UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

JUN 2 0 1995

Advanced Medical Systems, Inc.
ATTN: Mr. Robert Meschter
Radiation Safety Officer
1020 London Road
Cleveland, OH 44110

Dear Mr. Meschter:

Enclosed is Amendment No. 35 to your NRC Material License No. 34-19089-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all 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.

As requested in your May 15, 1995 letter and subsequent letter dated June 13, 1995, we have amended License Condition Numbers 19.B., D., E. and F.

Note that we have added License 19.G. This condition contains two parts. Condition G.i. requires that you contact us no later than July 14 to advise us on the status of the completion of projects described in License Condition Numbers 19.B., D. and E. Condition G.ii. requires that you also notify us no later than July 14 to confirm initiation of the remediation project described in License Condition 19.F.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

E/23

2. Notify NRC, in writing, within 30 days:

   a. When Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be

taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Kevin G. Null
Nuclear Materials Licensing Section

License No.: 34-19089-01
Docket No.: 030-16055/040-08764/030-17154

Enclosure: Amendment No. 35

NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 35

MATERIALS LICENSE

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.

Licensee	
1. Advanced Medical Systems, Inc. 2. 1020 London Road Cleveland, OH 44110	In accordance with letter dated May 15, 1995, and followup letter dated June 13, 1995 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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 34-19089-01

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

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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.

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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 Robert Meschter.

The licensee shall not perform service operations described in Subitems 9.B. and 9.C. until Robert Meschter 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				★	★ ★	★ ★					
Curtis Perry				3	1,2	1,2	1,2	1,2	1,2		1,2
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											
Curtis Perry		1,2	1,2	1,2	1,2	1,2					
Haddock	5	5	5	5	5	5					

11. (Continued)

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.

12. (Continued)

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 22, 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.

19. (Continued)

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 references 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. This project shall be completed by July 7, 1995.

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.

19. (Continued)

E. Immobilize the radioactive contamination present in the sewer manhole, lateral and four-inch discharge line. This project shall be completed by July 7, 1995.

i. Completely grout-in the radioactively contaminated four-inch sewer discharge line and the 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.

ii. Develop and implement a sub-surface radiological monitoring program to assess contamination migration as described in letter dated February 10, 1995. The program must be submitted in writing and approved by the NRC.

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. This project shall begin no later than July 8, 1995.

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.4 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.

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20. 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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SUPPLEMENTARY SHEET

License number
34-19089-01

Docket or Reference number
030-16055/040-08764/030-17154

Amendment No. 35

20. (Continued)

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; and

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, 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 evaporation of treated water or its discharge 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.

iv. Re-connection of the foundation underdrain system to the proposed new manhole and lateral.

I. Letters dated May 3, 1995, May 17, 1995, June 6, 1995 (excluding Item 3) and June 13, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 6/16/95

By K. G. N.
Materials Licensing Section, Region III

JUN 2 0 1995

Advanced Medical Systems, Inc.
ATTN: Mr. Robert Meschter
Radiation Safety Officer
1020 London Road
Cleveland, OH 44110

Dear Mr. Meschter:

Enclosed is Amendment No. 35 to your NRC Material License No. 34-19089-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all 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.

As requested in your May 15, 1995 letter and subsequent letter dated June 13, 1995, we have amended License Condition Numbers 19.B., D., E. and F.

Note that we have added License 19.G. This condition contains two parts. Condition G.i. requires that you contact us no later than July 14 to advise us on the status of the completion of projects described in License Condition Numbers 19.B., D. and E. Condition G.ii. requires that you also notify us no later than July 14 to confirm initiation of the remediation project described in License Condition 19.F.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

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2. Notify NRC, in writing, within 30 days:

   a. When Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be

taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Kevin G. Null
Nuclear Materials Licensing Section

License No.: 34-19089-01
Docket No.: 030-16055/040-08764/030-17154

Enclosure: Amendment No. 35

DOCUMENT NAME: M:\03017154.CL5
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OFFICE	DRSS/RIII							
NAME	KGNULL:jaw	(N)						
DATE	06/16/95							

OFFICIAL RECORD COPY

Advanced Medical Systems, Inc.

21 [illegible]th Eagle Street • Geneva, Ohio 44041
1[illegible]4671 FAX (216) 466-0186

June 16, 1995

Mr. John Madera
Chief-Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: License No. 34-19089-01
Control No. 97891

Dear John:

In response to your letter dated April 17, 1995 in which you request additional information for renewal of License No. 34-19089-01, the following are our responses:

I.A. The Radiation Safety Officer, by having a mandatory position on the Management Team, is a critical part of Senior Management. As such, he has direct access to not only other senior managers, but also to the President and/or Treasurer of the Company.

I.B. Both the Safety and Isotope Committees take minutes of their meetings. These minutes are put in writing and contain any findings, concerns or issues, etc. that the committees feel affect the company. Copies of these minutes are distributed to Senior Management including the President and Treasurer of Advanced Medical Systems. The President of Advanced Medical Systems is kept apprised of the ongoing operations through the minutes not only of the Safety and Isotope Committees, but also the Management Team. The President and Treasurer may, from time to time, elect to talk directly to the committee or its individual members on those issues which he feels requires his direct involvement. All members of the Safety and Isotope Committees and Management Team are made aware that they have direct access to the President and/or Treasurer of the company.

