

April 12, 2005

Ms. Sherry J. Epstein, Treasurer
Advanced Medical Systems, Inc.
121 North Eagle Street
Geneva, Ohio 44041

SUBJECT: QUALITY ASSURANCE PROGRAM APPROVAL FOR RADIOACTIVE
MATERIAL PACKAGES NO. 71-0354, REVISION 10

Dear Ms. Epstein:

Enclosed is the Quality Assurance (QA) Program Approval for Radioactive Material Packages No. 0354, Revision No. 10. This Approval satisfies the requirements of 10 CFR 71.17(b) and 71.101(f) for a QA Program approved by the U. S. Nuclear Regulatory Commission (NRC).

This Approval will remain in effect until the expiration date, indicated in Block No. 3. Termination of your materials license does not cause this Approval to be automatically terminated. If you wish to renew, amend, or terminate this Approval, please request it in writing.

This letter also serves as a reminder that if you are using or planning to use an NRC-approved packaging, you must be registered for use of that packaging with NRC. Registration for use of NRC-approved packagings should be made pursuant to 10 CFR 71.17(c)(3).

Finally, please note that, in accordance with NRC Regulatory Information Summary 2004-18, we have extended your expiration date in Block 3 of the approval form.

Sincerely,

/RA/

Mary Jane Ross-Lee, Chief
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards

Docket No.: 71-0354

Enclosure: QA Program Approval No. 71-0354, Rev. 10

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*See previous concurrence

OFC:	SFPO	E	SFPO		SFPO	
NAME:	FGee*		MDeBose*		MRoss-Lee	
DATE:	4/5/05		4/ 5 /05		4/12 /05	

OFFICIAL RECORD COPY

0354

REVISION NUMBER

10

**QUALITY ASSURANCE PROGRAM APPROVAL
FOR RADIOACTIVE MATERIAL PACKAGES**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Title 10, Code of Federal Regulations, Chapter 1, Part 71, and in reliance on statements and representations heretofore made in Item 5 by the organization named in Item 2, the Quality Assurance Program identified in Item 5 is hereby approved. This approval is issued to satisfy the requirements of Section 71.101 of 10 CFR Part 71. This approval 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.

2. NAME

Advanced Medical Systems, Inc.

STREET ADDRESS

121 North Eagle Street

CITY

Geneva.

STATE

OH

ZIP CODE

44041

3. EXPIRATION DATE

April 30, 2015

4. DOCKET NUMBER

71-0354

5. QUALITY ASSURANCE PROGRAM APPLICATION DATE(S)

December 17, 1999; and January 26, 2005

6. CONDITIONS

1. Activities conducted regarding transportation packagings are to be executed under applicable criteria of 10 CFR Part 71, Subpart H. Authorized activities include: design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use of transportation packagings.
2. Records shall be maintained in accordance with the provisions of 10 CFR Part 71. Specifically:
 - a. Records of each shipment of licensed material shall be maintained for three years after that shipment [10 CFR 71.91(a)].
 - b. Records providing evidence of packaging quality shall be maintained for three years after the life of the packaging [10 CFR 71.91(d)].
 - c. Records describing activities affecting packaging quality shall be maintained for three years after this Quality Assurance Program Approval is terminated [10 CFR 71.135].
3. Planned and periodic audits of all aspects of the Quality Assurance Program shall be conducted in accordance with written procedures or checklists, by appropriately trained personnel not having direct responsibility in the areas being audited, in accordance with 10 CFR 71.137.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

SIGNATURE

/RA/

DATE

April 12, 2005

MARY JANE ROSS-LEE, CHIEF
TRANSPORTATION AND STORAGE SAFETY AND INSPECTION SECTION
SPENT FUEL PROJECT OFFICE
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS