

June 7, 1995

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

Dear Mr. Cesar:

We have completed our review of your Emergency Plan (EP) submitted with your application for renewal of NRC License Number 34-19089-01 and find that we will need additional information as follows:

I. General Comments

- A. Due to the limited number of staff at your facility responsible for emergency response actions, we are concerned that you may not be able to effectively implement your Emergency Plan. Please provide an assessment regarding your ability to effectively implement your EP, and illustrate how current staffing levels will be able to fulfill all of the functions and responsibilities described in the plan.

As an alternative, you may wish to secure the services of a consultant to support implementation of the plan should an emergency occur. If you chose such an option, please submit a copy of the agreement describing the delineation of duties between AMS and the consultant.

- B. Section 3 of the EP includes your consultant's offsite dose assessment for a vandalism induced fire and explosion involving 15 curies of radwaste in the basement of the facility. The consultant's assessment also discusses natural disasters, discounting the release of radioactivity from such events due to their infrequent occurrence and because the majority of the cobalt-60 inventory is in "primary containment that is resistant to ready release." However, the assessment did not provide sufficient justification to support your conclusion that the worst case scenario would involve only 15 curies of radwaste. Specifically, your assessment did not adequately evaluate the effect of natural disasters and fire/explosion on the radioactive material you currently possess in various areas of your facility in the form of bulk and sealed sources. You currently possess about 70,000 curies of cobalt-60 in bulk and sealed source form.

E/S

In order to support your conclusion, you must conduct an engineering analysis of the facility structure and primary containment systems housing your cobalt-60 inventory to demonstrate its integrity will be maintained during a natural disaster or fire/explosion. The structural assessment of the facility and containment systems should also include the WHUT room and the offsite dose consequences if it is determined that the room's cobalt-60 inventory could be released to the environment. For example, evaluate the scenario of falling structural debris from an earthquake/tornado striking several containers of bulk cobalt-60 and releasing its contents. The loose bulk material is then exposed to a fire caused by a ruptured natural gas line in the building. Also, please evaluate the potential for an earthquake to crack the foundation of the building near the isotope garden, allowing a beam of unshielded radiation to exit the facility. Guidance for such an engineering analysis for reinforced concrete structures, for example, is contained in three documents of the American Concrete Institute (ACI) as follows. ACI 437R-91, "Strength Evaluation of Existing Concrete Buildings," ACI 201.1R, "Guide for Making a Condition Survey of Concrete in Services," and ACI 364.1R-94, "Guide for Evaluation of Concrete Structures Prior to Rehabilitation." As an example of a potential natural event, one should consider the ramifications of the January 31, 1986 NE Ohio seismic event on the facility and the magnitude of future seismic events.

In addition, the possibility of damage from an earthquake/tornado breaching the shield window to the hot cell, allowing an unshielded beam of radiation to exit the cell should also be evaluated. The potential direct radiation levels in the building and in unrestricted areas outside the building resulting from this breach should be calculated.

II. Facility Description

- A. Section 1.1 of your EP does not include the 40 curies of cobalt-60 in the form of radwaste specified in Section 1.1 of the license application nor the cobalt-60 waste housed in the WHUT room. This section should match the possession limits specified in the license and as discussed in Item III.A. of our deficiency letter dated April 17, 1995.
- B. The plan lacks a detailed site drawing as suggested in Section 1.2 of Regulatory Guide 3.67. Figure 1-11 provides a general area drawing and Figures 1-8, 1-9, and 1-10 provide floor plans for the interior of the building. The plan should contain a detailed drawing of the entire site showing or indicating the following information:

- (1) The property boundary and all structures on the property and within approximately 100 meters of the property boundary (with descriptive labels).
- (2) A bar scale and a compass indicating North.
- (3) Roads and parking lots onsite and within approximately 100 meters of the property boundary.
- (4) All fences and gates onsite.
- (5) Exhaust stacks, storage areas, and other significant site features. The fire pumphouse on Mandalay Avenue that will be used as the command center during an emergency should be shown.

We are concerned about the adequacy of the fire pumphouse on Mandalay Avenue as your proposed command center during an emergency. Unless the pumphouse is owned by AMS, you must describe the arrangements that have been made with the owner(s) to use the pumphouse. Also, demonstrate how communications will be arranged so that individuals at the pumphouse can keep in contact with response groups, government agencies, etc.

