



Advanced Medical Systems, Inc.

1020 London Road
Cleveland, OH 44110
(216) 692-3270

June 8, 1995

Mr. James Caldwell
Nuclear Materials Inspection, Section 2
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: Application to Amend License No. 34-19089-01

Dear Mr. Caldwell:

On March 22, 1995, Advanced Medical Systems, Inc. (AMS) requested an amendment of License No. 34-19089-01 to permit evaporation of water stored in the warehouse of the London Road facility. On June 8, 1995, Mr. Wayne Slawinski forwarded to us a series of questions that pertain to this request. The following are our responses.

A. What is the status of the City of Cleveland/EPA evaporation permit request?

The City of Cleveland relinquished jurisdiction on this issue to the U. S. Environmental Protection Agency on May 5, 1995 (see Attachment 1). Mr. Michael H. Murphy (USEPA Region 5) reviewed our permit application (see Attachment 2) and gave verbal authorization to proceed to David Cesar (AMS) on or about May 23, 1995. His written authorization is expected shortly. We will forward a copy to you immediately upon receipt.

B. Where will the evaporator be installed within your facility? Who will install the system and provide training in its operation?

AMS intends to install the evaporator in the warehouse at the location shown on the map enclosed in the permit application (see Attachment 2). However, the recommendations of the installation contractor will be taken into account before the final siting decision is made. We anticipate using the services of McPhillips Plumbing, Heating and Airconditioning (Cleveland, Ohio) to provide the installation services (e.g., gas, water and electrical plumbing). However, if McPhillips cannot accommodate our installation schedule, another local company will be contracted. Training in the proper operation of the system will be provided to AMS by the vendor.

E/7

C. Has operation of the evaporator system inside your facility been evaluated as a potential fire hazard? For example, will evaporator system operation generate sufficient heat to actuate the facility's automatic fire suppression systems?

The evaporator design is fully automated for unattended operation in facilities like the AMS warehouse. Monitors and sensors report on the temperature of fluid in the evaporator tank, and the unit is automatically shut down if elevated temperature conditions exist. There is no viable mechanism whereby sufficient heat can be generated to actuate the facility's fire suppression system.

D. Is system use planned during unoccupied hours? What are the system's automatic operation and shutdown capabilities? Specifically, if the system is not continually monitored during its operation, what features detect excessive heat buildup and actuate system shutdown. See response to Question C. The permit applications (Attachment 2) were based upon an assumption of continuous (24-hour) operation. However, final decisions on operating hours will not be made until system installation, check-out, and final procedure development. The system will not be operated unattended if AMS, the evaporator vendor or the installation contractor deems it unsafe to do so.

E. Describe the water feed system from the 25,000 gallon collapsible storage bladders to the evaporator. If the feed system is automatic and will be operated unattended, also describe its automatic shutdown and safety features to prevent spills and overflows.

See response to Questions C and D. The type and operating procedures for the feed system will be determined by the evaporator vendor and the installation contractor. Whether the system will be operated unattended or not, applicable safety and spill-control procedures will be developed and implemented prior to routine system operation.

F. Where will evaporator effluents for "water vapor" and "burner exhaust" be discharged? Is water vapor exhaust discharged to the atmosphere or a condenser? Does the system generate airborne radioactive effluents; if yes, how will these effluents be evaluated for compliance with 10 CFR Part 20?

The stack description and discharge mechanism is described in the permit applications (Attachment 2). The system to be installed is a small-scale system, capable of evaporating only 30 to 37 gallons per hour. In addition, there is no mist carryover from the unit. Therefore, radionuclide emissions will not occur. However, for the purposes of permitting and demonstrating compliance with USNRC (10 CFR 20) and USEPA (40 CFR 61, Appendix D) requirements, and to permit the use of a computer model for determining off-site population doses, a mist carryover rate and an emission factor of 100% was assumed. Using the COMPLY code, the postulated annual emissions using this unrealistically-conservative scenario, are 45.4 microcuries in 1995 (during the current remediation effort) and 37.9 microcuries for future years (if it continues to be used). Consequently, the effective dose equivalent calculated for the maximally-exposed individual (Level 4 Compliance) is 1.2 millirem during 1995.