I.C. The duties of the Safety Committee involve those issues which relate to the unit and service performed on that unit. The Safety Committee does not involve any issues which affect the Isotope Committee except those safety issues which involve the source operation within the unit. The Isotope Committee duties and responsibilities involve every issue that pertains to radioactive materials including radiation safety and possession of nuclear materials. The Isotope Committee has the primary responsibility for complying with our NRC Materials License.

I.D. Advanced Medical Systems confirms that records of Safety and Isotope Committee meetings will be maintained. The minutes will include at a minimum the date of the meeting, list of attendees, all topics discussed, any problems identified and corrective actions taken or planned. In addition, minutes of the previous meeting will be reviewed to insure action is being taken on those items that warrant it.

I.E. Your understanding is correct that the AMS Engineering Manager will make the determination whether a licensed AMS staff person will respond to a request for teletherapy unit service or if the service will be subcontracted. The primary criteria for determining whether AMS will service the call with in-house personnel or subcontract the service is whether AMS has people available. Currently, AMS does not have any employees available to perform licensed service work on teletherapy units. Accordingly, all service work, both domestic and international, is being subcontracted to a licensed third party. When AMS has licensed personnel, the primary criteria will be availability to perform the requested service; the second criteria would be cost. Advanced Medical Systems' internal operations take precedent over the dispatching of licensed staff personnel. Advanced Medical Systems' current Engineering Manager is Ed Svigel. His primary responsibility relates to the production of the teletherapy unit. Mr. Svigel has in-depth knowledge of the unit's construction, operation and characteristics. He has held his position since his date of hire. Mr. Svigel's qualifications are listed in Table 1 of the AMS Training Manual (Notebook 3 of 3). Mr. Svigel is qualified to make technical judgments relating to the ability of AMS personnel to service the unit. The Radiation Safety Officer is also involved in any service work which involved AMS personnel as it is his responsibility they have received the appropriate radiation safety training.

II. Your understanding is correct that service performed by AMS staff personnel is limited to Class I or II service engineers. Furthermore, it is correct that AMS currently does not have on staff a licensed Class I or Class II service engineer. We are very well aware of the fact that we cannot provide service until qualified personnel have been trained and their qualifications submitted to the NRC and our license amended.

II.A.1

The scope of a field service audit as it relates to radiological safety includes the proper use of dosimetry, the possession and use of survey equipment, and adherence to procedures. The fact that the RSO is qualified and approved by the NRC and named on the license to be the facility RSO as it relates to radiation safety is ample qualification to conduct field service audits as it relates to radiation safety. The RSO is knowledgeable with regard to the source exchange process and equipment used for the source exchange.

II.A.2

Over the last several years, Advanced Medical Systems has preferred to subcontract field service work. Though AMS does not currently have licensed personnel to perform service, in the future the company may have licensed service personnel and the amount of service work being performed by its employees may be limited. Advanced Medical Systems should have the option that the field service audit be conducted during a simulated service call. This option is necessary as a situation may arise in which a licensed staff person may not have an opportunity to perform an actual service call on an annual basis.

II.A.3

This is to confirm that service records will be maintained for NRC inspection. The records will contain at a minimum the service engineer who performed the work, any AMS supporting personnel who accompanied him, the equipment serviced, the date and type of service performed, the problem identified, and the corrective action performed on the unit. This commitment of maintaining records for NRC inspection also pertains to records of all field service audits.

II.B AMS will take under advisement your recommendation to establish a program for auditing the activities of the RSO and his staff. The Isotope Committee currently oversees the RSO's performance.

III.A

The following is the basis for the application request for possession of 40 curies of Cobalt-60 in the form of waste:

ITEM	FORM	MATERIAL DESCRIPTION	ESTIMATED ACTIVITY (Ci)
Packaged Waste	Solid	Materials contained in high-level waste storage, LSA boxes and drums in the basement of the facility.	29
Surface Contamination	Solid	Uncharacterized surface activity in the restricted areas of the facility.	11

Since this licensing action requested in the application addresses possession/storage/use rather than decommissioning, the total quantity of residual radioactive materials at the facility has not been fully characterized. However, the AMS conceptual decommissioning plan indicates that up to 11 Ci of solid waste may be generated during decommissioning and decontamination activities.

AMS concurs that the radioactivity that currently exists in the WHUT Room should be included in the possession limit. Therefore, the application will be modified to include the quantity of Cobalt-60 that currently exists in the WHUT Room, based upon an analysis of the data provided in the SEG "Waste Holdup Tank Room Survey", May, 1995:

ITEM	FORM	MATERIAL DESCRIPTION	ESTIMATED ACTIVITY (Ci)
Packaged Waste	Solid	Materials contained in high-level waste storage, LSA boxes and drums in the basement of the facility.	29
Packaged Waste	Solid	Solid waste generated during the water treatment project.	80
Unpackaged Waste	Solid/ Sludge	Materials contained in the WHUT Room.	40
Surface Contamination	Solid	Uncharacterized surface activity in the restricted area of the facility.	11
		TOTAL	160

III.B

The possession limits requested in Item 5, Section I.I of our application does include the suspected inventory in the Hot Cell front storage plug. Accordingly, we do not have to amend our licensed possession units at this time nor our Decommissioning Funding Plan cost estimate.

