NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 48

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

301524

Licensee	
1. Advanced Medical Systems, Inc. 2. 1020 London Road Cleveland, OH 44110	In accordance with the letter dated March 31, 1997 3. License Number 34-19089-01 is amended in its entirety to read as follows: 4. Expiration Date December 31, 1994 5. Docket or Reference No. 030-16055/040-08764/030-17154

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Cobalt-60	A. Solid Metal	A. 150,000 curies
B. Cobalt-60	B. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	B. 135,000 curies (no single source to exceed 13,700 curies)
C. Cesium-137	C. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	C. 40,000 curies (no single source to exceed 2,200 curies)
D. Depleted Uranium	D. Nickel Plated	D. 4,040 kilograms
E. Cobalt-60	E. Sealed Sources	E. 15,000 curies

110116

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 34-19089-01

Docket or Reference Number: 030-16055/040-08764/030-17154

Amendment No. 48

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
F. Cobalt-60	F. Sealed Sources (any sealed source approved by the NRC or an Agreement State)	F. 15 millicuries

9. Authorized Use:

A. For storage only incident to waste disposal or transfer to an authorized recipient. This license does not authorize the manufacture of sealed sources.

B. For installation, maintenance of, dismantling and servicing of Picker Corporation and Advanced Medical Systems, Inc. teletherapy units and Picker Model 6145 radiography units possessed by licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State. For installation and removal of sealed sources into Picker Corporation, Advanced Medical Systems, Inc. and Keleket Barnes teletherapy units of licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State. For training Hospital or Clinic personnel for in-house service operations on teletherapy equipment, on unit model per course, in accordance with letter dated August 15, 1988 and September 29, 1988.

C. For installation, maintenance, dismantling and servicing of Picker Corporation and Advanced Medical Systems radiography and teletherapy units of licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State.

D. Shielding material in Picker Corporation and Advanced Medical System, Inc., radiography and teletherapy devices.

E. For storage only, those non-NRC approved sources in the possession of the licensee prior to the issuance of this amendment.

F. For use in devices (including Tech OP Model 571 Calibrator described in application dated November 12, 1984) approved by the Nuclear Regulatory Commission or an Agreement State to calibrate radiation survey instruments.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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CONDITIONS

10. Licensed material in Items 6.A., 6.E. and 6.F. shall be used only at the licensee's facility at 1020 London Road, Cleveland, Ohio. Licensed material in Items 6.B. and 6.C. shall be used only at 1020 London Road, Cleveland, Ohio and at facilities of customers who possess a specific license from the NRC authorizing possession of the licensed material. Licensed material in Item 6.D. shall be used only at the licensee's facilities at 1020 London Road, Cleveland, Ohio or 121 North Eagle Street, Geneva, Ohio, and at facilities of customers who possess a specific license from the NRC authorizing possession of the licensed material.

11. A. The Radiation Protection Officer for service operations described in Subitems 9.B. and 9.C. and routine health physics activities is Stephen J. Haddock.

The Alternate Radiation Protection Officer for routine health physics activities only is Christopher Reed.

The licensee shall not perform service operations described in Subitems 9.B. and 9.C. until Stephen J. Haddock has completed the required training.

B. Licensed material shall be used by, or under the supervision of and in the physical presence of users listed in the table below. The users are only authorized to perform the indicated services on the teletherapy or radiography units specified in the table below:

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

	CS 600	C 1000	C 2000	C 3000	C 5000	C 10,000	C4	C8	C9	C12	Cyclops
USER											
Stephen Haddock	5	5	5	5	5	5	5	5	5	5	5

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

	V 1000	V 2000	V 3000	V 10,000	C V4	C V9					
USER											
Stephen Haddock	5	5	5	5	5	5					

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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1. Authorizes the servicing of AMS/Picker units, excluding source exchange.
2. Authorizes sealed source exchange.
3. Authorizes removal of unit and head from customer sites only.
4. Authorizes the training of AMS personnel in the manufacture of AMS/Picker sealed sources.
5. Authorizes the handling of sealed sources only.

12. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transfer or indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries of less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested 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.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designated for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in what the sealed source is permanently or semi-permanently mounted or stored on which one might expect contamination to accumulate. Records o leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action.

13. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. Inventory Requirements:

A. An inventory system will be established that accounts for the receipt, movement, transfer and disposal of all radioactive material possessed under this license. Records of inventories will be maintained for 10 years from the date of each inventory.

B. A complete examination of records will be completed every six months to confirm the location of all radioactive material and ensure that possession is within the limits specified in this license.

C. A physical inventory of all radioactive material possessed under this license will be conducted on or before June 1, 1993. Thereafter, a physical inventory of all radioactive material possessed under this license will be completed within 60 months of the previous physical inventory.

15. The licensee's field service audits (as described in the ATC Medical Group Management Plan, revised April 1, 1989, and submitted with letter dated April 17, 1989) shall be performed unannounced by the Radiation Protection Officer (i.e., Radiation Safety Officer).

16. The licensee shall follow the recommend survey frequencies outlined in Regulatory Guide 8.21, Revision 1, October 1979, in work areas where radioactive materials are handled or used.

17. The licensee shall maintain records of information important to safe and effective decommissioning at 1020 London Road, Cleveland, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

18. The licensee shall maintain and execute the response measure of their Emergency Plan dated October 25, 1991 and revised January 1992, May 27, 1992 and April 26, 1993. The licensee shall make no change in the emergency plan submitted pursuant to 10 CFR [30.32(i), 40.31(j), 70.22(i)] that would decrease the effectiveness of the plan without prior Commission approval. The licensee may make changes to its Emergency Plan without prior Commission approval if the changes do not decrease the effectiveness of the plan. The licensee shall maintain records of changes that are made to the plan without prior approval for a period of three years from the date of the changes and shall furnish the Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and the appropriate NRC Regional Office specified in Appendix D of 10 CFR 20, a report, within six months after the change is made, containing a description of each change.

19. The licensee is authorized to begin the following activities no sooner than March 17, 1995, and must complete them by the date specified in each item in accordance with letters dated January 27, February 2, 10, and 14, and March 1, 3, 8, and 10, 1995, wherein the licensee proposed and clarified its plans for: (1) dealing with the accumulation of ground water in and around its facility basement; (2) immobilizing and/or remediating contamination that has collected in below ground sewer piping and manholes; and (3) processing future ground water that builds up around the facility. These plans address the following actions the licensee will take.

    A. Process water that is currently stored outside its facility in above-ground tanks.

        i. Tanked water will be processed in-situ using a submersible water treatment system that includes filtration and ion-exchange demineralization as described in letters dated March 1, 3, 8, and 10, 1995.

        ii. Water will be treated until it contains no detectable non-soluble cobalt-60 and less than 1000 pCi/l of soluble cobalt-60 as determined by a contract analytical laboratory. The licensee may continue to pump treated water to the collapsible storage containers prior to receiving results of solubility tests from the contract laboratory. The treated water will subsequently be pumped to 25,000 gallon storage containers located in the facility warehouse, as described in letters dated March 3, 8 and 10, 1995.

    B. Simultaneously pump and process water currently residing in the sewer manhole and lateral, building sump pit and basement. This project shall be completed by June 30, 1995.

        i. Pumping will be sequenced as described in letter dated March 1, 1995, to ensure a positive hydrostatic pressure is maintained from outside to inside the facility's basement.

ii. Water in the sewer manhole, lateral, building sump pit, and basement will be pumped to a radiologically controlled area of the facility and processed using a skid mounted, multi-stage filtration and ion-exchange system as described in letters dated March 1, 3, 8 and 10, 1995. Spill procedures and radiological controls will be implemented as described in letter dated February 14, 1995, and Attachment 2 to letter dated March 1, 1995.

iii. Water removed from the sewer manhole, lateral, building sump pit, and basement will be treated to contain no detectable non-soluble cobalt-60 and less than 1000 pCi/l soluble cobalt-60 as determined by a contract analytical laboratory. The licensee may continue to pump treated water to the collapsible storage containers prior to receiving results of solubility tests from the contract laboratory. The treated water will subsequently be pumped to 25,000 gallon storage containers located in the facility warehouse, as described in letters dated March 3, 8, and 10, 1995.

C. Water sampling and analytical protocols will be as described in letter dated February 2, 1995, as clarified in letters dated February 14, and March 3, 1995. Solubility of cobalt-60 in samples containing detectable activity will be demonstrated in accordance with the reference in Supplement 2 to letter dated March 3, 1995. All solid radwaste generated from the water processing activities, including filter and demineralizer resin wastes, will be collected and stored at the London Road facility pending its ultimate disposal as radioactive waste.

D. Excavate areas around the facility to allow: (i) access to the radioactively contaminated four-inch waste discharge line; and (ii) the radiological evaluation of the facility's underdrain system and surrounding soils.

i. Excavate the soil in the vicinity of the building's four-inch waste discharge line and underdrains and disconnect these drains as described in letter dated March 1, 1995. Evaluate the radiological contamination status of the underdrain system and remediate or replace the system. Reconnect the underdrain system to the building sump pit and pump, test and process the underdrain system waters as described in letter dated March 1, 1995. The testing and processing of water pumped from the underdrain system will continue until sampling of the water consistently reveals no detectable non-soluble cobalt-60 and less than 200 pCi/l soluble cobalt-60.

ii. Evaluate the radiological status of the soil in the vicinity of the underdrain system and building sump pit as described in the letter dated March 1, 1995.

E. Immobilize the radioactive contamination present in the sewer manhole and lateral.

i. Completely grout-in the radioactively contaminated manhole and lateral up to the sewer interceptor as described in "Issue 4" of letter dated January 27 and letter dated March 1, 1995. The grouting will render the existing sewer discharge piping system inoperable and immobilize (fix) the radioactive contamination that resides in the system.

F. Remediate the London Road interceptor in the vicinity of the abandoned lateral, as described in letter dated January 27, 1995. The remediation activities will be coordinated with the Northeast Ohio Regional Sewer District.

G. i. The licensee shall notify the NRC Region III office no later than July 14, 1995, regarding the status of the completion of License Condition Numbers 19.B., 19.D. and 19.E.

ii. The licensee shall notify the NRC Region III office no later than July 14, 1995, to confirm initiation of the remediation project described in License Condition Number 19.F., and provide an estimated completion date.

H. The licensee shall notify the NRC Region III office in writing of any change in projected milestone dates specified in letter dated July 19, 1995 for the projects described in License Condition Nos. 19.D., E. & F. Included in the notification must be the reason for the change, and the revised milestone date.

20. The licensee is authorized to install a new manhole and lateral and re-connect this to the existing under drain system. The purpose of the new manhole is strictly to act as a means of collecting water from the under drain system which will be pumped to storage containers and subsequent analysis for cobalt-60 concentration.

21. The licensee is authorized to install and operate the water evaporation equipment described in letters dated March 22, 1995, June 8, 1995 and June 29, 1995.

22. Notwithstanding previous requirements, and based upon additional information provided in letters dated October 17, 1995, and December 11, 1995, the licensee is not required to grout-in the 4-inch sewer discharge line and the abandoned footer drain.

23. The licensee is authorized to perform Tasks 1 and 2 of the Building Recovery Project as described in letters dated June 10, 1996, July 8, 1996, September 18, 1996, October 3, 1996, October 11, 1996, and November 1, 1996.

24. The following are conditions under which the Building Recovery Project (BRP) funds may be used:

A. The BRP funds released from the collateral supporting the letter of credit dated January 27, 1995 shall be used solely for the purpose of completing Tasks 1 and 2 of the BRP.

B. Immediately after the release of funds, the licensee shall secure an amendment to the January 27, 1995 letter of credit to reflect the remaining balance of the supporting collateral. This shall be submitted to NRC for review immediately after the instrument is amended.

C. Any funds remaining after Tasks 1 and 2 are completed shall be added to the collateral supporting the letter of credit, and the letter of credit must be revised to reflect the addition of the collateral. This shall be submitted to the NRC for review.

D. The funds released from the collateral supporting the letter of credit shall not be used for implementation of Tasks 3 through 12 of the BRP.

25. A. Advanced Medical Systems, Inc. is authorized to collect, sample, and test the water from its foundation drainage system per the following procedures, dated April 3, 1997: RSP-018, "Operation of the Gamma Spectrometer," RSP-019, "Assessment of Radioactivity in Water Samples," and RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy." Each tank of water shall be analyzed for total cobalt-60 content (soluble and insoluble) and for insoluble cobalt-60.

B. Before the water may be discharged into the sanitary sewerage system, all of the following criteria must be satisfied: (1) discharges of water shall not exceed 25,000 gallons in a 24-hour period, (2) water that contains total cobalt-60 activity of greater than 100 picocuries per liter (pCi/l) shall not be discharged, (3) water that contains detectable insoluble cobalt-60 (minimum detectable activity no greater than 15 pCi/l of water) shall not be discharged. Insoluble cobalt-60 for purposes of this license condition is any cobalt-60 activity, above background, that is stopped by a filter of pore size no greater than 0.45 micrometer.

26. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated November 12, 1984;

B. Letters dated November 12, 1984 (excluding Item 4), February 12, 1985, June 7, 1985 (excluding letter Item 4), September 6, 1985 (excluding change to Page 29 of ISP-1 manual);

C. Letters dated May 29, 1986 (Response to Enclosure A, Significant Licensing Deficiencies of NRC letter dated March 7, 1986);

D. Letter dated July 23, 1986 (Response to Enclosure B, Additional Licensing Issues for Renewal Applications of NRC letter dated March 7, 1986) excluding approval of the licensee's in-house training program;

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E. Letters dated August 22, 1986, October 28, 1986, November 13, 1986, November 14, 1986 and December 4, 1986 (with Revised ISP-1 Manual, Appendices A and B attached), May 7, 1987, August 3, 1987, December 31, 1987, January 15, 1988 (Item V only), August 15, 1988 (with attached course manual), September 29, 1988 (with attachments) and November 21, 1988.

F. Letters dated March 29, 1989 (except Section 3.4 "Hot Cell Entry and Action Levels"), April 7, 1989, August 25, 1989 (except Item B(4)), July 23, 1990 (except Sections 3.0 and 5.0 of ISP-14 procedure), March 1, 1991 (with attachments), March 27, 1991 (with attachments), May 9, 1991, May 14, 1991, February 27, 1992, February 28, 1992, March 2, 1992, and March 5, 1992.

G. Letters dated April 16, 1992 (with enclosures), June 15, 1992 (with attachments), August 10, 1992, September 18, 1992, December 29, 1992 (with enclosures), January 20, 1993, March 30, 1993, March 31, 1994 (with enclosure), April 11, 1994, and September 21, 1994.

H. Letters with attachments dated January 27, 1995, February 2, 10, and 14, 1995, and March 1, 1995 (excluding reference to grouting-in the four-inch sewer discharge line), and March 3, 8, and 10, 1995.

Notwithstanding any reference to the specific activities in the above listed letters, the following activities are not addressed by this license.

i. The discharge of treated water to the sanitary sewer system.

ii. Installation of a composite sampler and flow gage.

iii. Conventional disposal of excavated soils exhibiting cobalt-60 concentrations greater than 8 pCi/g.

I. Letters dated May 3, 1995, May 17, 1995, June 6, 1995, June 13, 1995 and June 14, 1995 (received June 21, 1995) March 22, 1995 (Item 1 related to water evaporation use and associated attachments), June 8, 1995, June 14, 1995 (received June 19, 1995), June 29, 1995, July 19, 1995 (excluding all references to grouting-in the four-inch sewer discharge line and the abandoned footer drain in the vicinity of the Source Garden), July 20, 1995, July 21, 1995, October 17, 1995, December 11, 1995 (with referenced photograph), June 10, 1996 (excluding the use of funds released from the collateral supporting the letter of credit to implement Tasks 3 through 12 of the Building Recovery Project), April 24, 1996, July 1, 1996, July 15, 1996 and January 7, 1997.

J. Surveillance Plan for the London Road Facility submitted in letters dated September 5, 1995, December 18, 1995 and May 23, 1996.

K. Tasks 1 and 2 of the Building Recovery Project submitted in letters (with attachments) dated June 10, 1996, July 8, 1996, September 18, 1996, October 3, 1996, October 11, 1996, and November 1, 1996.

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L. Emergency Plan for the London Road facility (as required by 10 CFR 30.32) submitted in letters (with attachments) dated September 21, 1995, March 21, 1996, June 7, 1996, and August 14, 1996; and

M. Letter dated April 3, 1997 (with attachments RSP-018, "Operation of the Gamma Spectrometer," RSP-019, "Assessment of Radioactivity in Water Samples," and RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy").

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 4/4/97

By John R. Mack
Nuclear Materials Licensing Branch, Region III

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 2
FEE CATEGORY: 3P 3N 2B
EXP. DATE: 19941231
FEE COMMENTS:
DECOM FIN ASSUR REQD: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ADVANCED MEDICAL SYSTEMS, INC.
RECEIVED DATE: 960626
DOCKET NO: 3016055
CONTROL NO.: 301524
LICENSE NO.: 34-19089-01
ACTION TYPE: AMENDMENT

R2

2. FEE ATTACHED
AMOUNT:
CHECK NO.: * Addl Amts 39849-R1

3. COMMENTS

SIGNED D. Hersey
DATE 6-28-96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /✓/)

1. FEE CATEGORY AND AMOUNT: 3P 3N 2B FEE NOT REQUIRED

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL
LICENSE

3. OTHER

SIGNED AC
DATE 7/3/96

RECEIVED
JUL 12 1996
REGION III

RECEIVED BY LFDCB
Date July 2, 1996
Log July 3 III
By AC
Date Completed July 3, 1996

1996 JUL -2 AM 10:58

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

June 25, 1996

TAR + HQ
398249
RI

Mr. Geoffrey Wright
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34 19089-01

Dear Mr. Wright:

On March 1, 1995 and March 20, 1995, Advanced Medical Systems, Inc. (AMS) submitted applications to amend the referenced license to permit release of ground/surface water that collects in the *remediated* underdrain system of the London Road facility. As of the date of this letter, USNRC authorization to proceed on this request has not yet been received.

Since the date of those applications, AMS has faced a series of extenuating circumstances that have increased the urgency for action. However, we recognize that considerable time has passed since then, and that some of the original descriptions and specifications contained in the 1995 applications are no longer applicable. The purpose of this letter is to reiterate our request to amend the referenced license to permit free discharge of water pumped from the foundation drainage system. Attached is a brief description of the regulatory action on this issue to date, a discussion of the reason for our request and its justification, and a description of the procedure we intend to follow when USNRC authorization to proceed is given.

Please call me at (216) 692-3270 if you have any questions or if I can assist you in any way in expediting your review. We are asking for prompt USNRC action on this important issue.

Sincerely,

Robert Meschter

Robert Meschter, RSO

cc: D. Cesar
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

FEE NOT REQUIRED
ADD'L info-398249

RECEIVED
JUN 26 1996
REGION III

31524

REQUEST TO DISCHARGE GROUND/SURFACE WATER FROM THE REMEDIATED SEWER SYSTEM

Purpose

As a result of technically-indefensible legal action taken by the Northeast Ohio Regional Sewer District (NEORSD), the Advanced Medical Systems, Inc. (AMS) facility on London Road does not have a direct connection between the building and the regional sewer system for the discharge of sanitary waste, rain water from the building's roof drains or the storm water that surrounds the building. Even after completion of an extensive sewer remediation project that involved installation of a new foundation drainage system and a new manhole, the free-flow of water away from the building is still not possible for a variety of legal and regulatory reasons.

As of the date of this letter, AMS is bound by court order and USNRC license requirements to pump water from the foundation drains into hold-up tanks, sample the tanks for the presence of radioactivity, notify the NEORSD of pending discharge of each tank, and await the results of a NEORSD confirmatory sampling effort prior to discharge. As a result, a major portion of the daily activities performed by the AMS staff at the London Road facility involves water management.

Because of the delay associated with discharge of each tank (e.g., typically four days), coupled with the increased precipitation AMS experiences during the spring, early summer and fall months, temporary limitations in tank storage capacity may occur. If a spring or summer storm should cause our tank or pumping capacity to be exceeded, AMS has one of two options: (1) it must discharge the pumped water without sampling and in violation of the court order, or (2) it must cease pumping the water out of the manhole. If pumping ceases, (e.g., if the foundation drainage system is rendered non-functional), the storm water that accumulates around the building is likely to enter the building basement, come into contact with the contents of the WHUT Room and the stored waste, and become contaminated. This water cannot be discharged until the radioactivity has been removed.

The financial and radiological impacts associated with foundation drain failure or impaired tank capacity would be similar to those suffered during the financially-devastating flood of 1995. This occurrence forced AMS to implement an expensive water treatment and sewer remediation program that cost in excess of $1M.[1] It also drained the corporation of almost all of its cash reserves, rendering it unable to bear the cost of another water clean-up project if such an event should be required.

The 1995 basement flood also raised questions in regard to the structural integrity of the building. In subsequent inspections by the USNRC and a registered Professional Engineer working under contract to AMS, it was determined that this event caused no apparent damage to the building or its ability to contain its inventory of licensed radioactive materials. However, there is no guarantee that a future flood event will have a similar outcome. Thus it is imperative that AMS receive USNRC authorization to freely discharge the water from the foundation drainage system, without lengthy and costly hold-

[1] As of the date of this letter, the treated water from the 1995 project continues to be stored in the AMS warehouse in collapsible storage tanks.

up/sampling steps, so that a permanent (functional) drainage system can be installed. Only then will the potential for water incursion into the basement be minimized.[2]

Regulatory Action to Date

On March 1, 1995, AMS submitted an application to amend USNRC License No. 34-19089-01 to permit water treatment and sewer remediation to proceed at the London Road facility.[3] Included in that application was a proposed methodology for evaluating contaminant levels in the ground/surface water after the work was complete so that water could be freely discharged. In response, Amendment No. 32 to the license was issued. However, re-connection of the remediated foundation drainage system to a new manhole and installation of a methodology for evaluating contaminant levels were specifically excluded.

On March 20, 1995, AMS requested another amendment to License No. 34-19089 wherein re-connection of the remediated foundation underdrain system to a new manhole, installation of a sampling device, and authorization to discharge through the new lateral ground/surface water that meets the release criteria were specifically requested. In a June 14, 1995 communication, the USNRC solicited additional information in regard to AMS's request. AMS provided that information on June 16, 1996, and on June 21, 1996, the USNRC responded as follows:

> ". . . we have received your June 16, 1995 response to our June 14, 1995 deficiency letter and will make every effort to review your response in an expeditious manner. We will notify you if we have additional questions. Again, please note that we have only approved the installation of a new manhole and lateral and its re-connection to the existing under drain system. We will need to evaluate all of the other issues regarding cobalt-60 contamination within the existing underdrain system and soils both under the building and in the vicinity of the underdrain system prior to discharge of collected water."

On June 27, 1995, AMS received Amendment No. 37 to the referenced license, wherein the water discharge issue was again excluded. However, in the transmittal letter, the USNRC stated the following in regard to how effective the sewer remediation might be:

> "Note that we are still in the process of reviewing information you submitted relative to installation of a sampling device on the new lateral connection (reference Item 2 of your 3/22/95 letter, and letter dated June 16, 1995). Also regarding your June 16 letter, we are reviewing Item II.C. which describes your proposed soil sampling program to evaluate the radiological conditions of the soil under the building and in the vicinity of the under drain system. We anticipate that we will have additional questions on both of these issues and will forward them to you as soon as possible."

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[2] AMS recognizes that it is barred, by court order, from freely releasing the ground/surface water collected from the underdrain system. However, USNRC authorization to free-release the water is a necessary part of a permanent legal solution.

[3] The March 1, 1996 amendment application was supplemented in a March 3, 1995 communication.

On July 17, 1995, AMS received Amendment No. 38 to the referenced license. Again, the water discharge issue was excluded. However, the following statement in regard to the effectiveness issue and subsequent free-release of water was in the transmittal letter:

> "Note that we are still in the process of reviewing Item II. in your June 16, 1995 letter, regarding your proposed soil sampling program, and the grouting/remediation project. We anticipate that we will have additional questions on these issues and will forward them to you as soon as possible".

As of the date of this letter, no additional regulatory action on our requests to freely discharge ground/surface water from the remediated sewer system has been taken.

Effectiveness of the Sewer Remediation

In its June 27, 1995 and July 17, 1995 communications, the USNRC expressed concern over the effectiveness of the sewer remediation project, and implied that this was the reason for delayed action on issuing a license provision to discharge water from the underdrain system. AMS maintains that the sewer remediation project was completely effective in removing or isolating all residual radioactivity outside of the London Road building, and that the only residual contamination remaining outside of the building after the remediation (e.g., that in the abandoned footer drain in the immediate vicinity of the Source Garden and the abandoned lateral connection between the old manhole and the London Road interceptor) is hydraulically isolated from ground/surface water paths to the underdrain system. AMS also maintains that the soils upon which the London Road building was constructed have the same radiological character now as they did before the 1995 flood and thus cannot contribute to future contaminant migration. The following are the reasons why these positions are justified:

> (1) Throughout the period of time that the basement of the London Road facility was flooded due to the regional sewer district's intentional blocking of all discharge paths, AMS maintained a minimal pressure differential between the inside and outside water levels in order to minimize uplift on the floor slab and eliminate the possibility of "back flow" of contaminated water to areas outside of the building. AMS's pumping efforts clearly provided the necessary level of pressure control.[4] This was evidenced in USNRC Inspection Report No. 030-16055/95006(DNMS) wherein it was stated that, with the exception of one location on the second floor of the building, "the reinforced concrete core structure of the 1958 building that forms the hot cell, the WHUT room, the original radiography room, the source garden and the front and back basements was found to be in good condition". Furthermore, the inspection found "no additional signs of distress" on the basement slab, and concluded that "there was no observable significant impact on the structural integrity of the 1958 building as a result of the basement flooding event". This finding was confirmed during an independent evaluation performed by a registered Professional Engineer under contract to AMS.[5] Thus the structural evidence supports our position that pressure gradients sufficient to jeopardize the integrity of the slab did not occur.

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[4] Documentation to support this position is available for USNRC review.

[5] See June 7, 1996 letter from R. Meschter (AMS) to Mr. Geoffrey C. Wright (USNRC, Region III).

(2) During the 1995 sewer remediation project, AMS confirmed, through measurements and sampling, that the shale layer upon which the building is built and which formed the base of the existing footer drains, did not contain detectable radioactivity. In fact, no detectable activity was identified during the remediation other than that in the existing drain tile and the fill material upon which the drain tile rested. Thus the radiological data acquired during the remediation project support our position that the radiological conditions of the soil under the basement and the WHUT room are equivalent to their pre-flood conditions (e.g., when core samples taken through the basement in prior to the flood exhibited radiologically-benign conditions).

(3) In an April 12, 1996 communication to Mr. John Madera (USNRC, Region III), AMS attached a Registered Hydrogeologist's report wherein he concluded that the new drain tile is hydraulically connected to the soils under the basement floor. In other words, if contamination migrated from the basement to these soils, it would appear in the water that is pumped out of the system.

(4) Between the 1995 completion date of the sewer remediation project and the date of this letter, over 140,000 gallons of water have been pumped from the foundation drainage system, confirmed to be "clean" through laboratory analyses, and discharged.[4] This is further proof that no mobile contamination is under the basement or in the new drainage system.

The findings of the USNRC Inspection Report, the hydraulic connection between the soils under the building and the drain tile, and the fact that the water being pumped from the foundation drains has been and continues to be radiologically benign, provide an abundance of evidence to support our position that the new underdrain system is completely isolated from any sources of radioactivity.

Basis for Modifying the 1995 Discharge Procedure

In AMS's March 1, 1995 and March 20, 1995 license amendment requests to discharge ground/surface water, it was anticipated that an immediate outcome of the sewer remediation project would be re-connection of the sanitary and storm sewers from the London Road facility to the NEORSD's interceptor. Therefore, in those applications AMS proposed a monitoring methodology designed to accomplish two purposes:

- *Confirming* that water that entered the sewer system was free of radioactivity.
- Demonstrating that the remediation efforts were, in fact, effective.

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[4] Cobalt-60 was identified in two 3,000-gallon batch tanks and one 25,000 gallon frac tank. However, the source of this contamination was the tanks themselves, which were used as process tanks for the water treatment project. The residual ^{60}Co that remained in the batch tanks when they were first filled with water from the remediated underdrain system was removed by filtration. Sampling of subsequent batches of water held in these tanks has been negative for the presence of ^{60}Co. Remedial action for the frac tank is delayed pending resolution of a non-radiological issue.

Because the water in the remediated underdrain system was intended to flow by gravity into the London Road interceptor, the proposed monitoring methodology involved installation of an in line flow meter and composite sampler into the lateral connection. The intent was to collect and analyze composite samples on a planned and periodic basis until such time as all parties were confident of the effectiveness of the sewer remediation effort.

Unfortunately, due to the on-going litigation between AMS and the regional sewer district re-connection of the building sewers to the London Road interceptor is not likely in the foreseeable future. Therefore, an alternative methodology for meeting the intent of the March 1 and March 20, 1995 applications (e.g., one that does not require a gravity-fed discharge path) is necessary.