G. Describe the methods and equipment that will be used to conduct a radiological analysis of the solids removed from the evaporator. How will these solids be removed from the evaporator system?

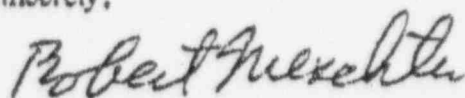
The specific procedure for removal and analysis of solids will be determined after system installation and checkout. Analytical methodologies being considered include gross screening, gamma spectroscopy, and others that would typically be used to determine the radiological constituents in solids.

H. Develop and submit a Standard Operating Procedure for monitoring and surveillance of the evaporator system.

A standard operating procedure (ISP) for operation and surveillance of this unit will be developed after system installation and checkout. The procedure will be reviewed and approved by the AMS RSO and the Isotope committee prior to implementation.

We hope that this information will permit you to complete your evaluation of our request to evaporate the treated water that currently exists in the warehouse at the AMS building. However, please call me at (216) 692-3270 if additional information is required. We are looking forward to your timely authorization to proceed.

Sincerely,



Robert Meschter, RSO

cc: D. Cesar
D. A. Miller, Esq., Stavole & Miller



COUNTY OF
CUYAHOGA

**Cuyahoga Emergency Management
Assistance Center (CEMAC)**

Commissioners

Mary O. Boyle
Timothy F. Hagan
Lee C. Weingart

June 9, 1995

Jane Harf
Ohio SERC
P.O. Box 163669
Columbus, Ohio 43216-3669

Re: Supplement to the Cuyahoga County Local Emergency Planning Committee's ("LEPC")
Requests for a Variance and for an Additional Facility Designation

Dear Ms. Harf:

The Cuyahoga County LEPC has requested that the Ohio State Emergency Response Commission ("SERC") grant a variance for the Cuyahoga County Local Emergency Planning District ("LEPD") that would authorize it to require Cuyahoga County facilities to submit annual inventories of ⁶⁰Cobalt in excess of "10 curies in any form other than a sealed source," and has further requested that the SERC designate Advanced Medical Systems, Inc. as an "additional facility" under Division (A) of Section 3750.05 of the Ohio Revised Code "for the development and annual update of the LEPC's SARA Plan." These two requests were well documented in the LEPC's request submitted on February 7, 1995 and in its supplemental request submitted on April 3, 1995. LEPC members and representatives have also appeared before both the SERC and the SERC Executive Committee on two previous occasions.

At the SERC meeting on April 12, 1995 it was requested that the LEPC submit a general summary of its formal requests, which had been designed to meet SERC legal requirements. I have attached the summary requested, and have also attached a letter of support from the Cleveland Fire Department.

The LEPC believes that its previous submittals have documented the need for these requests and that the requirements outlined in Ohio Revised Code Sections 3750.02(B)(2)(e), 3750.11(B), 3750.03(E)(3) and 3750.05(A) have been met. The LEPC believes that its requests, if granted,

E/S

COUNTY OF
CUYAHOGA

Jane Harf
Ohio SERC
June 9, 1995

will provide for improved emergency preparedness in the City of Cleveland and the Cuyahoga County LEPC in accordance with the local objectives of the Emergency Planning and Community Right-to-Know Law. Please give them your careful consideration. If you have any questions please contact me by telephone at (216) 443-7597 or by fax at (216) 443-5705.

Sincerely,



Michael S. Kalstrom, M.S.
Secretary, Cuyahoga County LEPC

encl.

cc: James L. Caldwell, Deputy Director, NRC Region III
David Cesar, AMS
Larry K. English, NEORS
Chief William Fisher, Vice Chairman, Cuyahoga County LEPC
Martha McCorkle, Cleveland Law Department
Edmund M. Mecklenburg, Cuyahoga County Emergency Management Div.
Timothy Kollin, Cuyahoga County Prosecutor's Office
Robert J. Patton, Chairman, Cuyahoga County LEPC
Chief Thomas Root, Cleveland Fire Department
Robert Staib, Cleveland Health Department

SUMMARY

CUYAHOGA COUNTY LEPC VARIANCE AND ADDITIONAL FACILITY DESIGNATION REQUESTS

What has been requested?