III.C

The 60-month cycle for a physical inventory is currently justified as 1) the inventory is a three to four month evolution, 2) few sources are being sold from the current inventory, and 3) there is little if any turnover or movement of sources currently anticipated. Additionally, if any sources are moved for any reason, the location is reflected on a current inventory listing which includes the source location and other pertinent data. This inventory listing is maintained on a PC spreadsheet for ease of data entry and revision and is revised at the time of source movement.

III.D

Section I.2 of the application discusses purposes for which the licensed material will be used. Advanced Medical Systems had agreements with third parties to accept transfer of the majority of our Cobalt-60 sealed source inventory. This program has been delayed due to various events at our facility. We have not had any recent contact with these third parties and will not have any contact until we are in a position to begin source transfers. We estimated that it would take approximately twelve (12) months to complete these source transfers from the date of the first shipment. Due to ongoing events at the facility, preparing milestone dates, is not appropriate at this time. The primary purpose of the materials license for Advanced Medical Systems at this time is to possess Cobalt-60. For the purpose of license renewal, the disposition of this material as storage incident to disposal or transfer to a licensed third party is sufficient.

III.E "Devices" means fixed radiation monitor with built-in "check sources" of less than 10 microcuries Cs-137 each and a pocket dosimeter calibrator with less than 10 microcuries of Cs-137. The 665 curies is listed in the license renewal to cover the possible existence of a Cs-137 teletherapy source that may be in the front cell plug which is stuck and pending removal. This unknown regarding this teletherapy source is due to a possible discrepancy in a prior physical inventory.

IV. The training status of Mr. Reed is irrelevant to this license renewal application and should have no bearing on the issue. Isotope Technicians do not appear on the license by name or by duties as do Isotope Handlers. Accordingly, Mr. Reed's Isotope qualifications will not be submitted to the NRC. When and if Mr. Reed completes the qualifications for Isotope Handler, the documentation will be submitted as required. Mr. Reed's Isotope Technician training records are maintained at the facility and are available for review.

V.A. Instructions to Ancillary Personnel, ISP-28, is intended to provide basic radiation safety knowledge to part time or temporary personnel. It could be viewed as the AMS equivalent to nuclear power plant General Employee Training (GET) and Radiological Controls Training (RCT). The intent of this training is not to produce highly qualified health physics technicians, isotope technicians, or isotope handlers. Also, ancillary personnel are further trained and limited in their activities by the RWP process. Since the nature of the ancillary personnel training is so fundamental, it is felt that any experienced or qualified permanent AMS isotope technician, or isotope handler can be designated when appropriate or as needed to provide this training. The use of a "designee" is common practice throughout the nuclear industry and is used to allow for uninterrupted activities during the absence of a responsible individual, in this case the RSO.

Item 2.5 does not state that "ancillary personnel may be tested on their comprehension". It states that they may be asked general questions relating to the training to determine their overall comprehension. The purpose of this item is to provide for a mechanism to weed out individuals who are felt to be intellectually incapable of working in a radiological environment. Should this rare condition present itself, it would be documented on the training form under "comments". Due to the nature, purpose, and level of training discussed above, it is not necessary to make a "formal production" of this concern.

V.B The typo in "routing" will be changed to "routine". Corrected ISP-31 is enclosed (Attachment A).

Item 4.2 is clear as written as to who conducts the training and their qualifications.

A copy of the test with answers is included for Isotope Technician (Attachment B).

Dosimetry training is covered in ISPs which are covered in the Basic Radiation Safety Training.

V.C A copy of the test with answers for Isotope Handler is included (Attachment C).

An Isotope Handler must first be an Isotope Technician. Emergency Plan Training is covered in ISP-31 (See Attachment A).

An Isotope Handler must first be an Isotope Technician. Dosimetry training is covered in ISPs which are covered in Basic Radiation Safety Training.

Section 4.3 of ISP-32, Isotope Handler Training Program, specifies who trains an Isotope Handler. The current licensed handler is already on the AMS license. Steve Haddock's qualifications were submitted when originally licensed and were submitted with the license renewal. A third submittal should not be necessary.

V.D The company will update the basic Radiation Training Manual to reflect current operating conditions. This update will be completed by January 1, 1996. The company has retained a third party to assist in the update.

VI.A The hot cell will be used to load sources into shipping casks when appropriate, inspect sources when appropriate, or any activity related to source handling that can only be accomplished by using the hot cell.

VI.B&C

See USNRC Inspection Report No. 030-16055/93002(DRSS) (Attachment D) prepared by W. Slawinski, NRC Inspector, et al April, May 1993. The facility ventilation system has been reviewed in extreme detail and documented in the referenced report. The only change made to the system since this report is a reduction of the set point that shuts the system down to prevent a release to the environment. The current set point is 500 cpm over a current background of 500 cpm. This set point is orders of magnitude lower than previous acceptable set points.

The only credible potential point of airborne release from the facility is through the described and NRC inspected system.

