

MATERIALS LICENSE

Amendment No. 25

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, 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.

91080

Licensee

1. Advanced Medical Systems, Inc.

2. 1020 London Road
Cleveland, OH 44110

In accordance with letter dated
February 19, 1992
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. 030-16055/040-08764/030-171546. Byproduct, source, and/or
special nuclear material7. Chemical and/or physical
form8. 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

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 and training of licensee personnel in the manufacture of NRC approved sealed sources. This license does not authorize manufacture of sealed sources for distribution.

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9. (Continued)

- 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.

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 Mark Loeser.

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11. 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											
Edmond											
DeRosa				3			1,2	1,2	1,2	1,2	1,2
Curtis											
Perry				3	1,2	1,2	1,2	1,2	1,2		1,2
William											
Turbett	2,4	4	4	2	2,4	2,4	2,4	2,4	2,4	2,4	2,4
Ginzel	5	5	5	5	5	5	5	5	5	5	5
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						
Edmond						
DeRosa		1,2	1,2	*	1,2	1,2
Curtis						
Perry		1,2	1,2	1,2	1,2	1,2
William						
Turbett		2,4	2,4	2,4	2,4	2,4
Ginzel	5	5	5	5	5	5
Haddock	5	5	5	5	5	5

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.

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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 designed 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 which the sealed source is permanently or semipermanently 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.
- 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, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action.

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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 March 31, 1993. Thereafter, a physical inventory of all radioactive material possessed under this license will be completed within 60 months of the previous physical inventory.
 - D. The following schedule of activities will be accomplished to complete the physical inventory on or before March 31, 1993:
 - i. By May 31, 1992, a contractor will be selected for the installation of the hot cell ventilation system.
 - ii. By August 31, 1992, the hot cell ventilation system will be installed, tested and declared operational.
 - iii. By September 30, 1992:
 - a. AMS staff will be trained on the handling of sealed sources and performance of hot cell operations in accordance with the AMS training procedures by an organization authorized by the NRC or an Agreement State to handle sealed sources and perform hot cell operations; and
 - b. Physical inventory of the cesium-137 sealed sources will be accomplished.
 - iv. By March 31, 1993, physical inventory of the remaining radioactive material possessed under this license will be accomplished.
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).

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16. The licensee shall follow the recommended survey frequencies outlined in Regulatory Guide 8.21, Revision 1, October 1979, in work areas when 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 and May 27, 1992. The licensee shall make no change in the emergency plan submitted pursuant to 10 CFR 30.32(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, D.C. 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. 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;
 - 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

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- F. Letters dated March 29, 1989 (except Section 3.4 "Hot Cell Entry and Action Levels"), April 7, 1989, August 25, 1989 (except Item 8(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.

For the U.S. Nuclear Regulatory Commission

Date:

7/30/92

By

J. R. Mad
Materials Licensing Section, Region

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MATERIALS LICENSE
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License number

34-00869-04

Docket or Reference number

030-00396

Amendment No. 15

St. John Hospital
Department of Radiology
7911 Detroit Avenue
Cleveland, OH 44102

In accordance with letter dated September 14, 1992, License Number 34-00869-04 is hereby terminated.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date SEP 17 1992

By Robert D. Hattang
Materials Licensing Section, Region III

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