The water that enters the underdrain system is neither effluent from the London Road facility per 10 CFR 20.1302(b)(2)(i), nor is it discharged licensed materials into the sanitary sewer system per 10 CFR 20.2003(a). It is simply groundwater and storm water that collects within the "bathtub" of shale surrounding the building. Since this groundwater and storm water does not come in contact with any sources of ^{60}Co, continuous monitoring of the radionuclide content of this water as required in 10 CFR 20.1302(a) is not necessary.

On the other hand, 10 CFR 20.1501 and license condition 23.J of License No. 34-19089-01 require AMS to conduct a surveillance program in order to estimate doses to the public and to document that migration of radioactive materials from known locations does not occur. USNRC Regulatory Guide Reg Guide 8.37, "ALARA Levels for Effluents from Materials Facilities" indicates that Regulatory Guide 4.14, "Radiological Effluent and Environmental Monitoring at Uranium Mills" is a useful source of guidance for materials licensees in this regard.

Regulatory Guide 4.14 recommends that samples of water from "any surface water crossing the site boundary and offsite streams or rivers that may be subject to drainage from potentially contaminated areas or from a tailings impoundment failure" be collected at least monthly.[1] Pursuant to this guidance, AMS intends to implement an even more aggressive sampling program for the surface water that enters the underdrain system in order to document that migration of radioactivity from potentially contaminated areas has not occurred. The following section describes the proposed sampling program.

Description of the Ground/Surface Water Sampling Program

Once USNRC and legal authority to freely discharge the storm/ground water that collects in the underdrain system of the London Road building has been received, AMS will operate a temporary automatic pumping system to remove water that accumulates in the new manhole. This water will be discharged to a storm sewer catch basin on the west side of the building's west parking lot. AMS will then pursue the legal authority to re-institute a permanent (gravity-fed) discharge system.

Consistent with the Regulatory Guide 4.14 guidance, a one liter sample of water will be collected from the manhole once per week and analyzed pursuant to Radiation Safety Procedure No. RSP-018.

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[1] The Regulatory Guide also states that "operational samples should be collected upstream and downstream of the area of potential influence", and that "any unusual releases (such as surface seepage) that are not part of normal operations should be sampled".

"Operation of the Gamma Spectrometer", and RSP-019, "Assessment of Radioactivity in Water Sample ".* All results will be documented and maintained as described in RSP-003, "Radiation Protection Records".

Regulatory Guide 4.14 recommends that the lower limits of detection for the sample analysis be 10% of the appropriate concentration limit listed in Table II of Appendix B to 10 CFR 20 (e.g., 300 pCi per liter for ^{60}Co). However, the following release criteria that are specific to AMS (see RSP-019) and which demand a more stringent performance standard, are applicable:

- Water that contains greater than 100 pCi per liter of ^{60}Co in any form (e.g., "soluble" or "insoluble"), as determined from the sampling and analysis effort, shall not be discharged.

- Water than contains no detectable ^{60}Co activity by direct counting (e.g., analytical results that are below a nominal detection limit of 70 pCi per liter) may be discharged.

- Water that exhibits both of the following may be discharged:

  Less than 100 pCi per liter of ^{60}Co by direct counting and

  No detectable ^{60}Co activity (e.g., analytical results that are below a nominal detection limit of 15 pCi per liter) on a 0.45 micrometer filter after filtration.

Since AMS would consider any detectable ^{60}Co in samples collected from the manhole to be an "unusual release", such an occurrence would trigger re-instatement of "tanking" procedures (e.g., the water will be pumped to hold-up tanks, sampled, and confirmed to meet the release criteria prior to discharge) until the cause has been identified and corrective action instituted.

* As recommended in Regulatory Guide 4.14, if the manhole is dry on a scheduled sampling collection date, that sample will be collected immediately after water starts to flow.

Advanced Medical Systems, Inc.

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

Fax Cover Sheet

Date 6/26/96

ATTN: Geoffre Wright FAX NO.:

COMPANY:

FROM: Bob Mescher EXT.

SUBJECT:

MESSAGE

See attached - Original via US. Mail

APR 0 4 1997

Stephen J. Haddock
Radiation Safety Officer
Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110

Dear Mr. Haddock:

Enclosed is Amendment No. 48 to your NRC Material License No. 34-19089-01 in accordance with your request.

This amendment authorizes Advanced Medical Systems, Inc. (AMS) to collect, sample, and test the water from its foundation drainage system per the following procedures: RSP-018, "Operation of the Gamma Spectrometer," RSP-019, "Assessment of Radioactivity in Water Samples," and RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy." The amendment also requires AMS to analyze each tank of water for total cobalt-60 content (soluble and insoluble) and for insoluble cobalt-60. In addition, the amendment authorizes AMS to discharge the tanked water into the sanitary sewerage system if all of the following criteria are satisfied: (1) discharges of water shall not exceed 25,000 gallons in a 24-hour period, (2) water that contains total cobalt-60 activity of greater than 100 picocuries per liter (pCi/l) shall not be discharged, (3) water that contains detectable insoluble cobalt-60 (minimum detectable activity no greater than 15 pCi/l of water) shall not be discharged.

Please review the enclosed document carefully and be sure that you understand all of the conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office so that we can provide appropriate corrections and answers.

Sincerely,

Original Signed By
Michael F. Weber
Nuclear Materials Licensing Branch

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

Enclosure: Amendment No. 48

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NAME	MFWeber:brt							
DATE	04/ 4 /97							

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301524

From: Sami Sherbini
To: CHD1.CHP2(MFW1)
Date: 4/3/97 8:02am
Subject: AMS license condition -Reply -Reply -Reply

Mike,

It looks good. Thanks.

CC: TWD2.TWP8(JMP1, SWM),

This is in response to my 4/3/97 7:12 am e-mail, which included a revised LC for AMS.

As soon as I received this e-mail from Sami, I called him and asked if we had NMSS' approval for the LC - he replied in the affirmative.

M.T. Wake 4/3/97.

From: Michael Weber
To: TWD2.TWP8(SXS2)
Date: 4/3/97 7:12am
Subject: AMS license condition -Reply -Reply

Sami,

We removed a few words to make it easier to read. Let me know what you think.

Thanks, Mike

CC: TWD2.TWP8(JMP1, SWM),

Attachment to 4/3/97 7:12am e-mail from M. Weber to S. Sherbini

Advanced Medical Systems, Inc. is authorized to collect, sample, and test the water from its foundation drainage system per the following procedures, dated April ??, 1997: RSP-018, "Operation of the Gamma Spectrometer," RSP-019, "Assessment of Radioactivity in Water Samples," and RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy." Each tank of water shall be analyzed for total cobalt-60 content (soluble and insoluble) and for insoluble cobalt-60.

Before the water may be discharged into the sanitary sewerage system, all of the following criteria must be satisfied: (1) discharges of water shall not exceed 25,000 gallons in a 24-hour period, (2) water that contains total cobalt-60 activity of greater than 100 picocuries per liter (pCi/l) shall not be discharged, (3) water that contains detectable insoluble cobalt-60 (minimum detectable activity no greater than 15 pCi/l of water) shall not be discharged. Insoluble cobalt-60 for purposes of this license condition is any cobalt-60 activity, above background, that is stopped by a filter of pore size no greater than 0.45 micrometer.

Advanced Medical Systems, Inc.

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

April 3, 1997

Mr. Michael Weber
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Radiation Safety Procedures for USNRC License No. 34-19089

Dear Mr. Weber:

Pursuant to our telephone conversation of April 3, 1997, under separate cover you will receive the following Advanced Medical Systems, Inc. (AMS) Radiation Safety Procedures:

- RSP-018, *Operation of the Gamma Spectrometer*, Revision No. 000, April 3, 1997
- RSP-019, *Assessment of Radioactivity in Water Samples*, Revision No. 000, April 3, 1997
- RSP-022, *Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy*, Revision No. 000, April 3, 1997.

These unsigned procedures have been reviewed and approved by the AMS Radiation Safety Committee. Immediately after we have received USNRC approval, the original copy of each procedure will be signed, and the procedure will be implemented as part of the AMS radiation protection program.

USNRC response on this important issue is imperative. Please call me at (216) 692-3270 if there is anything I can do to expedite your approvals.

Sincerely

Stephen J. Haddock

Stephen J. Haddock, R.S.O.

cc: E. L. Svigel
D. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

Advanced Medical Systems, Inc.

OPERATION OF THE GAMMA SPECTROMETER	Procedure: RSP-018	Revision No.: 000
	Page: 1 of 20	Date: April 3, 1997
	Approved by (Engineering Manager):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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CONTROLLED COPY NO. : _____

1 PURPOSE

The purpose of this Radiation Safety Procedure (RSP) procedure is to provide instruction on the operation of the sodium-iodide-based gamma spectroscopy system at Advanced Medical Systems, Inc. (AMS).

2 SCOPE

This RSP applies to the routine operation of the gamma spectroscopy system in use at the London Road facility for analysis of samples used to demonstrate compliance with regulations, requirements or RSPs. Analysis of other than water or soil samples or filters, or analyses for purposes other than compliance demonstration, are exempt from the requirements of this RSP.

3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission License No. 34-19089-01 (as amended).

3.2 U. S. Nuclear Regulatory Commission, NUREG-1507, "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions - Draft Report for Comment", August, 1995.

3.3 Strom-92 - Strom, D. J. and P. S. Stansbury, "Minimum Detectable Activity when Background is Counted Longer than the Sample", *Health Physics* 63(3):360-361, 1992.

3.4 Currie-68 - Currie, L.A. (1968), "Limits for Qualitative Detection and Quantitative Determination", *Analytical Chemistry* 40(3):586-593.

3.5 Currie-84 - Currie, L.A. (1984), "Lower Limit of Detection: Definition and Elaboration of a Proposed Position for Radiological Effluent and Environmental Measurements", NUREG/CR-4007, Nuclear Regulatory Commission.

3.6 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy".

4 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be included in RSP-002, "Definitions".

5 PROCEDURE

5.1 General Instructions

5.1.1 The spectroscopy system should be positioned in a location (counting room) that is confirmed to have as little competing background as possible.

Note: To confirm that the detector canning is free of contamination, smear the outside of the canning and ensure that the smear count is less than "2x background".

5.1.2 The counting room should not exhibit significant fluctuations in temperature over a 24-hour period.

Note: Temperature fluctuations of $\pm$ 20°F may cause phototube drift and apparent gain shifts.

5.1.3 All values should be recorded in scientific notation with two (2) figures to the right of the decimal point.

Note: For example, an efficiency of 0.02065 is recorded as 2.07×10^{-2}.

5.1.4 The quality assurance and quality control provisions of RSP-022 shall be incorporated into all analyses.

5.1.5 The RSO shall perform a final review of the data package associated with all sample results for completeness, accuracy, consistency, and compliance with RSP-022.

5.2 Determine Energy Response and Regions of Interest

5.2.1 Energy response and regions of interest shall be determined daily prior to initial use.

5.2.2 Place a ^{60}Co calibration source over the detector.

5.2.3 Adjust amplifier gain and/or high voltage so that the two primary photopeaks fall in channels 155 (1.17 MeV peak) and 176 (1.33 MeV).

5.2.4 Acquire data until approximately 4,000 counts appear in Channel 176, then stop data acquisition.

5.2.5 Determine the regions of interest.

5.2.5.1 Place the left cursor to the left of channel 155 at the location where the peak tail intersects the continuum.

5.2.5.2 Place the right cursor to the right of channel 176 at the location where the peak tail intersects the continuum.

5.2.6 Record the left and right channel numbers on Attachment 1

5.3 Determination of Water Background

5.3.1 Background count rates in the regions of interest should be determined at least once per work week, at the end of a shift.

5.3.2 Place a Marinelli Beaker containing deionized water over the detector.

5.3.3 Acquire background counts for t_B = 28,800 seconds (eight hours).

5.3.4 Determine the number of counts, C_B, in the Region shown on Attachment 1, and record on Attachment 2.

Note: Maintain a separate Attachment 2 for each media type (e.g., water, soil or filter).

5.3.5 Determine the background count rate, R_B, as follows and record on Attachment 2:

$$R_B = \frac{C_B}{t_B}$$

where R_B = the background count rate (counts per second), C_s = the number of sample counts, and t_s = the sample count time (sec).

5.4 Determination of Soil Background

5.4.1 Background count rates in the regions of interest should be determined at least once per work week, at the end of a shift.

5.4.2 Place a Marinelli Beaker containing dry, cobalt-free soil collected from the AMS property over the detector.

5.4.3 Acquire background counts for t_B = 28,800 seconds (eight hours).

5.4.4 Determine the number of counts, C_B, in the Region shown on Attachment 1, and record on Attachment 2.

Note: Maintain a separate Attachment 2 for each media type (e.g., water, soil or filter).

5.4.5 Determine the background count rate, R_B, as follows and record on Attachment 2:

$$R_B = \frac{C_B}{t_B}$$

where R_B = the background count rate (counts per second), C_s = the number of sample counts, and t_s = the sample count time (sec).

5.5 Determination of Filter Background

5.5.1 Background count rates in the regions of interest should be determined at least once per work week, at the end of a shift.

5.5.2 Place the planchette and an unused filter of the same size and composition as those used to filter water over the detector.

5.5.3 Acquire background counts for t_B = 28,800 seconds (eight hours).

5.5.4 Determine the number of counts, C_B, in the Region shown on Attachment 1, and record on Attachment 2.

Note: Maintain a separate Attachment 2 for each media type (e.g., water, soil or filter).

5.5.5 Determine the background count rate, R_B, as follows and record on Attachment 2:

$$R_B = \frac{C_B}{t_B}$$

where R_B = the background count rate (counts per second), C_s = the number of sample counts, and t_s = the sample count time (sec).

5.6 Determine Detection Efficiency for Water

5.6.1 The detection efficiency for water should be determined daily, at the start of each shift, after the energy calibration and regions of interest are determined.

5.6.2 Place the water-equivalent calibration source in a Marinelli beaker geometry (Source No. A3082) over the detector.

5.6.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 526.3\ e^{\frac{-0.693 \times t}{1923.92}}$$

where t = the number of days since March 1, 1995, and 526.3 = the number of nanocuries of ^{60}Co in the source on March 1, 1995.

5.6.4 Record corrected activity on Attachment 3.

5.6.5 Acquire data for t_{std} = 600 seconds.

5.6.6 Determine the number of counts, C_{std}, in the Region shown on Attachment 1, and record on Attachment 3.

5.6.7 Determine the count rate, R_{std}, by the following and record on Attachment 3.

$$R_{std} = \frac{C_{std}}{t_{std}}$$

where R_{std} = the standard count rate (counts per second), C_{std} = the number of standard counts, and t_s = the standard count time (sec).

5.6.8 Determine the detection efficiency, E_{water}, by the following and record on Attachment 3.

$$E_{media} = \frac{R_{std}}{A_{today} \times 37}$$

where R_{std} = the standard count rate (counts per second) and A_{today} = the standard activity on the data of data collection (nanocuries).

5.7 Determine Detection Efficiency for Soil

5.7.1 Detection efficiencies for soil should be determined daily, at the start of each shift after the energy calibration and regions of interest are determined.

5.7.2 Place the soil-equivalent calibration source in a Marinelli beaker geometry (Source No. A3083) over the detector.

5.7.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 587.6\ e^{\frac{0.693 \times t}{1923.92}}$$

where t = the number of days since March 1, 1995, and 587.6 = the number of nanocuries of ^{60}Co in the source on March 1, 1995.

5.7.4 Record corrected activity on Attachment 4.

5.7.5 Acquire data for t_{std} = 600 seconds.

5.7.6 Determine the number of counts, C_{std}, in the Region shown on Attachment 1, and record on Attachment 4.

5.7.7 Determine the count rate, R_{std}, by the following and record on Attachment 4.

$$R_{std} = \frac{C_{std}}{t_{std}}$$

where R_{std} = the standard count rate (counts per second), C_s = the number of standard counts, and t_s = the standard count time (sec).

5.7.8 Determine the detection efficiency, E_{soil}, by the following and record on Attachment 4.

$$E_{media} = \frac{R_{std}}{A_{today} \times 37}$$

where R_{std} = the standard count rate (counts per second) and A_{today} = the standard activity on the data of data collection (nanocuries).

5.8 Determine Detection Efficiency for Filter

5.8.1 Detection efficiencies for filters should be determined daily, at the start of each shift after the energy calibration and regions of interest are determined.

5.8.2 Place the disk calibration source (Source No. IPL-495-51) in a plated source geometry over the detector.

5.8.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 13.4\ e^{\frac{0.693 \times t}{1923.92}}$$

where t = the number of days since June 1, 1995, and 13.4 = the number of nanocuries of ^{60}Co in the source on June 1, 1995.

5.8.4 Record corrected activity on Attachment 5.

5.8.5 Acquire efficiency data for t_{std} = 600 seconds.

5.8.6 Determine the number of counts, C_{std}, in the Region shown on Attachment 1, and record on Attachment 5.

5.8.7 Determine the count rate, R_{std}, by the following and record on Attachment 5.

$$R_{std} = \frac{C_{std}}{t_{std}}$$

where R_{std} = the standard count rate (counts per second), C_s = the number of standard counts, and t_s = the standard count time (sec).

5.8.8 Determine the efficiency, E_{filter}, by the following and record on Attachment 5.

$$E_{media} = \frac{R_{std}}{A_{today} \times 37}$$

where R_{std} = the standard count rate (counts per second) and A_{today} = the standard activity on the data of data collection (nanocuries).

5.9 Data Acquisition for Water

5.9.1 Collect a full Marinelli beaker of water.

5.9.2 Label the sample by W-xxxxxx-yy, W = Water, xxxxxx = today's date (e.g., 030195 for March 1, 1995), and yy = a unique sequential identifier that repeats at the start of each day (e.g., 01, 02, etc.).

5.9.3 Seal the sample container

5.9.4 The sample amount (A), in liters, on Attachment 6 shall be assumed to be one (1).

5.9.5 Confirm that the outside of the sample container is free of contamination by smearing the outside of the container and ensuring that the smear count is less than "2x background".

Note: If contamination by a radionuclide other than ^{60}Co or other non-radiological material is suspected, place the container in a thin-walled plastic bag prior to its placement on the detector.

5.9.6 Place the sample over the detector and acquire data for t_S = 7,200 seconds (two hours).

Note: For underdrain water, if the measured concentration is greater than 100 pCi per liter, or if the calculated MDA is greater than 50 pCi per liter, the sample should be sent to an analytical laboratory for confirmatory analysis.

5.9.7 Filter the water sample through a 0.45 micrometer filter pursuant to RSP-019 and place the filter in a petrie dish (or similar container).

5.9.8 Place the filter over the detector and acquire data for t_S = 14,400 seconds (four hours).

5.9.9 Remove and archive the filter.

Note: For underdrain water, if the filter is positive for the presence of ^{60}Co, or if the MDA is greater than 15 pCi per liter, the filter should be sent to an analytical laboratory for confirmatory analysis.

5.10 Data Acquisition for Soil

5.10.1 Collect a full Marinelli beaker of soil.

5.10.2 Label the sample by S-xxxxxx-yy S = Soil, xxxxxx = today's date (e.g., 030195 for March 1, 1995), and yy = a unique sequential identifier that repeats at the start of each day (e.g., 01, 02, etc.).

5.10.3 Seal the sample container

5.10.4 Determine the sample amount (A), in grams, by the following and record on Attachment 6:

$$A = MB_F - MB_E$$

where MB_E = the weight of the empty Marinelli beaker (grams), and MB_F = the weight of the full Marinelli beaker (grams).

5.10.5 Confirm that the outside of the sample container is free of contamination by smearing the outside of the container and ensuring that the smear count is less than "2x background".

Note: If contamination by a radionuclide other than ^{60}Co or other non-radiological material is suspected, place the container in a thin-walled plastic bag prior to its placement on the detector.

5.10.6 Place the sample over the detector and acquire data for t_S = 7,200 seconds (two hours).

5.10.7 Remove and archive the sample.

5.11 Data Analysis

5.11.1 Determine the number of counts, C_S, in the Region shown on Attachment 1, and record counts on Attachment 6

Note: Maintain a separate Attachment 6 for each media type (e.g., water, soil or filter).

5.11.2 Determine the sample net count rate, R_S, by the following and record on Attachment 6:

$$R_S = \frac{C_S}{t_S} - R_B$$

where R_B = the most recent value from the applicable Attachment 2 (counts per second), and the remainder of the variables are as defined previously.

5.11.3 Determine the decision level , $DL(R_S)$, by the following and record on Attachment 6:

$$DL(R_S) = 1.645 \times \sqrt{R_B \left(\frac{1}{t_B} + \frac{1}{t_S}\right)}$$

where $DL(R_S)$ = the decision level for the sample (counts per second), R_B = the most recent value from the applicable Attachment 2 (counts per second), and the remainder of the variables are as defined previously.

Note: This methodology, taken from Reference Strom-92, states that if R_S is less than $DL(R_S)$, the sample is assumed to contain no ^{60}Co.

5.11.4 Determine the ^{60}Co concentration in the sample by the following and record on Attachment 6:

$$Concentration = \frac{R_S}{E_{media} \times 0.037 \times A}$$

where R_S = the net sample count rate as determined in 5.10.2 (counts per second), and A = the sample volume for filters or water samples (liters), or the sample mass for soil samples (grams).

Note: Both negative and positive results should be recorded.

5.11.5 Determine the measurement uncertainty due to counting statistics by the following and record on Attachment 6:

$$Uncertainty = \frac{1.96 \times \frac{\sqrt{C_s}}{t_s}}{E_{media} \times 0.037 \times A}$$

where Uncertainty = the measurement uncertainty (pCi per liter or gram), and the remainder of the variables are as defined previously.

Note: This methodology was taken from References Currie-68 and Currie-84.

5.11.6 Determine the minimum detectable activity, MDA, for this measurement as follows and record on Attachment 6:

$$MDA = \frac{2.71 + 3.29 \sqrt{R_B \, t_S \, (1 + \frac{t_S}{t_B})}}{t_S \times E_{media} \times 0.037 \times A}$$

where MDA = the minimum detectable activity (pCi per gram), and the remainder of the variables are as defined previously.

Note: This methodology was taken from References Currie-68 and Currie-84.

5.12 Confirmatory Analysis for Water, Soil or Filters

5.12.1 Ensure that the lid of the Marinelli beaker is securely closed or, as applicable, the filter is securely contained within the petrie dish (or similar enclosure).

5.12.2 Log the sample number and other pertinent information onto a Chain of Custody form (Attachment 7).

5.12.2.1 The analysis to be requested for water samples is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 15 pCi/l"

5.12.2.2 The analysis to be requested for soil samples is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 5 pCi/g"

5.12.2.3 The analysis to be requested for filters is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 5 pCi/l"

5.12.3 Forward the sample and the Chain of Custody form to a pre-selected analytical laboratory by overnight mail carrier (Federal Express or equivalent)

5.12.4 Maintain a copy of the Chain of Custody form and the airbill as the chain of custody record.

5.12.5 When results are received from the laboratory, record them on Attachment 8 and retain the Certificates of Analysis.

6 EXEMPTION PROVISIONS

Minor changes to this RSP shall be permitted pursuant to the written authorization of the RSO. Other variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the RSC, and after approval by the USNRC.

7 DOCUMENTATION

Records shall be maintained pursuant to RSP-004, "Radiation Protection Records"

8 ATTACHMENTS

8.1 Attachment 1 - Daily Energy Response and Regions of Interest

8.2 Attachment 2 - Background Data

8.3 Attachment 3 - Efficiency Determination for Water Samples

8.4 Attachment 4 - Efficiency Determination for Soil Samples

8.5 Attachment 5 - Efficiency Determination for Filters

8.6 Attachment 6 - Analysis of Samples

8.7 Attachment 7 - Chain of Custody Form

ATTACHMENT 1
DAILY ENERGY RESPONSE AND REGIONS OF INTEREST

Date	Initials	Confirm Peaks are in Channels 155 and 176	Channel to the left of Channel 155 Where Peak Meets Continuum (Channel A)	Channel to the right of Channel 176 Where Peak Meets Continuum (Channel B)
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		
		☐ yes ☐ no		

ATTACHMENT 2
BACKGROUND DATA

Type (check one): ☐ Water ☐ Soil ☐ Filter

Initials	Start		Stop		Count Time t_s (seconds)	Number of Counts in Region C_s (counts)	Background Count Rate R_s (counts per second)
	Date	Time	Date	Time			

ATTACHMENT 3
EFFICIENCY DETERMINATION - WATER SAMPLES
Standard Source Number A3082, Activity of 526.3 nCi on 0300 March 1, 1995

Initials	Date	Corrected Standard Activity A_{today} (nCi)	Counts in Region C_{std} (counts)	Count Time t_{std} (seconds)	Count Rate R_{std} (counts per second)	Efficiency E_{water} (counts per disintegration)

ATTACHMENT 4
EFFICIENCY DETERMINATION - SOIL SAMPLES
Standard Source Number A3083, Activity of 587.6 nCi on 0300 March 1, 1995

Initials	Date	Corrected Standard Activity A_{today} (nCi)	Counts in Region C_{std} (counts)	Count Time t_{std} (seconds)	Count Rate R_{std} (counts per second)	Efficiency E_{soil} (counts per disintegration)

ATTACHMENT 5
EFFICIENCY DETERMINATION - FILTERS
Standard Source Number IPL-595-51, Activity of 13.4 nCi on 0300 June 1, 1995

Initials	Date	Corrected Standard Activity A_{today} (nCi)	Counts in Region C_{std} (counts)	Count Time t_{std} (seconds)	Count Rate R_{std} (counts per second)	Efficiency E_{filter} (counts per disintegration)

ATTACHMENT 6
ANALYSIS OF SAMPLES

Type (check one): ☐ Water ☐ Soil ☐ Filter

Initials	Date/Time	Sample No.	Sample Amount (A, grams or liters)	Count Time (t_s, seconds)	Counts in Region (C_s, counts)	Net Count Rate (R_s, counts per second with R_b taken from Attachment 2)	Decision Level ($DL(R_s)$, counts per second)	Concentration (pCi per liter, gram or filter)	Uncertainty (pCi per liter, gram or filter)	MDA (pCi per liter, gram or filter)	Confirmatory Result	RSO Review

ADVANCED MEDICAL SYSTEMS, INC.
ANALYSIS REQUEST AND CHAIN OF CUSTODY RECORD

Reference No. _____

(1) Client Name	(7) Samples Shipment Date	(5) Bill to:
(2) Sample Team Leader	(8) Lab Destination	
(3) Task No.	(9) Lab Contact	
(4) Project Manager	(12) Technical Contact/Phone	(10) Report to:
(6) Purchase Order No.	(13) Carrier/Waybill No.	
(11) Required Report Date		

ONE CONTAINER PER LINE

(14) Sample Number	(15) Sample Description/Type	(16) Date/Time Collected	(17) Container Type	(18) Sample Volume	(19) Preservative	(20) Requested Testing Program

(23) Special Instructions

(24) Possible Hazard Identification Non-hazard ☐ Flammable ☐ Skin Irritant ☐ Poison B ☐ Unknown ☐	(25) Sample Disposal Return to Client ☐ Disposal by Lab ☐ Archive _____ months
(26) Turnaround Time Required: Normal ☐ Rush ☐	(27) QC Level: I ☐ II ☐ III ☐ Project Specific _____

(28) Relinquished by: (signature, date, time):	Received by: (signature, date, time)
Relinquished by: (signature, date, time):	Received by: (signature, date, time)
Relinquished by: (signature, date, time):	Received by: (signature, date, time)

Advanced Medical Systems, Inc.

ASSESSMENT OF RADIOACTIVITY IN WATER SAMPLES	Procedure: RSP-019	Revision No.: 000
	Page: 1 of 10	Date: April 3, 1997
	Approved by (Engineering Manager):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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1 PURPOSE

The purpose of this Radiation Safety Procedure (RSP) is to provide instruction on collecting and analyzing tanked and free-flowing water samples for the presence of ^{60}Co, and the criteria for discharge of water into the sanitary sewer system.

2 SCOPE

This RSP applies to the routine collection and analysis of water samples at the London Road facility of Advanced Medical Systems, Inc. (AMS) for the purpose of demonstrating compliance with discharge criteria. Samples collected for reasons other than compliance demonstration are exempt from the provisions of this RSP.

3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission License No. 34-19089-01 (as amended).

3.2 American Public Health Association, Method 7110, "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)", Standard Methods for the Examination of Water and Wastewater.

3.3 U. S. Environmental Protection Agency, Gamma Emitting Radionuclides in Drinking Water, Method 901.1, Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA 600/4-30-032.

3.4 U. S. Department of Energy, Gamma, Section 4.5.2.3, EML Procedures Manual, HASL-300, Environmental Measurements Laboratory.

3.5 U. S. Nuclear Regulatory Commission Regulatory Guide No. 4.8, "Environmental Technical Specifications for Nuclear Power Plants" (draft for comment), December, 1975.

3.6 U. S. Nuclear Regulatory Commission, NUREG-1507, "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions - Draft Report for Comment", August, 1995.

3.7 U. S. Nuclear Regulatory Commission, NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20".

3.8 U. S. Nuclear Regulatory Commission, Communication from J. A. Grobe (Chief, Nuclear Materials Inspection Section 2) to D. Cesar (Treasurer, Advanced Medical Systems), February 1, 1995.