- C. The plan should describe any hazardous chemicals used at the site including typical quantities possessed and locations of storage and use.
- D. The terminology used to describe areas in the facility should be consistent with the labeling on Figures 1-8, 1-9, and 1-10 of your plan. The paragraph at the bottom of page 1-4 refers to a decontamination room, but no decontamination room is identified on Figure 1-8. Likewise, the discussion on page 1-6 refers to the change areas and the control area, but these areas are also not identified on Figure 1-8. Please review the description of each area in the facility (primarily in Chapters 1 and 2) and verify that each area is clearly identified on Figures 1-8, 1-9, and 1-10 using the same terminology.
- E. The description of the air handling system on page 1-6 should include the stack height, flow rate, and the efficiency of the emission control devices. Incorporate this information into your EP.

- F. The quality of Figure 1-11 of your EP is poor and some of the symbols are hard to read. It is difficult to identify the location of the site. The site should have a larger label so it is easier to identify. The schools, hospitals, and other major facilities within 1 mile of the site should be identified by name. The nearest fire and police stations should be identified by name also. Please submit a modified figure(s) to address these concerns.

III. Classification and Notification of Accidents

- A. The second action item in Sections 3.2.1 and 3.2.2 of your EP should state that the NRC Operations Center shall be notified immediately after the State and local response organizations are notified, but no later than 1 hour after an Alert or Site Area Emergency is declared.
- B. The first action item in Section 3.2.2 should include an initial offsite protective action recommendation for the offsite officials. By definition, a Site Area Emergency is an event that could require actions by offsite response organizations to protect persons offsite (sheltering, evacuation, etc.). The plan should contain the initial protective action recommendations that have been established in advance for transmittal with the initial notification. If there are no postulated accidents which would require actions by offsite response organizations to protect persons offsite, then there would be no need to declare a Site Area Emergency or prepare protective action recommendations. Please make the necessary modifications to address this issue.

In addition, your plan should contain emergency action levels (EALs). EALs are site-specific equipment readings or readily available indicators that will be used to immediately declare an Alert or Site Area Emergency. EALs should be based on conditions that can be identified within the first few minutes of an accident. Refer to Appendix A of the enclosed Regulatory Guide 3.67 for a list of example initiating conditions for declaring an Alert or Site Area Emergency.

- C. Modify Section 3.2 so that your definitions for "Alert" and "Site Area Emergency" match the definitions for these terms in 10 CFR 30.4 (enclosed).

IV. Types of Accidents

- A. The consultant's report beginning on page 3-5 provides a detailed analysis of one scenario (fire involving radioactive waste). The quantity of cobalt-60 assumed to be involved in the fire is 15

curies, however, the renewal application requests authorization to possess 40 curies of cobalt-60 in the form of radioactive waste. It would appear that the worst case situation in this scenario would be a fire involving 40 curies of cobalt-60. The analysis should assume that a deliberately set fire would involve the entire inventory of radioactive waste. If there are specific license restrictions which would limit the amount of radioactive waste available for this scenario, those restrictions should be clearly stated. Also, you should include the inventory in the WHUT room with the scenario, or provide justification why it should not be included in the source term.

- B. Section 5.3 of your plan contains a statement that Chapter 3 described the postulated accidents as spills, fires, and natural phenomena. However, Section 3.3 lists the postulated accidents as fires, natural disasters, and vandalism. Please review these chapters and make the necessary changes so that they are consistent.

V. Responsibilities of Key Individuals and Groups

- A. Section 3.0 in Appendix A states that the Director of Regulatory Affairs has certain responsibilities including the quarterly communications checks to verify telephone numbers. However, Section 7.3 of the plan states that the Radiation Safety Officer (RSO) is responsible for the quarterly checks. The conflicting responsibilities should be resolved and the role of the Director of Regulatory Affairs (and any other company officials) in the emergency response program should be clearly defined in Chapter 4 of the plan.
- B. Section 4.1 of the plan, entitled "Normal Plan Operations" states that the RSO has overall responsibility for all aspects of the facility. Section 4.1 should provide a brief description of the entire organization present at the facility under normal circumstances.
- C. Section 4.2.1 states that when the RSO is absent, "the emergency personnel on call will contact offsite authorities." It is unclear which individuals serve as the emergency personnel on call. The plan should identify who is responsible for declaring an emergency and assuming the role of Emergency Manager when the RSO is absent.
- D. The description of the emergency organization in Sections 4.2 through 4.2.2.3 is too vague. The plan should describe how many workers have been assigned to support the RSO in responding to an emergency, and how many workers are simply responsible for

evacuating when an alarm sounds. Organizational charts comparing the normal facility organization to the emergency organization would be helpful. We have concerns that a single individual cannot reasonably be expected to fulfill all of the responsibilities assigned to the RSO in an emergency. The plan should describe the number of workers assigned to each applicable function listed in Section 4.2.2 of Regulatory Guide 3.67. It is unclear who is responsible for controlling site access and maintaining security during an emergency.

