

JUN 27 1995

Advanced Medical Systems, Inc.
ATTN: David Cesar
Treasurer
121 North Eagle Street
Geneva, OH 44841

Dear Mr. Cesar:

Enclosed is Amendment No. 37 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.

License Condition No. 21 has been added to authorize installation of the water evaporation device described in your March 22, 1995 letter. Please note that the Condition also specifies that operation of the evaporator is not granted. During a June 26 telephone conference between Carol Berger, Bob Meschter, Kevin Null of my staff, and me, we explained why operation of the device would not be granted at this time. To summarize, we explained that the following information would need to be submitted for our review and approval prior to operation of the device: 1) safety and spill-control procedures; 2) procedures for removal and analysis of solids from the evaporator; 3) SOP for operation and surveillance of the evaporator; 4) final decision on hours of operation; and 5) a roof area survey program near and around the exhaust point for the evaporator. When submitting this information please reference as additional information to Control Number 98334. An additional fee will not be charged.

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.

Finally, in reviewing your permit application to the EPA which was submitted as an enclosure to your June 8 letter, we are concerned that the information in the application may not reflect recent changes in the water processing project as it relates to the concentration of cobalt-60 and total volume of processed water. Specifically, your application and COMPLY code report assume evaporation of 60,000 gallons of water with a cobalt-60 concentration of 200

pCi/l. It is our understanding that you have greater than 60,000 gallons of water with a varying concentration of cobalt-60, possibly up to 1000 pCi/l. Therefore, a re-evaluation of cobalt-60 effluent using current values (i.e. total volume of water and cobalt-60 concentration) may be warranted. Furthermore, such changes in these values may necessitate resubmittal of a permit application to the EPA.

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.
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

Enclosure: Amendment No. 37

DOCUMENT NAME: M:\03016055.CL5

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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 March 22, 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 A. Cobalt-60 B. Cobalt-60 C. Cesium-137 D. Depleted Uranium E. Cobalt-60	7. Chemical and/or Physical Form A. Solid Metal B. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State) C. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State) D. Nickel Plated E. Sealed Sources	8. Maximum Amount that Licensee May Possess at Any One Time Under This License A. 150,000 curies B. 135,000 curies (no single source to exceed 13,700 curies) C. 40,000 curies (no single source to exceed 2,200 curies) D. 4,040 kilograms E. 15,000 curies	

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6. Byproduct, source,
and/or special nuclear
material

F. Cobalt-60

7. Chemical and/or physical
form

F. Sealed Sources
(any sealed source
approved by the NRC
or an Agreement
State)

8. Maximum amount that
licensee may possess at
any one time under this
license

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				

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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 or 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 of 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.

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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, 301 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 recommended 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.

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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.

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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 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. 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.

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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.C., 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.

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 the water evaporation equipment described in letter dated March 22, 1995. Operation of the evaporator is not authorized by this amendment.

22. 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);

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- 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;
- 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 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, March 22, 1995 (excluding Item 2 and associated attachments), June 8, 1995 and June 14, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 6/27/95

By

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