VI.D The source garden is the storage location for sources that are not in the cell nor in a head or source exchange container. Procedures include ISP-18, Source Installation and Exchange Procedures Using Catalog 3320/3320AR Loading and Exchange Containers at Authorized Third Party Facilities; ISP-27, Source Transfer Out of Hot Cell and Source Calibration; and ISP-29, Radiation Work Permits. Additionally, sources are moved only by the licensed Isotope Handler. The NRC currently has the pertinent details on this individual.

VI.E. The "mounted" gamma alarms are response checked monthly in accordance with ISP-6, Monthly Check List. This response check involves the use of a "beam" calibrated check source. The source is decay corrected and the required distance to place the source to achieve the desired dose rate alarm point is calculated using industry standard calculations (performed on a computer). The calculations are printed out and attached to the checklist. Since these gamma monitors are used for indication of a possible situation only and are not used in any way to calculate official whole body exposure, a "calibration" methodology beyond this scope is not necessary.

VII. The need to revise and modify procedures as required without license amendment is essential to maintaining proper and adequate control of the facility and programs in a timely and efficient manner. This flexibility allows for immediate inclusion of revised regulations into the procedures, deleting obsolete methods and incorrect techniques, upgrading or enhancing procedures to effect improved performance, allow for editorial changes to improve user comprehension, and add new procedures in a timely manner as appropriate.

Currently, hundreds of other licensees revise and change procedures to meet the changing scope of regulations, work environment, and technology without being required to submit a license amendment. AMS will generate a procedure to prepare, revise, delete, review and approve procedures and will include the Isotope Committee in the review and approval cycle for procedure changes.

VII.A.1

The Victoreen Model 550 is used in the hot cell for relative dose rate indicating purposes only. AMS is aware that the unit is out of calibration, hence the use of the term "or equivalent" on page 31, item C.2. Because of this knowledge, the unit would never be used for official dose rate survey purposes. Only calibrated dose rate meters such as a Teletector or Eberline PIC-6 ion chamber are used to set dose rates and calculate stay times. Past cell entries and surveys with a Teletector have shown close agreement with the Victoreen Model 550 measured dose rates; therefore, AMS is confident in the use of the Victoreen Model 550 as an "information only" device. Should the Victoreen cable, probe, electronics fail at some point in the future, the unit will be replaced or an alternative and appropriate method for accomplishing cell dose rates will be established at that time.

Electric wiring in the cell will be replaced when needed. Should the lighting fail, temporary lighting may and will be substituted as appropriate until permanent repairs are made. In keeping with the ALARA concept of exposure control, it is not considered appropriate to receive exposure to verify that "all is well" with the wiring.

VII.A.2.a

Self reading pocket dosimeters are calibrated in accordance with ISP-23, Calibration of Portable Radiation Detection Instruments, section 3.2. This procedure was submitted with the license renewal application.

VII.A.2.b

Adding the statement "per 10CFR20.1502(a)(3)" is not necessary as radiation areas and high radiation areas at AMS are included in the category of "restricted" areas. Our dosimetry requirements are more restrictive than 10CFR20.

VII.A.2.c

Clarification of the obvious need not be addressed in this section. ISP-28, Instructions to Ancillary Personnel covers workers responsibilities as well as AMS responsibilities for monitoring and reporting worker exposure to workers.

VII.A.2.d

AMS dosimetry service is currently (and has been since Sept., 1985) provided by Landauer, Inc., 2 Science Rd, Glenwood, IL 60425-1586. A copy of their accreditation is included with this response (Attachment E).

VII.A.2.e

Units will be incorporated into the formula. Whole Body Count criteria will be included. Reference to Regulatory Guide 8.9 will be included. See Attachment F, revised Page 28.

VII.A.2.f

In order to maintain the flexibility to effect safe operations of the facility, it is necessary to provide for the exceptional occurrence that the hot cell may need to be entered in the absence of the RSO. This section clearly defines the requirements that need to be met should a cell entry in the RSO's absence be needed. It is not anticipated that this situation will ever come to pass; however, this contingency needs to be available if ever needed.

Reference to ISP-11 has been corrected. See Attachment G, revised Page 31.

VII.A.2.g

Item D.1.f. on page 32 "Check source inventory" means inventory the Check sources. These are small sealed sources used for instrument checks etc. AMS employees understand what this item means.

VII.A.2.h

It is assumed that your reference to "section III.D of this letter" really means section III.C which discusses inventory. Section III.D discusses inventory reduction issues separate from the inventory cycle. Page 33 of ISP-1 currently reflects our response to item III.C.

VII.A.2.i

ISP-2, Area Survey Procedure, will be changed to include a hot cell survey requirement. See Attachment H, revised ISP-2.

VII.A.3.a

Personnel frisking is addressed on page 42 under the section "Personnel Monitoring" item F. Frisking is required upon exit of a contaminated area - defined elsewhere as greater than 1000 dpm/100 cm . (your comment is missing the value of 100 and is assumed to be a typo)

The use of protective clothing is specified and addressed in the RWP process. Specification and use of dosimetry is addressed in Personnel Exposure Monitoring, Page 26, and in the RWP process.