The Cuyahoga County LEPC has requested that the SERC take the following actions:

1. Grant a variance that would authorize the Cuyahoga County LEPC to require that all facilities within the Cuyahoga County Local Emergency Planning District (LEPD/Cuyahoga County) forward an annual inventory for all unsealed sources of ⁶⁰Cobalt stored in excess of 10 curies. In other words 10 curies would be established in Cuyahoga County as an annual inventory threshold for unsealed sources of ⁶⁰Cobalt. Granting this request would affect only one facility at this time, Advanced Medical Systems, Inc. It is the only facility in Cuyahoga County known to store more than 10 curies of unsealed sources of ⁶⁰Cobalt.
2. Designate Advanced Medical Systems, Inc. ("AMS") as an "additional facility" subject to the requirements of Sections 3750.05 and 3750.04 of the Ohio Revised Code. This would authorize the Cuyahoga County LEPC to request from AMS "the information necessary for developing and implementing the chemical emergency response and preparedness plan for the Cuyahoga County LEPD" under Section 3750.05(C) and to add Advanced Medical Systems, Inc. to the 307 facilities currently included in its SERC required "SARA Plan."

Why have these requests been made?

1. To improve local emergency response preparedness in the City of Cleveland and Cuyahoga County.
2. To secure accurate, detailed information regarding the amounts and locations of radioactive materials stored at Advanced Medical Systems, Inc. The LEPC has been working on this issue for over seven months, but still has not received a credible accounting of the amounts and locations of these materials from either AMS or the Nuclear Regulatory Commission ("NRC").
3. To secure a hazards analysis for this facility that meets current standards for local facilities storing extremely hazardous substances and to include this information in local plans for emergency response (including the SARA Plan and the Cleveland Fire Department's Pre-Plan for AMS). Current procedures for Cuyahoga County are summarized in Attachment B of the document submitted to the SERC on April 3, 1995.

Cuyahoga County LEPC
Variance and Facility Designation Requests
June 9, 1995

4. To assure annual updates of the information requested. This request would allow annual updates for the LEPC, for the Cleveland Fire Department and for the SERC. The NRC requires a complete inventory of all radioactive material only every five years, and the "current" update, which was due on June 1, 1993, has not been completed.
5. To provide a local mechanism to assure the cooperation of Advanced Medical Systems, Inc.

These requests are not an attempt to preempt the authority of the Nuclear Regulatory Commission. On the contrary, the LEPC is aware of no conflicts between its petitions and NRC regulations, and believes that the establishment of the local authority outlined above would supplement the efforts of the NRC, by helping to improve the information provided by AMS. The LEPC also believes that the NRC should welcome and encourage this kind of local initiative, which should enhance its performance and provide assurance that the local community is prepared to respond to emergency incidents. These first responders will be required to make important decisions prior to the availability of on-scene assistance from the NRC.

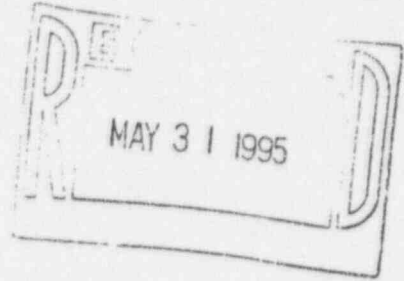


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(216) 664-6800
FAX (216) 664-6816

City of Cleveland

MICHAEL R. WHITE, MAYOR

WILLIAM E. LEE
CHIEF OF FIRE



May 25, 1995

Ms. Jane Harf, Chairperson
Ohio State Emergency Response Commission
Emergency Planning & Right-to-Know
P. O. Box 163669
1800 Watermark Drive
Columbus, OH 43216-3669

RE: 1020 London Road
Cleveland, OH
Advanced Medical
Systems

Dear Ms. Harf:

The Cleveland Fire Department supports the variance and additional facility designation requests regarding Advanced Medical Systems, 1020 London Road in Cleveland, which have been submitted to the Ohio State emergency Response Commission by the Cuyahoga County Local Emergency Planning Committee (LEPC). I am a member of the LEPC and requested its assistance in this matter last November. The Cleveland Fire Department believes that Advanced Medical Systems, Inc. should be required to annually report the exact location and amounts (in curies) of all unsealed sources of cobalt-60 on site and that this facility should also be required to forward planning information each year so that it can be included in the LEPC's emergency response plan for hazardous materials.