3.9 Advanced Medical Systems, Inc., RSP-018, "Operation of the Gamma Spectrometer".

3.10 Advanced Medical Systems, Inc., RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy".

4 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be included in RSP-002, "Definitions".

5 PROCEDURE

5.1 Responsibilities

5.1.1 Sample collection and analysis shall be performed by a Radiation Surveyor.

5.1.2 The RSO shall select and pre-qualify a commercial analytical laboratory to perform confirmatory analyses by the methodology described in RSP-022, as required.

5.1.3 Water shall be discharged to the sewer system only upon the authorization of the RSO.

5.2 Sample Collection from a Hold-up Tank

5.2.1 Two re-circulation pumps (approximately 2,500 gph capacity each), or similar methodology, shall be activated within a hold-up tank that is staged for discharge.

5.2.2 Re-circulation shall continue for a minimum of two (2) tank volumes prior to sample collection to ensure adequate mixing.

Note: For example, if the hold-up tank volume is 3,000 gallons, the re-circulation pumps shall be activated 40 minutes prior to sample collection.

5.2.3 A sample of water shall be collected from the hold-up tank into a clean one-liter Marinelli beaker.

Note: Samples may be collected from any location of the hold-up tank.

5.2.4 The location, date and time of sample collection shall be documented.

5.2.5 No additional water shall be added to the hold-up tank after the sample has been collected.

5.2.6 The re-circulation pumps, or equivalent agitation device, shall remain in operation until the results of the analysis are received.

5.2.7 The collection frequency shall be once per tank for water free-flowing from the underdrain system of the London Road facility.

5.3 Sample Collection from a Free-flowing Source

5.3.1 A sample of water shall be collected from a free-flowing source into a clean one-liter Marinelli beaker.

5.3.2 The location, date and time of sample collection shall be documented.

5.3.3 The collection frequency shall be once per week for water free-flowing from the underdrain system of the London Road facility.

5.4 Sample Collection from a Free-flowing Source with an In-line Hold-up Point

5.4.1 A sample of water shall be collected from the hold-up point (tank) of a free-flowing source into a clean one-liter Marinelli beaker.

Note: Samples may be collected from any location of the tank.

5.4.2 The location, date and time of sample collection shall be documented.

5.4.3 The collection frequency shall be once per week for water free-flowing from the underdrain system of the London Road facility.

5.5 Total Activity Determination

5.5.1 Water samples shall be analyzed by direct counting pursuant to the methodologies described in RSP-018.

5.5.2 If the net sample count rate is less than the Decision Level, the sample may be assumed to contain no radioactivity above background.

5.5.3 Counting conditions shall result in a minimum detectable activity (MDA) of no greater than 50 pCi per liter.

5.5.4 If the sample MDA is greater than 50 pCi per liter, the sample should be forwarded to a commercial analytical laboratory for confirmatory analysis by the methodology described in RSP-018.

5.6 Insoluble Activity Determination

5.6.1 Samples that contain ^{60}Co in concentrations of less than 100 pCi per liter shall be drawn (by vacuum pump) through a 0.45 micrometer filter.

Note: The entire one (1) liter sample shall be drawn through the filter.

5.6.2 The filter shall be analyzed pursuant to RSP-018.

5.6.3 If the net filter count rate is less than the Decision Level, the filter may be assumed to contain no radioactivity above background.

5.6.4 Counting conditions shall result in a MDA of no greater than 15 pCi per filter.

5.6.5 If the filter MDA is greater than 15 pCi per liter, the filter should be forwarded to a commercial analytical laboratory for confirmatory analysis by the methodology described in RSP-018.

5.7 Confirmatory Analysis

5.7.1 The sample container or the filter, as applicable, shall be enclosed inside of <u>two</u> zip-lock baggies, labeled, a Chain of Custody Form shall be completed, and the sample shall be shipped to the laboratory as described in RSP-018.

5.7.2 The samples shall be analyzed by gamma spectroscopy for Cobalt-60 pursuant to EPA Method 901.1, or HASL-300, or equivalent, with a nominal LLD of no greater than 15 pCi/l.

5.7.2.1 Analytical results that are less than the decision level or greater than 100 pCi/liter shall be forwarded to the RSO and no additional analyses shall be necessary.

5.7.2.2 Analytical results that are greater than 15 pCi per liter but less than 100 pCi per liter shall cause the sample to be analyzed for suspended gross alpha and gross beta radioactivity pursuant to American Public Health Association Method 7110.

5.7.3 When results from the analytical laboratory are received, they shall be recorded and retained as described in RSP-018.

5.8 Criteria for Discharge of Water into the Sewer System

Note: Attachment 1 contains the technical basis for the discharge criteria.

5.8.1 Discharges of water shall not exceed 25,000 gallons in a 24-hour period.

5.8.2 Water that contains total activity of greater than 100 pCi per liter of ^{60}Co shall not be discharged.

5.8.3 Water that contains insoluble activity of greater than 15 pCi per liter of ^{60}Co shall not be discharged.

6 EXEMPTION PROVISIONS

Minor changes to this RSP shall be permitted pursuant to the written authorization of the RSO. Other variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the RSC, and after approval by the USNRC.

7 DOCUMENTATION

7.1 Records to be maintained shall include:

7.1.1 Forms generated pursuant to RSP-018 and RSP-022.

7.1.2 Chain of Custody documentation (forms, airbills, etc.)

7.1.3 Requests for analysis

7.1.4 Certificates of Analysis

7.1.5 Discharge logs/records

7.2 Records shall be maintained pursuant to RSP-004,

8 ATTACHMENTS

Attachment 1 - Technical Basis for Water Discharge Criteria

ATTACHMENT 1
TECHNICAL BASIS FOR WATER DISCHARGE CRITERIA

System Description

The Advanced Medical Systems, Inc. (AMS) gamma spectroscopy system is comprised of a scintillation detector and a multichannel analyzer (MCA). The MCA is a Nucleus Model MC800A 256-channel analyzer that includes the main housing, the monitor, and an uninterruptable power supply. The detector is a 2 in. by 2 in. thallium-activated sodium iodide crystal that is optically-coupled to a photomultiplier tube on a voltage divider. The detector, the tube and the divider are housed inside a 2 in.-thick lead shield.

The system is located in a non-atmospherically-controlled office in the vicinity of the AMS conference room. While the ambient temperature in this area cannot be readily controlled, it does remain somewhat stable (e.g., within $\pm$ 20° F) throughout typical counting times. The ambient gamma exposure rate in the counting room is approximately 10 microR per hour.

Since the only radionuclide of interest to AMS is ^{60}Co, the system is calibrated daily, using water-equivalent, soil-equivalent, or filter-equivalent standardized sources of ^{60}Co that are traceable to the National Institute of Standards and Technology (NIST). The standardized sources of water and soil are in a Marinelli beaker geometry, while the geometry of the filter source is an electroplated disk.

AMS also has a contract arrangement with a commercial analytical laboratory. On demand, this laboratory analyzes water samples, soil samples, or filters in order to demonstrate compliance with applicable criteria, or to provide confirmation that the AMS spectroscopy system is functioning as expected and required.

Objective of the Sampling/Discharge Program

The objective of the water sampling and discharge program at AMS is to ensure compliance with applicable regulations for the discharge of water into the sanitary sewer system, and to ensure the radiological health and safety of employees and members of the general public is adequately protected. To demonstrate that these objectives are met, there must be clear instruction on how to interpret the results of sampling and analysis.

Performance Criteria

The following are the criteria for discharge of wastewater from the AMS facility on London Road:

(1) A maximum of 25,000 gallons of water may be discharged over a single day.

(2) Water to be discharged must be sampled and confirmed to contain less than 100 pCi of ^{60}Co per liter.

(3) If a sample exhibits a net count rate by direct counting that is greater than the Decision Level, and if the total ^{60}Co concentration (soluble plus insoluble) is less than 100 pCi per liter, the water may be discharged if the insoluble fraction is shown to be less than 15 pCi per liter.[1]

Basis for the Discharge Criteria

These discharge criteria were based upon an analysis of a series of regulatory and technical constraints and requirements. The following is a listing of the pertinent requirement and constraints in regard to gross radioactivity that were considered in developing the water discharge criteria for AMS:

- In Title 10, Code of Federal Regulations, Part 20, the USNRC authorizes discharge of licensed material into the sanitary sewage *provided the material is readily soluble* (or is readily dispersible biological material) in water, and the concentration of licensed material does not exceed that listed in Table 3 of Appendix B to 10 CFR 20.1001-20.2401. For ^{60}Co, that concentration is 30,000 pCi/l.

- In a United States District Court Order on Consent, the Northeast Ohio Regional Sewer District, who services the AMS facility, entered into a pre-treatment agreement with AMS in regard to radionuclide discharge limits.[2] This agreement stipulates that "water proposed for discharge from the foundation footer drain system that shows the presence of Cobalt 60 in a concentration of 100 pCi per liter or less, may be discharged".

In regard to the means of determining whether a discharged material is "readily soluble", the guidance found in USNRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20" applies. This document lists the acceptable methods for demonstrating compliance with the solubility requirements. One of these is the American Public Health Association (APHA), Method 7110, "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)", Standard Methods for the Examination of Water and Wastewater.

APHA Method 7110 contains an analytical procedure for determining the quantity of insoluble gross beta activity in water samples. However, water typically contains significant gross beta activity from isotopes such as uranium and daughters, radium and daughters, thorium and daughters, and ^{40}K. The standard does not provide guidance on how much gross beta activity indicates an insoluble material.

The USEPA, on the other hand, recognizes the presence of naturally-occurring radioactivity in water. Consequently, 40 CFR 141 indicates that if the average annual concentration of gross beta activity in water is less than 50 pCi per liter, no further analyses are required. Concentrations greater than 50

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[1] This value was selected to be consistent with the guidance found in USNRC Regulatory Guide 4.5, "Environmental Technical Specifications for Nuclear Power Plants (draft for comment)".

[2] United States District Court, Northern District of Ohio, Eastern Division, Order on Consent, Case No. 1:94 CV 2555, December 22, 1995.

pCi/l may still be acceptable for a drinking water supply, but isotope-specific analyses are required before the decision is made. For ^{60}Co, the isotope-specific limit is 200 pCi per liter.

To summarize, federal regulations and a court order dictate that the maximum concentration of ^{60}Co that may be released into the sewer system or drinking water supplies by AMS is 100 pCi per liter, as determined by gamma spectroscopy. However, any detectable activity (e.g., greater than the MDA) must meet the USNRC's criteria for solubility (e.g., there must be no detectable insoluble ^{60}Co activity). Since the USNRC has not defined an acceptable MDA for the purposes of determining compliance, the USEPA's recognition of up to 50 pCi per liter of radioactivity in water as being an acceptable component of the natural background is used to set a performance criterion (e.g., an acceptable MDA).[3] As long as the AMS measurement system is capable of detecting *at least* 50 pCi of ^{60}Co in its discharges, AMS can ensure compliance with all applicable regulations, significant conservatism in its discharge practices, and no radiological impact on the local sewage treatment system.[4]

System Capabilities

The following is a listing of the performance characteristics of the AMS spectroscopy system:

- The average detection efficiency of the AMS spectroscopy system for the water-equivalent standardized source of ^{60}Co, is approximately two (2) percent. This efficiency is achievable when the region of integration on the gamma spectrum encompasses the

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[3] In USNRC Regulatory Guide 4.5, "Environmental Technical Specifications for Nuclear Power Plants" (draft for comment), the USNRC states that analytical techniques used to demonstrate compliance with 10 CFR 20 release criteria shall be such that the detection capabilities in Table 3 of the Regulatory Guide are achieved. In this table, the acceptable lower limit of detection, defined at the 95% confidence level, is 15 pCi of ^{60}Co per liter. Therefore, it can be assumed that any water that contains less than 15 pCi of ^{60}Co per liter can be discharged without regard for the solubility of the materials contained therein. However, this guidance document is a "draft for comment", rather than an approved Regulatory Guide. Without the USNRC's concurrence that this guidance is applicable to licensee programs, AMS does not feel that it can cite this as an acceptable performance criterion.

[4] The USNRC considers soils with ^{60}Co concentrations of 8 pCi per gram or less to be acceptable for release for unrestricted use. (AMS has been unable to determine the source or the technical basis for this limit. However, the USNRC deemed it acceptable during a 1995 drainage system remediation project at the London Road facility.) To ensure that the waste ash produced at the sewage treatment plant that services AMS remains exempt from regulation, AMS must not discharge ^{60}Co in concentrations that might result in concentrations in excess of 8 pCi per gram. If it is assumed that every atom of ^{60}Co discharged from AMS is transported to the ash, that 25,000 gallons of cobalt-bearing wastewater is discharged per day from AMS, and that the sewage treatment plant produces 7.5 tons of ash per day. The following results:

$$\text{Discharge Limit} = \frac{8\ pcilg}{\frac{94{,}625\ l}{day} \times \frac{1\ day}{7.5\ ton} \times \frac{1\ ton}{9.08\times10^{-5}\ grams}} = 576\ \frac{pCi}{l}$$

Therefore, to ensure that there are no adverse radiological impacts on the local sewage treatment plant, AMS must ensure its discharge concentration is less than 545 pCi of ^{60}Co per liter, which is well-above the limiting regulatory and court-ordered discharge limit.

"full width, full max" (FWFM) of the 1.17 and the 1.32 MeV "peaks" associated with the decay of ^{60}Co.

- A nominal detection limit for ^{60}Co in water after a four-hour count time ranges from 30 to 50 pCi/l, depending upon the quantity of naturally-occurring radionuclides that are present in the sample and the counting time.[5,6]

- The nominal detection limit for ^{60}Co on a filter after a four-hour count time ranges from eight (8) to 15 pCi/l, depending upon the quantity of naturally-occurring radionuclides that are present in the sample.

The following are nominal performance characteristics of the commercial analytical laboratory used to analyze samples for AMS:

- The nominal detection sensitivity for ^{60}Co in water by the methodology of gamma spectroscopy with hyperpure germanium detectors is less than 15 pCi per liter in a one-hour count time, depending upon the quantity of naturally-occurring radionuclides present in the sample.

- The nominal detection sensitivity for ^{60}Co on a filter by the methodology of gamma spectroscopy with hyperpure germanium detectors is less than five (5) pCi per filter in a one-hour count time, depending upon the quantity of naturally-occurring radionuclides present in the sample.

Conclusions

For water samples analyzed at AMS pursuant to RSP-018, "Operation of the Gamma Spectrometer" and RSP-019, "Assessment of Radioactivity in Water Samples", a performance criterion of 50 pCi of ^{60}Co per liter of water by direct counting is deemed acceptable. Since discharges at this concentration clearly impose no radiological impact on the public water supply or the local sewage treatment plant, water that exhibits analytical results that are below the decision level, with MDAs of less than 50 pCi per liter, and with a maximum daily discharge volume of 25,000 gallons is considered to be "below radiological concern" since it is consistent with the intent of 10 CFR 20, and is sufficiently protective of workers and the general public.

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[5] The methodology for MDA determination was taken from Curie, L.A. (1968), "Limits for Qualitative Detection and Quantitative Determination", *Analytical Chemistry* 40(3):586-593, and Currie, L.A. (1984), "Lower Limit of Detection: Definition and Elaboration of a Proposed Position for Radiological Effluent and Environmental Measurements", NUREG/CR-4007, Nuclear Regulatory Commission.

[6] Water samples acquired and analyzed by AMS between June 17, 1996 and October 22, 1996 exhibit a mean MDA of 42.9 $\pm$ 0.4 pCi per liter for a four (4) hour count time.

Advanced Medical Systems, Inc.

QUALITY ASSURANCE FOR RADIONUCLIDE ANALYSIS BY GAMMA SPECTROSCOPY	Procedure: RSP-022	Revision No.: 000
	Page: 1 of 15	Date: April 3, 1997
	Approved by (Engineering Manager):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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1 PURPOSE

This procedure establishes the methods and responsibilities for assuring that all measurement data generated using by the Advanced Medical Systems, Inc. (AMS) gamma spectroscopy system are scientifically and legally defensible, of known and appropriate quality, and are documented.

2 SCOPE

This Radiation Safety Procedure (RSP) applies to the analysis of all samples analyzed for compliance purposes using the AMS gamma spectroscopy system or commercial analytical laboratory support. Samples that are analyzed for reasons other than compliance are exempt from the requirements of this RSP.

3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.

3.2 U. S. Nuclear Regulatory Commission Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment".

3.3 American Society of Mechanical Engineers, ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities"

3.4 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-006, "Training and Qualifications of Radiation Protection Personnel"

3.5 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-013, "Control of Radioactive Waste".

3.6 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-018, "Operation of the Gamma Spectrometer"

3.7 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-019, "Assessment of Radioactivity in Water Samples"

3.8 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-020, "Quality Assurance Audits".

4 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be found in RSP-002, "Definitions".

5 PROCEDURE

5.1 Responsibilities

5.1.1 The Engineering Manager shall:

5.1.1.1 Ensure sufficient resources are made available to comply with the requirements of this RSP.

5.1.1.2 Support quality assurance as an essential element in all functional, management, and administrative activities related to radionuclide analysis by gamma spectroscopy.

5.1.2 The RSO shall:

5.1.2.1 Establish and maintain an effective quality assurance program for gamma spectroscopy.

5.1.2.2 Ensure all gamma spectroscopy operations are conducted in accordance with this RSP.

5.1.2.3 Ensure that quality control (QC) limits are established and followed for critical points in the measurement process and that they are based on sound statistical methods.

5.1.2.4 Perform an independent review of a 100% of the data reports.

5.1.2.5 Ensure analytical procedures are performed by Radiation Surveyors who are qualified as described in RSP-006.

5.1.2.6 Select and pre-qualify the commercial analytical laboratory used to perform confirmatory analyses

5.1.3 Radiation Surveyors shall:

5.1.3.1 Use QC steps and RSPs properly during sample collection, sample analysis, data interpretation, or any routine sampling or analysis activity.

5.1.3.2 Maintain complete documentation of analytical activities.

5.1.3.3 Correct and document problems and deficiencies in any portion of the measurement system.

5.1.3.4 Evaluate 100% of the data for acceptability based upon QC limits and professional judgement.

5.1.3.5 Periodically review this RSP for continued applicability.

5.2 Sample Management

5.2.1 Sample containers shall consist of commercially pre-cleaned one (1) liter Marinelli beakers.

5.2.2 Sample containers shall be kept in a contaminant-free, secure area.

5.2.3 Sample preservatives shall not be used unless so instructed by the analytical laboratory performing confirmatory analysis.

5.2.4 Samples shall be processed through the entire analytical method as specified in RSP-018 and RSP-019.

5.2.5 After analysis is complete and there is no further use for a sample, it shall be disposed of as described in RSP-013 and RSP-019.

5.3 Analytical Methods

5.3.1 QC procedures shall be incorporated into sample analysis activities.

Note: These procedures may include calibration verification, background verification, duplicate analyses, or confirmatory analyses.

5.3.2 All analyses shall be performed according to the uniform, standard method documented in RSP-018

5.4 Control Charts

5.4.1 Control charts shall be generated and used to demonstrate stati[illegible]ontrol counting room conditions and the operational status of the equipment.

5.4.2 Control limits shall be experimentally determined and should include:

5.4.2.1 An upper and lower warning limit.

5.4.2.2 An upper and lower control limit.

5.4.3 Control Levels shall be determined by the following:

5.4.3.1 Acquire background data (counts per minute) and efficiency data (per cent) as described in RSP-018 for a total of ten (10) measurements each.

5.4.3.2 From the 10 individual measurements, determine the control mean (CM) of each measurement type by:

$$CM_r = \frac{\sum_{i=1}^{n} C_i}{n}$$

where C_i = the results of measurement number "i", and n = the total number of that measurement type performed.

5.4.3.3 From the 10 individual measurements, determine the standard deviation (σ) by:

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n} (CM_r - C_i)^2}{n-1}}$$

5.4.3.4 Determine the Upper Warning Level (UWL) by:

$$UWL = CM_r + (2 \times \sigma)$$

5.4.3.5 Determine the Lower Warning Level (LWL) by:

$$LWL = CM_r - (2 \times \sigma)$$

5.4.3.6 Determine the Upper Control Level (UCLM) by:

$$UCL = CM_r + (3 \times \sigma)$$

5.4.3.7 Determine the Lower Control Level (LCL) by:

$$LCL = CM_i - (3 \times \sigma)$$

5.4.4 Control Charts shall be prepared as follows:

5.4.4.1 Create a Background Control Chart and an Efficiency Control Chart by plotting measurements on the y-axis and date on the x-axis of graphing paper.

5.4.4.2 Show the control mean (CM), the $\pm$ 2σ (UWL and LWL) and the $\pm$ 3σ (UCL and LCL) levels by horizontal lines.

5.4.4.3 Plot each week's background measurement and each day's efficiency measurement on the applicable control chart.

5.4.5 The control limits shall be updated every 30 data points or when a significant change in the measurement system configuration occurs.

5.4.6 The system may be considered to be "out of control" when one of the following occurs:

5.4.6.1 A single point falls outside the control limit.

5.4.6.2 A series of ten (10) successive points fall on the same side of the central line.

5.4.6.3 A series of seven (7) successive points trend in the same direction.

5.4.6.4 Any three (3) consecutive points fall outside of the warning limit

5.4.6.5 A cyclical pattern of control values.

5.4.7 If the system is "out of control", it shall be removed from service, the RSO shall be notified, and the system shall be repaired.

5.5 System and Performance Audits

5.5.1 Internal audits to determine on-going compliance with this RSP and to assess the overall quality of data collected during the measurement process shall be performed.

5.5.1.1 The frequency of internal audits shall be twice per calendar year.

5.5.1.2 Internal audits shall be accomplished through:

5.5.1.2.1 Observing measurement activities.

5.5.1.2.2 Inspecting operating conditions and documentation

5.5.1.2.3 Interviewing radiation surveyors performing the analyses.

5.5.1.3 The internal audit methodology shall be as described in RSP-020.

5.5.2 External audits shall be performed at the frequency of and as described in RSP-020.

5.6 Quality Control Steps

5.6.1 Duplicate analyses to verify the precision of results shall be performed.

5.6.1.1 One duplicate sample analysis shall be performed for each ten (10) samples analyzed (e.g., a frequency of 10%).

5.6.1.2 Duplicate samples shall be analyzed in the same manner and with the same count time as the original sample analysis.

5.6.1.3 If the results of the duplicate sample analysis is significantly different from the results of the original sample analysis, the matrix homogeneity shall be evaluated to determine if re-analysis is required.

Note: For example, "significantly different" may be interpreted as follows:

$$C_1 - 2\sqrt{C_1} < C_2 < C_1 + 2\sqrt{C_1}$$

where C_1 = the counts from the first analysis, and C_2 = counts from the second analysis.

5.6.1.4 If the duplicate analysis is "out of control":

5.6.1.4.1 A second, different sample, of the same matrix should be analyzed in duplicate; or

5.6.1.4.2 Data acquired prior to the original duplicate analysis should be qualified.

5.6.1.5 If the results from the second sample are "out of control", a background and efficiency check shall be performed as described in section 5.4 and in RSP-018.

5.6.2 Duplicate collections shall be performed for grab samples in order confirm that the collected samples are representative of the entire stream.

5.6.2.1 One duplicate sample collection shall be performed for each ten (10) grab samples collected from a specific stream (e.g., a frequency of 10%).

5.6.2.2 Duplicate sample collections shall be analyzed in the same manner and with the same count time.

5.6.2.3 If the analytical results from the duplicate collections differ significantly, the collection methodology shall be evaluated to determine continued applicability.

Note: For example, "significantly different" may be interpreted as follows:

$$C_1 - 2\sqrt{C_1} < C_2 < C_1 + 2\sqrt{C_1}$$

where C_1 = the counts from the first collection, and C_2 = counts from the second collection.

5.6.3 An external intercomparison to verify the capability of the AMS spectroscopy system shall be performed.

5.6.3.1 The frequency of external intercomparisons shall be once per calendar quarter.

5.6.3.2 For the external intercomparison, a sample of water, soil, or a filter that has been analyzed using the AMS spectroscopy system shall be forwarded to the pre-qualified commercial analytical laboratory.

5.6.3.3 The water sample selected for intercomparison shall be unfiltered, and shall exhibit a net count rate by direct counting that was less than the Decision Level *and* an MDA of less than 50 pCi per liter.

5.6.3.4 The methodology for packaging, shipping, and analyzing external intercomparison samples shall be as described in RSP-018.

5.6.3.5 If the results from the analytical laboratory differ significantly from the results generated by AMS, the intercomparison results may be "out of control".

Note: For example, "significantly different" may be interpreted as follows:

$$C_1 - 2\sqrt{C_1} < C_2 < C_1 + 2\sqrt{C_1}$$

where C_1 = the radionuclide concentration determined by AMS, and C_2 = radionuclide concentration determined by the commercial analytical laboratory.

5.6.3.6 If the intercomparison analysis is "out of control":

5.6.3.6.1 A second, different sample, of the same matrix should be subject to intercomparison analysis; or

5.6.3.6.2 Data acquired prior to the original intercomparison analysis should be qualified.

5.6.3.7 If the results from the second intercomparison are "out of control", a background and efficiency check shall be performed as described in section 5.4 and in RSP-018.

5.7 Data Validation

5.7.1 All data and results generated by the gamma spectroscopy system shall be evaluated for acceptability on the basis of the criteria contained in this RSP.

5.7.2 The radiation surveyor shall incorporate all applicable QC steps as specified in this RSP (e.g., control chart generation, duplicate sample analysis).

5.7.3 Following each QC analysis, the radiation surveyor shall perform the necessary calculations.

5.7.4 If a QC step does not meet the acceptance criteria described in this RSP, the radiation surveyor shall perform the following, in concert with the RSO:

5.7.4.1 An appropriate corrective action shall be identified and implemented.

5.7.4.2 If an appropriate corrective action cannot be performed, data acquired prior to the validation shall be qualified.

5.7.4.3 Information related to the analyses shall be thoroughly documented.

5.7.5 The RSO shall perform a final review of 100% the data package associated with all sample results for completeness, accuracy, consistency, and compliance with this RSP.

5.8 Chain of Custody Elements

5.8.1 In order to establish the documentation necessary to trace sample possession from the time of collection, a serially-numbered Chain of Custody Form (Attachment 1) shall be completed and should accompany every sample.

5.8.2 The Chain of Custody Form shall contain the following types of information:

5.8.2.1 Sample identification.

5.8.2.2 Signature of sample collector

5.8.2.3 Date and time of sample collection

5.8.2.4 Sample type (e.g., water, soil or filter)

5.8.2.5 Chemical and physical constituents and methods for which analysis will be conducted.

5.8.2.6 Signature(s) of person(s) involved in the chain of possession

5.8.2.7 Inclusive dates and time of possession

5.8.3 The Chain of Custody Form shall accompany the sample(s) on delivery to a commercial analytical laboratory.

5.8.4 The data package received from the commercial analytical laboratory shall include a copy of the Chain of Custody Form with all signatures.

5.8.5 To maintain chain of custody during shipment, overnight air carriers (e.g., Federal Express or equivalent) shall be used for sample transport to the commercial analytical laboratory.

5.9 Corrective Actions

5.9.1 If sample handling, analytical equipment, QC sample analysis results, or analytical systems fail to meet the criteria established in this RSP, corrective action shall be implemented by the RSO.

5.9.2 Corrective action should consist of immediate actions and long-term actions.

5.9.2.1 The need for immediate corrective action may be identified by the radiation surveyor as a result of system checks and QC sample analyses.

5.9.2.2 Immediate action shall be designed to correct or repair non-confirming measurement systems.

5.9.2.3 Long-term action may be identified by quality assurance audits and performance reviews, and may consist of the following:

5.9.2.3.1 Training and qualification of personnel

5.9.2.3.2 Revising the quality assurance system

5.9.2.3.3 Replacing personnel

5.9.2.3.4 Revising RSPs

5.9.2.3.5 Replacing equipment

5.9.3 The steps for instituting corrective action should be as follows:

5.9.3.1 Define the problem

5.9.3.2 Assign responsibility for investigating the problem

5.9.3.3 Investigate and determine the cause of the problem

5.9.3.4 Determine a corrective action to eliminate the problem

5.9.3.5 Assign and accept responsibility for implementing the corrective action

5.9.3.6 Establish effectiveness of the corrective action and implement the correction

5.9.3.7 Verify that the corrective action has eliminated the problem

5.10 Control of Purchased Items

5.10.1 The procurement of AMS instruments, equipment, standards and services shall be controlled to ensure compliance with this RSP and RSP-018,

5.10.2 Procured articles, materials, or services shall meet AMS purchase requirements, technical specifications, and quality assurance provisions.

5.10.3 When an article, material, or service procured by AMS does not conform to applicable specifications or other requirements,, it shall be identified as non-conforming, segregated to the extent practicable, and held for review action.

5.10.4 Pre-approval of a commercial analytical laboratory shall require written certification by a corporate official of the laboratory that the following are maintained:

5.10.4.1 Conformance to recognized standards

Note: USEPA QAMS-005/80, "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans"; ANSI/ASQC-E5-19xx, "Specifications and guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs"; ANSI/ASQC Q94 (ISO 9004), "Quality Management and Quality System Elements - Guidelines"; and NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities", or equivalent, are acceptable standards.