We do not wear protective clothing in "potentially" contaminated areas. This facility, as any other including nuclear power plants, has clean or uncontaminated areas and contaminated areas. All areas of this or any like facility have the potential to become a contaminated area although the probability is very slight. If an area becomes contaminated, protective clothing is used in that area until it is decontaminated and released as clean. This is industry standard practice.

VII.A.3.b

The "as soon as possible" notification of the RSO will be included. See Attachment I.

VII.A.4

It should be noted that ISP-1 is a general overview of the AMS facility and operations and is not intended to be an all encompassing to the last absolute detail description of the facility. AMS feels that the current description regarding storage, postings and security is adequate as written. To further detail security items and measures could lead to a compromise of the building security should this detail become available to unauthorized individuals. USNRC inspection personnel such as W. Slawinski, M. Weber, et al, are intimately familiar with the details regarding this issue and have conducted past inspections with no discrepancies noted.

VII.A.5

The reference to research and development has been deleted (Attachment J).

VII.A.6

Given the sensitivity of a count rate meter with G-M pancake probe and considering the typical background for frisking (200 cpm nominal, possibly up to 300 cpm) and factoring in normal meter fluctuation of 100 cpm, the specified limit of 100 cpm above background equates to saying that the contamination limit is "none detected above background". In other words, 100 cpm above background represents the lower limit of detection for the instrument and evaluation situation. Since we are dealing with an imprecise measurement to begin with, certain latitudes of judgment must be allowed. It is also an industry standard practice to state personnel contamination limits in the manner specified in this section when using the described instrument.

To make a blanket all encompassing statement that decontamination will be performed until levels reach background is not considered to be appropriate or desirable. Decontamination efforts beyond three cleanings may result in the degradation of the skin and result in aggravating the contamination situation or lead to an internal deposition through abraded skin. Severe cases of contamination may require medical attention prior to subsequent decontamination attempts and would be dealt with on a case by case basis. Therefore, AMS will subscribe to industry standard and acceptable practices such as those outlined in "The Health Physics and Radiological Health Handbook" revised edition 1992, Bernard Shleien, or other credible source of guidance (also see Reg. Guides 8.21, 8.23, 8.24, 8.30).

VII.B

Response to "General Comments":

The procedures submitted with the license renewal were revised versions of the "old" I.S. Procedures (ISPs). The primary focus of the revisions was to bring the procedures into compliance with the "new" 10CFR20, eliminate obsolete and incorrect practices, and improve the workability and "user friendliness" aspects of the procedures. Every attempt was made to use the word "shall" to denote those items that reflect regulatory compliance requirements. In those areas that did not require regulatory compliance, the word "should" was used to allow for flexibility of interpretation based on the working situation at hand. Not all phases of operation at this facility (or others) are absolute thereby requiring inflexible and rigid procedures. It should be noted that the regulations cited in 10CFR20 allow for flexibility in procedural approach and decision making (see 10CFR20.1204). AMS procedures are dynamic (not static) in nature and are subject to change as appropriate; therefore, changing "shalls & shoulds" will be made when appropriate in the best judgment of the RSO, Isotope Committee, and when required by regulations. If our submitted procedures have failed to specify a "shall" regarding regulatory compliance, it is due to an unintentional oversight and will be corrected in subsequent reviews or upon specific identification in the NRC inspection process. AMS does not have to defend or justify the use of the word "should" in those areas not specifically related to regulatory compliance. Additionally, the new procedure mentioned in the response to Item VII will address the use of the words "shall, should, and may" in accordance with the definitions in NQA-1, 1989.

All incorrect references to mr/hr will be changed to mrem/hr.

Action levels ("trigger") are specified in ISP-2 Part 3.3 and are listed on the bottoms of forms ISP-2A,B,C. RSO notification is required in section 3.3.3 of ISP-2.

VII.B.1

A statement regarding the reference to 20.1301(a)(2) for 2 mrem in any one hour has been included.

3.3.4.c has been changed to say "...at least weekly, or more frequently as appropriate, or as directed by the RSO."

Survey forms for controlled and restricted area surveys have been changed to include surveys outside the south end of the building.

The incorrect location listed for the clean equipment room has been corrected.

Changes to the survey forms regarding the WHUT room and 1SA roof have been made.

See Attachment H, 1SP-2 for revisions.

VII.B.2

The MDC formula AMS uses, as stated in the procedure, is presented in NUREG 1156, "Accuracy and Detection Limits for Bioassay Measurements in Radiation Protection: Statistical Considerations" (1986) and NUREG/CR-4007, "Lower Limit of Detection: Definition and Elaboration of a Proposed Position for Radiological Effluent and Environmental Measurements" (1984) and is consistent with that contained in Regulatory Guide 8.25 "Air Sampling in the Work Place" (1992). However, it is important to note that this equation is used to demonstrate a system capability. Therefore, the count rates and count times are obtained from measurements made with "background" filters and smears, and the radical contains the standard error of background counting conditions. If the MDA for a sample smear or filter is desired, the equation from Reg. Guide 8.25, section 6.3 would be used. In this case, the radical contains the standard error from the sample smear or filter.

