

August 18, 1995

MEMORANDUM TO: Carl J. Paperiello, Director  
Office of Nuclear Materials Safety and Safeguards

FROM: Hubert J. Miller, Regional Administrator, RIII

SUBJECT: DEMAND FOR INFORMATION ISSUED TO ADVANCED MEDICAL  
SYSTEMS, INC.

Attached is a Demand for Information (DFI) with its accompanying transmittal letter for your review and approval.

RIII is proposing the issuance of the DFI to Advanced Medical Systems, Inc. (AMS) due to the concerns associated with: (1) the continued noncompliance of AMS with two NRC license requirements, and (2) the unnecessary risks posed by the storage of large quantities of cobalt-60 waste, facility surface contamination, and large amounts of unsealed and sealed cobalt-60 at the AMS facility.

Both documents have been reviewed by members of RIII, NMSS, and OGC.

Attachments: As stated

cc w/atts: H. Thompson, DEDO  
J. Lieberman, OE  
S. Lewis, OGC  
D. Cool, NMSS

CONTACT: James L. Caldwell, RIII/DRSS  
708/829-9801

DOCUMENT NAME: G:\LTRS2LIC\MTLS\030\95316055.DFI

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DATE	08/18/95		08/18/95		08/18/95		08/18/95

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION

In the Matter of

Advanced Medical Systems, Inc.  
Cleveland, Ohio

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Docket No. 030-16055  
License No. 34-19089-01

DEMAND FOR INFORMATION

I

Advanced Medical Systems, Inc. (AMS or Licensee) is the holder of NRC License No. 34-19089-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The license authorizes the Licensee to possess and use up to: (1) 150,000 curies of cobalt-60 as solid metal for storage only incident to waste disposal or transfer; (2) 135,000 curies of cobalt-60 in sealed sources for installation in, maintenance on, servicing and dismantling of, and training on teletherapy units; (3) 40,000 curies of cesium-137 for installation in, maintenance on, and servicing and dismantling of radiography and teletherapy units; (4) 4,040 kilograms of depleted uranium for shielding in radiography and teletherapy units; (5) 15,000 curies of cobalt-60 in non-NRC approved sealed sources for storage only; and (6) 15 millicuries of cobalt-60 in sealed sources for calibration of survey instruments. The license was originally issued on November 2, 1979, was renewed on December 13, 1989, with an expiration date of December 31, 1994, and was most recently amended on August 8, 1995. The Licensee submitted a timely renewal application, and the existing license continues to be effective pending completion of the NRC review of the renewal application.

II

The NRC has concerns related to the continued noncompliance of AMS with two NRC license requirements, and the avoidable risks posed by the storage of large quantities of cobalt-60 at the AMS facility. These concerns require that the Licensee address the issues discussed below.

A. Failure to Complete Physical Inventory

License Condition No. 14 of Amendment No. 27, which became effective on April 19, 1993, requires the Licensee to have conducted a physical inventory by June 1, 1993, and thereafter every sixty months to account for all sources and/or devices received and possessed under the license.

On March 30, 1993, the Licensee had completed all aspects of the required physical inventory except for the contents of the front storage well in the hot cell. The floor plug covering this storage well could not be removed; thus the sources within the cell could not be inventoried.

The Licensee made several attempts to remove the stuck floor plug in 1993 and in 1994 but was unsuccessful. Thus, to date the Licensee's inventory requirement has not been met.

#### B. Failure to Conduct Emergency Exercise

License Condition No. 18 of Amendment No. 25, which became effective on July 30, 1992, required the Licensee to conduct an emergency exercise every two years. During an NRC inspection conducted at AMS in October 1994, NRC inspectors identified that the Licensee had failed to conduct an emergency exercise.

By letter dated December 29, 1994, the Licensee indicated that a full-scale exercise with off-site emergency personnel would be scheduled by February 28, 1995 and conducted by August 31, 1995. To date the emergency exercise has not been scheduled and this requirement has not been met.

#### C. Avoidable Risks from Unused Materials and Extensive Contamination

Pursuant to 10 CFR 20.1101(b), a licensee is required to use, to the extent practicable, procedures and engineering controls to achieve radiation doses to workers and members of the public that are as low as is reasonably achievable (ALARA).

By letter dated June 16, 1995, the Licensee indicated that approximately 29 curies of packaged, solid cobalt-60 waste resides in the high-level waste storage room, and in boxes and drums in the basement. In addition, approximately 11 curies of cobalt-60 resides in various rooms in the facility as uncharacterized surface contamination. The waste and surface contamination have been accumulating for many years, and do not benefit the Licensee; rather, they pose avoidable risks to the workers, and potentially to members of the public.

