

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of)

Advanced Medical Systems, Inc.)
Cleveland, Ohio)

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

DEMAND FOR INFORMATION

I

Advanced Medical Systems, Inc. (AMS or Licensee) is the holder of U. S. Nuclear Regulatory Commission License No. 34-19089-01, issued by NRC (or Commission) pursuant to 10 CFR Part 30. The license authorizes the Licensee to possess and use up to: (1) 5,550 terabecquerels (TBq) [150,000 curies (Ci)] of cobalt-60 as solid metal, for storage only incident to waste disposal or transfer; (2) 5,000 TBq (135,000 Ci) of cobalt-60 in sealed sources for installation in, maintenance on, servicing and dismantling of, and training on teletherapy units; (3) 1,480 TBq (40,000 Ci) of cesium-137 for installation in, maintenance on, and servicing and dismantling of radiography and teletherapy units; (4) 4,040 kilograms (8,907 pounds) of depleted uranium for shielding in radiography and teletherapy units; (5) 555 TBq (15,000 Ci) of cobalt-60 in non-NRC-approved sealed sources, for storage only; and (6) 555 megabecquerels (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 NRC's review of the renewal application.

II

NRC is concerned about the avoidable risks posed by the storage of large quantities of radioactive material at the AMS facility, and the Licensee's continued noncompliance with two NRC license requirements, as described below.

A. 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.

Enclosure

We understand that AMS no longer intends to manufacture sealed sources and has no plans to make use of the majority of the sealed sources currently stored at the facility. In light of this, the radioactive material inventory, composed of "tens of TBq" ("kilocurie") quantities of sealed and unsealed sources, does not benefit AMS, and is not necessary for AMS operations. Although the material is properly stored, this storage poses avoidable risks to the workers, and potential risk to members of the public.

There also remains a large quantity of packaged low-level radioactive waste in the AMS facility basement, and radioactive surface contamination in various rooms in the facility, which have been accumulating for many years. This radioactive waste material serves no useful purpose to AMS operations and also poses avoidable risks to the workers, and potential risk to members of the public.

Furthermore, based on radiological surveys, "several TBq" ("tens of Ci") of radioactive material exist in the waste hold-up tank (WHUT) room, which is no longer used and was made inaccessible to workers in the late 1980s. In a letter to AMS dated October 20, 1988, NRC authorized isolation and postponement of decontamination of the WHUT room for a 5-year period, at which time the decision would be reevaluated. Because of the recent flooding of the AMS basement and the subsequent water removal and treatment project, it is possible that the radiological conditions in the WHUT room have changed. Therefore, it is appropriate at this time to reevaluate the decision to postpone the decontamination of this room.

B. Failure to Complete Physical Inventory

On July 26, 1990, a Notice of Violation (NOV) was issued to the Licensee for a violation of License Condition No. 14, which had become effective on January 26, 1988, and required the Licensee to conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. During the period January 1988 through January 26, 1990, the Licensee had not conducted this physical inventory. Subsequently, License Condition No. 14 was amended to require the Licensee to conduct a physical inventory of radioactive materials on or before June 1, 1993, and thereafter every 60 months, to account for all sources and/or devices received and possessed under the license. On August 13, 1993, NRC issued a letter to the Licensee stating that as a result of letters received from the Licensee dated May 17 and May 27, 1993, the NRC staff believed that the majority of the inventory was completed before June 1, 1993. In addition, the August 13 letter reflected the staff's understanding that an inventory of the radioactive material in the front well of the "hot cell" had not been performed before June 1, 1993, because the well plug could not be removed, and thus the sources within the well could not be inventoried.

Although the Licensee made several attempts to remove the stuck floor plug in 1993 and in 1994, the Licensee was unsuccessful and no inventory was conducted to determine the number of sources in the well. Thus, to date, the Licensee's inventory requirement has not been satisfied.

