

Advanced Medical Systems, Inc.

21 North Eagle Street • Geneva, Ohio 44041
466-4671 FAX (216) 466-0186

November 29, 1994

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

RE: License No. 34-19089-01

Dear John:

Enclosed are two (2) copies of our Application for Renewal of our Material License No. 34-19089-01 along with our renewal fee in the amount of \$2,200.00.

There are several issues which remain open at the time of this mailing which we realize need to be resolved. The first item is the Decommissioning Funding Plan has been prepared. We are not submitting it at this time pending the completion of the WHUT Room evaluation requested by the NRC. SEG has completed the first phase of the project which consisted of obtaining soil samples from outside the WHUT Room. These samples are being tested and we expect the results this week.

The second phase of this project would be to look into the WHUT Room, assess the contamination levels and obtain a videotape of the interior. This work is scheduled to be completed sometime the week of December 5. The Decommissioning Funding Plan is subject to change pending the results of the WHUT Room evaluation. The Decommissioning Funding Plan and WHUT Room Evaluation Report will be submitted to the NRC not later than December 31, which is the expiration date of our license.

The second item which needs to be resolved is the completion of our physical inventory. ALARON was in the week of November 14 with the contractor who will perform the destructive removal of the stuck floor plug. They observed the cell firsthand, took measurements and got an understanding on how helpful the manipulators will be during the operation. I hope to have a proposal from them the week of November 28. This is a priority project for us as it is our intention to remove all sealed sources and bulk capsules from our facility. Once the WHUT Room evaluation is complete, we will be able to concentrate on completion of the physical inventory.

Enclosed are the changes to our Materials License we wish to make at this time. Under Item 19 of our Materials License, numerous letters are referenced. I have reviewed these and provided comments on each in the Material License Renewal Application. It is my intention to remove references and conditions which no longer apply.

DEC 1

REGION 1

D129

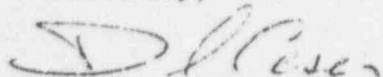
Mr. John R. Madera

-2-

November 29, 1994

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

Sincerely,

A handwritten signature in cursive script, appearing to read "D. Cesar".

DAVID CESAR
Treasurer

DC/mz
Enclosures

(6-93)
10 CFR 30, 32, 33
4, 35, 36, 39 and 40

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW
MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S.
TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5366

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☒ C. RENEWAL OF LICENSE NUMBER 34-19089-01

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Advanced Medical Systems, Inc.
121 North Eagle Street
Geneva, OH 44041

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

1020 London Road
Cleveland, OH 44110
121 North Eagle Street
Geneva, OH 44041

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

David Cesar

TELEPHONE NUMBER

(216) 466-4671

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>3B</u> AMOUNT ENCLOSURE \$ <u>2,200.00</u>
13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.	

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

David Cesar, Treasurer

SIGNATURE

DATE

11-29-94

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		NFC
APPROVED BY				DATE	
4505230323 10 pp					397891

ADVANCED MEDICAL SYSTEMS, INC.
LICENSE RENEWAL
LICENSE NO. 34-19089-01

The following are the changes and/or deletions to our current Materials License.

Item 5: Radioactive Material - Reduce the possession limits as follows:

A. Byproduct, Source and/or Special Nuclear Material	B. Chemical and/or Physical Form	C. Maximum Amount That Licensee May Possess at Any One Time Under This License
Cobalt-60	Solid Metal	20,000 Curies
Cobalt-60	Sealed sources (teletherapy/radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	60,000 Curies (no single source to exceed 13,700 Curies)
Depleted Uranium	Nickel Plated	4,040 Kilograms
Cobalt-60	Sealed Sources	15,000 Curies
Cobalt-60	Sealed Sources	15 Millicuries
Cesium-137	Sealed Source	1 Millicurie

Delete Cesium-137.

Add 9: Authorized use Cesium-137: for use in devices.

Item 12(b): Delete the words "fabricated by the Licensee" as they reference source fabrication by Advanced Medical Systems. Advanced Medical Systems will not manufacture sealed sources in the future.

Item 14(c): Change To: A physical inventory of all radioactive material possessed under this License will be completed within sixty (60) months of the previous inventory.

Item 19: Add: Licensee will notify the NRC of any structural changes or modifications to the London Road Hot Cell Facility.

Licensee will submit any changes, additions or deletions to their ISP Manual or training programs to the NRC for review and comment.

Item 19(a): Delete application dated November 12, 1984. All of the items covered under the application dated November 12, 1984 have either been updated or covered in our ISP Manual.

Item 19(b): Delete letter dated November 12, 1984. The License currently excludes Item No. 4. Item No. 1 combines three (3) licenses into one. We have been operating under one License for over ten (10) years. Items 2 and 3 reference operating procedures and service procedures which have since been incorporated into our ISP Manual.

Delete letter dated February 12, 1985. Item No. 1 references address change which has been implemented. Item Nos. 2 and 3 reference ISP No. 1.

Delete June 7, 1985 letter. All topics have been updated.

Delete letter dated September 6, 1985 as both Item Nos. 1 and 2 are covered in the ISP Manual.

Item 19(c): Delete letter dated May 29, 1986 in response to Enclosure A of NRC letter dated March 7, 1986. This letter deals with several deficiencies and concerns back in 1986. All of these requirements have been fulfilled. The deficiencies no longer exist.

Item 19(d): Delete letter dated July 23, 1986. This letter is in response to the March 7, 1986 NRC letter regarding issues for renewal application. These items have all been fulfilled and have either been incorporated into an ISP or are currently listed in the Materials License.

Item 19(e): Delete letter dated August 22, 1986. It references conditions which have since been fulfilled.

