixed for approximately three days.