This request is based upon the following:

1. If a fire should occur at the facility one major concern is contamination off-site. The Cleveland Fire Department must decide either to extinguish the fire with water or to let the facility burn and protect exposures. In either case, there will be contamination spread - either by water or by heat and smoke.

1., Continued:

The Nuclear Regulatory Commission could not advise on which method would best control the contamination. Therefore, it is imperative that the first responders have precise knowledge of the inventory and hazardous areas to make response decisions.

This information needs to be supplied annually to effectively meet our fire pre-planning requirement.

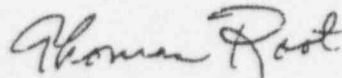
2. The Nuclear Regulatory Commission is the Federal licensing agency. They are not on site and in any emergency their response to the site would be well after the Cleveland Fire Department had committed to a containment or extinguish strategy.
3. This request in no way infringes upon the Nuclear Regulatory Commission's jurisdiction nor does it in any way attempt to regulate or suggest regulation of any radiological material. The request is for information planning that will help protect the citizens of Cleveland.
4. The current characterization of community risk from this facility is inadequate. If there is little risk to the community, as claimed by Advanced Medical Systems, why has the LEPC's request been challenged?
5. In meetings in the summer of 1994, Advanced Medical Systems advised that they had a buyer for the Cobalt 60 and that the material would be shipped by the end of the year. This did not take place. It is likely that this material will remain on site through enough half-lives to be rendered inert.
6. This request places no great financial burden on the Advanced Medical Systems facility and the LEPC is requesting only that they act in a responsible manner, as thousands of other hazardous facilities have done voluntarily throughout the State of Ohio.

Advanced Medical Systems
May 25, 1995
page 3 of 3

7. The Fire Service in the State of Ohio has dedicated hundreds of man hours in assisting the local communities and the State in implementing Chapter 3750 of the Ohio Revised Code. The Cleveland Fire Department is now asking for your assistance.

If you have any questions regarding this matter, please contact me at [216] 664-6664.

Sincerely,



Battalion Chief Thomas Root
Fire Marshal

TR/pjp

cc: William E. Lee, Chief of Division
James J. McNamee, Chief, Ohio Fire Marshal
Michael S. Kalstrom, SARA Information Coordinator
Edmund M. Mecklenburg, Mgr., CC Emergency Management
Robert J. Patton, Chairman, Cuyahoga County LEPC
Ken Schutz, Ohio SERC
Robert Staib, Dir., Environmental Health (City)
file

June 9, 1995

Advanced Medical Systems, Inc.
ATTN: David Cesar
Treasurer
121 North Eagle Street
Geneva, OH 44041

Dear Mr. Cesar:

The U.S. Nuclear Regulatory Commission (NRC) recently received concerns regarding certain of your recent and past NRC licensed activities. Details of these concerns are enclosed for your review and followup.

We request that you evaluate these concerns and that the results of your review be submitted to Region III within 30 days of the date of this letter. We request that your response contain no personal privacy, proprietary, or safeguards information so it can be released to the public and placed in the NRC Public Document Room. If necessary, such information shall be contained in a separate attachment which will be withheld from public disclosure. The affidavit required by 10 CFR 2.790(b) must accompany your response if proprietary information is included.

The enclosure to this letter should be controlled and distribution limited to personnel with a "need to know" until your investigation for these matters has been completed and reviewed by NRC Region III. The enclosure to this letter is considered Exempt from Public Disclosure in accordance with Title 10, Code of Federal Regulations, Part 2.790(a). However, a copy of this letter, excluding the enclosure, will be placed in the NRC Public Document Room.

The response requested by this letter and the accompanying enclosure are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated. We will gladly discuss any questions you may have concerning this information.

Sincerely,
Original signed by James L. Caldwell

James L. Caldwell, Deputy Director
Division of Radiation Safety and Safeguards

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

Enclosure: Details
(10 CFR 2.790(a) INFORMATION)

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