VII.B.3

Given: The air sampling/monitoring system is set to isolate and shut down the ventilation system when a count rate of 500 cpm above a current background of 500 cpm is achieved. The system configuration is such that the ventilation cannot restart automatically. Restart of the system requires that the trip logic be manually reset by human action. Should the system shut down as the result of a spurious or random spike in ambient radiation levels in the vicinity of the stack detector, then the strip chart would record this spike and return to a normal recorded level on the paper. Should the system shut down due an increased count rate on the sampler filter paper as the result of cobalt deposition on the filter paper, the strip chart would record an increase and that level would stay increased on the chart. The system cannot be reset without remedial action. AMS personnel are and have been instructed that any reading above background is considered abnormal and that follow up actions are required per the instructions in the ISP. Therefore, it is not necessary to specify a "trigger" level on the check list.

VII.B.4

The Isotope Shop Air Samples deleted from the check list referred to two fixed station sample heads in line with calibrated rotometers. The fixed locations for these sample points were at the exhaust louvers of the shop ventilation system located near the floor and against the walls of the shop area. It was erroneously assumed in the past that these samples could be used to adequately evaluate airborne radioactivity in the shop area and could be used to monitor worker intake of airborne radioactivity. Upon evaluation of this situation by the current RSO, it was decided that this past practice and methodology was inappropriate for the past and, in light of the current regulatory requirements, inappropriate for the present. Therefore, AMS now requires that all entries into contaminated areas include the use of breathing zone air samplers by individuals. This requirement is specified on the RWP and falls under the category of "as directed by the RSO" in ISP-9. All air samples for individuals are recorded per ISP-9 and dose is assigned based on the sample results. This issue and methodology was reviewed and discussed with, and accepted by W. Slawinski, USNRC, during the last quarter of 1994.

VII.B.5

The air pump for the system is not calibrated. The rotometer for the system is sent to our calibration vendor (GTS, Pittsburgh, PA) for calibration semi-annually. AMS possesses two rotometers, one in service and one out for calibration.

There are, as stated in 2.1, two conditions when this check is done. Condition one is monthly - "It is to be performed monthly". Condition two is when there is an abnormal increase on the monitor. The two conditions are connected by the word "or" meaning that either condition will cause a system check. To connect the two conditions with the word "and" is illogical. If the two conditions are connected by the word "and", then both conditions would have to occur simultaneously to cause a system check. Please read 2.1 again for the obvious and specific intent.

The limit specified in 3.9 is the limit from 10CFR20 for Cobalt-60 and is a true and correct statement as written. AMS has added an action guide statement to notify the RSO if 10% of this value is approached (Attachment K).

VII.B.6

AMS has changed the set point to 10% of the current value (Attachment L).

VII.B.7

The AMS policy for requiring breathing zone air samples (BZAS)is more conservative and restrictive than current regulation and regulatory guidance. There is a potential at this facility to exceed 10% of the limits; therefore, all work in contaminated areas requires the use of BZAS (see response to VII.B.4).

Currently, AMS feels that section 3.1 of this procedure is sufficient and appropriate guidance for calibrating the samplers. Who better than the manufacturer is qualified in this area?

VII.B.8

AMS stands by the position outlined in the response to VII.A.2.f. Not making this change to ISP-11 was an oversight.

Item 2.6 has been changed to reflect training with respect to ISP-11 and the RWP requirements for the entry. Dosimetry requirements are specified in the RWP written for the cell entry. RWPs are written by the RSO. AMS has added a guidance statement pertaining to dosimetry in the procedure (Attachment M).

It is common knowledge at this facility that "isotopes" as mentioned in 3.1.1 refers to sealed sources or source material used to make sealed sources. AMS has clarified this statement.

Given the current and future state of operations at this facility, a maximum contamination level cannot be specified. As soon as conditions permit, the next project for the cell is removal of the stuck front cell plug. Part of the plug removal project will employ strippable coatings to 1) fix contamination during the removal process and 2) facilitate decontamination after the project. After these evolutions, the cell should not re-contaminate to the degree in the past as future cell activities will not be of the nature that will cause an increase in contamination. The statement in the procedure is a hold over from the past. Removal of the statement cannot be justified as "decontamination to the degree practicable" is always a consideration when considering the task at hand. For example, if the task at hand is to enter the cell for 15 seconds to remove an article from the table, then decontamination may not be considered warranted or justified.

See response to VII.A.1 regarding cell surveys.

The intent of "as determined by the RSO" is to allow the flexibility to set the alarming dosimeter at a lower alarm point if desired. The limit specified in the procedure is considered a maximum alarm set point with the federal exposure limits being the absolute limit. It should be noted that AMS uses and administrative control limit of 4500 mrem/y.

Is "clarify what is meant by the term at the door opening" a serious question? "At the door opening" means the space the door occupies when the door is shut. When the door is open, the "door opening" is the point where the door was before it was opened. Beyond the "door opening" is the interior of the cell

The use of 20 rem/h is a hold over from previous procedures and past operating experience. It is believed that this limit was picked as a dose rate greater than this may indicate the presence of a source pellet or other condition of equal concern. It cannot be justified to set this limit higher or lower at this time. It is anticipated that this limit may be reduced in the future as cell conditions improve.