Delete the October 28, 1986 letter. The condition requests have since been fulfilled.

Delete the November 13, 1986 letter. This correspondence discussed clarifying the Emergency Pre-Plan.

Delete the November 14, 1986 letter. The correspondence discusses former employee Bill Turbett and consultant Paul Tomlin, neither of which are currently retained by Advanced Medical Systems.

Delete the December 4, 1986 letter. This letter references changes to the ISP Manual which were implemented.

Change May 7, 1987 letter to read: "May 7, 1987 letter, Item 1 only". Item 2 concerns waste disposal resulting from Cobalt-60 source fabrication. We no longer fabricate sources. Item 3 references the Radiation Safety Management Program which has since been updated.

Change the August 3, 1987 letter to read: "August 3, 1987 letter, Item 1 only". Item 1 pertains to the training program for our service engineers. Items 2 through 5 are either not applicable or since then implemented into an ISP.

Leave in December 31, 1987 letter.

Delete January 15, 1988 letter. Only Item V is currently covered and is incorporated into the addition at the beginning of Section 19.

Leave in August 15, 1988 letter.

Leave in September 29, 1988 letter.

Leave in November 21, 1988 letter.

Item 19(f): Delete March 29, 1989 letter. This letter deals with the redesign of the Hot Cell ventilation system which has since been completed.

Delete the April 7, 1989 letter. This letter deals with a personnel change in the RSO position and also forwarded to you a copy of the Management Plan.

Delete the August 25, 1989 letter. This letter discusses issues which have since been closed or superceded by 10 CFR.

Delete July 23, 1990 letter. This letter discusses changes to various items which have since been implemented.

Delete the March 1, 1991 letter. This correspondence concerns a former employee, Mike Ginzel. As he is no longer employed, it is unnecessary to have this information part of our License. This letter also concerned the installation of the HEPA System which has since been completed.

Change March 27, 1991 letter to correct date. Should read March 26, 1991.

Delete the May 9, 1991 letter as it concerns training regarding former employee, Michael Ginzel.

Delete the May 14, 1991 letter. Advanced Medical Systems has no plans to train personnel or manufacture in the areas of sealed sources.

Delete February 27, 1991 letter. It concerns former employees' qualifications and positions.

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Leave in March 2, 1992 letter.

Leave in March 5, 1992 letter.

Item 19(g): Delete April 16, 1992 letter. This letter concerns contractors being considered for repairing the Hot Cell Ventilation System. This work has since been completed.

Delete June 15, 1992 letter. It addresses information regarding the HEPA System.

Delete the August 10, 1992 letter. This letter concerned issues concerning Fire Protection, ventilation system and various other areas which have since been addressed.

Delete the September 18, 1992 letter. This letter confirmed that an independent consultant completed testing of the HEPA System and it was certified to be 99.99% efficient.

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Delete the January 20, 1993 letter. It discusses prior Hot Cell decontamination projects.

Delete the March 30, 1993 letter. This letter updates the NRC regarding developments.

Delete the March 31, 1994 letter. This letter concerned the qualifications of Joseph Michuta as RSO. He is no longer employed.

Delete the April 11, 1994 letter. This letter provides additional information on former employee, Joe Michuta's, qualifications.

Leave in the September 21, 1994 letter as this contains the qualifications of our current RSO, Robert Meschter.

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611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94598-5368

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- ☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☒ C. RENEWAL OF LICENSE NUMBER 34-19089-01

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Geneva, OH 44041

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Geneva, OH 44041

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David Cesar

TELEPHONE NUMBER

(216) 466-4671

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11 WASTE MANAGEMENT	12 LICENSEE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY <u>3B</u> AMOUNT ENCLOSED \$ <u>2,200.00</u>

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THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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ISSUING OFFICER - TYPED/PRINTED NAME AND TITLE

David Cesar, Treasurer

SIGNATURE

DATE

11-29-94

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

DEC 1

REGION III

397891
397891

ADVANCED MEDICAL SYSTEMS, INC.
LICENSE RENEWAL
LICENSE NO. 34-19089-01

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Advanced Medical Systems, Inc.

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November 29, 1994

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

RE: License No. 34-19089-01

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The second phase of this project would be to look into the WHUT Room, assess the contamination levels and obtain a videotape of the interior. This work is scheduled to be completed sometime the week of December 5. The Decommissioning Funding Plan is subject to change pending the results of the WHUT Room evaluation. The Decommissioning Funding Plan and WHUT Room Evaluation Report will be submitted to the NRC not later than December 31, which is the expiration date of our license.

The second item which needs to be resolved is the completion of our physical inventory. ALARON was in the week of November 14 with the contractor who will perform the destructive removal of the stuck floor plug. They observed the cell firsthand, took measurements and got an understanding on how helpful the manipulators will be during the operation. I hope to have a proposal from them the week of November 28. This is a priority project for us as it is our intention to remove all sealed sources and bulk capsules from our facility. Once the WHUT Room evaluation is complete, we will be able to concentrate on completion of the physical inventory.

Enclosed are the changes to our Materials License we wish to make at this time. Under Item 19 of our Materials License, numerous letters are referenced. I have reviewed these and provided comments on each in the Material License Renewal Application. It is my intention to remove references and conditions which no longer apply.

DEC 1

REGION 11

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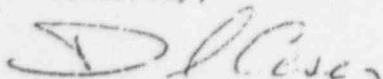
Mr. John R. Madera

-2-

November 29, 1994

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

Sincerely,

A handwritten signature in cursive script, appearing to read "D. Cesar".

DAVID CESAR
Treasurer

DC/mz
Enclosures

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