- E. Section 4.3 states that arrangements have been made with local police, fire, and medical services to respond to emergencies at the site. No letters of agreements were found in the plan or the renewal application. Please establish and submit for our review, formal letters of agreement with each offsite response organization and submit copies of the letters signed by each organization to NRC with the emergency plan.
- F. Section 4.3 states that letters indicating to whom the plan was sent are contained in Appendix B to the plan. Appendix B, however, contains maps and drawings. Please submit the letters for our review. Also, pursuant to 10 CFR 30.32(i)(4), provide any comments received from those offsite response organizations.
- G. Section 4.4 contains a single statement that the Ohio Emergency Management Agency maintains the Governor's response team for radiation accidents. Based on correspondence from the City of Cleveland and the Cuyahoga Emergency Management Assistance Center, it appears that there are city and county agencies that have responsibilities for emergencies at the facility also. For each of these agencies, the plan should describe the following:
 - (1) Its authority and responsibility in an emergency at the facility.
 - (2) Its specific response capabilities in terms of personnel and resources.
 - (3) Its location with respect to the facility.
 - (4) The rumor control arrangements that have been made including where the public and media can obtain information during an emergency.
- H. The emergency plan should contain a commitment to meet at least annually with each offsite response organization to review items of mutual interest, including changes to the licensee's program, the emergency action level scheme, notification procedures, and response coordination.

VI. Emergency Response Measures

- A. Section 5.5 of your EP states that the U.S. Environmental Protection Agency (EPA) guidelines for emergency exposures are 75 rem for lifesaving actions and 25 rem to protect the facility and control fires. The EPA Manual of Protective Action Guides and Protective Actions for Nuclear Incidents (EPA 400-R-92-001) was revised in 1991. The current EPA guidelines are 5 rem for general emergency actions, 10 rem for protecting valuable property, and 25 rem for lifesaving or protection of large populations. Lifesaving actions exceeding 25 rem should be authorized only on a voluntary basis to persons fully aware of the risks involved (e.g., informed consent). Tables describing the risks are provided in the EPA manual. The emergency plan should be consistent with the current EPA guidelines. (See Sections 5.5, 5.5.1, 9.1, and the emergency procedures in Appendix A.) Training offered to offsite rescue personnel should include the health risks associated with emergency exposures exceeding 25 rem so these individuals can decide in advance if they would be willing to volunteer for such lifesaving actions during an emergency at the facility. The emergency plan should describe how the Emergency Manager/RSO will verify that a person is aware of the health risks before authorizing emergency exposures exceeding 25 rem. Please make the necessary modifications to your plan as noted above, and submit them for our review.
- B. Section 5.5.3 should describe how you will assure that all offsite response personnel entering the building during a fire or other emergency have been issued a dosimeter before they enter the building. The means of tracking the number of dosimeters issued, who wore each dosimeter, and the number of dosimeters returned should be described.
- C. Sections 5.6 and 5.7 should provide a better description of how contamination inside the ambulance and at the hospital will be controlled. Will licensee personnel always travel with the ambulance to the hospital to survey and release the ambulance and hospital treatment areas, or are there other qualified individuals at the hospital who can survey and release areas when licensee personnel are not available?
- D. Section 5.7 should describe the hospital's capability to evaluate and treat injuries from radiation exposure. Does the hospital have a nuclear medicine department with in-house expertise, or do they plan to use medial consultants such as the Department of Energy's Radiation Emergency Assistance Center/Training Site (REACTS)? It is often useful to have the hospital describe its capabilities in its letter of agreement.

- E. Section 7.4.2.b in Appendix A states that when smoke or fumes can be seen coming from the facility, response personnel remain upwind and police should establish road blocks to prevent traffic from passing through the downwind area. This appears to be a protective action recommendation for offsite officials. If actions by offsite officials to protect persons offsite are necessary for any airborne release, a site area emergency should be declared and an initial protective action recommendation, such as Section 7.4.2.b, should be transmitted with the initial notification to offsite officials. The procedures in Appendix A and the classification scheme in Chapter 3 should be consistent, and should clearly state how each type of emergency will be classified and what initial protective action recommendations will be made to offsite officials.
- F. Sections 13, 14, and 15 in Appendix A contain rules for ambulance and hospital personnel based on Department of Energy (DOE) documents. It is not clear whether ambulance and hospital officials have agreed to adopt these rules and train their staff to follow them. In addition, it is not clear that all of the rules are appropriate. The following are some examples that should be addressed:
- (1) Section 13.2.2 in Appendix A instructs rescue squad personnel to perform surveys, but it is not clear that rescue squad personnel will have the equipment and training to perform that function.
 - (2) Section 14.2 of Appendix A instructs emergency room personnel to notify trained health physicists/technicians and obtain a survey meter, but it is not clear that the hospital has the equipment or staff required.
 - (3) The statement at the bottom of page 11 of Appendix A refers to hospital procedures for radioactive liquid waste, but it is not clear that the hospital has such procedures.
 - (4) Section (g) on page 12 of Appendix A refers to a consultant who will provide detection equipment and treatment advice, but it is not clear that arrangements for such a consultant have been made.
 - (5) Section 15.2 instructs the hospital administrator to notify DOE and consult with DOE officials. There is no reference to NRC and it is not clear exactly which DOE officials are to be contacted.