C. Failure to Conduct Emergency Exercise

License Condition No. 18 of Amendment 25, which became effective on July 30, 1992, required the Licensee to conduct an emergency exercise every 2 years. During an NRC inspection conducted at AMS in October 1994, NRC inspectors identified that the Licensee failed to conduct an emergency exercise. On November 29, 1994, NRC issued an NOV for, among other violations, this failure to conduct an emergency exercise. On December 29, 1994, AMS submitted a written response to the NOV in which a full-scale exercise with offsite emergency response personnel was estimated to be completed by August 31, 1995. On March 3, 1995, NRC acknowledged receipt of AMS' response to the NOV and stated that with regard to a full-scale exercise involving offsite emergency response personnel, the exercise should be conducted as soon as all off-site participants were prepared, and should not be delayed beyond July or August, 1995.

To date, the emergency exercise has not been conducted and this requirement has not been satisfied. However, NRC is aware that AMS will soon be submitting a revised emergency plan incorporating comments from both NRC and the local emergency response agencies. We understand that an emergency exercise will be planned and conducted after NRC review and approval of the emergency plan.

III

To provide NRC with the assurance that these significant issues will be appropriately prioritized, evaluated, and addressed, it is necessary for the Licensee to develop a comprehensive, integrated schedule outlining the sequence and steps, with projected milestone dates, that will be taken to reduce the radiological risk to occupational workers and members of the public, and to achieve compliance with NRC license conditions. The Licensee should particularly emphasize the reduction of the radioactive material inventory located within the facility, as this material poses the greatest risk relative to other issues confronting AMS.

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), for the Commission to determine whether your license should be modified, suspended or revoked, or other enforcement action taken to ensure compliance with NRC 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:

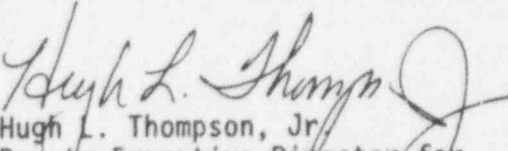
A schedule, including the sequence of activities, with projected milestone and completion dates and priorities, for the following activities. Include for each activity an outline describing how the activity will be completed. If some or all the activities will occur sequentially, justify why they cannot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

- A. Reduction of Inventory - 10 CFR 20.1101(b)
 - 1. Offsite transfer of sealed byproduct material
 - 2. Offsite disposal of wastes
 - 3. Offsite transfer of unsealed byproduct material
- B. Inventory - License Condition 14
 - 1. Removal of the stuck plug of the front storage well
 - 2. Completion of the physical inventory
- C. Emergency Exercise - License Condition 18
- D. Decommissioning/decontamination of the WHUT room - NRC letter dated October 20, 1988
- E. 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 high efficiency particulate air (HEPA) filter room
 - 6. Decontamination of other contaminated areas

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, 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

Date: October 3, 1995

Call made October 3, 1995 to Tom Lenhart (NEORS) ((216) 881-6600) at 4:30 pm our local time.

Information given: It has been sixty days since my last contact, and that being the Petition manager for the two 2.206 Petitions that NEORS has sent, I was calling to indicate that the draft director's decisions were in the OGC upper management level, being addressed.

(Petition Manager - Responsible for ensuring that the petitioner is notified at least every 60 days of the status of the petition, or more frequently if significant action occurs.)

Tom Lenhart asked how many Commissioners we presently had. I indicated that at present we had two, with Dr. Shirley Jackson as the Chairman, and that Greta Dicus was presently before Congress for confirmation as the third Commissioner.

Mr. Lenhart did not have any questions at this time.

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Date: December 4, 1995

Call made December 4, 1995 to Tom Lenhart (NEORSD) ((216) 881-6600) at 4:00 pm our local time.

Information given: It has been sixty days since my last contact, and that being the Petition manager for the two 2.206 Petitions that NEORSD has sent, I was calling to indicate that

a) the draft director's decision for the petition dated March 3, 1994 was in the OGC upper management level, being addressed;

b) the draft director's decision for the petition dated August 19, 1994 had been deferred until the completion of the license review hearing proceedings. This had been conferred to NEORSD in an NRC letter dated November 9, 1995.

(Petition Manager - Responsible for ensuring that the petitioner is notified at least every 60 days of the status of the petition, or more frequently if significant action occurs.)

Tom Lenhart asked about the Policy Issue Paper (SECY-95-162) and the progress on the option recommended to the Commission. He expressed a concern that a methodology in a pathway analysis based on dose may still not be adequate to protect the treatment plant from adverse effects of reconcentrated radioactive material.

Mr. Lenhart did not have any other questions at this time.

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