5.10.4.2 Staff training programs

5.10.4.3 Good laboratory and measurement practices

5.10.4.4 State-of-the-art facilities and instrumentation

5.10.4.5 Standard operating procedures

5.10.4.6 Non-blind standard reference materials (NIST-traceable)

5.10.4.7 Document control

5.10.4.8 Replicate blank, matrix spike, background yield tracer, quench standards, and surrogate measurements

5.10.4.9 Preventative maintenance

5.10.4.10 Prompt and efficiency backup services

5.10.4.11 Sample chain of custody.

5.10.4.12 An independent QA organization

5.10.4.13 A Quality Assurance Management Plan

5.10.4.14 Data quality objectives

5.10.4.15 Independent QA data validation

5.10.4.16 Interlaboratory comparison studies

5.10.4.17 Formal laboratory accreditations

5.10.4.18 Statistical evaluations of analytical precision and accuracy

5.10.4.19 Independent QA verification of computer software

5.10.4.20 Evaluation of subcontractor laboratories.

6 EXEMPTION PROVISIONS

Minor changes to this RSP shall be permitted pursuant to the written authorization of the RSO. Other variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the RSC, and after approval by the USNRC.

7 DOCUMENTATION

All records and reports associated with implementation of this RSP, including control charts, shall be maintained pursuant to RSP-004.

8 ATTACHMENTS

Attachment 1 - Chain of Custody Form

ATTACHMENT 1

ADVANCED MEDICAL SYSTEMS, INC.
ANALYSIS REQUEST AND CHAIN OF CUSTODY RECORD

Reference No. _____

(1) Client Name	(7) Samples Shipment Date	(5) Bill to:
(2) Sample Team Leader	(8) Lab Destination	
(3) Task No.	(9) Lab Contact	
(4) Project Manager	(12) Technical Contact/Phone	(10) Report to:
(6) Purchase Order No.	(13) Carrier/Waybill No.	
(11) Required Report Date		

ONE CONTAINER PER LINE

(14) Sample Number	(15) Sample Description/Type	(16) Date/Time Collected	(17) Container Type	(18) Sample Volume	(19) Preservative	(20) Requested Testing Program

(23) Special Instructions

(24) Possible Hazard Identification
Non-hazard ☐ Flammable ☐ Skin Irritant ☐ Poison B ☐ Unknown ☐

(25) Sample Disposal
Return to Client ☐ Disposal by Lab ☐ Archive _____ months

(26) Turnaround Time Required: Normal ☐ Rush ☐

(27) QC Level I ☐ II ☐ III ☐ Project Specific _____ _____

(28) Relinquished by: (signature, date, time):	Received by: (signature, date, time)
Relinquished by: (signature, date, time):	Received by: (signature, date, time)
Relinquished by: (signature, date, time):	Received by: (signature, date, time)

(See Reverse for Instructions)

INSTRUCTIONS FOR COMPLETING THIS FORM

1. **Client Name**: Record the name of the client (**AMS**)

2. **Sample Team Leader**: List the name of the team taking these samples.

3. **Task No.**: Indicate the **AMS** task number, if applicable.

4. **Project Manager**: Record the project manager's name.

6. **Purchase Order No.**: Non-**AMS** personnel should use this space to record the purchase order number authorizing the analysis of these samples. **AMS** and **AMS** subcontractors should leave this space blank if a project number has been given for billing.

7. **Samples Shipment Date**: Indicate the date these samples are shipped to the laboratory.

8. **Lab Destination**: Indicate the laboratory designated for sample shipment. Do not list more than one lab on this form. Be certain before sending samples that the laboratory you are designating is aware of the shipment and is capable of accepting these sample types and has available capacity.

9. **Lab Contact**: Give the name of the laboratory contact (typically the lab's project manager).

10. **Report to**: Give the name, address and phone number of the person to receive the data report for these samples.

11. **Required Report Date**: Record the date which you and the laboratory contact have determined the results will be reported (include verbal or final report as appropriate).

12. **Technical Contact/Phone**: Indicate the name of the person to be contacted in case of any questions regarding these samples and the phone number where the contact may be reached the day the samples arrive in the laboratory.

13. **Carrier/Waybill Number**: If you are sending the samples by a commercial carrier such as Airborne or Federal Express, record the courier company name and the waybill or airbill number under which these samples will be shipped (Example - Fed-Ex/#513631771).

14. **Sample Number**: List the complete, unique identification number of each sample. These numbers must correspond with the identification numbers on the sample containers and the field sample collection document(s).

15. **Sample Description/Type**: Provide a short physical description of the sample and the sample type such as soil, sediment, sludge, water, wipe, air, concentrated waste or bulk.

16. **Date/Time Collected**: Record date and exact time each sample was collected. Use a 24-hour clock; i.e., 1645 not 4:45 p.m.

17. **Container Type**: Indicate the volume, color and type of the sample container used (Example - 1 gallon amber glass, 1 liter clear plastic, 40 milliliter clear glass).

18. **Sample Volume**: Estimate the amount of sample in the container. For air samples, indicate the volume of air sampled.

19. **Preservative**: Indicate what type of preservative, if any, has been used for the samples (Example - ice to 4°C nitric acid, hydrochloric acid).

20. **Requested Testing Program**: List the analyses to be performed on each sample by method number or quotation number.

23. **Special Instructions**: Use this space to record any special instructions to the lab regarding the processing of these samples.

24. **Possible Hazard Identification**: Indicate all hazard classes associated with the sample(s).

25. **Sample Disposal**: Indicate how the samples should be disposed of following analysis. The lab may charge for packing, additional archiving and disposal.

26. **Turnaround Time Required**: Check "Normal" or "Rush" as determined by the Technical Contact and the Lab Contact. Rush samples are subject to a surcharge.

27. **QC Level**: These should be specific to the analytical laboratory and should not be confused with USEPA Analytical Levels. Project Specific should reference a quotation number or other specifications that have been submitted to the laboratory before beginning work.

28 **Signatures**: When releasing custody of these samples, use the "Relinquished By" space to sign your full legal name, date and time of release. After verifying that all samples are present, the person receiving the samples must sign the "Received By" space to take custody of the samples.

Advanced Medical Systems, Inc.

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

March 31, 1997

Mr. John R. Madera, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Madera:

As follow-up to the March 31, 1997 telephone conversation between representatives of Advanced Medical Systems, Inc. (AMS) and the USNRC, the following is a summary of recent events at the London Road facility that pertain to water being pumped from the foundation drainage system:

- During the weekend of March 15, 1997, the pump used to remove water from the foundation drainage system failed. The cause of the failure was later determined to be the float switch.
- The failure was identified on Monday, March 17, 1997, when AMS personnel discovered approximately 1,000 gallons of water in the basement of the London Road facility.
- The water was collected from the basement and placed into a storage tank located in the Isotope Shop Warehouse. The ^{60}Co concentration in the basement water is approximately two (2) microcuries per liter. The action plan for this water not yet determined

The immediate follow-up actions taken by AMS include the following:

- Additional tank capacity was secured.
- The security service was asked to install sensor in manhole and basement that will alert AMS during off-hours if water levels rise.
- A duplex pump will be installed in the manhole in the place of the existing pump to ensure redundant operations.
- AMS personnel will check the status of the pump and basement once per day, including weekends, until the sensors and duplex pump are installed.
- A hydrogeologist was brought in for consultation, and has rendered the following initial opinion (to be confirmed during a pending on-site inspection). In general, he stated that the pump failure caused storm water to back up into the foundation drainage system. Because it was not possible to maintain a hydraulic gradient into the basement during the flooding event, ^{60}Co was carried back into the system. During subsequent rainfall events, the ^{60}Co will move preferentially through the footer drains and into the manhole, and over

time, the ^{60}Co concentrations in the manhole will decrease to those noted prior to the basement flooding event.

- An aggressive sampling program of water pumped from the foundation drainage system was instituted in order to track the contamination status of the system. To date, the ^{60}Co concentrations have dropped from a high of 332 pCi per liter to less than 36 pCi per liter as determined by direct counting. There has been no evidence of the presence of insoluble ^{60}Co above a nominal detection limit of nine (9) pCi per liter.

The longer-term actions to be instituted by AMS include the following:

- Immediately after the water sampling program demonstrates no detectable ^{60}Co from the foundation drainage system (e.g., after 5,000 gallons of water are tanked and confirmed to contain no detectable ^{60}Co above a nominal detection limit of 50 pCi per liter by direct counting and 15 pCi per liter by the filtration method), the soils in the immediate vicinity of the system will be sampled to confirm there is no residual contamination. The soils will be collected using a drill rig at specific points along the foundation drainage system. The ^{60}Co concentration in the samples will be determined using a combination of in-house screening capability and confirmatory analyses by a commercial analytical laboratory.

- AMS will tank and sample all water that accumulates in the underdrain system prior to discharge until the soil sampling effort demonstrates there is no residual contamination in the underdrain system, and until 10,000 gallons of water are tanked and confirmed to contain no detectable ^{60}Co above a nominal detection limit of 50 pCi per liter by direct counting and 15 pCi per liter by the filtration method. At that time, USNRC approval to "free release" the water from the foundation drainage system will be solicited.

- Once the 16 drums and 4 inserts of high-level waste are removed, the basement of the London Road facility will be decontaminated, and the WHUT Room will be hydrologically-stabilized as described in the June 10, 1996 Building Recovery Project proposal.

- Once the basement is remediated, the lateral connection from the AMS building for storm water and sanitary discharges to the regional sewer system will be re-established.

All of the ^{60}Co that was released from the basement during the flooding event did not leave the underdrain system, thus there has been no impact on the environment or the surrounding population. Furthermore, residual contamination of the underdrain system is improbable because of the local hydrology, and because the ^{60}Co at AMS has consistently demonstrated a lack of ionic strength.

Because our available tank space is limited, AMS request that the USNRC approve Radiation Safety Procedure RSP-018, "Operation of the Gamma Spectrometer", and RSP-019, "Assessment of Radioactivity in Water Samples", with the provision that AMS will only release water from the foundation drainage system that has been tanked, sampled, and confirmed to contain no residual ^{60}Co above the release criteria contained in RSP-019 by the close of business on Friday, April 4, 1997. In addition, because AMS continues to be at risk of underdrain system contamination as long as the basement of the London Road facility remains contaminated, we are also asking for timely approval of our February 21, 1997 request for release of additional decommissioning funds in order to complete Task 2 (Waste Disposal) of the Building Recovery Project. (AMS has issued purchase orders for the disposal of all of its packaged waste with the exception of 16 shielded drums and 4 drum inserts of high-level waste that

are currently stored in the basement. The basement cannot be remediated until these drums are removed. Because the exposure rates associated with the handling of these drums are relatively high, AMS is desirous of moving them only once - from the basement to the vehicle that will be used to ship them to Barnwell. However, if additional funds are not released in a timely fashion, the drums will be moved from the basement to High Level Waste Storage until such time as funds become available for their disposal. At that time, they will be moved again to the transport vehicle.)

Please call me at (216) 692-3270 if I can answer any questions or provide you with additional information. Timely USNRC response on this request is imperative.

Sincerely,

Stephen J. Haddock

Stephen J. Haddock, R.S.O.

cc: E. L. Svigel
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

Advanced Medical Systems, Inc.
1020 London Road
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Fax (216) 692-3269

March 20, 1997

Mr. John R. Madera, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Madera:

On March 13, 1997, Advanced Medical Systems, Inc. (AMS) forwarded a description of changes to our water collection/analysis/discharge procedures. Included in those changes was the following criterion:

> "Discharges of sampled water shall not exceed 25,000 gallons in a 24-hour period."

Since the intent of this criterion is simply to ensure that the program remains consistent with the "Technical Basis for Water Discharge Criteria" contained in Radiation Safety Procedure No. RSP-019, "Assessment of Radioactivity in Water Samples", such that the total discharge of water into the regional sewer system from the London Road facility does not exceed 25,000 gallons in a 24-hour period, AMS wishes to modify the criterion as follows:

> "Discharges of water shall not exceed 25,000 gallons in a 24-hour period."

Please call me at (216) 692-3270 if I can answer any questions or provide you with additional information. AMS is awaiting USNRC action on this important issue.

Sincerely,

Christopher Reed, A.R.S.O.

cc: E. L. Svigel
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

fmi 5-27-97

Advanced Medical Systems, Inc.

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

March 13, 1997

Mr. John R. Madera, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Madera:

On March 4, 1997, Advanced Medical Systems, Inc. (AMS) provided responses to your February 27, 1997 comments in regard to Radiation Safety Procedure RSP-018, "Operation of the Gamma Spectrometer", RSP-019, "Assessment of Radioactivity in Water Samples", and RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy". Subsequent to that date, as discussed in your March 11, 1997 telephone conversation with Dwight Miller, Esq. (legal counsel to AMS), the following fundamental changes were made to our water collection/analysis/discharge procedures:

- All samples of underdrain water will be analyzed for *both* total ^{60}Co content (e.g., soluble and insoluble) *and* for insoluble ^{60}Co content using the methodology described in RSP-018.
- The following are the criteria for discharge of underdrain water into the regional sewer system based upon the sampling/analysis results:

  i. Discharges of sampled water shall not exceed 25,000 gallons in a 24-hour period.

  ii. Water that contains total ^{60}Co activity of greater than 100 pCi per liter shall not be discharged.

  iii. Water that contains insoluble ^{60}Co activity of greater than 15 pCi per liter shall not be discharged.

  iv. Water that exhibits net *filter* count rates (e.g., insoluble activity) that are less than the decision level may be discharged without regard for solubility if the MDA for the analysis is no greater than 15 pCi of ^{60}Co.

Under separate cover I will forward the referenced RSPs, revised to incorporate these changes and the commitments made in our March 4, 1997 response. When AMS receives USNRC approval, the three RSPs will be signed and implemented as described in RSP-003, "Control of Radiation Safety Procedures". In the meantime, if you have any questions or if I can provide you with additional information, please call me at (216) 692-3270. Timely USNRC action on this important issue would be greatly appreciated.

Sincerely,

Stephen J. Haddock

Stephen J. Haddock, R.S.O.

cc: E. L. Sviges
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

RECEIVED
MAR 17 1997
REGION III

pm; 3-14-97

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio 44110
(216) 692-3270
Fax (216) 692-3269

March 4, 1997

Mr. John R. Madera, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Madera:

Advanced Medical Systems, Inc. (AMS) is in receipt of your letter dated February 27, 1997 wherein additional comments in regard to Radiation Safety Procedure RSP-018, "Operation of the Gamma Spectrometer", RSP-019, "Assessment of Radioactivity in Water Samples", and RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy" were provided. Enclosed are our responses to your comments, along with a description of our proposed follow-up actions. When AMS receives your approval, the three RSPs will be signed and implemented as described in RSP-003, "Control of Radiation Safety Procedures".

On March 1, 1995 and March 20, 1995, AMS submitted applications to amend the referenced license to permit release of ground/surface water that collects in the *remediated* foundation drainage system of the London Road facility. As of the date of this letter, USNRC authorization to proceed on this request has not yet been received. Please call me at (216) 692-3270 if you have any questions or if I can assist you in any way in expediting your review of our March 1, 1996 and March 20, 1996 amendment requests and subsequent supporting information. Timely USNRC action on this important but long-overdue issue would be greatly appreciated.

Sincerely,

Stephen J. Haddock

Stephen J. Haddock, R.S.O.

cc: E. L. Svigel
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

Pm: 3-5-97

ADVANCED MEDICAL SYSTEMS, INC.
RESPONSE TO USNRC COMMENTS ON WATER DISCHARGE PROCEDURES

USNRC Comment 1 on Procedure RSP-018: Most of the equations and quantities used in the procedure do not have units associated with them. The procedure moves from counts to nCi to pCi/l without any indication of the units involved. Units are needed to avoid confusion.

AMS Response: Concur.

Action Taken: Units will be included in the variable definitions for each equation.

USNRC Comment 2 on Procedure RSP-018: Sections 5.6, 5.7 and 5.8 describe the determination of the counting efficiency. Source numbers are given for the different geometries, but it is not clear from the procedure that these sources duplicate the counting geometries, such as Marinelli beakers for water and soil, and filter paper for insoluble materials. It should be noted that the sources must duplicate the counting geometries.

AMS Response: The purchase specifications for the calibration sources ensured that the source geometry was similar to the intended counting geometry. It is for this reason that the source number is specified in RSP-018. Nonetheless, the reviewer's request to specify the counting geometry will be accommodated.

Action Taken: The geometry for each of the numbered sources will be given in sections 5.6.2, 5.7.2 and 5.8.2, respectively.

USNRC Comment 3 on Procedure RSP-018: Section 5.2.1 states that energy response and regions of interest shall be determined daily, immediately prior to acquisition of background data. This implies a daily background determination. However, Sections 5.3.1, 5.4.1 and 5.5.1 state that background is to be determined at least weekly. There appears to be some inconsistency.

AMS Response: Concur.

Action Taken: Section 5.2.1 will be modified to read: "Energy response and regions of interest shall be determined daily prior to initial use."

USNRC Comment 4 on Procedure RSP-018: It should be clearly stated that Section 5.6 efficiency determination, should be implemented after energy and region of interest determinations.

AMS Response: Concur.

Action Taken: Sections 5.6.1, 5.7.1 and 5.8.1 will be modified to read: "The detection efficiency for water/soil/filters should be determined daily, at the start of each shift after the energy calibration and regions of interest are determined."

USNRC Comment 5 on Procedure RSP-018: The equation in Section 5.10.6 to calculate the MDA is incorrect. The quantity under the square root, as shown in the procedure should be:

$$\sqrt{R_B t_S (1 + t_S/t_B)}$$

AMS Response: Concur.

Action Taken: The typographical error that appeared in the equation in Section 5 10.6 has been corrected to read:

$$MDA = \frac{2.71 + 3.29\sqrt{R_B\, t_S\, (1 + \frac{t_S}{t_B})}}{t_S \times E_{meas} \times 0.037 \times A}$$

USNRC Comment 6 on Procedure RSP-018: Contaminated beakers should not be counted, as is suggested in Section 5.9.6 note, because they do not duplicate the efficiency determination geometry.

AMS Response: Because the thickness of any residual contamination is likely to be small with respect to the Marinelli beaker size, because the gamma energies of interest at AMS are 1.17 and 1.32 MeV, and because of the stopping power of sodium iodide for these gamma energies is not great, the geometry difference posed by the reviewer, in light of other associated counting errors, is negligible and certainly not detectable. However, the presence of surface contamination on the outside of a beaker will cause the analytical result to be biased high. Therefore, the reviewer's recommendation will be accommodated.

Action Taken: The Note under Section 5.9.6 will be modified to read: "If contamination by a radionuclide other than ^{60}Co or other non-radiological material is suspected, place the container in a thin-walled plastic bag prior to its placement on the detector".

USNRC Comment 7 on Procedure RSP-018: Attachment 2 is entitled "Daily Background Data", but the procedure indicates that the background is determined weekly. Which is the correct one, or is there an explanation?

AMS Response: Concur.

Action Taken: The title of Attachment 2 will be modified to read "Background Data".

USNRC Comment 8 on Procedure RSP-018: Attachment 6 does not contain a column following the Decision Level column to indicate whether activity was or was not detected. This is necessary to indicate whether additional steps need be taken or the analysis is terminated at that point.

AMS Response: The Note under Statement 5.10.3 states that "if R_S is less than $DL(R_S)$, the sample is assumed to contain no ^{60}Co". AMS maintains that this instruction is sufficient for decision-making and that an additional column in Attachment 6 is unnecessary. The remainder of the Attachment 6 entry must be completed regardless of whether the Decision Level is exceeded or not.

USNRC Comment 1 on Procedure RSP-019: Section 5.5.1 states that all samples with detectable cobalt-60 activity in concentrations of less than 100 pCi per liter will be passed through a 0.45 µm filter. It is not clear, however, what detectable activity means here. It presumably means activity that is above the decision level. If so, then this specific criterion should be given, rather than the vaguer "detectable activity."

AMS Response: Concur.

Action Taken: Section 5.5.1 will be modified to read: "Samples that contain ^{60}Co in concentrations of less than 100 pCi per liter shall be drawn (by vacuum pump) through a 0.45 micrometer filter".

USNRC Comment 2 on Procedure RSP-019: Section 5.5.2 states that the "filter should be re-analyzed" after water is drawn through it. When was it analyzed before this re-analysis? If this re-analysis refers to the water, then the text should be changed to reflect this idea.

AMS Response: Concur.

Action Taken: Section 5.5.2 will be modified to read: "The filter shall be analyzed pursuant to RSP-018".

USNRC Comment 3 on Procedure RSP-019: Sections 5.4.3, 5.4.4 and 5.5.4 are inconsistent. According to the logic presented in these sections, all samples with detectable activity less than 100 pCi/l will be filtered and the filtrate counted to an MDA of 15 pCi/l. Detectable activity in the water sample is determined using a setup that provides an MDA of 50 pCi/l. However, samples may well contain activity that is not detectable using an MDA of 50 pCi/l, but that is substantially above the 15 pCi/l level. The net result is that samples with activities between roughly 50 pCi/l and 15 pCi/l will be discharged as clean when in fact they do not meet the 15 pCi/l insoluble material criterion in Section 5.5.4. This situation should be corrected by lowering the MDA in section 5.4.3 to 15 pCi/l.

AMS Response: AMS assumes the reviewer is referring to some combination of Sections 5.4 and 5.5 in this comment. If that is the case, the reviewer's interpretation of the logic is correct. However, the recommendation given by the reviewer is not applicable. If samples are counted by the method of direct counting, which is less time-consuming than the method of filtering, and if no detectable radioactivity is present, RSP-019 states that the water may be discharged without regard for solubility. This means that it is, theoretically, possible for water containing insoluble ^{60}Co in concentrations greater than 15 pCi per liter but less than the MDA to be discharged. However, the performance criterion for this counting system, as described in Attachment 1, "Technical Basis for Water Discharge Criteria", is intended to be 50 pCi per liter, not 15 pCi per liter. (See response to USNRC Comment 1 on the Technical Basis for additional information.) This criterion is a factor of four (4) lower than the drinking water standard for ^{60}Co (40 CFR 141), and the methodology for its development is consistent with that contained in NUREG/CR-5814, "Evaluation of Exposure Pathways to Man from Disposal of Radioactive Materials into Sanitary Sewer Systems" (May, 1992).

USNRC Comment 4 on Procedure RSP-019: Section 5.6.2.1 incorrectly uses the MDA to reach detection decisions. This section should state that analytical results greater than 100 pCi/l or showing results below the corresponding decision level shall be forwarded, etc.

AMS Response: Concur.

Action Taken: Section 5.6.2.1 will be modified to read "Analytical results that are less than the decision level or greater than 100 pCi/liter shall be forwarded to the RSO and no additional analyses shall be necessary".

USNRC Comment 5 on Procedure RSP-019: As in Item 3 above, the MDA is incorrectly used to make detection decisions. This section should state that analytical results showing results above the corresponding decision level but less than 100 pCi/l, etc.

AMS Response: AMS assumes the reviewer is referring to Section 5.6.2.1, the response for which was presented in response to USNRC Comment 4 on Procedure RSP-019.

USNRC Comment 6 on Procedure RSP-019: According to section 5.7.3.1, water that does not contain any detectable activity cannot be discharged, since it would not meet this criterion, which must be met for any discharges according to the procedure.

AMS Response: Concur.

Action Taken: For clarity, Section 5.7.4 and 5.7.4 will be reversed. The new Section 5.7.4 will be modified to read: "Water that exhibits net count rates in excess of the Decision Level may be discharged if it contains *all* of the following:"

USNRC Comment 7 on Procedure RSP-019: The condition in section 5.7.4 is not acceptable because it does not meet the 15 pCi/l criterion for insoluble material noted in various sections of the procedure, such as 5.7.3.3.

AMS Response: The performance criterion for the AMS spectroscopy system for direct counting is 50 pCi per liter, not 15 pCi per liter. (See response to USNRC Comment 1 on the Technical Basis for additional information.) Therefore, AMS maintains that Section 5.7.4 is appropriate. However, for clarity, the reference to the MDA requirement for each counting event will be deleted.

Action Taken: Section 5.7.4.1 will be deleted.

USNRC Comment on Procedure RSP-022(a): The sample to be analyzed for external intercomparison should be obtained from an external, reference source engaged in "round robin" testing, rather than being generated in-house, because this will nullify the blind testing element of the comparison.

AMS Response: Section 5.3.6 does not require blind testing of the AMS spectroscopy system. It merely requires that a fraction of all sample results obtained by AMS be confirmed by an outside laboratory.

Because the AMS system is calibrated daily prior to use using a NIST-traceable standard of the only radionuclide and geometry of interest (i.e., ^{60}Co), because a peak search or nuclide identification program is not used to complete an analysis, and because the results are obtained by simple comparison of net counts between a sample and the standard, AMS maintains that blind testing is not necessary.

USNRC Comment on Procedure RSP-022(b): In addition, the sample to be analyzed in this manner should have low levels of activity, comparable to the levels expected in the water samples, that is, levels that are close to the MDA used in the various analyses.

AMS Response: Concur.

Action Taken: The following statement will be added after section 5.6.3.2: "The sample selected for intercomparison shall have exhibited a net count rate by direct counting that was less than the Decision Level *and* an MDA of less than 50 pCi per liter".

USNRC Comment 1 on Technical Basis: The last paragraph on Page 8, and the ensuing conclusions, is inconsistent with Item 3 at the top of the same page. Item 3 states that water may be discharged if the insoluble fraction is shown to be less than 15 pCi/l. The last paragraph on the page, and the conclusion that follows from it, state that "as long as the AMS measurement system is capable of detecting at least 50 pCi of cobalt-60 in its discharges (presumably 50 pCi/l), AMS can ensure compliance . . ." However, it is not possible to show that insoluble activity is less than 15 pCi/l if the detection system is capable only of detecting 50 pCi/l.

AMS Response: Concur.

Action Taken: Item (3) will be modified to read: "If a sample exhibits a net count rate by direct counting that is greater than the Decision Level, and if the total ^{60}Co concentration (soluble plus insoluble) is less than 100 pCi per liter, the water may be discharged if the insoluble fraction is shown to be less than 15 pCi per liter".

USNRC Comment 3 on Technical Basis: For the same reasons discussed above, the conclusion is not acceptable. It states that "water below the decision level with MDAs of less than 50 pCi per liter. . . ." Such water discharges do not meet the insoluble activity criterion of less than 15 pCi/l.

AMS Response: See response to USNRC Comment 1 on the Technical Basis.

USNRC Comment 3 on Technical Basis: At a detection efficiency of 2% for cobalt 60 in a Marinelli beaker, and a background count rate of 4.6 counts per second, it does not appear that AMS' system is capable of achieving an MDA of 50 pCi/l in a 4 hour count, as stated in your document. We suggest that the calculation for MDA be reviewed to ensure its accuracy.

AMS Response: As shown in Attachment 4 of our December 13, 1996 letter, the nominal background count rate in the regions of interest for the AMS spectroscopy system is approximately 0.46 counts per second, not 4.6 counts per second as cited by the reviewer.

AMS maintains that the equation used to calculate the MDA in Section 5.10.6 of RSP-018 is correct, and that an MDA of less than 50 pCi per liter is achievable by direct counting in a four-hour count time. The following is an example calculation for a one (1) liter sample, an efficiency of two (2) percent, and a background count rate of 0.46 counts per second, along with the nominal sample and background count times given in Attachment 4 of our December 13th letter:

$$MDA = \frac{2.71 + 3.29\sqrt{R_B\, t_S\,(1 + \frac{t_S}{t_B})}}{t_S \cdot E_{media} \times 0.037 \times A}$$

$$MDA = \frac{2.71 + 3.29\sqrt{4.6\times10^{-1}\ 1.44\times10^{4}\ (1 + \frac{1.44\times10^{4}}{2.88\times10^{4}})}}{1.44\times10^{4} \times 2\times10^{-2} \times 0.037 \times 1}$$

$$MDA = \frac{330.66}{10.66}$$

$$MDA = 31.02$$

Weber

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: 12/17/96

Mail or E-Mail to: Donald A. Cool (DAC), Mail Stop: 6H3-OWFN, If E-mail, cc: CLE
Division of Industrial and Medical Nuclear Safety, NMSS

From: John R. Madera, Chief, Nuclear Materials Inspection Branch 1, Region III

Licensee: Advanced Medical Systems *License No.* 34-19089-01

☐ *Control No.* _____ *(if applicable)*

☒ *Letter dated:* Dec. 13, 1996

☐ *Suggested change in licensing procedure (enclosed):*

☒ *Problem/Issue:* Please review AMS' Dec. 13, 1996 response letter (with attachments). This letter responds to the issues discussed in the TAR response dated Nov. 8, 1996, by Sami Sherbini.

☐ *Action Required:*

☐ *Recommended Action (with revisions):* ☐ *Approve or* ☐ *Reject*

Remarks:

Headquarters Reviewer: _____
Regional Reviewer: M. Weber
Reviewer Code: S2
Reviewer Phone No.: (630)829-9825 *Fax No.:* (630) 515-1259
Request Needed by: ASAP

Attachment: 12/13/96 letter from AMS

cc w/o att: C. Pederson, RIII
M. Weber, RIII

Form TAR-10
10/96

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio 44110
(216) 692-3270
Fax (216) 692-3269

December 13, 1996

Mr. John R. Madera, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Madera:

In my letter dated September 26, 1996, Advanced Medical Systems, Inc. (AMS) forwarded additional information in regard to Radiation Safety Procedure RSP-018, "Operation of the Gamma Spectrometer" and RSP-019, "Assessment of Radioactivity in Water Samples". This information was provided in response to your September 3, 1996 solicitation.