Periodic monitoring is accomplished by 1) reading the SRPD, 2) reading the display of the alarming dosimeter, 3) quickly estimating dose based on dose rate vs. stay time, or combinations of these steps, all of which are industry normal practices.

Air sampling was addressed in the response to VII.B.4. Again, breathing zone air samples are required for any work in a contaminated area.

VII.B.9

The statement the "current staff has not performed this activity" is not a complete and true statement. The RSO has changed HEPA filters and pre-filters (portable units and building ventilation systems) at nuclear power plants and research laboratory (plutonium oxide filters on laboratory glove boxes), the current licensed Isotope Handler has changed the AMS HEPA filters and pre-filters, and the current technician has changed HEPA filters and pre-filters (portable type) at a nuclear power plant. The procedure is sufficiently written for use by experienced personnel. An inexperienced person would never be assigned this task without the assistance of an experienced person. Keep in mind that procedures (ours and other facilities) are not intended for the "man off the street" to read and follow with no training or input from the facility staff.

The current installed system was installed and finally placed in service in 1992. Since that time the filters have only been changed once and that was due to high DP across the filters. Previously no change criteria was established. The procedure has been changed to give the criteria (dose rate or DP) for changing the filters (Attachment N). It is anticipated that at minimum, the pre-filter will be change prior to the project to remove the stuck front cell plug.

Due to the nature of a filter change, the use of a portable HEPA is second nature to experienced personnel and would be used. Additionally, respirators would be worn for this activity. Dosimetry requirements will be addressed in the RWP and will be appropriate based on the dose rates encountered.

The "special" box is special only in that it is sized to contain the filter adequately.

All tools and equipment removed from a contaminated area are frisked (checked for contamination), this includes respirators (ISP-30 addresses smears inside respirators). Also, personnel frisk their face upon exit from contaminated areas. Respirators are not disposed of after use, they are cleaned as appropriate and inspected and reused.

VII.B.10

3.2.1 of this procedure does not specify an order to do the surveys. It merely states "Record the following on form..." A trained individual knows to approach the package with the survey meter on. If there is a "dose rate problem" with the package it would be obvious during the initial stages of the survey.

VII.B.11

Each air sample result is reviewed by the RSO as it is generated. While not detailed in a procedure, each individual has a log sheet showing the current status of internal exposure monitoring. Also, this information is kept on a PC that will "flag" the log at 200 DAC-HRS of exposure for that individual. Since this item is subject to continuous scrutiny, it is felt that including a review statement is not necessary.

3.2.3 (a) will be clarified (Attachment O).

VII.B.12

AMS interprets the use of the word "governed" to mean "has the responsibility for" or other equivalent interpretation (see Webster's Dictionary).

3.4.3 has been changed to read "source handling or related activities" (Attachment P).

The assignment of an individual as a "designee" is predicated on sound judgment by the RSO in relation to the knowledge level of the individual and the confidence level the RSO has in that individual with regard to the task at hand.

VII.B.13

Our depleted uranium parts and subassemblies fall under the category of "excepted" (49CFR173.424) and are exempt from the requirements of sub-part G per paragraph 172.600(d) as no shipping papers are required (Attachment Q).

VII.B.14

Alarming dosimeters and SRPDs with greater than 200 mr range are sent to a commercial vendor for calibration once every six months. The 6-month frequency has been added to the procedure (Attachment R).

VII.B.15

10CFR19.13 gives the reporting requirements as annually, para. (b); for formally engaged workers para. (c); when reporting is required per 20.2202, 2203, 2204 or 2206, para (d); and for terminating employees. AMS specifies that individuals be informed of their film badge results <u>any time</u> they ask for the information. They need not wait until the end of the year to receive a Form 5 or terminate to obtain this information. Also, this statement regarding film badge reports is in reference to the vendor supplied results of the film badges processed. Refer to the Purpose statement at the beginning of the procedure.

VII.B.16

Reference to compactor operations has been deleted from this procedure (Attachment S).

VII.B.17

The regulations require that the Bill of Lading contain an emergency phone number. An emergency phone number requirement has been included in this section.

Item 3.6.3 has been clarified (See Attachment T).

VII.B.18

The AMS position on the use of a "designee" is covered in the responses to V.A, VII.A.2.f and VII.B.12.

The "radiation safety job coverage" determination is made based on the experience and sound judgment of the RWP preparer. This determination is also based on the nature of the job and the experience level of the workers involved. Absolute and rigid criteria is neither warranted nor desired. Flexibility to meet changing demands must be maintained to ensure overall safe operations.

VII.B.19

The intent of the regulations pertaining to the use of respiratory protection state that if respirators are used then they will be used in accordance with the regulations. AMS intends to use respirators; therefore, AMS will have a respiratory protection program in accordance with the regulations. No where in the regulations does it require that a licensee establish and use protection factors for the respirators. AMS will not establish and use protection factors; hence the reason for breathing zone air samples and the assignment of dose based on the air sampling results regardless of whether a respirator was worn or not. The probability that a worker could receive an internal exposure in excess of 20.1502 exists at AMS; therefore, monitoring and assessment of the dose is required. Again, the reason for breathing zone air samples. The use of respiratory protection device, when appropriate, is industry common sense and a "good practice" to minimize internal exposure even though no credit is taken for the degree of protection. ISP-9 satisfies the requirements of 20.1703 (a)(3)(i). ISP-1, page 28 satisfies the requirements of 20.1703 (a)(3)(ii); additionally, ISP-1 page 28 is being revised per our response to Item VII.A.2.e.