Moreover, by letter dated January 26, 1995, the Licensee indicated that approximately 22,000 curies of unsealed and 48,000 curies of sealed source solid metal cobalt-60 resides at the facility. Prior to mid-1990, the Licensee used the unsealed material to manufacture sealed sources. This amount of unsealed cobalt-60 greatly exceeds the 5000 curie threshold in Schedule C of 10 CFR 30.72 requiring an emergency plan for responding to a release of radioactive material. Thus, NRC considers that the possession of this amount of material on site poses potential hazards to members of the public in the case of a release. The Licensee has not shipped any unsealed or sealed cobalt-60 offsite since 1994, when 4161 curies of cobalt-60 were shipped offsite. Since the Licensee is no longer manufacturing sealed sources and has no plans to make use of the sealed sources, this unsealed and sealed cobalt-60 does not benefit the Licensee and is not necessary for the Licensee's operations; rather, it poses avoidable risks to the workers, and potentially to members of the public.

In addition, in the June 16, 1995 letter, the Licensee indicated that approximately 40 curies of unpackaged cobalt-60 waste is contained in the Waste Hold Up Tank (WHUT) room. This room is no longer used and was made inaccessible to workers in the late 1980s. In a letter to the Licensee dated October 20, 1988, NRC authorized isolation and postponement of decontamination

of the WHUT room for a five year period, at which time the decision would be reevaluated. Due to the recent flooding of the AMS basement and the subsequent water removal and treatment project, it is very likely that the radiological conditions in the WHUT room have changed significantly since 1988. Therefore, it is appropriate at this time to reevaluate the postponement of decontamination of this room.

Due to the concerns associated with: (1) the Licensee continuing to be in violation of two NRC license requirements, and (2) the avoidable risks posed by the storage of large quantities of cobalt-60 waste, facility surface contamination, and large amounts of unsealed and sealed cobalt-60 at the AMS facility, it is necessary that the NRC have an integrated schedule from the Licensee outlining the sequence and steps, with projected milestone dates, that the Licensee will take to achieve compliance with NRC license conditions and to reduce the radiological risk to occupational workers, members of the public, and the environment.

### III

Accordingly, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 30.32(b), in order for the Commission to determine whether your license should be modified, suspended or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the Licensee is required to submit to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, IL 60532, within 45 days of the date of this Demand for Information, the following information in writing and under oath or affirmation:

A schedule, including the sequence of activities, with projected milestone dates and priorities, for the following activities. Include for each activity an outline describing how the activity will be completed. If some or all of the activities will occur sequentially, justify why they cannot occur in parallel.

- A. Inventory - License Condition 14
  - 1. Removal of the stuck plug of the front storage well
  - 2. Completion of the physical inventory
- B. Emergency Exercise - License Condition 18
- C. Reduction of Inventory - 10 CFR 20.1101(b)
  - 1. Offsite disposal of wastes
  - 2. Offsite transfer of unsealed byproduct material
  - 3. Offsite transfer of sealed byproduct material
- D. Decontamination - 10 CFR 20.1101(b)
  - 1. Decontamination of the hot cell
  - 2. Decontamination of the basement
  - 3. Decontamination of the Isotope Shop
  - 4. Decontamination of the Isotope Warehouse
  - 5. Decontamination of the HEPA filter room
  - 6. Decontamination of other contaminated areas

- E. Decommissioning/decontamination of the WHUT room - NRC letter dated October 20, 1988

A copy shall also be sent to the Assistant General Counsel for Hearings and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

After reviewing your response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.  
Deputy Executive Director for  
Nuclear Materials Safety, Safeguards,  
and Operations Support

Dated at Rockville, Maryland  
this \_\_\_\_ day of

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

SUBJECT: DEMAND FOR INFORMATION

Dear Mr. Cesar:

The enclosed Demand for Information (DFI) is being issued to Advanced Medical Systems, Inc. (AMS) due to the concerns associated with: (1) the continued noncompliance of AMS with two NRC license requirements, and (2) the avoidable risks posed by the storage of large quantities of cobalt-60 waste, facility surface contamination, and large amounts of unsealed and sealed cobalt-60 at the AMS facility.

Considering the resource requirements and difficulty of tasks currently being undertaken by AMS, the NRC deems it necessary, as discussed in the DFI, that AMS develops an integrated, comprehensive schedule outlining the sequence and steps, with projected milestone dates, that AMS will take to achieve compliance with NRC license conditions and to reduce the radiological risk to its workers.

Failure to comply with the provisions of this Demand for Information may result in civil or criminal sanctions.

Questions concerning this Demand for Information should be addressed to Mr. James L. Caldwell, Deputy Director, Division of Radiation Safety and Safeguards, Region III, who can be reached at (708) 829-9801.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.  
Deputy Executive Director for  
Nuclear Materials Safety, Safeguards,  
and Operations Support

Enclosure: As stated

See Attached Distribution

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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801 WARRENVILLE ROAD  
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