In our September 26th letter, AMS agreed to certain modifications to the referenced RSPs that were recommended by the USNRC. We also agreed to develop a quality assurance program for our in-house analytical procedures. Attachment 1 of this letter contains the revised RSP-018. Attachment 2 contains the revised RSP-019. Attachment 3 contains RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy". These procedures were reviewed and approved by the AMS Radiation Safety Committee. They will be signed and implemented immediately upon your concurrence.

AMS is still awaiting USNRC action on our March 1, 1995 and March 20, 1995 applications to amend the referenced license to permit release of ground/surface water that collects in the *remediated* foundation drainage system of the London Road facility. As of the date of this letter, USNRC authorization to proceed on this request has not yet been received. Therefore, I would like to take this opportunity to summarize the information pertinent to this decision, and propose performance criteria for the AMS program in the hope of a timely and favorable response.

AMS maintains that if we sample and discharge the water that collects in the underdrain system at the London Road facility pursuant to the attached procedures, and if our monitoring system meets the proposed performance criteria, we will be in compliance with all applicable regulations. Furthermore, this action will result in no negative health and safety impact on people or the environment. The following is a brief review of the technical capability of our in-house analysis program, the regulatory basis for our program, information on public health and safety, the proposed performance criteria, and a programmatic summary.

Pm: 12-16-96

Technical Capability of the AMS Gamma Spectrometer

The Advanced Medical Systems, Inc. (AMS) gamma spectroscopy system is comprised of a scintillation detector and a multichannel analyzer (MCA). The MCA is a Nucleus Model MC800A 256-channel analyzer that includes the main housing, the monitor, and an uninterruptable power supply. The detector is a 2 in. by 2 in. thallium-activated sodium iodide crystal that is optically-coupled to a photomultiplier tube on a voltage divider. The detector, the tube and the divider are housed inside of a 2 in.-thick lead shield.

The system is located in a non-atmospherically-controlled office in the vicinity of the AMS conference room. While the ambient temperature in this area cannot be readily controlled, it does remain somewhat stable (e.g., within $\pm$ 20° F) throughout typical counting times. The ambient gamma exposure rate in the counting room is approximately 10 microR per hour.

The operational procedures for the system are described in RSP-018 and RSP-019. Methods for assuring data quality are described in RSP-022. Since the only radionuclide of interest to AMS is ^{60}Co, the system is calibrated daily using water-equivalent, soil-equivalent, or filter-equivalent standards of ^{60}Co that are traceable to the National Institute of Standards and Technology (NIST). The standardized sources of water and soil are in a Marinelli beaker geometry, while the geometry of the filter source is an electroplated disk.

The average detection efficiency of the AMS spectroscopy system for the water-equivalent standardized source of ^{60}Co, is approximately two (2) percent. For the filter-equivalent source, the efficiency is approximately seven (7) percent. These efficiencies are achievable when the region of integration on the gamma spectrum encompasses the "full width, full max" (FWFM) of the 1.17 and the 1.32 MeV "peaks" associated with the decay of ^{60}Co.

Water Sampling Program Summary

AMS is currently bound by court order and USNRC license requirements to pump water from the underdrain system into hold-up tanks, sample the tanks for the presence of radioactivity, notify the Northeast Ohio Regional Sewer District (NEORSD) of pending discharge of each tank, and await the results of a NEORSD confirmatory sampling effort prior to discharge. Between the 1995 completion date of the sewer remediation project and the date of this letter, over 225,000 gallons of water have been pumped from the foundation drainage system and sampled.

Attachment 4 is a table showing the results of direct counting of water samples collected and analyzed at AMS between June 17, 1996 and November 20, 1996. Using the calculational methodology shown and referenced in RSP-018, only five (5) of these results exceed the decision level. This means that the radioactivity in the remaining 18 samples is not distinguishable from background.

Attachment 4 also shows that the average background count rate in the energy region of interest for an eight (8) hour counting time is 4.61 $\pm$ 0.005 counts per second. Again using the calculational methodology shown and referenced in RSP-018, the average detection limit exhibited by the AMS

spectroscopy system between June and November of 1996 for direct counting of water samples was 42.9 $\pm$ 0.42 pCi per liter. None of the results from the 23 analyses exceeded the detection limit.[1]

It is also important to note that prior to and during this same time period (June through November of 1995), the NEORSD, and occasionally the USNRC, performed confirmatory analyses of samples from the same tanks of water sampled by AMS. Throughout this effort, neither agency positively identified the presence of either soluble or insoluble ^{60}Co in any of the water pumped from the underdrain system.[2] Even at the significantly lower detection limits achieved by the NEORSD and the USNRC during their analyses, there is no evidence that ^{60}Co exists in or near the underdrain system.[3]

Regulatory Basis

The primary purpose of federal regulations to control radioactive materials is to protect people and the environment from the potentially-harmful effects of radiation. The stated objectives of the regulations are to assure that workers and members of the general public are not exposed to ionizing radiation at dose rates in excess of recommended limits, and that any exposure is kept to a practical minimum, economic and societal factors taken into account.

In order to achieve these objectives, agencies such as the USNRC promulgate default criteria designed to facilitate compliance. For example, in Title 10, Code of Federal Regulations, Part 20, the USNRC authorizes release of liquid effluents as long as the concentration of radionuclides does not exceed the concentrations shown in Appendix B to 10 CFR 20.1001-20.2401. Compliance with these criteria by licensees will ensure the primary dose limits are met.[4] Title 10 CFR 20 also authorizes the discharge of licensed material into the sanitary sewage *provided the material is readily soluble* (or is readily dispersible biological material) in water, and the concentration of licensed material does not exceed that

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[1] On November 21, 1996, AMS initiated a modified filter counting program as described in RSP-018. The data acquired to date by this methodology indicate a background count rate in the energy region of interest for an eight (8) hour counting time of 0.506 counts per second, and a MDA of 12.5 pCi per liter. However, as of the date of this letter, insufficient data to adequately characterize the capabilities of this program are available. Therefore, it will not be addressed further in this communication.

[2] While ^{60}Co was identified in two 3,000-gallon batch tanks and one 25,000 gallon frac tank, the source of this contamination was the tanks themselves, which were used as process tanks for the water treatment project. The residual ^{60}Co that remained in the batch tanks when they were first filled with water from the remediated underdrain system was removed by filtration. Sampling of subsequent batches of water held in these tanks has been negative for the presence of ^{60}Co. Remedial action for the frac tank is delayed pending resolution of a non-radiological issue.

[3] Over 225,000 gallons of underdrain water have been pumped into tanks, sampled, confirmed to be "clean" by the NEORSD, and discharged. Because of the effectiveness of the sewer remediation, none of this water has contained ^{60}Co in any form (e.g., soluble or insoluble).

[4] At AMS, the water that enters the foundation drainage system is neither effluent from the London Road facility per 10 CFR 20.1302(b)(2)(i), nor is it discharged licensed materials into the sanitary sewer system per 10 CFR 20.2003(a). It is simply groundwater and storm water that collects within the "bathtub" of shale surrounding the building. Since this groundwater and storm water does not come in contact with any sources of ^{60}Co, continuous monitoring of the radionuclide content of this water as required in 10 CFR 20.1302(a) is not necessary.

listed in Table 3 of Appendix B to 10 CFR 20.1001-20.2401. For ^{60}Co, that concentration is 30,000 pCi per liter.

In regard to the means of determining whether a discharged material is "readily soluble", the guidance found in USNRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20" applies. This document lists the acceptable methods for demonstrating compliance with the solubility requirements. One of these is the American Public Health Association (APHA), Method 7110, "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)", Standard Methods for the Examination of Water and Wastewater, which is an analytical procedure for determining the quantity of insoluble *gross beta activity* in water samples.

Attachment 5 is a table that shows either regulatory criteria or analytical performance criteria in regard to discharge of ^{60}Co. This table clearly shows that the detection limit of AMS's spectroscopy system is sufficiently low to detect any ^{60}Co concentration in water that might be of regulatory concern. However, since conventional radioanalytical methods for water are not capable of confirming the presence or absence of "one atom of insoluble cobalt", performance criteria in regard to lower limits of detection are necessary in order to apply the USNRC's regulations and guidance to "real world" operations. Unfortunately, neither 10 CFR 20 nor Method 7110 specify performance criteria for analytical laboratories that analyze samples for compliance purposes and, as of the date of this letter, the USNRC has not taken a position on this issue.

Proposed Performance Criteria

AMS proposes a performance criterion of 50 pCi per liter of ^{60}Co in water by direct counting to determine if water can be discharged into the sanitary sewer system. This value is consistent with the USEPA's standards for drinking water, and is achievable using the AMS gamma spectroscopy system.[5] Furthermore, it also ensures no adverse radiological impact on people, the environment, and the local sewage treatment plant. If AMS is unable to detect the presence of ^{60}Co below this performance criterion, the intent of the federal regulations for discharge into the sanitary sewer system will have been met, and the water may be discharged without regard for solubility.

Even after extensive tanking and sampling of over 225,000 gallons of water from the underdrain system, neither AMS, the NEORSD or the USNRC have detected the presence of ^{60}Co. However, in the unlikely event that a water sample is analyzed by direct counting and found to contain more than 50 pCi per liter, AMS proposes the following additional criteria:

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[5] It is also consistent with a United States District Court Order on Consent wherein the NEORSD entered into a pre-treatment agreement with AMS in regard to radionuclide discharge limits (United States District Court, Northern District of Ohio, Eastern Division, Order on Consent, Case No. 1:94 CV 2555, December 22, 1995). This agreement stipulates that "water proposed for discharge from the foundation footer drain system that shows the presence of Cobalt 60 in a concentration of 100 pCi per liter or less, may be discharged".

- If the ^{60}Co concentration by direct counting is less than 100 pCi per liter, the water may be discharged as long as the insoluble fraction is shown to be less than 15 pCi per liter.[6]

- If the total ^{60}Co concentration exceeds 100 pCi per liter, it will not be discharged.

Health and Safety Impacts of AMS Water Discharge Program

Attachment 4 shows that none of the measured concentration of ^{60}Co in the foundation drainage system between June and November of 1996 are statistically reliable. Analysis performed by the NEORSD with detection levels a factor of 10 or more lower than those achievable by AMS have likewise failed to identify the presence of ^{60}Co in the underdrain water. The same is true for samples collected and analyzed by the USNRC. Since no radioactivity has been found, there is no radiological impact on people and the environment if AMS discharges water from the underdrain system directly to the regional sewer system.

Program Summary

In AMS's March 1, 1995 and March 20, 1995 license amendment requests to discharge ground/surface water, it was anticipated that an immediate outcome of the sewer remediation project would be re-connection of the sanitary and storm sewers from the London Road facility to the NEORSD's interceptor. Therefore, in those applications AMS proposed a monitoring methodology designed to *confirm* that water that entered the sewer system was free of radioactivity, and demonstrate that the remediation efforts were, in fact, effective.[7]

Once USNRC authorization to freely discharge the storm/ground water that collects in the foundation drainage system of the London Road building has been received, AMS will operate a temporary automatic pumping system to remove water that accumulates in the new manhole. The discharge point for this water will be discharged to a storm sewer catch basin on the west side of the building's west parking lot.[8]

A one-liter sample of water will be collected from the new manhole once per week and analyzed pursuant to RSP-018 and RSP-022. If the manhole is dry on a scheduled sample collection date, that sample will be collected immediately after water flow resumes. All results will be documented and

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[6] The 100 pCi per liter criterion is 50 % of the USEPA drinking water standard for ^{60}Co found in 40 CFR 141. The 15 pCi per liter standard is consistent with the guidance found in USNRC Regulatory Guide 4.5, "Environmental Technical Specifications for Nuclear Power Plants (draft for comment)".

[7] Because the water in the remediated underdrain system was intended to flow by gravity into the London Road interceptor, the proposed monitoring methodology involved installation of an in-line flow meter and composite sampler into a new lateral connection. The intent was to collect and analyze composite samples on a planned and periodic basis until such time as all parties were confident of the effectiveness of the sewer remediation effort. For a variety of reasons, re-connection of the building foundation drainage system to the London Road interceptor has not occurred. Therefore, an alternative methodology for meeting the intent of the March 1 and March 20, 1995 applications (e.g., one that does not require a gravity-fed discharge path) will be implemented.

[8] AMS will then pursue the legal authority to re-institute a permanent (gravity-fed) discharge system.

maintained as described in RSP-003, "Radiation Protection Records". The sampling schedule will be included in RSP-008, "Instrumentation and surveillance".

The criteria for determining whether the water from the underdrain system is suitable for discharge in RSP-019 are:

- Water that contains greater than 100 pCi per liter of ^{60}Co will not be discharged.
- Water that contains greater than 50 pCi of ^{60}Co per liter by direct counting *and* an insoluble component (e.g., material that will not pass through a 0.45 micrometer filter) of greater than 15 pCi per liter will not be discharged.
- Water than contains no detectable ^{60}Co activity by direct counting may be discharged, as long as the MDA for the analysis does not exceed 50 pCi per liter.

Since AMS would consider any detectable ^{60}Co in samples collected from the manhole to be an unusual occurrence, such an event would trigger re-instatement of "tanking" procedures (e.g., the water will be pumped to hold-up tanks, sampled, and confirmed to meet the release criteria prior to discharge) until the cause has been identified and corrective action instituted.

Please call me at (216) 692-3270 if you have any questions or if I can assist you in any way in expediting your review of our March 1, 1996 and March 20, 1996 amendment requests and subsequent supporting information. Timely USNRC action on this important but long-overdue issue would be greatly appreciated.

Sincerely,

Stephen J. Haddock

Stephen J. Haddock, R.S.O.

cc: E. L. Svigel
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

Attachment 1 - RSP-018

Advanced Medical Systems, Inc.

OPERATION OF THE GAMMA SPECTROMETER	Procedure: RSP-018	Revision No.: 000
	Page: 1 of 18	Date: December 13, 1996
	Approved by (President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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CONTROLLED COPY NO. : _____

1 PURPOSE

The purpose of this Radiation Safety Procedure (RSP) procedure is to provide instruction on the operation of the sodium-iodide-based gamma spectroscopy system at Advanced Medical Systems, Inc. (AMS).

2 SCOPE

This procedure applies to the routine operation of the gamma spectroscopy system in use at the London Road facility for analysis of samples used to demonstrate compliance with regulations, requirements or RSPs. Analysis of other than water or soil samples or filters, or analyses for purposes other than compliance, are exempt from the requirements of this RSP.

3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission License No. 34-19089-01 (as amended).

3.2 U. S. Nuclear Regulatory Commission, NUREG-1507, "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions - Draft Report for Comment", August, 1995.

3.3 Strom-92 - Strom, D. J. and P. S. Stansbury, "Minimum Detectable Activity when Background is Counted Longer than the Sample", *Health Physics* 63(3):360-361, 1992.

3.4 Currie-68 - Currie, L.A. (1968), "Limits for Qualitative Detection and Quantitative Determination", *Analytical Chemistry* 40(3):586-593.

3.5 Currie-84 - Currie, L.A. (1984), "Lower Limit of Detection: Definition and Elaboration of a Proposed Position for Radiological Effluent and Environmental Measurements", NUREG/CR-4007, Nuclear Regulatory Commission.

3.6 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy".

4 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be included in RSP-002, "Definitions".

5 PROCEDURE

5.1 General Instructions

5.1.1 The spectroscopy system should be positioned in a location (counting room) that is confirmed to have as little competing background as possible.

Note: To confirm that the detector canning is free of contamination, smear the outside of the canning and ensure that the smear count is less than "2x background".

5.1.2 The counting room should not exhibit significant fluctuations in temperature over a 24-hour period.

Note: Temperature fluctuations of ± 20°F may cause phototube drift and apparent gain shifts.

5.1.3 All values shall be recorded in scientific notation with two (2) figures to the right of the decimal point.

Note: For example, an efficiency of 0.02065 is recorded as 2.07×10^{-2}.

5.1.4 The quality assurance and quality control provisions of RSP-022 shall be incorporated into all analyses.

5.1.5 The RSO shall perform a final review of the data package associated with all sample results for completeness, accuracy, consistency, and compliance with RSP-022.

5.2 Determine Energy Response and Regions of Interest

5.2.1 Energy response and regions of interest shall be determined daily, immediately prior to acquisition of background data.

5.2.2 Place a ^{60}Co calibration source over the detector.

5.2.3 Adjust amplifier gain and/or high voltage so that the two primary photopeaks fall in channels 155 (1.17 MeV peak) and 176 (1.33 MeV).

5.2.4 Acquire data until approximately 4,000 counts appear in Channel 176, then stop data acquisition.

5.2.5 Determine the regions of interest.

5.2.5.1 Place the left cursor to the left of channel 155 at the location where the peak tail intersects the continuum.

5.2.5.2 Place the right cursor to the right of channel 176 at the location where the peak tail intersects the continuum.

5.2.6 Record the left and right channel numbers on Attachment 1

5.3 Determination of Water Background

5.3.1 Background count rates in the regions of interest should be determined at least once per work week, at the end of a shift.

5.3.2 Place a Marinelli Beaker containing deionized water over the detector.

5.3.3 Acquire background counts for t_B = 28,800 seconds (eight hours).

5.3.4 Determine the number of counts, C_B, in the Region shown on Attachment 1, and record on Attachment 2.

Note: Maintain a separate Attachment 2 for each media type (e.g., water, soil or filter).

5.3.5 Determine the background count rate, R_B, as follows and record on Attachment 2:

$$R_B = \frac{C_B}{t_B}$$

5.4 Determination of Soil Background

5.4.1 Background count rates in the regions of interest should be determined at least once per work week, at the end of a shift.

5.4.2 Place a Marinelli Beaker containing dry, cobalt-free soil collected from the AMS property over the detector.

5.4.3 Acquire background counts for t_B = 28,800 seconds (eight hours).

5.4.4 Determine the number of counts, C_B, in the Region shown on Attachment 1, and record on Attachment 2.

Note: Maintain a separate Attachment 2 for each media type (e.g., water, soil or filter).

5.4.5 Determine the background count rate, R_B, as follows and record on Attachment 2:

$$R_B = \frac{C_B}{t_B}$$

5.5 Determination of Filter Background

5.5.1 Background count rates in the regions of interest should be determined at least once per work week, at the end of a shift.

5.5.2 Place the filter stand and an unused 90-mm diameter filter of the same composition as those used to filter water over the detector.

5.5.3 Acquire background counts for t_B = 28,800 seconds (eight hours).

5.5.4 Determine the number of counts, C_B, in the Region shown on Attachment 1, and record on Attachment 2.

Note: Maintain a separate Attachment 2 for each media type (e.g., water, soil or filter).

5.5.5 Determine the background count rate, R_B, as follows and record on Attachment 2:

$$R_B = \frac{C_B}{t_B}$$

5.6 Determine Detection Efficiency for Water

5.6.1 The detection efficiency for water should be determined daily, at the start of each shift.

5.6.2 Place the water-equivalent calibration source (Source No. A3082) over the detector.

5.6.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 526.3\ e^{\frac{-0.693 \times t\ (days\ since\ March\ 1,\ 1995)}{1923.92}}$$

5.6.4 Record corrected activity on Attachment 3.

5.6.5 Acquire data for t_{std} = 600 seconds.

5.6.6 Determine the number of counts, C_{std}, in the Region shown on Attachment 1, and record on Attachment 3.

5.6.7 Determine the count rate, R_{std}, by the following and record on Attachment 3.

$$R_{std} = \frac{C_{std}}{t_{std}}$$

5.6.8 Determine the detection efficiency, E_{water}, by the following and record on Attachment 3.

$$E_{media} = \frac{R_{std}}{A_{today} \times 37}$$

5.7 Determine Detection Efficiency for Soil

5.7.1 Detection efficiencies for soil should be determined daily, at the start of each shift.

5.7.2 Place the soil-equivalent calibration source (Source No. A3083) over the detector.

5.7.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 587.6\ e^{\frac{0.693 \times t\ (\text{days since March 1, 1995})}{1923.92}}$$

5.7.4 Record corrected activity on Attachment 4.

5.7.5 Acquire data for t_{std} = 600 seconds.

5.7.6 Determine the number of counts, C_{std}, in the Region shown on Attachment 1, and record on Attachment 4.

5.7.7 Determine the count rate, R_{std}, by the following and record on Attachment 4.

$$R_{std} = \frac{C_{std}}{t_{std}}$$

5.7.8 Determine the detection efficiency, E_{soil}, by the following and record on Attachment 4.

$$E_{media} = \frac{R_{std}}{A_{today} \times 37}$$

5.8 Determine Detection Efficiency for Filter

5.8.1 Detection efficiencies for filters should be determined daily, at the start of each shift.

5.8.2 Place the disk calibration source (Source No. IPL-495-51) over the detector.

5.8.3 Perform decay correction on source activity by:

$$A_{today}\ (nCi) = 13.4\ e^{\frac{0.693 * t\ (days\ since\ June\ 1,\ 1995)}{1923.92}}$$

5.8.4 Record corrected activity on Attachment 5.

5.8.5 Acquire efficiency data for t_{std} = 600 seconds.

5.8.6 Determine the number of counts, C_{std}, in the Region shown on Attachment 1, and record on Attachment 5.

5.8.7 Determine the count rate, R_{std}, by the following and record on Attachment 5.

$$R_{std} = \frac{C_{std}}{t_{std}}$$

5.8.8 Determine the efficiency, E_{filter}, by the following and record on Attachment 5.

$$E_{media} = \frac{R_{std}}{A_{today} * 37}$$

5.9 Data Acquisition

5.9.1 Collect a <u>full</u> Marinelli beaker of water or soil, or place a filter in a petrie dish (or similar container).

5.9.2 Label the sample by S-xxxxxx-yy or W-xxxxxx-yy, where S = Soil, W = Water, xxxxxx = today's date (e.g., 030195 for March 1, 1995), and yy = a unique sequential identifier that repeats at the start of each day (e.g., 01, 02, etc.).

5.9.3 Seal the sample container

5.9.4 If the sample is a soil sample, determine the sample amount (A), in grams, by the following and record on Attachment 6:

$$A = MB_F - MB_E$$

where MB_E = the weight of the empty Marinelli beaker, and MB_F = the weight of the full Marinelli beaker.

5.9.5 If the sample is a water sample (filtered or unfiltered), the sample amount (A), in liters, on Attachment 6 shall be assumed to be one (1).

5.9.6 Confirm that the outside of the sample container (if the sample is soil or water) is free of contamination by smearing the outside of the container and ensuring that the smear count is less than "2x background".

Note: If contaminated, place the container in a thin-walled plastic bag prior to placement on the detector.

5.9.7 As necessary, filter the water sample through a 0.45 micrometer filter pursuant to RSP-019.

5.9.8 Place the sample or filter over the detector and acquire data for t_S = 14,400 seconds (four hours) for water samples or filters and t_s = 7,200 seconds (two hours) for soil samples.

5.9.9 Remove and archive the sample.

5.10 Data Analysis

5.10.1 Determine the number of counts, C_S, in the Region shown on Attachment 1, and record counts on Attachment 6

Note: Maintain a separate Attachment 6 for each media type (e.g., water, soil or filter).

5.10.2 Determine the sample net count rate, R_S, by the following and record on Attachment 6:

$$R_S = \frac{C_S}{t_S} - R_B$$

where R_B = the most recent value from the applicable Attachment 2.

5.10.3 Determine the decision level , $DL(R_S)$, by the following and record on Attachment 6:

$$DL(R_S) = 1.645 \times \sqrt{R_B \left(\frac{1}{t_B} + \frac{1}{t_S}\right)}$$

where R_B = the most recent value from the applicable Attachment 2.

Note: This methodology, taken from Reference Strom-92, states that if R_S is less than $DL(R_S)$, the sample is assumed to contain no ^{60}Co.

5.10.4 Determine the ^{60}Co concentration in the sample by the following and record on Attachment 6:

$$Concentration = \frac{R_S}{E_{media} \times 0.037 \times A}$$

where R_S = the net sample count rate as determined in 5.10.2, and A = the sample volume for filters or water samples, or the sample mass for soil samples.

Note: Both negative and positive results should be recorded.

5.10.5 Determine the measurement uncertainty due to counting statistics by the following and record on Attachment 6:

$$Uncertainty = \frac{1.96 \times \frac{\sqrt{C_s}}{t_s}}{E_{media} \times 0.037 \times A}$$

Note: This methodology was taken from References Currie-68 and Currie-84.

5.10.6 Determine the minimum detectable activity, MDA, for this measurement as follows and record on Attachment 6:

$$MDA = \frac{2.71 + 3.29 \sqrt{R_B t_B \left(1 + \frac{t_S}{t_B}\right)}}{t_S \times E_{media} \times 0.037 \times A}$$

Note: This methodology was taken from References Currie-68 and Currie-84.

5.11 Confirmatory Analysis for Water, Soil or Filters

5.11.1 Ensure that the lid of the Marinelli beaker is securely closed or, as applicable, the filter is securely contained within the petrie dish (or similar enclosure).

5.11.2 Log the sample number and other pertinent information onto a Chain of Custody form (Attachment 7).

5.11.2.1 The analysis to be requested for water samples is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 15 pCi/l"

5.11.2.2 The analysis to be requested for soil samples is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 5 pCi/g"

5.11.2.3 The analysis to be requested for filters is "gamma spectroscopy for Cobalt-60, with a nominal LLD of no greater than 5 pCi/l"

5.11.3 Forward the sample and the Chain of Custody form to a pre-selected analytical laboratory by overnight mail carrier (Federal Express or equivalent)

5.11.4 Maintain a copy of the Chain of Custody form and the airbill as the chain of custody record.

5.11.5 When results are received from the laboratory, record them on Attachment 8 and retain the Certificates of Analysis.

6 EXEMPTION PROVISIONS

Minor changes to this RSP shall be permitted pursuant to the written authorization of the RSO. Other variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the RSC, and after approval by the USNRC.

7 DOCUMENTATION

Records shall be maintained pursuant to RSP-004, "Radiation Protection Records"

8 ATTACHMENTS

8.1 Attachment 1 - Daily Energy Response and Regions of Interest

8.2 Attachment 2 - Daily Background Data

8.3 Attachment 3 - Efficiency Determination for Water Samples

8.4 Attachment 4 - Efficiency Determination for Soil Samples

8.5 Attachment 5 - Efficiency Determination for Filters

8.6 Attachment 6 - Analysis of Samples

8.7 Attachment 7 - Chain of Custody Form

ATTACHMENT 1
DAILY ENERGY RESPONSE AND REGIONS OF INTEREST

Date	Initials	Confirm Peaks are in Channels 155 and 176	Channel to the left of Channel 155 Where Peak Meets Continuum (Channel A)	Channel to the right of Channel 176 Where Peak Meets Continuum (Channel B)
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
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		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		
		□ yes □ no		

ATTACHMENT 2
DAILY BACKGROUND DATA

Type (check one): ☐ Water ☐ Soil ☐ Filter

Initials	Start		Stop		Count Time t_s (seconds)	Number of Counts in Region C_s (counts)	Background Count Rate R_s (counts per second)
	Date	Time	Date	Time			

ATTACHMENT 3

EFFICIENCY DETERMINATION - WATER SAMPLES

Standard Source Number A3082, Activity of 526.3 nCi on 0300 March 1, 1995

Initials	Date	Corrected Standard Activity A_{today} (nCi)	Counts in Region C_{std} (counts)	Count Time t_{std} (seconds)	Count Rate R_{std} (counts per second)	Efficiency E_{water} (counts per disintegration)

ATTACHMENT 4

EFFICIENCY DETERMINATION - SOIL SAMPLES

Standard Source Number A3083, Activity of 587.6 nCi on 0300 March 1, 1995

Initials	Date	Corrected Standard Activity A_{std} (nCi)	Counts in Region C_{std} (counts)	Count Time t_{std} (seconds)	Count Rate R_{std} (counts per second)	Efficiency E_{std} (counts per disintegration)

ATTACHMENT 5
EFFICIENCY DETERMINATION - FILTERS
Standard Source Number IPL-595-51, Activity of 13.4 nCi on 0300 June 1, 1995

Initials	Date	Corrected Standard Activity A_{today} (nCi)	Counts in Region C_{std} (counts)	Count Time t_{std} (seconds)	Count Rate R_{std} (counts per second)	Efficiency E_{filter} (counts per disintegration)

ATTACHMENT 6
ANALYSIS OF SAMPLES

Type (check one): ☐ Water ☐ Soil ☐ Filter

Initials	Date/Time	Sample No.	Sample Amount (A, grams or liters)	Count Time (t_s, seconds)	Counts in Region (C_s, counts)	Net Count Rate (R_s, counts per second with R_b taken from Attachment 2)	Decision Level ($DL(R_s)$, counts per second)	Concentration (pCi per liter, gram or filter)	Uncertainty (pCi per liter, gram or filter)	MDA (pCi per liter, gram or filter)	Confirmatory Result	RSO Review

ADVANCED MEDICAL SYSTEMS, INC.
ANALYSIS REQUEST AND CHAIN OF CUSTODY RECORD

Reference No. _____

1) Client Name	(7) Samples Shipment Date	(5) Bill to:
2) Sample Team Leader	(8) Lab Destination	
3) Task No.	(9) Lab Contact	
4) Project Manager	(12) Technical Contact/Phone	(10) Report to:
6) Purchase Order No.	(13) Carrier/Waybill No.	
11) Required Report Date		

ONE CONTAINER PER LINE

(14) Sample Number	(15) Sample Description/Type	(16) Date/Time Collected	(17) Container Type	(18) Sample Volume	(19) Preservative	(20) Requested Testing Program

23) Special Instructions

24) Possible Hazard Identification
Non-hazard ☐ Flammable ☐ Skin Irritant ☐ Poison B ☐ Unknown ☐

(25) Sample Disposal
Return to Client ☐ Disposal by Lab ☐ Archive _____ months

26) Turnaround Time Required: Normal ☐ Rush ☐

(27) QC Level: I ☐ II ☐ III ☐ Project Specific _____

1) Relinquished by: (signature, date, time):	Received by: (signature, date, time)
Relinquished by: (signature, date, time):	Received by: (signature, date, time)
Relinquished by: (signature, date, time):	Received by: (signature, date, time)

Attachment 2 - RSP-019

Advanced Medical Systems, Inc.