AMS does not measure for oxygen deficient atmospheres as AMS has no confined spaces to be entered. This statement is included as a general warning and can be found in the literature supplied by the manufacturer as well as most respiratory protection programs even when not applicable to that specific program.

The "R" in ALARA stands for reasonable which includes economic and other factors to be considered. Respirator filters are not inexpensive. A 2mrem/h filter on a respirator being worn in a hot cell with a general area dose rate of 12 rem (not mrem)/h with contamination levels possibly in excess of 100 mrem/h smearable would not be considered unacceptable nor unreasonable. It is common practice at nuclear power plants and other facilities to set aside respirators and filters as well as cotton coveralls, gloves etc. with fixed radioactive contamination on the item (typically up to 5 mrem/h) for use in high radiation and high contamination areas. The radiological concerns for the item being worn in these cases are negligible in comparison to the area the item is worn in; therefore, AMS reserves the right to follow ALARA practices as other licensees do. Also, there is no requirement that new or non-contaminated filters be used each time a respirator is worn.

VII.B.20

The statement about isotope technicians being able to calibrate survey instruments and meters have been deleted (Attachment A, ISP-31). These personnel will be trained to ISP-23.

VII.B.21

"Calibrate sources" means to verify and document the source strength with a condenser R-Chamber or equivalent.

VII.B.22

Steps 3.1 and 3.2 will be reversed (Attachment U).

VIII.A

AMS never intended to compact waste at our facility. This reference was to state AMS may ship waste to a third party for compaction.

VIII.B.1

AMS is not aware of any additional permits required.

VIII.B.2

Waste is stored in the facility basement below grade. Waste in this area is from prior cell operations (plug removal attempt) with some items in concrete/lead shielded 55 gallon drums. Waste is stored in a designated "high level" waste storage area consisting of 3' thick walls and ceiling with slab on grade floor. This room also has a labyrinth entrance and is used to store waste greater than 50 mrem/h. Low level DAW (protective clothing etc.) is stored in LSA boxes in the Isotope Shop Warehouse. All areas are weather secure. Vulnerability to hazards is considered low with the hazard probabilities the same now as it was for previous licenses.

VIII.B.3

See response to VIII.B.2. Additional shielding will be addressed on a case-by-case basis when appropriate. Monitoring is currently performed under existing procedures and routine surveys.

IX.A Page 3 under the heading "General" in the AMS Service Procedures Manual has been updated to reflect that shutter service will be performed only by NRC-licensed individuals (Attachment V).

IX.B The instrument referenced in Section C of Page 8 is a device that gives an audible response (beep or chirp) at a rate relative to the dose rate it is present in. It does not have display of dose received nor does it have a means to preset any dose rate. It is used by the Service Technician as a quick and handy method to determine when the cobalt source is in the teletherapy head or in the source exchange container or in transit between the two units; i.e., slow chirp rate when the source is in either container and fast chirp rate when the source passes from one container to the other.

IX.C Items B.2 and 3 provide for a field assessment of a leaking source. The specified count rate is used as decision point as to which direction to proceed in the procedure. If greater than 2000 cpm, go to the emergency procedure. If less than 2000 cpm, proceed with normal service operations. The procedure is adequate as written.

X. Advanced Medical Systems is aware that the Decommissioning Funding Plan and Emergency Plan issues are a part of our license renewal. The items discussed and deficiency letters have been addressed and, pending further questions, have been resolved.

Mr. John Madera

June 16, 1995

If you have any further questions, please do not hesitate to contact me.

Sincerely,

DAVID CESAR
Treasurer

DC/mz
Enclosures

LISTING OF ATTACHMENTS

ATTACHMENT	DESCRIPTION	QUESTION
A	Revised ISP-31	V.B., V.C., VII.B.20
B	Isotope Technicial Exam with Answers	V.B.
C	Isotope Handler Exam with Answers	V.C.
D	USNRC Report 030-16055/93002 (DRSS)	VI.B and C
E	Landauer Accrediation	VII.A.2.d
F	Revised Page 28 of ISP-1	VII.A.2.e
G	Revised Page 31 of ISP-1	VII.A.2.f
H	Revised ISP-2	VII.A.2.i, VII.B.1
I	Revised Page 37 of ISP-1	VII.A.3.b
J	Revised Page 40 of ISP-1	VII.A.5
K	Revised ISP-7	VII.B.5
L	Revised ISP-8	VII.B.6
M	Revised ISP-11	VII.B.8
N	Revised ISP-12	VII.B.9
O	Revised ISP-14	VII.B.11
P	Revised ISP-15	VII.B.12
Q	Revised ISP-21	VII.B.13
R	Revised ISP-23	VII.B.14
S	Revised ISP-25	VII.B.16
T	Revised ISP-26	VII.B.17
U	Revised ISP-33	VII.B.22
V	Revised Page 3 - General Section of AMS's Service Procedure Manual	IX.A