ASSESSMENT OF RADIOACTIVITY IN WATER SAMPLES	Procedure: RSP-019	Revision No.: 000
	Page: 1 of 10	Date: December 13, 1996
	Approved by (President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

TABLE OF CONTENTS

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1 PURPOSE

The purpose of this Radiation Safety Procedure (RSP) is to provide instruction on collecting and analyzing tanked and free-flowing water samples for the presence of ^{60}Co, and the criteria for discharge of water into the sanitary sewer system.

2 SCOPE

This procedure applies to the routine collection and analysis of water samples at the London Road facility of Advanced Medical Systems, Inc. (AMS) for purposes of demonstrate compliance with discharge criteria. Samples collected for reasons other than compliance demonstration are exempt from the provisions of this RSP.

3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission License No. 34-19089-01 (as amended).

3.2 American Public Health Association, Method 7110, "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)", Standard Methods for the Examination of Water and Wastewater.

3.3 U. S. Environmental Protection Agency, Gamma Emitting Radionuclides in Drinking Water, Method 901.1, Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA 600/4-30-032.

3.4 U. S. Department of Energy, Gamma, Section 4.5.2.3, EML Procedures Manual, HASL-300, Environmental Measurements Laboratory.

3.5 U. S. Nuclear Regulatory Commission Regulatory Guide No. 4.8, "Environmental Technical Specifications for Nuclear Power Plants" (draft for comment), December, 1975.

3.6 U. S. Nuclear Regulatory Commission, NUREG-1507, "Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions - Draft Report for Comment", August, 1995.

3.7 U. S. Nuclear Regulatory Commission, NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20".

3.8 U. S. Nuclear Regulatory Commission, Communication from J. A. Grobe (Chief, Nuclear Materials Inspection Section 2) to D. Cesar (Treasurer, Advanced Medical Systems), February 1, 1995.

3.9 Advanced Medical Systems, Inc., RSP-018, "Operation of the Gamma Spectrometer".

3.10 Advanced Medical Systems, Inc., RSP-022, "Quality Assurance for Radionuclide Analysis by Gamma Spectroscopy".

4 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be included in RSP-002, "Definitions".

5 PROCEDURE

5.1 Responsibilities

5.1.1 Sample collection and analysis shall be performed by a Radiation Surveyor.

5.1.2 The RSO shall select and pre-qualify a commercial analytical laboratory to perform confirmatory analyses by the methodology described in RSP-022, as required.

5.1.3 Water shall be discharged to the sewer system only upon the authorization of the RSO.

5.2 Sample Collection from a Hold-up Tank

5.2.1 Two re-circulation pumps (approximately 2,500 gph capacity each), or similar methodology, shall be activated within a hold-up tank that is staged for discharge.

5.2.2 Re-circulation shall continue for a minimum of two (2) tank volumes prior to sample collection to ensure adequate mixing.

Note: For example, if the hold-up tank volume is 3,000 gallons, the re-circulation pumps shall be activated 40 minutes prior to sample collection.

5.2.3 A sample of water shall be collected from the hold-up tank into a clean one-liter Marinelli beaker.

Note: Samples may be collected from any location of the hold-up tank.

5.2.4 The location, date and time of sample collection shall be documented.

5.2.5 No additional water shall be added to the hold-up tank after the sample has been collected.

5.2.6 The re-circulation pumps, or equivalent agitation device, shall remain in operation until the results of the analysis are received.

5.3 Sample Collection from a Free-flowing Source

5.3.1 A sample of water shall be collected from a free-flowing source into a clean one-liter Marinelli beaker.

5.3.2 The location, date and time of sample collection shall be documented.

5.4 Data Acquisition

5.4.1 Water samples shall be analyzed by the methodologies described in RSP-018.

5.4.2 If the net sample count rate is less than the Decision Level calculated pursuant to RSP-018, the sample may be assumed to contain no radioactivity above background.

5.4.3 Counting conditions shall result in a minimum detection limit (MDA) of no greater than 50 pCi per liter.

5.4.4 If the sample MDA is greater than 50 pCi per liter, the sample shall be forwarded to a commercial analytical laboratory for confirmatory analysis by the methodology described in RSP-018.

5.5 Solubility Determination

5.5.1 Samples that contain detectable ^{60}Co in concentrations of less than 100 pCi per liter shall be drawn (by vacuum pump) through a 0.45 micrometer filter.

Note: The entire one (1) liter sample shall be drawn through the filter.

5.5.2 The filter shall be re-analyzed pursuant to RSP-018.

5.5.3 If the net filter count rate is less than the Decision Level calculated pursuant to RSP-018, the filter may be assumed to contain no radioactivity above background.

5.5.4 Counting conditions shall result in a MDA of no greater than 15 pCi per filter.

5.5.5 If the filter MDA is greater than 15 pCi per liter, the filter shall be forwarded to a commercial analytical laboratory for confirmatory analysis by the methodology described in RSP-018.

5.6 Confirmatory Analysis

5.6.1 The sample container or the filter shall be enclosed inside of two zip-lock baggies, labeled, a Chain of Custody Form shall be completed, and the sample shall be shipped to the laboratory as described in RSP-018.

5.6.2 The samples shall be analyzed by gamma spectroscopy for Cobalt-60 pursuant to EPA Method 901.1, or HASL-300, or equivalent, with a nominal LLD of no greater than 15 pCi/l.

5.6.2.1 Analytical results that are less than the MDA or greater than 100 pCi/liter shall be forwarded to the RSO and no additional analyses shall be necessary.

5.6.2.2 Analytical results that are greater than 15 pCi per liter but less than 100 pCi per liter shall cause the sample to be analyzed for suspended gross alpha and gross beta radioactivity pursuant to American Public Health Association Method 7110.

5.6.3 When results from the analytical laboratory are received, they shall be recorded and retained as described in RSP-018.

5.7 Criteria for Discharge of Water into the Sewer System

5.7.1 Discharges of sampled water shall not exceed 25,000 gallons in a 24-hour period.

5.7.2 Water that contains greater than 100 pCi per liter of ^{60}Co in any form (e.g., "soluble" or "insoluble") shall not be discharged.

5.7.3 Water that contains *all* of the following may be discharged:

5.7.3.1 More than 50 pCi of ^{60}Co per liter by direct counting;

5.7.3.2 Net count rates from a 0.45 micrometer filter through which the water has been drawn that are less than the Decision Level; and

5.7.3.3 An MDA of less than 15 pCi of ^{30}Co for the filter.

5.7.4 Water that exhibits net count rates by direct counting that are less than the Decision Level *and* an MDA of less than 50 pCi per liter may be discharged without regard for solubility.

Note: Attachment 1 contains the technical basis for the discharge criteria.

6 EXEMPTION PROVISIONS

Minor changes to this RSP shall be permitted pursuant to the written authorization of the RSO. Other variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the RSC, and after approval by the USNRC.

7 DOCUMENTATION

7.1 Records to be maintained shall include:

7.1.1 Forms generated pursuant to RSP-018 and RSP-022.

7.1.2 Chain of Custody documentation (forms, airbills, etc.)

7.1.3 Requests for analysis

7.1.4 Certificates of Analysis

7.1.5 Discharge logs/records

7.2 Records shall be maintained pursuant to RSP-004,

8 ATTACHMENTS

Attachment 1 - Technical Basis for Water Discharge Criteria

ATTACHMENT 1
TECHNICAL BASIS FOR WATER DISCHARGE CRITERIA

System Description

The Advanced Medical Systems, Inc. (AMS) gamma spectroscopy system is comprised of a scintillation detector and a multichannel analyzer (MCA). The MCA is a Nucleus Model MC800A 256-channel analyzer that includes the main housing, the monitor, and an uninterruptable power supply. The detector is a 2 in. by 2 in. thallium-activated sodium iodide crystal that is optically-coupled to a photomultiplier tube on a voltage divider. The detector, the tube and the divider are housed inside a 2 in.-thick lead shield.

The system is located in a non-atmospherically controlled office in the vicinity of the AMS conference room. While the ambient temperature in this area cannot be readily controlled, it does remain somewhat stable (e.g., within $\pm$ 20° F) throughout typical counting times. The ambient gamma exposure rate in the counting room is approximately 10 microR per hour.

Since the only radionuclide of interest to AMS is ^{60}Co, the system is calibrated daily, using water-equivalent, soil-equivalent, or filter-equivalent standardized sources of ^{60}Co that are traceable to the National Institute of Standards and Technology (NIST). The standardized sources of water and soil are in a Marinelli beaker geometry, while the geometry of the filter source is an electroplated disk.

AMS also has a contract arrangement with a commercial analytical laboratory. On demand, this laboratory analyzes water samples, soil samples, or filters in order to demonstrate compliance with applicable criteria, or to provide confirmation that the AMS spectroscopy system is functioning as expected and required.

Objective of the Sampling/Discharge Program

The objective of the water sampling and discharge program at AMS is to ensure compliance with applicable regulations for the discharge of water into the sanitary sewer system, and to ensure the radiological health and safety of employees and members of the general public is adequately protected. To demonstrate that these objectives are met, there must be clear instruction on how to interpret the results of sampling and analysis.

Performance Criteria

The following are the criteria for discharge of wastewater from the AMS facility on London Road:

(1) A maximum of 25,000 gallons of water may be discharged over a single day.

(2) Water to be discharged must be sampled and confirmed to contain less than 100 pCi of ^{60}Co per liter.

(3) If the total ^{60}Co concentration (soluble plus insoluble) is less than 100 pCi per liter, the water may be discharged if the insoluble fraction is shown to be less than 15 pCi per liter.[1]

Basis for the Discharge Criteria

These discharge criteria were based upon an analysis of a series of regulatory and technical constraints and requirements. The following is a listing of the pertinent requirement and constraints in regard to gross radioactivity that were considered in developing the water discharge criteria for AMS:

- In Title 10, Code of Federal Regulations, Part 20, the USNRC authorizes discharge of licensed material into the sanitary sewage *provided the material is readily soluble* (or is readily dispersible biological material) in water, and the concentration of licensed material does not exceed that listed in Table 3 of Appendix B to 10 CFR 20.1001-20.2401. For ^{60}Co, that concentration is 30,000 pCi/l.

- In a United States District Court Order on Consent, the Northeast Ohio Regional Sewer District, who services the AMS facility, entered into a pre-treatment agreement with AMS in regard to radionuclide discharge limits.[2] This agreement stipulates that "water proposed for discharge from the foundation footer drain system that shows the presence of Cobalt 60 in a concentration of 100 pCi per liter or less, may be discharged".

In regard to the means of determining whether a discharged material is "readily soluble", the guidance found in USNRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20" applies. This document lists the acceptable methods for demonstrating compliance with the solubility requirements. One of these is the American Public Health Association (APHA), Method 7110, "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)", Standard Methods for the Examination of Water and Wastewater.

APHA Method 7110 contains an analytical procedure for determining the quantity of insoluble gross beta activity in water samples. However, water typically contains significant gross beta activity from isotopes such as uranium and daughters, radium and daughters, thorium and daughters, and ^{40}K. The standard does not provide guidance on how much gross beta activity indicates an insoluble material.

The USEPA, on the other hand, recognizes the presence of naturally-occurring radioactivity in water. Consequently, 40 CFR 141 indicates that if the average annual concentration of gross beta activity in water is less than 50 pCi per liter, no further analyses are required. Concentrations greater than 50

[1] This value was selected to be consistent with the guidance found in USNRC Regulatory Guide 4.5, "Environmental Technical Specifications for Nuclear Power Plants (draft for comment)".

[2] United States District Court, Northern District of Ohio, Eastern Division, Order on Consent, Case No. 1:94 CV 2555, December 22, 1995.

pCi/l may still be acceptable for a drinking water supply, but isotope-specific analyses are required before the decision is made. For ^{60}Co, the isotope-specific limit is 200 pCi per liter.

To summarize, federal regulations and a court order dictate that the maximum concentration of ^{60}Co that may be released into the sewer system or drinking water supplies by AMS is 100 pCi per liter, as determined by gamma spectroscopy. However, any detectable activity (e.g., greater than the MDA) must meet the USNRC's criteria for solubility (e.g., there must be no detectable insoluble ^{60}Co activity). Since the USNRC has not defined an acceptable MDA for the purposes of determining compliance, the USEPA's recognition of up to 50 pCi per liter of radioactivity in water as being an acceptable component of the natural background is used to set a performance criterion (e.g., an acceptable MDA).[3] As long as the AMS measurement system is capable of detecting *at least* 50 pCi of ^{60}Co in its discharges, AMS can ensure compliance with all applicable regulations, significant conservatism in its discharge practices, and no radiological impact on the local sewage treatment system.[4]

System Capabilities

The following is a listing of the performance characteristics of the AMS spectroscopy system:

- The average detection efficiency of the AMS spectroscopy system for the water-equivalent standardized source of ^{60}Co, is approximately two (2) percent. This efficiency is achievable when the region of integration on the gamma spectrum encompasses the

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[3] In USNRC Regulatory Guide 4.5, "Environmental Technical Specifications for Nuclear Power Plants" (draft for comment), the USNRC states that analytical techniques used to demonstrate compliance with 10 CFR 20 release criteria shall be such that the detection capabilities in Table 3 of the Regulatory Guide are achieved. In this table, the acceptable lower limit of detection, defined at the 95% confidence level, is 15 pCi of ^{60}Co per liter. Therefore, it can be assumed that any water that contains less than 15 pCi of ^{60}Co per liter can be discharged without regard for the solubility of the materials contained therein. However, this guidance document is a "draft for comment", rather than an approved Regulatory Guide. Without the USNRC's concurrence that this guidance is applicable to licensee programs, AMS does not feel that it can cite this as an acceptable performance criterion.

[4] The USNRC considers soils with ^{60}Co concentrations of 8 pCi per gram or less to be acceptable for release for unrestricted use. (AMS has been unable to determine the source or the technical basis for this limit. However, the USNRC deemed it acceptable during a 1995 drainage system remediation project at the London Road facility.) To ensure that the waste ash produced at the sewage treatment plant that services AMS remains exempt from regulation, AMS must not discharge ^{60}Co in concentrations that might result in concentrations in excess of 8 pCi per gram. If it is assumed that every atom of ^{60}Co discharged from AMS is transported to the ash, that 25,000 gallons of cobalt-bearing wastewater is discharged per day from AMS, and that the sewage treatment plant produces 7.5 tons of ash per day. The following results:

$$\text{Discharge Limit} = \frac{8\ pci/g}{\frac{94{,}625\ l}{day} \times \frac{1\ day}{7.5\ ton} \times \frac{1\ ton}{9.08\times10^{-5}\ grams}} = 576\ \frac{pCi}{l}$$

Therefore, to ensure that there are no adverse radiological impacts on the local sewage treatment plant, AMS must ensure its discharge concentration is less than 545 pCi of ^{60}Co per liter, which is well-above the limiting regulatory and court-ordered discharge limit.

"full width, full max" (FWFM) of the 1.17 and the 1.32 MeV "peaks" associated with the decay of ^{60}Co.

- A nominal detection limit for ^{60}Co in water after a four-hour count time ranges from 30 to 50 pCi/l, depending upon the quantity of naturally-occurring radionuclides that are present in the sample and the counting time.[5,6]

- The nominal detection limit for ^{60}Co on a filter after a four-hour count time ranges from eight (8) to 15 pCi/l, depending upon the quantity of naturally-occurring radionuclides that are present in the sample.

The following are nominal performance characteristics of the commercial analytical laboratory used to analyze samples for AMS:

- The nominal detection sensitivity for ^{60}Co in water by the methodology of gamma spectroscopy with hyperpure germanium detectors is less than 15 pCi per liter in a one-hour count time, depending upon the quantity of naturally-occurring radionuclides present in the sample.

- The nominal detection sensitivity for ^{60}Co on a filter by the methodology of gamma spectroscopy with hyperpure germanium detectors is less than five (5) pCi per filter in a one-hour count time, depending upon the quantity of naturally-occurring radionuclides present in the sample.

Conclusions

For water samples analyzed at AMS pursuant to RSP-018, "Operation of the Gamma Spectrometer" and RSP-019, "Assessment of Radioactivity in Water Samples", a performance criterion of 50 pCi of ^{60}Co per liter of water by direct counting is deemed acceptable. Since discharges at this concentration clearly impose no radiological impact on the public water supply or the local sewage treatment plant, water that exhibits analytical results that are below the decision level, with MDAs of less than 50 pCi per liter, and with a maximum daily discharge volume of 25,000 gallons is considered to be "below radiological concern" since it is consistent with the intent of 10 CFR 20, and is sufficiently protective of workers and the general public.

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[5] The methodology for MDA determination was taken from Curie, L.A. (1968), "Limits for Qualitative Detection and Quantitative Determination", *Analytical Chemistry* 40(3):586-593, and Currie, L.A. (1984), "Lower Limit of Detection: Definition and Elaboration of a Proposed Position for Radiological Effluent and Environmental Measurements", NUREG/CR-4007, Nuclear Regulatory Commission.

[6] Water samples acquired and analyzed by AMS between June 17, 1996 and October 22, 1996 exhibit a mean MDA of 42.9 $\pm$ 0.4 pCi per liter for a four (4) hour count time.

Attachment 3 - RSP-022

Advanced Medical Systems, Inc.

QUALITY ASSURANCE FOR RADIONUCLIDE ANALYSIS BY GAMMA SPECTROSCOPY	Procedure: RSP-022	Revision No.: 000
	Page: 1 of 15	Date: December 13, 1996
	Approved by (President):	
	Approved by (RSO):	
	Approved by (RSC Chair):	

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CONTROLLED COPY NO. : _____

1 PURPOSE

This procedure establiches the methods and responsibilities for assuring that all measurement data generated using by the Advanced Medical Systems, Inc. (AMS) gamma spectroscopy system are scientifically and legally defensible, of known and appropriate quality, and are documented.

2 SCOPE

This Radiation Safety Procedure (RSP) applies to the analysis of all samples analyzed for compliance purposes using the AMS gamma spectroscopy system or commercial analytical laboratory support. Samples that are analyzed for reasons other than compliance are exempt from the requirements of this RSP.

3 REFERENCES

3.1 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19089-01.

3.2 U. S. Nuclear Regulatory Commission Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment".

3.3 American Society of Mechanical Engineers, ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities"

3.4 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-006, "Training and Qualifications of Radiation Protection Personnel"

3.5 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-013, "Control of Radioactive Waste".

3.6 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-018, "Operation of the Gamma Spectrometer"

3.7 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-019, "Assessment of Radioactivity in Water Samples"

3.8 Advanced Medical Systems, Inc., Radiation Safety Procedure No. RSP-020, "Quality Assurance Audits".

4 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be found in RSP-002, "Definitions".

5 PROCEDURE

5.1 Responsibilities

5.1.1 The Engineering Manager shall:

5.1.1.1 Ensure sufficient resources are made available to comply with the requirements of this RSP.

5.1.1.2 Support quality assurance as an essential element in all functional, management, and administrative activities related to radionuclide analysis by gamma spectroscopy.

5.1.2 The RSO shall:

5.1.2.1 Establish and maintain an effective quality assurance program for gamma spectroscopy.

5.1.2.2 Ensure all gamma spectroscopy operations are conducted in accordance with this RSP.

5.1.2.3 Ensure that quality control (QC) limits are established and followed for critical points in the measurement process and that they are based on sound statistical methods.

5.1.2.4 Perform an independent review of a 100% of the data reports.

5.1.2.5 Ensure analytical procedures are performed by Radiation Surveyors who are qualified as described in RSP-006.

5.1.2.6 Select and pre-qualify the commercial analytical laboratory used to perform confirmatory analyses

5.1.3 Radiation Surveyors shall:

5.1.3.1 Use QC steps and RSPs properly during sample collection, sample analysis, data interpretation, or any routine sampling or analysis activity.

5.1.3.2 Maintain complete documentation of analytical activities.

5.1.3.3 Correct and document problems and deficiencies in any portion of the measurement system.

5.1.3.4 Evaluate 100% of the data for acceptability based upon QC limits and professional judgement.

5.1.3.5 Periodically review this RSP for continued applicability.

5.2 Sample Management

5.2.1 Sample containers shall consist of commercially pre-cleaned one (1) liter Marinelli beakers.

5.2.2 Sample containers shall be kept in a contaminant-free, secure area.

5.2.3 Sample preservatives shall not be used unless so instructed by the analytical laboratory performing confirmatory analysis.

5.2.4 Samples shall be processed through the entire analytical method as specified in RSP-018 and RSP-019.

5.2.5 After analysis is complete and there is no further use for a sample, it shall be disposed of as described in RSP-013 and RSP-019.

5.3 Analytical Methods

5.3.1 QC procedures shall be incorporated into sample analysis activities.

Note: These procedures may include calibration verification, background verification, duplicate analyses, or confirmatory analyses.

5.3.2 All analyses shall be performed according to the uniform, standard method documented in RSP-018

5.4 Control Charts

5.4.1 Control charts shall be generated and used to demonstrate statistical control counting room conditions and the operational status of the equipment.

5.4.2 Control limits shall be experimentally determined and should include:

5.4.2.1 An upper and lower warning limit.

5.4.2.2 An upper and lower control limit.

5.4.3 Control Levels shall be determined by the following:

5.4.3.1 Acquire background data (counts per minute) and efficiency data (per cent) as described in RSP-018 for a total of ten (10) measurements each.

5.4.3.2 From the 10 individual measurements, determine the control mean (CM) of each measurement type by:

$$CM_r = \frac{\sum_{i=1}^{n} C_i}{n}$$

where C_i = the results of measurement number "i", and n = the total number of that measurement type performed.

5.4.3.3 From the 10 individual measurements, determine the standard deviation (σ) by:

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n} (CM_r - C_i)^2}{n-1}}$$

5.4.3.4 Determine the Upper Warning Level (UWL) by:

$$UWL = CM_r + (2 \times \sigma)$$

5.4.3.5 Determine the Lower Warning Level (LWL) by:

$$LWL = CM_r - (2 \times \sigma)$$

5.4.3.6 Determine the Upper Control Level (UCLM) by:

$$UCL = CM_r + (3 \times \sigma)$$

5.4.3.7 Determine the Lower Control Level (LCL) by:

$$LCL = CM_i - (3 \times \sigma)$$

5.4.4 Control Charts shall be prepared as follows:

5.4.4.1 Create a Background Control Chart and an Efficiency Control Chart by plotting measurements on the y-axis and date on the x-axis of graphing paper.

5.4.4.2 Show the control mean (CM), the $\pm$ 2σ (UWL and LWL) and the $\pm$ 3σ (UCL and LCL) levels by horizontal lines.

5.4.4.3 Plot each week's background measurement and each day's efficiency measurement on the applicable control chart.

5.4.5 The control limits shall be updated every 30 data points or when a significant change in the measurement system configuration occurs.

5.4.6 The system may be considered to be "out of control" when one of the following occurs:

5.4.6.1 A single point falls outside the control limit.

5.4.6.2 A series of ten (10) successive points fall on the same side of the central line.

5.4.6.3 A series of seven (7) successive points trend in the same direction.

5.4.6.4 Any three (3) consecutive points fall outside of the warning limit.

5.4.6.5 A cyclical pattern of control values.

5.4.7 If the system is "out of control", it shall be removed from service, the RSO shall be notified, and the system shall be repaired.

5.5 System and Performance Audits

5.5.1 Internal audits to determine on-going compliance with this RSP and to assess the overall quality of data collected during the measurement process shall be performed.

5.5.1.1 The frequency of internal audits shall be twice per calendar year.

5.5.1.2 Internal audits shall be accomplished through:

5.5.1.2.1 Observing measurement activities.

5.5.1.2.2 Inspecting operating conditions and documentation

5.5.1.2.3 Interviewing radiation surveyors performing the analyses.

5.5.1.3 The internal audit methodology shall be as described in RSP-020.

5.5.2 External audits shall be performed at the frequency of and as described in RSP-020.

5.6 Quality Control Steps

5.6.1 Duplicate analyses to verify the precision of results shall be performed.

5.6.1.1 One duplicate sample analysis shall be performed for each ten (10) samples analyzed (e.g., a frequency of 10%).

5.6.1.2 Duplicate samples shall be analyzed in the same manner and with the same count time as the original sample analysis.

5.6.1.3 If the results of the duplicate sample analysis is significantly different from the results of the original sample analysis, the matrix homogeneity shall be evaluated to determine if re-analysis is required.

Note: For example, "significantly different" may be interpreted as follows:

$$C_1 - 2\sqrt{C_1} < C_2 < C_1 - 2\sqrt{C_1}$$

where C_1 = the counts from the first analysis, and C_2 = counts from the second analysis.

5.6.1.4 If the duplicate analysis is "out of control":

5.6.1.4.1 A second, different sample, of the same matrix should be analyzed in duplicate; or

5.6.1.4.2 Data acquired prior to the original duplicate analysis should be qualified.

5.6.1.5 If the results from the second sample are "out of control", a background and efficiency check shall be performed as described in section 5.4 and in RSP-018.

5.6.2 Duplicate collections shall be performed for grab samples in order confirm that the collected samples are representative of the entire stream.

5.6.2.1 One duplicate sample collection shall be performed for each ten (10) grab samples collected from a specific stream (e.g., a frequency of 10%).

5.6.2.2 Duplicate sample collections shall be analyzed in the same manner and with the same count time.

5.6.2.3 If the analytical results from the duplicate collections differ significantly, the collection methodology shall be evaluated to determine continued applicability.

Note: For example, "significantly different" may be interpreted as follows:

$$C_1 - 2\sqrt{C_1} < C_2 < C_1 + 2\sqrt{C_1}$$

where C_1 = the counts from the first collection, and C_2 = counts from the second collection.

5.6.3 An external intercomparison to verify the capability of the AMS spectroscopy system shall be performed.

5.6.3.1 The frequency of external intercomparisons shall be once per calendar quarter.

5.6.3.2 For the external intercomparison, a sample of water, soil, or a filter that has been analyzed using the AMS spectroscopy system shall be forwarded to the pre-qualified commercial analytical laboratory.

5.6.3.3 The methodology for packaging, shipping, and analyzing external intercomparison samples shall be as described in RSP-018.

5.6.3.4 If the results from the analytical laboratory differ significantly from the results generated by AMS, the intercomparison results may be "out of control".

Note: For example, "significantly different" may be interpreted as follows:

$$C_1 - 2\sqrt{C_1} < C_2 < C_1 + 2\sqrt{C_1}$$

where C_1 = the radionuclide concentration determined by AMS, and C_2 = radionuclide concentration determined by the commercial analytical laboratory.

5.6.3.5 If the intercomparison analysis is "out of control":

5.6.3.5.1 A second, different sample, of the same matrix should be subject to intercomparison analysis; or

5.6.3.5.2 Data acquired prior to the original intercomparison analysis should be qualified.

5.6.3.6 If the results from the second intercomparison are "out of control", a background and efficiency check shall be performed as described in section 5.4 and in RSP-018.

5.7 Data Validation

5.7.1 All data and results generated by the gamma spectroscopy system shall be evaluated for acceptability on the basis of the criteria contained in this RSP.

5.7.2 The radiation surveyor shall incorporate all applicable QC steps as specified in this RSP (e.g., control chart generation, duplicate sample analysis).

5.7.3 Following each QC analysis, the radiation surveyor shall perform the necessary calculations.

5.7.4 If a QC step does not meet the acceptance criteria described in this RSP, the radiation surveyor shall perform the following, in concert with the RSO:

5.7.4.1 An appropriate corrective action shall be identified and implemented.

5.7.4.2 If an appropriate corrective action cannot be performed, data acquired prior to the validation shall be qualified.

5.7.4.3 Information related to the analyses shall be thoroughly documented.

5.7.5 The RSO shall perform a final review of 100% the data package associated with all sample results for completeness, accuracy, consistency, and compliance with this RSP.

5.8 Chain of Custody Elements

5.8.1 In order to establish the documentation necessary to trace sample possession from the time of collection, a serially-numbered Chain of Custody Form (Attachment 1) shall be completed and should accompany every sample.

5.8.2 The Chain of Custody Form shall contain the following types of information:

5.8.2.1 Sample identification.

5.8.2.2 Signature of sample collector

5.8.2.3 Date and time of sample collection

5.8.2.4 Sample type (e.g., water, soil or filter)

5.8.2.5 Chemical and physical constituents and methods for which analysis will be conducted.

5.8.2.6 Signature(s) of person(s) involved in the chain of possession

5.8.2.7 Inclusive dates and time of possession

5.8.3 The Chain of Custody Form shall accompany the sample(s) on delivery to a commercial analytical laboratory.

5.8.4 The data package received from the commercial analytical laboratory shall include a copy of the Chain of Custody Form with all signatures.

5.8.5 To maintain chain of custody during shipment, overnight air carriers (e.g., Federal Express or equivalent) shall be used for sample transport to the commercial analytical laboratory.

5.9 Corrective Actions

5.9.1 If sample handling, analytical equipment, QC sample analysis results, or analytical systems fail to meet the criteria established in this RSP, corrective action shall be implemented by the RSO.

5.9.2 Corrective action should consist of immediate actions and long-term actions.

5.9.2.1 The need for immediate corrective action may be identified by the radiation surveyor as a result of system checks and QC sample analyses.

5.9.2.2 Immediate action shall be designed to correct or repair non-confirming measurement systems.

5.9.2.3 Long-term action may be identified by quality assurance audits and performance reviews, and may consist of the following:

5.9.2.3.1 Training and qualification of personnel

5.9.2.3.2 Revising the quality assurance system

5.9.2.3.3 Replacing personnel

5.9.2.3.4 Revising RSPs

5.9.2.3.5 Replacing equipment

5.9.3 The steps for instituting corrective action should be as follows:

5.9.3.1 Define the problem

5.9.3.2 Assign responsibility for investigating the problem

5.9.3.3 Investigate and determine the cause of the problem

5.9.3.4 Determine a corrective action to eliminate the problem

5.9.3.5 Assign and accept responsibility for implementing the corrective action

5.9.3.6 Establish effectiveness of the corrective action and implement the correction

5.9.3.7 Verify that the corrective action has eliminated the problem

5.10 Control of Purchased Items

5.10.1 The procurement of AMS instruments, equipment, standards and services shall be controlled to ensure compliance with this RSP and RSP-018,

5.10.2 Procured articles, materials, or services shall meet AMS purchase requirements, technical specifications, and quality assurance provisions.

5.10.3 When an article, material, or service procured by AMS does not conform to applicable specifications or other requirements,, it shall be identified as non-conforming, segregated to the extent practicable, and held for review action.

5.10.4 Pre-approval of a commercial analytical laboratory shall require written certification by a corporate official of the laboratory that the following are maintained:

5.10.4.1 Conformance to recognized standards

Note: USEPA QAMS-005/80, "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans"; ANSI/ASQC-E5-19xx, "Specifications and guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs"; ANSI/ASQC Q94 (ISO 9004), "Quality Management and Quality System Elements - Guidelines"; and NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities", or equivalent, are acceptable standards.

5.10.4.2 Staff training programs

5.10.4.3 Good laboratory and measurement practices

5.10.4.4 State-of-the-art facilities and instrumentation

5.10.4.5 Standard operating procedures

5.10.4.6 Non-blind standard reference materials (NIST-traceable)

5.10.4.7 Document control

5.10.4.8 Replicate blank, matrix spike, background yield tracer, quench standards, and surrogate measurements

5.10.4.9 Preventative maintenance

5.10.4.10 Prompt and efficiency backup services

5.10.4.11 Sample chain of custody.

5.10.4.12 An independent QA organization

5.10.4.13 A Quality Assurance Management Plan

5.10.4.14 Data quality objectives

5.10.4.15 Independent QA data validation

5.10.4.16 Interlaboratory comparison studies

5.10.4.17 Formal laboratory accreditations

5.10.4.18 Statistical evaluations of analytical precision and accuracy

5.10.4.19 Independent QA verification of computer software

5.10.4.20 Evaluation of subcontractor laboratories.

6 EXEMPTION PROVISIONS

Minor changes to this RSP shall be permitted pursuant to the written authorization of the RSO. Other variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the RSC, and after approval by the USNRC.

7 DOCUMENTATION

All records and reports associated with implementation of this RSP, including control charts, shall be maintained pursuant to RSP-004.

8 ATTACHMENTS

Attachment 1 - Chain of Custody Form

ATTACHMENT 1

ADVANCED MEDICAL SYSTEMS, INC.
ANALYSIS REQUEST AND CHAIN OF CUSTODY RECORD

Reference No. _____

) Client Name	(7) Samples Shipment Date	(5) Bill to:
1) Sample Team Leader	(8) Lab Destination	
1) Task No.	(9) Lab Contact	
1) Project Manager	(12) Technical Contact/Phone	(10) Report to:
1) Purchase Order No.	(13) Carrier/Waybill No.	
1) Required Report Date		

ONE CONTAINER PER LINE

(14) Sample Number	(15) Sample Description/Type	(16) Date/Time Collected	(17) Container Type	(18) Sample Volume	(19) Preservative	(20) Requested Testing Program

3) Special Instructions

4) Possible Hazard Identification on-hazard ☐ Flammable ☐ Skin Irritant ☐ Poison B ☐ Unknown ☐	(25) Sample Disposal Return to Client ☐ Disposal by Lab ☐ Archive _____ months
6) Turnaround Time Required: Normal ☐ Rush ☐	(27) QC Level: I ☐ II ☐ III ☐ Project Specific _____
8) Relinquished by: (signature, date, time):	Received by: (signature, date, time)
Relinquished by: (signature, date, time):	Received by: (signature, date, time)
Relinquished by: (signature, date, time):	Received by: (signature, date, time)

(See Reverse for Instructions)

INSTRUCTIONS FOR COMPLETING THIS FORM

. **Client Name**: Record the name of the client (**AMS**)

. **Sample Team Leader**: List the name of the team taking these samples.

. **Task No.**: Indicate the **AMS** task number, if applicable.

. **Project Manager**: Record the project manager's name.

. **Purchase Order No.**: Non-**AMS** personnel should use this space to record the purchase order number authorizing the analysis of these amples. **AMS** and **AMS** subcontractors should leave this space blank if a project number has been given for billing.

. **Samples Shipment Date**: Indicate the date these samples are shipped to the laboratory.

. **Lab Destination**: Indicate the laboratory designated for sample shipment. Do not list more than one lab on this form. Be certain before ending samples that the laboratory you are designating is aware of the shipment and is capable of accepting these sample types and has available capacity.

. **Lab Contact**: Give the name of the laboratory contact (typically the lab's project manager).

10. **Report to**: Give the name, address and phone number of the person to receive the data report for these samples.

11. **Required Report Date**: Record the date which you and the laboratory contact have determined the results will be reported (include verbal or final report as appropriate).

12. **Technical Contact/Phone**: Indicate the name of the person to be contacted in case of any questions regarding these samples and the phone number where the contact may be reached the day the samples arrive in the laboratory.

13. **Carrier/Waybill Number**: If you are sending the samples by a commercial carrier such as Airborne or Federal Express, record the courier company name and the waybill or airbill number under which these samples will be shipped (Example - Fed-Ex/#513631771).

14. **Sample Number**: List the complete, unique identification number of each sample. These numbers must correspond with the identification numbers on the sample containers and the field sample collection document(s).

15. **Sample Description/Type**: Provide a short physical description of the sample and the sample type such as soil, sediment, sludge, water, wipe, air, concentrated waste or bulk.

16. **Date/Time Collected**: Record date and exact time each sample was collected. Use a 24-hour clock; i.e., 1645 not 4:45 p.m.

17. **Container Type**: Indicate the volume, color and type of the sample container used (Example - 1 gallon amber glass, 1 liter clear plastic, 40 milliliter clear glass).

18. **Sample Volume**: Estimate the amount of sample in the container. For air samples, indicate the volume of air sampled.

19. **Preservative**: Indicate what type of preservative, if any, has been used for the samples (Example - ice to 4°C nitric acid, hydrochloric acid).

20. **Requested Testing Program**: List the analyses to be performed on each sample by method number or quotation number.

23. **Special Instructions**: Use this space to record any special instructions to the lab regarding the processing of these samples.

24. **Possible Hazard Identification**: Indicate all hazard classes associated with the sample(s).

25. **Sample Disposal**: Indicate how the samples should be disposed of following analysis. The lab may charge for packing, additional archiving and disposal.

26. **Turnaround Time Required**: Check "Normal" or "Rush" as determined by the Technical Contact and the Lab Contact. Rush samples are subject to a surcharge.

27. **QC Level**: These should be specific to the analytical laboratory and should not be confused with USEPA Analytical Levels. Project Specific should reference a quotation number or other specifications that have been submitted to the laboratory before beginning work.

28 **Signatures**: When releasing custody of these samples, use the "Relinquished By" space to sign your full legal name, date and time of release. After verifying that all samples are present, the person receiving the samples must sign the "Received By" space to take custody of the samples.

Attachment 4 - AMS Water Sampling Results (6/95 through 11/95)

AMS Water Sampling Results

Collection Date	Net Sample Rate (cps)	Sample Count Time (sec)	Background Count Time (sec)	Background Count Rate (cps)	Efficiency c/d	MDA (pCi/l)	Decision Leve (net sample rate)	Co-60 Activity (pCi/l)	Uncertainty (pCi/l)
06/17/96	4.58E-01	1.44E+04	2.88E+04	4.66E-01	2.05E-02	4.30E+01	1.15E-02	-1.09E+01	1.46E+01
06/18/96	4.54E-01	1.44E+04	2.88E+04	4.54E-01	2.03E-02	4.29E+01	1.13E-02	1.33E-01	1.47E+01
06/20/96	4.67E-01	1.44E+04	2.88E+04	4.61E-01	2.01E-02	4.35E+01	1.14E-02	8.06E+00	1.50E+01
06/22/96	4.60E-01	1.44E+04	2.88E+04	4.59E-01	2.08E-02	4.21E+01	1.14E-02	1.43E+00	1.44E+01
07/08/96	4.55E-01	1.44E+04	2.88E+04	4.64E-01	2.03E-02	4.34E+01	1.14E-02	-1.25E+01	1.47E+01
07/22/96	4.60E-01	1.44E+04	2.88E+04	4.63E-01	2.04E-02	4.30E+01	1.14E-02	-3.31E+00	1.47E+01
08/22/96	4.57E-01	1.44E+04	2.88E+04	4.57E-01	2.07E-02	4.22E+01	1.14E-02	-9.14E-01	1.44E+01
08/26/96	4.72E-01	1.44E+04	2.88E+04	4.52E-01	2.02E-02	4.29E+01	1.13E-02	2.72E+01	1.50E+01
09/13/96	4.53E-01	1.44E+04	2.88E+04	4.68E-01	2.03E-02	4.36E+01	1.15E-02	-2.01E+01	1.47E+01
09/24/96	4.61E-01	1.44E+04	2.88E+04	4.63E-01	2.03E-02	4.33E+01	1.14E-02	-2.40E+00	1.48E+01
09/25/96	4.66E-01	1.44E+04	2.88E+04	4.58E-01	2.04E-02	4.29E+01	1.14E-02	1.02E+01	1.48E+01
09/25/96	4.64E-01	1.44E+04	2.88E+04	4.58E-01	2.04E-02	4.29E+01	1.14E-02	7.30E+00	1.48E+01
09/30/96	4.74E-01	1.44E+04	2.88E+04	4.61E-01	2.06E-02	4.26E+01	1.14E-02	1.76E+01	1.48E+01
09/30/96	4.73E-01	1.44E+04	2.88E+04	4.61E-01	2.06E-02	4.26E+01	1.14E-02	1.58E+01	1.48E+01
10/01/96	4.62E-01	1.44E+04	2.88E+04	4.61E-01	2.06E-02	4.26E+01	1.14E-02	1.05E+00	1.48E+01
10/08/96	4.60E-01	1.44E+04	2.88E+04	4.75E-01	2.07E-02	4.29E+01	1.16E-02	-1.92E+01	1.44E+01
10/11/96	4.58E-01	1.44E+04	2.88E+04	4.54E-01	2.03E-02	4.29E+01	1.13E-02	5.07E+00	1.47E+01
10/14/96	4.70E-01	1.44E+04	2.88E+04	4.57E-01	2.06E-02	4.24E+01	1.14E-02	1.68E+01	1.47E+01
10/21/96	4.69E-01	1.44E+04	2.88E+04	4.62E-01	2.03E-02	4.33E+01	1.14E-02	8.54E+00	1.49E+01
10/22/96	4.62E-01	1.44E+04	2.88E+04	4.62E-01	2.03E-02	4.33E+01	1.14E-02	-1.20E+00	1.48E+01
10/22/96	4.66E-01	1.44E+04	2.88E+04	4.62E-01	2.03E-02	4.33E+01	1.14E-02	4.54E+00	1.49E+01
11/20/96	4.71E-01	1.44E+04	2.88E+04	4.55E-01	2.06E-02	4.23E+01	1.13E-02	2.10E+01	1.47E+01
					Mean	4.29E+01	1.14E-02	3.37E+00	
					Std. De.	4.20E-01	6.23E-05	1.20E+01	

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 8, 1996

MEMORANDUM FOR: John R. Madera, Chief
Materials Inspection Branch 1, RIII

FROM: Josephine Piccone, Chief
Operations Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TAR: REVIEW OF ADVANCED MEDICAL SYSTEMS' RESPONSE TO SEPTEMBER 3, 1996, DEFICIENCY LETTER

I am responding to your technical assistance request (TAR) dated October 8, 1996, regarding Advanced Medical Systems' (AMS') proposed actions to correct deficiencies identified in your letter to AMS dated September 3, 1996. In their response, dated September 26, 1996, AMS described the actions they plan to take to correct four items identified by NRC: (1) the basis for the 70 pCi/l MDA proposed by AMS; (2) the absence of a viable quality assurance (QA) program for their radiation detection systems; (3) the basis for deciding if activity is present in a measured sample; and (4) errors in the formula for calculating the MDA.

We have reviewed AMS' proposed actions and concluded that they have adequately addressed 2 of the 4 items noted. Item (1) has not been adequately addressed, because sufficient information was not provided to determine whether 70 pCi/l is indeed the best MDA that AMS can attain under the conditions existing at their facility. They have not provided the description of their detection system, nor of its operating environment, that would enable such a determination. Therefore, as indicated in a telephone conversation in October between Sami Sherbini of my staff and Mike Weber of your staff, AMS should be asked to provide the necessary information.

Item (2) also has not been resolved, although AMS has acknowledged the need for developing a QA program, and indicated that a QA procedure is being developed. The QA program will need to be reviewed when its development is completed. Items (3) and (4) have been adequately addressed; the proposed method of identifying samples that differ from background, and the proposed equation for calculating the MDA are correct.

Contact: Sami Sherbini, NMSS
(301) 415-7902

OCT 0 8 1996

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: 10/8/96

Mail or E-Mail to: Donald A. Cool (DAC), Mail Stop: 6H3-OWFN, If E-mail, cc: CLE
Division of Industrial and Medical Nuclear Safe:,, NMSS

From: for John R. Madera [signature] 10/8/96 - Region III
Chief, Nuclear Materials Licensing Branch

Licensee: Advanced Medical Systems License No. 34-19089-01

☐ Control No. ____________(if applicable)

☒ Letter dated: Sept. 26, 1996

☐ Suggested change in licensing procedure (enclosed):

☒ Problem/Issue: Please review AMS' response to our Sept. 3, 1996 deficiency letter (which was developed from the TAR response dated Aug. 14, 1996, by Sami Sherbini).

☐ Action Required:

☐ Recommended Action (with revisions): ☐ Approve or ☐ Reject

Remarks:

Headquarters Reviewer: ____________
Regional Reviewer: M. Weber
Reviewer Code: S2
Reviewer Phone No.: (630)829-9825 Fax No.: (630) 515-1259
Request Needed by: ASAP

Attachment: 9/26/96 letter from AMS

cc w/o att: C. Pederson, RIII
M. Weber, RIII

Form TAR-10
10/96

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110
(216) 692-3270

September 26, 1996

Mr. John R. Madera, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Madera:

Advanced Medical Systems, Inc. (AMS) is in receipt of your September 3, 1996 letter wherein comments on Radiation Safety Procedure RSP-018, "Operation of the Gamma Spectrometer" and RSP-0189, "Assessment of Radioactivity in Water Samples" were provided. Enclosed are our responses to your comments, along with a description of our proposed follow-up actions.

On March 1, 1995 and March 20, 1995, AMS submitted applications to amend the referenced license to permit release of ground surface water that collects in the *remediated* foundation drainage system of the London Road facility. As of the date of this letter, USNRC authorization to proceed on this request has not yet been received. However, when that authorization is given, AMS intends to collect and analyze confirmatory samples by the methodology described in RSP-018 and RSP-019. Therefore, your timely concurrence with enclosed is necessary.

Please call me at (216) 692-3270 if you have any questions or if I can assist you in any way in expediting your review of the attached information.

Sincerely,

Stephen J. Haddock, R.S.O.

cc: E. L. Svigel
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

RESPONSE TO USNRC COMMENTS ON RSP-018 AND RSP-019

USNRC Comment No. 1: The bases for the proposed minimum detectable activity (MDA) of 70 pCi/l for water samples and 15 pCi/l for filters are not well developed or justified in the technical basis section of Procedure RSP-019. AMS should provide a more defensible basis for its choice of MDA. In our letter dated May 31, 1996, we indicated that the MDA should be based on the capability of a detection system that is state of the art for the application but not necessarily extraordinarily specialized or sophisticated. Thus, AMS should expand its technical basis section to include a detailed description of its measurement systems and testing of these systems to evaluate its measurement capabilities.

AMS Response: Partially concur. RSP-019 does not state that the MDA for the counting system is 70 pCi/l for water samples and 15 pCi/l for filters. It does, however, state that the MDA calculated for each sample cannot exceed those values. By meeting this criterion, AMS can demonstrate compliance with mandated release limits. In reality, achievable detection limits for the AMS system have always been less than the maximum permissible values. The technical basis document merely serves to show what the maximum acceptable MDA for both analyses should be.

Action Taken: Step 5.4.3 of RSP-019 will be modified to read: "If the MDA for the sample exceeds 70 pCi per liter, the sample shall be forwarded to a commercial analytical laboratory for confirmatory analysis." Step 5.5.4 will be added to RSP-019 to read: "If the MDA for the sample exceeds 15 pCi per liter, the sample shall be forwarded to a commercial analytical laboratory for confirmatory analysis." Attachment 1, "Technical Basis for Water Discharge Criteria" will be revised to include a description of the AMS gamma spectrometer and its measurement capabilities. A revised copy of RSP-019 will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003, "Control of Radiation Safety Procedures."

USNRC Comment No. 2: The procedures make only brief mention of the quality assurance program to be used for AMS's measuring systems. AMS should develop a more detailed quality assurance program, and provide a detailed description of that program in the technical basis section. The quality assurance program should extend to any outside analytical laboratories that AMS may use to confirm its results.

AMS Response: Concur.

Action Taken: A new Radiation Safety Procedure will be developed to address quality assurance provisions for in-house analyses as well as for samples sent to a commercial analytical laboratory. That procedure will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003.

USNRC Comment No. 3: The procedures do not fully develop the bases for determining whether a sample does or does not show activity. AMS is still using the MDA as a criterion for this purpose, which is incorrect. Thus, AMS needs to develop decision levels which are independent of the MDA, to allow this determination to be made. The development of this decision level should be described in detail in the technical basis section.

AMS Response: Partially concur. The methodology for determining the decision level for the net count rate in a sample will follow an industry-standard or peer-reviewed recommendation. Therefore, it will not be necessary to include the development of the methodology in the technical basis section.

Action Taken: In addition to determination of MDA in Step 5.8.14 of RSP-018, the procedure will be revised to include calculation of a decision level (DL) as an indicator of whether a measurement (e.g., count rate) exceeds "background" by the following methodology:

$$DL(R_s) = 1.645 \times \sqrt{\frac{R_b}{t_s + t_s}}$$

where $DL(R_s)$ = the net count rate (counts per second) below which a sample is considered to have no radioactivity present, R_b = the background count rate (counts per second), t_s = the sample count time, and t_b = the background count time. The reference for this method (Strom, D. J. and P. S. Stansbury, "Minimum Detectable Activity when Background is Counted Longer than the Sample", *Health Physics* 63(3):360-361, 1992) will be listed in Section 3 of RSP-018. This method, in conjunction with a demonstration that the sample's MDA is below release limits, will provide assurance that water discharged is compliant with license limits. A revised copy of RSP-018 will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003, "Control of Radiation Safety Procedures".

USNRC Comment No. 4: The procedures contain several errors concerning the manipulation of the data, most notably the error of using the MDA for making field decisions, and the incorrect equations provided in the procedures for calculating the MDA.

AMS Response: In regard to the use of MDA for making field decisions, this issue was addressed in our response to USNRC Comment 3.

In regard to the use of an incorrect equation for calculation of MDA, we concur if the reviewer is only taking exception to rounding-off of the 2.71 term to three (3) and to the use of the 4.65 term instead of 3.29 for unpaired data (e.g., when the sample count time and the background count time differ). In general, as long as the background count used in the analysis is from a well-known, stable blank, and as long as it is well above zero, the generic use of the 4.65 term will ensure that the chance of detecting an MDA quantity or more would be at least 95%, and that the probability of a Type II error would be less than 0.05. This position, which is supported in Brodsky, A., "Accuracy and Detection Limits for Bioassay Measurements in Radiation Protection - Statistical Considerations" (NUREG-1156, U. S. Nuclear Regulatory Commission, 1986), is applicable to AMS because RSP-018 and RSP-019 dictate the use of *paired blank counts* for the analyses. In other words, the counts are adjusted from a well-known blank (e.g., acquired from a long background count time) so that they reflect a count duration equivalent to that of the sample count (e.g., acquired from a short sample count time). As long as counting conditions remain constant during acquisition of sample count data, a 0.05 probability of a Type II error will be associated with each MDA calculated by either of the following:

$$MDA = \frac{2.71}{t_s} + 4.65\,\sigma_0 = \frac{2.71 + 4.65\sqrt{B_0\, t_s}}{t_s\, E\, k}$$

or

$$MDA = \frac{2.71}{t_s} + 3.29\,\sigma_0 = \frac{2.71 + 3.29\sqrt{B_0\, t_s\,(1+\frac{t_s}{t_b})}}{t_s\, E\, k}$$

Action Taken: The equations for MDA listed in Step 5.8.14 of RSP-018 and Steps 5.4.2 and 5.5.3 will be modified to the following

$$MDA = \frac{2.71 + 3.29\sqrt{B_b t_s \left(1 + \frac{t_s}{t_b}\right)}}{t_s E k}$$

where MDA = the minimum detectable activity (pCi/l), B_b = the background count rate (counts per second), t_s = sample count time (seconds), t_b = the background count time (seconds), E = the detector efficiency for ^{60}Co for counting geometry "i" (e.g., either a one-liter Marinelli beaker geometry or a filter geometry), and k = a conversion factor used to convert the results of the calculation into units of "pCi per liter". The reference for this method (Currie, L.A., "Limits for Qualitative Detection and Quantitative Determination", *Analytical Chemistry*, Vol. 40, No. 3, 1968, pp. 586-593) will be listed in Section 3 of RSP-018 and RSP-019. A revised copy of RSP-018 and RSP-019 will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003, "Control of Radiation Safety Procedures"

DATE: November 8, 1996

SUBJECT: TAR: REVIEW OF AMS RESPONE TO SEPTEMBER 3, 1996, DEFICIENCY LTR

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Advanced Medical Systems, Inc.

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

September 26, 1996

Mr. John R. Madera, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Madera:

Advanced Medical Systems, Inc. (AMS) is in receipt of your September 3, 1996 letter wherein comments on Radiation Safety Procedure RSP-018, "Operation of the Gamma Spectrometer" and RSP-0189, "Assessment of Radioactivity in Water Samples" were provided. Enclosed are our responses to your comments, along with a description of our proposed follow-up actions.

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Please call me at (216) 692-3270 if you have any questions or if I can assist you in any way in expediting your review of the attached information.

Sincerely,

Stephen J. Haddock

Stephen J. Haddock, R.S.O.

cc: E. L. Svigel
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

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Action Taken: Step 5.4.3 of RSP-019 will be modified to read: "If the MDA for the sample exceeds 70 pCi per liter, the sample shall be forwarded to a commercial analytical laboratory for confirmatory analysis. Step 5.5.4 will be added to RSP-019 to read: "If the MDA for the sample exceeds 15 pCi per liter, the sample shall be forwarded to a commercial analytical laboratory for confirmatory analysis." Attachment 1, "Technical Basis for Water Discharge Criteria" will be revised to include a description of the AMS gamma spectrometer and its measurement capabilities. A revised copy of RSP-019 will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003, "Control of Radiation Safety Procedures"

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$$MDA = \frac{2.71}{t_s} + 3.29\,\sigma_s = \frac{2.71 + 3.29\sqrt{B_R\,t_s\,(1+\frac{t_s}{t_b})}}{t_s\,E_i\,k}$$

Action Taken: The equations for MDA listed in Step 5.8.14 of RSP-018 and Steps 5.4.2 and 5.5.3 will be modified to the following:

$$MDA = \frac{2.71 + 3.29\sqrt{B_R\, t_s\, (1+\frac{t_s}{t_b})}}{t_s\, E_i\, k}$$

where MDA = the minimum detectable activity (pCi/l), B_R = the background count rate (counts per second), t_s = sample count time (seconds), t_b = the background count time (seconds), E_i = the detector efficiency for ^{60}Co for counting geometry "i" (e.g., either a one-liter Marinelli beaker geometry or a filter geometry), and k = a conversion factor used to convert the results of the calculation into units of "pCi per liter". The reference for this method (Currie, L.A., "Limits for Qualitative Detection and Quantitative Determination", *Analytical Chemistry*, Vol. 40, No. 3, 1968, pp. 586-593) will be listed in Section 3 of RSP-018 and RSP-019. A revised copy of RSP-018 and RSP-019 will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003, "Control of Radiation Safety Procedures"

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

96-47

September 12, 1996

MEMORANDUM TO: John R. Madera, Chief
Nuclear Materials Licensing Branch, RIII

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

SUBJECT: TECHNICAL ASSISTANCE REQUEST RE LICENSE 34-19089-01 AND FREELY DISCHARGING FOUNDATION DRAINAGE SYSTEM WATER

I am responding to your technical assistance request (TAR) dated July 1, 1996, (Attachment 1) regarding Advanced Medical Systems', Inc. (AMS), request for authorization to discharge water pumped from their foundation drainage system through the new manhole directly to a storm sewer catch basin. Presently, AMS is bound by a court order and NRC license requirements to pump water from the foundation drainage system into hold-up tanks, sample the tanks for the presence of radioactivity, notify the Northeast Ohio Regional Sewer District (NEORSD) of pending discharge of each tank, and await results of a NEORSD confirmatory sampling effort prior to discharge of water to the sewer. AMS based its request on the following: (1) minimal water pressure differential existed between the inside and outside of the building during the period of time the basement of the London Road facility was flooded (this minimal differential would cause minimal back flow of water from the basement to the outside of the building, preventing contamination from inside to outside of the building); (2) radioactivity was not detected in the shale layer under the facility during the 1995 sewer remediation project; (3) a registered hydrologist's report concluding that the new foundation drainage system is hydraulically connected to the soils under the basement, and if contamination migrated from the basement, it would appear in water pumped out of the system; and (4) over 140,000 gallons of water have been pumped from the existing foundation drain and been confirmed "clean" through laboratory analyses.

Based on the review of the attached submittal, and further supported by IMNS's TAR response dated August 16, 1996 (Attachment 2), we recommend approval of AMS' request to discharge water pumped from the AMS foundation drainage system through the new manhole directly to a storm sewer catch basin, provided the licensee adequately addresses the items raised in the August 14, 1996 (Attachment 3), memorandum to you regarding AMS' water analysis procedures. In particular, the determination of the lower limit of detection addressed on page 7 of AMS' request dated June 25, 1996, is not adequately addressed; the "nominal detection limit" of 70 pCi/liter in determining no detectable cobalt-60 activity is not adequately justified. This approval does not change AMS' responsibility to comply with any court orders, Federal, State or local regulations requirements which relate to discharges.

Attachments:
1. TAR dtd 7/1/96
2. TAR response dtd 8/16/96
3. HQ's memo dtd 8/14/96

Contact: Joe DeCicco, NMSS
(301) 415-7833

JUL 0 3 1996

96-47

IMOB

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: 7/1/96

Mail or E-Mail to: *Donald A. Cool, Director*
Division of Industrial and Medical Nuclear Safety, NMSS

From: John R. Madera, Chief
Nuclear Materials Licensing Branch

Licensee: Adv. Medical Systems *License No. 34-19089-01*

☐ *Control No. 01524*

☐ *Letter dated: 6/25/96*

☐ *Suggested change in licensing procedure (enclosed):*

☐ *Problem/Issue: AMS is requesting the NRC authorize it to freely discharge water pumped from the foundation drainage system through the new manhole.*

☐ *Action Required: Please review AMS' proposal and provide feedback/comments.*

☐ *Recommended Action (with revisions): X Approve or ☐ Reject*

AMS provides solid justification for their request. Region III has no reason to believe that water which accumulates in the foundation drainage system would become contaminated. However, one issue remains that may have a bearing on NRC's decision, and that is the sampling program AMS employed to evaluate the soil under the basement floor. We were concerned that the three samples taken by AMS were not representative of the condition of the soil under the floor. This is currently under review by Mr. Jack Parrott of your office. If NRC is satisfied with the 3 samples then Region III feels that the licensee should be allowed to free release water that collects in the underdrain system. As the licensee points out, if they will continue to be required to pump water to tanks and hold for sampling and approval for release, the risk of contaminated water in the basement due to flooding will always be present. Finally, AMS has committed to implementing a program for sampling surface water that enters the underdrain system. Samples will be collected from the new manhole on a weekly basis and analyzed for Co-60 at AMS using AMS' equipment. [Note: NMSS is currently reviewing AMS' counting procedures]. If they detect any Co-60 above of the stated limits as noted on page 7 of their attachment, they will reinstate the "tanking" procedures.

ATTACHMENT 1

Remarks:

Headquarters Reviewer: _____
Regional Reviewer: Kevin Null
Reviewer Code: R2
Reviewer Phone No.: (708) 829-9854 Fax No.: ( )_____
Request Needed by: __/__/__ (date) *Form TAR-10*

8/93

Advanced Medical Systems, Inc.
1020 London Rd
Cleveland, Ohio 44110
216-692-3270

June 25, 1996

Mr. Geoffrey Wright
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Wright:

On March 1, 1995 and March 20, 1995, Advanced Medical Systems, Inc. (AMS) submitted applications to amend the referenced license to permit release of ground surface water that collects in the *remediated* foundation drainage system of the London Road facility. As of the date of this letter, USNRC authorization to proceed on this request has not yet been received.

Since the date of those applications, AMS has faced a series of extenuating circumstances that have increased the urgency for action. However, we recognize that considerable time has passed since then, and that some of the original descriptions and specifications contained in the 1995 applications are no longer applicable. The purpose of this letter is to reiterate our request to amend the referenced license to permit free discharge of water pumped from the foundation drainage system. Attached is a brief description of the regulatory action on this issue to date, a discussion of the reason for our request and its justification, and a description of the procedure we intend to follow when USNRC authorization to proceed is given.

Please call me at (216) 692-3270 if you have any questions or if I can assist you in any way in expediting your review. We are asking for prompt USNRC action on this important issue.

Sincerely,

Stephen J. Haddock for
Robert Meschter, RSO

cc: D. Cesar
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

REQUEST TO DISCHARGE GROUND/SURFACE WATER FROM THE REMEDIATED FOUNDATION DRAINAGE SYSTEM

Purpose

As a result of technically-indefensible legal action taken by the Northeast Ohio Regional Sewer District (NEORSD), the Advanced Medical Systems, Inc. (AMS) facility on London Road does not have a direct connection between the building and the regional sewer system for the discharge of sanitary waste, rain water from the building's roof drains or the storm water that surrounds the building. Even after completion of an extensive sewer remediation project that involved installation of a new foundation drainage system and a new manhole, the free-flow of water away from the building is still not possible for a variety of legal and regulatory reasons.

As of the date of this letter, AMS is bound by court order and USNRC license requirements to pump water from the foundation drainage system into hold-up tanks, sample the tanks for the presence of radioactivity, notify the NEORSD of pending discharge of each tank, and await the results of a NEORSD confirmatory sampling effort prior to discharge. As a result, a major portion of the daily activities performed by the AMS staff at the London Road facility involves water management.

Because of the delay associated with discharge of each tank (e.g., typically four days), coupled with the increased precipitation AMS experiences during the spring, early summer and fall months, temporary limitations in tank storage capacity may occur. If a spring or summer storm should cause our tank or pumping capacity to be exceeded, AMS has one of two options: (1) it must discharge the pumped water without sampling and in violation of the court order, or (2) it must cease pumping the water out of the manhole. If pumping ceases, (e.g., if the foundation drainage system is rendered non-functional), the storm water that accumulates around the building is likely to enter the building basement, come into contact with the contents of the WHUT Room and the stored waste, and become contaminated. This water cannot be discharged until the radioactivity has been removed.

The financial and radiological impacts associated with foundation drain failure or impaired tank capacity would be similar to those suffered during the financially-devastating flood of 1995. This occurrence forced AMS to implement an expensive water treatment and sewer remediation program that cost in excess of $1M.[1] It also drained the corporation of almost all of its cash reserves, rendering it unable to bear the cost of another water clean-up project if such an event should be required.

The 1995 basement flood also raised questions in regard to the structural integrity of the building. In subsequent inspections by the USNRC and a registered Professional Engineer working under contract to AMS, it was determined that this event caused no apparent damage to the building or its ability to contain its inventory of licensed radioactive materials. However, there is no guarantee that a future flood event will have a similar outcome. Thus it is imperative that AMS receive USNRC authorization to freely discharge the water from the foundation drainage system, without lengthy and costly hold-up sampling steps, so that

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[1] As of the date of this letter, the treated water from the 1995 project continues to be stored in the AMS warehouse in collapsible storage tanks.

a permanent (functional) drainage system can be installed. Only then will the potential for water incursion into the basement be minimized.[1]

Regulatory Action to Date

On March 1, 1995, AMS submitted an application to amend USNRC License No. 34-19089-01 to permit water treatment and sewer remediation to proceed at the London Road facility.[2] Included in that application was a proposed methodology for evaluating contaminant levels in the ground surface water after the work was complete so that water could be freely discharged. In response, Amendment No. 32 to the license was issued. However, re-connection of the remediated foundation drainage system to a new manhole and installation of a methodology for evaluating contaminant levels were specifically excluded.

On March 20, 1995, AMS requested another amendment to License No. 34-19089 wherein re-connection of the remediated foundation drainage system to a new manhole, installation of a sampling device, and authorization to discharge through the new lateral ground surface water that meets the release criteria were specifically requested. In a June 14, 1995 communication, the USNRC solicited additional information in regard to AMS's request. AMS provided that information on June 16, 1996, and on June 21, 1996, the USNRC responded as follows:

> ". . we have received your June 16, 1995 response to our June 14, 1995 deficiency letter and will make every effort to review your response in an expeditious manner. We will notify you if we have additional questions. Again, please note that we have only approved the installation of a new manhole and lateral and its re-connection to the existing under drain system. We will need to evaluate all of the other issues regarding cobalt-60 contamination within the existing underdrain system and soils both under the building and in the vicinity of the underdrain system prior to discharge of collected water."

On June 27, 1995, AMS received Amendment No. 37 to the referenced license, wherein the water discharge issue was again excluded. However, in the transmittal letter, the USNRC stated the following in regard to how effective the sewer remediation might be:

> "Note that we are still in the process of reviewing information you submitted relative to installation of a sampling device on the new lateral connection (reference Item 2 of your 3/22/95 letter, and letter dated June 16, 1995). Also regarding your June 16 letter, we are reviewing Item II.C. which describes your proposed soil sampling program to evaluate the radiological conditions of the soil under the building and in the vicinity of the under drain system. We anticipate that we will have additional questions on both of these issues and will forward them to you as soon as possible."

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[1] AMS recognizes that it is barred, by court order, from freely releasing the ground surface water collected from the underdrain system. However, USNRC authorization to free-release the water is a necessary part of a permanent legal solution.

[2] The March 1, 1995 amendment application was supplemented in a March 3, 1995 communication.

On July 17, 1995, AMS received Amendment No. 38 to the referenced license. Again, the water discharge issue was excluded. However, the following statement in regard to the effectiveness issue and subsequent free-release of water was in the transmittal letter:

> "Note that we are still in the process of reviewing Item II. in your June 16, 1995 letter, regarding your proposed soil sampling program, and the grouting remediation project. We anticipate that we will have additional questions on these issues and will forward them to you as soon as possible".

As of the date of this letter, no additional regulatory action on our requests to freely discharge ground surface water from the remediated foundation drainage system has been taken.

Effectiveness of the Sewer Remediation

In its June 27, 1995 and July 17, 1995 communications, the USNRC expressed concern over the effectiveness of the sewer remediation project, and implied that this was the reason for delayed action on issuing a license provision to discharge water from the foundation drainage system. AMS maintains that the sewer remediation project was completely effective in removing or isolating all residual radioactivity outside of the London Road building, and that the only residual contamination remaining outside of the building after the remediation (e.g., that in the abandoned footer drain in the immediate vicinity of the Source Garden and the abandoned lateral connection between the old manhole and the London Road interceptor) is hydraulically isolated from ground surface water paths to the foundation drainage system. AMS also maintains that the soils upon which the London Road building was constructed have the same radiological character now as they did before the 1995 flood and thus cannot contribute to future contaminant migration. The following are the reasons why these positions are justified:

> (1) Throughout the period of time that the basement of the London Road facility was flooded due to the regional sewer district's intentional blocking of all discharge paths, AMS maintained a minimal pressure differential between the inside and outside water levels in order to minimize uplift on the floor slab and eliminate the possibility of "back flow" of contaminated water to areas outside of the building. AMS's pumping efforts clearly provided the necessary level of pressure control.[4] This was evidenced in USNRC Inspection Report No. 030-16055/95006(DNMS) wherein it was stated that, with the exception of one location on the second floor of the building, "the reinforced concrete core structure of the 1958 building that forms the hot cell, the WIIUT room, the original radiography room, the source garden and the front and back basements was found to be in good condition". Furthermore, the inspector found "no additional signs of distress" on the basement slab, and concluded that "there was no observable significant impact on the structural integrity of the 1958 building as a result of the basement flooding event". This finding was confirmed during an independent evaluation performed by a registered Professional Engineer under contract to AMS.[5] Thus the structural evidence supports our position that pressure gradients sufficient to jeopardize the integrity of the slab did not occur.

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[4] Documentation to support this position is available for USNRC review.

[5] See June 7, 1996 letter from R. Meschter (AMS) to Mr. Geoffrey C. Wright (USNRC, Region III).

(2) During the 1995 sewer remediation project, AMS confirmed, through measurements and sampling, that the shale layer upon which the building is built and which formed the base of the existing foundation drainage system did not contain detectable radioactivity. In fact, no detectable activity was identified during the remediation other than that in the existing drain tile and the fill material upon which the drain tile rested. Thus the radiological data acquired during the remediation project support our position that the radiological conditions of the soil under the basement and the WTUT room are equivalent to their pre-flood conditions (e.g., when core samples taken through the basement in prior to the flood exhibited radiologically-benign conditions).

(3) In an April 12, 1996 communication to Mr. John Madera (USNRC, Region III), AMS attached a Registered Hydrogeologist's report wherein he concluded that the new foundation drainage system is hydraulically connected to the soils under the basement floor. In other words, if contamination migrated from the basement to these soils, it would appear in the water that is pumped out of the system.

(4) Between the 1995 completion date of the sewer remediation project and the date of this letter, over 140,000 gallons of water have been pumped from the foundation drainage system, confirmed to be "clean" through laboratory analyses, and discharged.[6] This is further proof that no mobile contamination is under the basement or in the new drainage system.

The findings of the USNRC Inspection Report, the hydraulic connection between the soils under the building and the foundation drainage system, and the fact that the water being pumped from the foundation drains has been and continues to be radiologically benign, provide an abundance of evidence to support our position that the new foundation drainage system is completely isolated from any sources of radioactivity.

Basis for Modifying the 1995 Discharge Procedure

In AMS's March 1, 1995 and March 20, 1995 license amendment requests to discharge ground surface water, it was anticipated that an immediate outcome of the sewer remediation project would be re-connection of the sanitary and storm sewers from the London Road facility to the NEORSD's interceptor. Therefore, in those applications AMS proposed a monitoring methodology designed to accomplish two purposes:

- *Confirming* that water that entered the sewer system was free of radioactivity;
- Demonstrating that the remediation efforts were, in fact, effective.

Because the water in the remediated underdrain system was intended to flow by gravity into the London Road interceptor, the proposed monitoring methodology involved installation of an in-line flow meter and composite sampler into a new lateral connection. The intent was to collect and analyze composite samples on a planned and periodic basis until such time as all parties were confident of the effectiveness of the sewer remediation effort.

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[6] Cobalt-60 was identified in two 3,000-gallon batch tanks and one 25,000 gallon frac tank. However, the source of this contamination was the tanks themselves, which were used as process tanks for the water treatment project. The residual ^{60}Co that remained in the batch tanks when they were first filled with water from the remediated underdrain system was removed by filtration. Sampling of subsequent batches of water held in these tanks has been negative for the presence of ^{60}Co. Remedial action for the frac tank is delayed pending resolution of a non-radiological issue.

Unfortunately, due to the on-going litigation between AMS and the regional sewer district, re-connection of the building foundation drainage system to the London Road interceptor is not likely in the foreseeable future. Therefore, an alternative methodology for meeting the intent of the March 1 and March 20, 1995 applications (e.g., one that does not require a gravity-fed discharge path) is necessary.

The water that enters the foundation drainage system is neither effluent from the London Road facility per 10 CFR 20.1302(b)(2)(i), nor is it discharged licensed materials into the sanitary sewer system per 10 CFR 20.2003(a). It is simply groundwater and storm water that collects within the "bathtub" of shale surrounding the building. Since this groundwater and storm water does not come in contact with any sources of ^{60}Co, continuous monitoring of the radionuclide content of this water as required in 10 CFR 20.1302(a) is not necessary.

On the other hand, 10 CFR 20.1501 and license condition 23.J of License No. 34-19089-01 require AMS to conduct a surveillance program in order to estimate doses to the public and to document that migration of radioactive materials from known locations does not occur. USNRC Regulatory Guide Reg Guide 8.37, "ALARA Levels for Effluents from Materials Facilities" indicates that Regulatory Guide 4.14, "Radiological Effluent and Environmental Monitoring at Uranium Mills" is a useful source of guidance for materials licensees in this regard.

Regulatory Guide 4.14 recommends that samples of water from "any surface water crossing the site boundary and offsite streams or rivers that may be subject to drainage from potentially contaminated areas or from a tailings impoundment failure" be collected at least monthly.[a] Pursuant to this guidance, AMS intends to implement an even more aggressive sampling program for the surface water that enters the foundation drainage system in order to document that migration of radioactivity from potentially contaminated areas has not occurred. The following section describes the proposed sampling program.

Description of the Ground/Surface Water Sampling Program

Once USNRC and legal authority to freely discharge the storm/ground water that collects in the foundation drainage system of the London Road building has been received, AMS will operate a temporary automatic pumping system to remove water that accumulates in the new manhole. This water will be discharged to a storm sewer catch basin on the west side of the building's west parking lot. AMS will then pursue the legal authority to re-institute a permanent (gravity-fed) discharge system.

Consistent with the Regulatory Guide 4.14 guidance, a one-liter sample of water will be collected from the manhole once per week and analyzed pursuant to Radiation Safety Procedure No. RSP-018, "Operation of the Gamma Spectrometer", and RSP-019, "Assessment of Radioactivity in Water Samples".[b] All results will be documented and maintained as described in RSP-003, "Radiation Protection Records".

Regulatory Guide 4.14 recommends that the lower limits of detection for the sample analysis be 10% of the appropriate concentration limit listed in Table II of Appendix B to 10 CFR 20 (e.g., 300 pCi per liter for

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[a] The Regulatory Guide also states that "operational samples should be collected upstream and downstream of the area of potential influence", and that "any unusual releases (such as surface seepage) that are not part of normal operations should be sampled".

[b] As recommended in Regulatory Guide 4.14, if the manhole is dry on a scheduled sampling collection date, that sample will be collected immediately after water starts to flow.

^{60}Co). However, the following release criteria that are specific to AMS (see RSP-019) and which demand a more stringent performance standard, are applicable:

- Water that contains greater than 100 pCi per liter of ^{60}Co in any form (e.g., "soluble" or "insoluble"), as determined from the sampling and analysis effort, shall not be discharged.

- Water than contains no detectable ^{60}Co activity by direct counting (e.g., analytical results that are below a nominal detection limit of 70 pCi per liter) may be discharged.

- Water that exhibits both of the following may be discharged:

  Less than 100 pCi per liter of ^{60}Co by direct counting and

  No detectable ^{60}Co activity (e.g., analytical results that are below a nominal detection limit of 15 pCi per liter) on a 0.45 micrometer filter after filtration.

Since AMS would consider any detectable ^{60}Co in samples collected from the manhole to be an "unusual release", such an occurrence would trigger re-instatement of "tanking" procedures (e.g., the water will be pumped to hold-up tanks, sampled, and confirmed to meet the release criteria prior to discharge) until the cause has been identified and corrective action instituted.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 16, 1996

MEMORANDUM TO: John R. Madera, Chief
Nuclear Materials Safety and Safeguards Branch
Region III

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

SUBJECT: TECHNICAL ASSISTANCE REQUEST CONCERNING ADVANCED MEDICAL SYSTEMS, INC., LICENSE NO. 34-19089-01, LETTER DATED APRIL 12, 1996

I am responding to your Technical Assistance Request (TAR), Control Number 98507 (Attachment), that requested review and comment of a letter response from Advanced Medical Systems, Inc. (AMS) dated April 12, 1996. A March 20, 1996, letter from Region III to AMS indicated that AMS had not demonstrated that the soil under the building was free of contamination, and that AMS' proposed disposal cost for the radioactive waste was underestimated. The April 12, 1996, AMS letter provided comments to the Region III letter, a report and findings of a registered hydrologist to address the concern about the possibility of contamination under the building, and a more detailed estimate for a SAFSTOR alternative. Your TAR requested review and comment, specifically on whether the findings in the hydrologist's report are acceptable, and whether the NRC will accept the SAFSTOR method of decommissioning of this facility.

With regard to the hydrologist's report and the need for further sampling of soils below the basement/WHUT room floors, we agree with the Region that the hydrologist's report be accepted. It is unlikely that there is significant contamination of the soil beneath the floor of the basement or WHUT room based on:

1) the hydraulic gradient during the flooding of the basement from the soils to the basement;

2) the hydraulic gradient since the removal of the water from the basement and the installation of the new footer drain has been toward the footer drain system and the basement has remained dry, indicating that the soils surrounding the basement are hydraulically connected to the footer drain system; and

3) no contamination has been found in the water removed from the footer drain system.

CONTACT: Joe DeCicco, IMNS
(301) 415-7833

ATTACHMENT 2

For contamination to leach or leak from the basement, it would have to be somewhat soluble. Therefore, the contamination, if released, would likely show up in the footer drain system that appears to be hydraulically connected to the soils surrounding the basement.

Some contamination of the soils below the basement can not be completely ruled out, but widespread contamination is unlikely given the information at hand. The cost of remediation of small areas of soil contamination, if they exist, could easily be covered if a contingency is applied to the cost estimate of decommissioning of the site. If further information comes to light at a later date, indicating more extensive contamination than anticipated here, the cost estimates should be adjusted then.

With regard to the acceptable method of decommissioning, the March 20, 1996, letter to Mr. David Cesar continues to be our position. In that letter, we provided our reasons why SAFSTOR would not be an option, and that the Generic Environmental Impact Statement (GEIS), NUREG-0586 states in Chapter 14 that SAFSTOR for some materials facilities would be an advantage if the materials are relatively short-lived and would decay to levels permitting unrestricted use of the facility in a short time. AMS contends that the GEIS shows SAFSTOR as an acceptable alternative for materials licensees and cites page 04, section 0.2.4 and page 14-9, section 14.3.2.2 as support for materials licensees decommissioning. A careful reading of the citations shows that the intention of the GEIS was to allow use of a safe storage period of a few days to a few months, and not a period of decades of years. The deferment of decommissioning through SAFSTOR is only applicable to power reactors.

With regards to the adequacy of decommissioning cost estimates for the London Road facility, the $3.3M may not be realistic in reflecting the total cost. We are concerned because the cost estimate does not address the following: 1) disposal of the 2,200 kilograms of depleted uranium inventory; 2) removal and disposal of the 11,700 curies of bulk cobalt-60 metal and the 49,000 curies of cobalt-60 sealed sources; 3) the remote decontamination techniques for the Hot Cell and the WHUT Room (generally remote techniques are used when exposure rates exceed 5 R per hour; the Hot Cell has a range from 12 to 200 R per hour, and the WHUT Room a range of 50 to 240 R per hour); 4) the work difficulty factors associated with the decommissioning (when remote techniques are used, significant amounts of time are lost due to the high exposure areas, access in and out of these areas, and maintenance of equipment; and 5) the disposal charges for curie content or special handling of high activity packages, or for transportation of shielded casks materials, which can substantially increase waste management costs. In addition, the cost estimate to decontaminate/decommission a similar facility was $17M; therefore, the cost estimate of $3.3M may be off by several times the actual cost to decommission the site.

Since changes in assumptions can have a significant impact on the total decommissioning cost, it is recommended that we require AMS to conduct a detailed characterization of the existing buildings, and develop a cost

estimate that addresses the decontamination methods. This is especially important since AMS was recently given a license amendment that allows AMS to significantly reduce their inventory.

Attachments: As stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 14, 1996

MEMORANDUM TO: John Madera, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety, RIII

FROM: Josephine Piccone, Acting Chief
Operations Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: REVIEW OF THE PROPOSED WATER ANALYSIS PROCEDURES RECENTLY SUBMITTED BY ADVANCED MEDICAL SYSTEMS (AMS)

We have reviewed the water analysis procedures recently developed by AMS and sent to region III on June 11, 1996. These procedures included RSP-018, Operation of the Gamma Spectrometer, and RSP-019, Assessment of Radioactivity in Water Samples. Both procedures were dated June 11, 1996. Our major concerns with the procedures are discussed below. More detailed comments are provided in the attachment to this memorandum.

1. The bases for the proposed maximum detectable activity (MDA) of 70 pCi/l for water samples and 15 pCi/l for filters are not well developed and justified in the technical basis section of Procedure RSP-019. We suggest that AMS provide a more defensible basis for their choice of MDA. In our letter to them dated May 31, 1996, we suggested that the MDA be based on the capability of a detection system that is state of the art for the application but not necessarily extraordinarily specialized or sophisticated. We recommend that AMS expand their technical basis section to include a detailed description of their measurement systems and their testing of these systems to evaluate their measurement capabilities.

2. The procedures make only brief mention of the quality assurance program to be used for their measuring systems. We suggest that AMS develop a better quality assurance program, and provide a detailed description of that program in the technical basis section. The quality assurance program should extend to any outside analytical laboratories that AMS may use to confirm their results.

Contact: Sami Sherbini
(301) 415-7902

ATTACHMENT 3

3. The procedures do not fully develop the bases for determining whether a sample does or does not show activity. They are still using the MDA as a criterion for this purpose, which is incorrect. They need to develop decision levels, independently of the MDA, to allow this determination to be made. The development of this decision level should be described in detail in the technical basis section.

4. AMS has not resolved the discrepancies that appeared several times between their water analyses and those performed by The Northeast Ohio Regional Sewer District (NEORSD). These discrepancies appear to have been due to differences in sampling protocols.

5. The procedures contain several errors in the manipulation of the data, most notably the error of using the MDA for making field decisions, and the incorrect equations provided in the procedures for calculating the MDA.

Attachment: As stated

ATTACHMENT

COMMENTS ON AMS PROCEDURES

Procedure RSP-018: Operation of the Gamma Spectrometer

Page 2, 5.1.3:

It is not clear what is meant by "so that the two primary peaks fall in channels 155 and 176." Confirm that the maxima of the Co-60 peaks occur at these channel numbers?

Procedure RSP-019: Assessment of Radioactivity in Water

1. Page 3, 5.1.2: It is not clear whether the analysis is to be performed in-house or by a commercial laboratory. It should be clear that the laboratory performing the analyses must participate in a quality assurance/quality control program that is approved by AMS and periodically audited by a recognized group or organization outside the organization that operates the laboratory. Pre-qualification of the laboratory is only part of this ongoing program. A later section (5.4.3) states that samples may be forwarded to a commercial analytical laboratory for confirmatory analysis. Some indication should be provided as to when such an action may be necessary.

2. Page 3, 5.2.1: Sampling these tanks has a history that indicates that different results are obtained from samples taken from various locations within the tank. The differences in the results have not been explained, giving the impression that the mixing used by AMS to date has not been effective, and that there remained stratification of the Co-60 even after prolonged mixing. It is therefore necessary for AMS to do one of two things: either explain the differences in the results obtained in the past, or conduct tests to demonstrate that their proposed method does indeed produce representative samples. Without such data, the results will remain suspect because of unexplained past anomalies.

3. Page 3, 5.2.3: In the note, it is stated that samples may be collected from any location in the tank. In the interest of consistency, we suggest specifying a sampling method at this point.

4. Page 4, 5.4.2: It is not clear where the MDA of 70 pCi/l comes from. In our letter to AMS, we stated that AMS should establish a counting method that is considered typical of current and ordinary state of the art for such an

application. We have not seen any data to show that the licensee has done that. We therefore suggest that the licensee establish their well-shielded counting system, in a low background area, select a reasonably long counting time, and then establish the sensitivities achievable by such a system. We are confident that the MDA will be far lower than the proposed 70 pCi/l. Also, in the equation for MDA, if the time is to be in seconds, the procedure should clearly indicate that the count rate B_R must also be in counts per second.

The Note at the end of this section is not correct. The MDA will not ensure a 0.05 probability of a Type II error when comparing the sample result to the background result. Suggest removing or rewriting to more accurately reflect the technical meaning of the MDA.

The equation for MDA given in this section, and elsewhere in the procedure, is incorrect. The equation, in the form given, contains the implicit assumption that the sample (or gross) counting time and the background counting time are equal. This is not the case, however, because the background is counted for 8 hours, whereas the samples are counted for times less than 8 hours (See procedure RSP-018 for sample counting times). The equation in the form given will underestimate the MDA.

5. Page 4, 5.5.1: This step requires that all samples less than 100 pCi/l be drawn through a filter, even those that show no activity that is statistically different from background. The licensee should confirm that this is the intent.

Finally, information should be added to the section that indicates that proper procedures performed by trained individuals will be used to ensure that the sample will be drawn correctly through the filter.

6. Page 5, 5.5.3: Although the origin of the 15 pCi/l detection concentration level is mentioned in the technical basis section of the document, adequate techincal support for this number is not provided. This information should be provided.

This step, or the remainder of the procedure, does not describe what to do with the results of the analyses on the filter. What criteria are to be used to decide if the filter indicates insoluble activity?

7. Page 6, 5.7.4:

The condition given in 5.7.4.2 is not acceptable. The use of MDA as criterion for deciding if activity significantly different from background was detected is incorrect. The licensee must establish a decision level, independently of the MDA, that will be used to make this determination.

Technical Basis for Water Discharge Criteria

1. Page 7, Second point:

This point contradicts the first point. The first point stresses the regulatory requirement that no insoluble Co-60 may be discharged to the sewer. The second point tries to estimate the amount of insoluble Co-60 that may be discharged to the sewer without causing the ash to exceed 8 pCi/g. The analysis in the second point also neglects to consider the possibility that Co-60 discharged to the sewer as soluble cobalt may still end up in the ash because of a number of reasons, such as precipitation of the "soluble" cobalt during waste treatment, or settling of the "soluble" cobalt that is, in fact, not soluble but very finely dispersed insoluble material. We suggest re-assessment of the second point and possibly deleting.

2. Page 7, Third point:

The drinking water standard is not relevant in this case. It is suggested that it be removed because it does not contribute to the technical basis being developed.

3. Page 8, Second Point from the bottom:

This statement concerning Information Notice (IN) 94-07, that "the standard does not provide guidance on how much gross beta activity indicates an insoluble material," is incorrect. The standard states, on Page 4, that "activity in the suspended solids portion of the effluent greater than that found in similarly processed background water samples would indicate the presence of insoluble radioactive material." In other words, the IN states that any activity that is statistically distinguishable from background indicates the presence of insoluble material. Background in this case is the filter residue from water filtered in the same manner as the sample. The water used to produce the background filter is water obtained locally but that is not contaminated by the licensee's operation.

4. Page 9, First point:

This point is at variance with the data NRC has been getting from both commercial

laboratories that were used by AMS and NEORSD to analyze the water samples from the discharge tanks. The results from these laboratories were routinely reported as having been obtained using equipment capable of measuring 1-2 pCi/l using counting times as low as one to two hours. How can these values be reconciled with the values indicated in this point?

In this connection, AMS has not described the system it intends to use for sample analyses. We suggest including this in the technical basis section. It is necessary to know the system to be used, type and size of detector, counting times, background levels in the counting laboratory, location of laboratory within the AMS facility, shielding for the detector, methods of spectral analysis to be used, type of blank samples, and source of water to serve as the background, and the quality assurance program for the system.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

June 28, 1996

Robert Meschter
Radiation Safety Officer
Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(✓ Letter ✓ Dated June 25, 1996)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

_ New License ✓ Amendment _ Renewal
_ Termination _ Auth User (Amendment not required) _ QMP Revision
_ Other _____.

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information, technical issues that require additional information, or policy/technical issues that require coordination with headquarters or other NRC regional offices.

It appears that your request is routine (see 1-3 below, as applicable) and complete.

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (708) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301524
License No. 34-19089-01