VII. Emergency Response Equipment and Facilities

The list of emergency supplies in Section 6.4 should specify the minimum quantity of each item that will be stored. For each survey meter/frisker, the plan should describe the type of detector, the range of detection, and calibration of the instrument.

VIII. Maintaining Emergency Preparedness Capability

- A. Section 7.2 of your EP states that staff with limited emergency responsibilities receive limited emergency response training. This description of the training program is inadequate. Section 4.2.2.2 states that "supporting staff" shall assist the Emergency Manager/RSO with dose assessment, personnel monitoring, surveys, and decontamination. It appears that supporting staff may be required to use respirators to perform some of these functions. Section 7.2 should specify the topics and general content of the training that the supporting staff will receive to fulfill the responsibilities listed in Chapter 4. The plan should specify the frequency of retraining, and the estimated number of hours of initial training and retraining that will be provided. Section 8.2 implies that there will be annual retraining for some personnel, but the applicability of the statement is unclear. Please clarify this issue.
- B. Section 7.2 should describe the instructions and orientation tours that the applicant will offer fire, police, medical, and other offsite response personnel. You may wish to coordinate this training with the annual meeting with offsite response organizations (see Item V.H).
- C. Section 7.3 should specify that one or more nonparticipating observers will be used during drills and exercises to evaluate the effectiveness of the response and recommend changes for improvement. The plan should describe how criteria for acceptable performance will be developed and provided to these observers. Also, the plan should specify that exercise scenarios will not be known to exercise participants.
- D. Sections 7.4 and 7.5 should specify who will be responsible for tracking findings from critiques and audits, and verifying that corrective actions are completed. In addition, Section 7.5 should specify that audits will be performed by persons not having direct responsibility for implementing the emergency response program. Section 7.6 should specify that equipment calibration dates and material shelf lives will be tracked, and that operational checks of equipment will be performed.

IX. Records and Reports

- A. Section 8.2 of your EP should state that training records will include lesson plans and test questions used in training sessions. Letters of agreement with offsite response organizations should also be maintained in the records.
- B. Section 8.3 should specify a minimum frequency of updates after the initial notification. This frequency may be revised during an emergency by mutual agreement of the parties involved.

X. Recovery and Plant Restoration

- A. Section 9.1 specifies that whole body exposures will be limited to 3 rem/quarter during re-entry. A quarterly exposure limit conflicts with occupational limits of 5 rem per year annual dose in 10 CFR Part 20. Radiation exposures during re-entry and restoration should be kept within normal occupational limits. Modify your dose limit to be consistent with 10 CFR Part 20.
- B. Section 9.3 should describe provisions for documenting the recovery effort and maintaining records important to decommissioning pursuant to 10 CFR 30.35(g). Please make this modification.

XI. Compliance with Community Right-to-Know Act

Your emergency plan does not contain a certification that AMS has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986. A certification or an explanation why this Act is not applicable to the applicant's activities must be provided.

XII. List of Effective Pages

The table of contents of your Emergency Plan should include a list of effective pages. This list should include every page of the plan (including enclosures and attachments) and the revision number or date of each page. In addition to the list of effective pages, the page numbering in the plan does not follow the standard format described in Regulatory Guide 3.67. The revision number or date does not appear at the bottom of each page. Several pages in the appendices have no page number and those that are numbered do not reflect the appendix designation (e.g., A-1, B-1). Please modify your table of contents and appendices accordingly.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 398538.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 829-9887.

Sincerely,

Original Signed By

Original Signed by John R. Madera

J. R. Madera, Chief

Nuclear Materials Licensing Section

License No.: 34-19089-01

Docket No.: 030-16055

Enclosures: 1. Regulatory Guide 3.67
2. P&GD 84-14, Rev. 1
3. 10 CFR Parts 20 and 30

cc w/o encl: Ms. Jane Harf
State Emergency Response
Commission

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DATE	06/7/95									

on 6/7/95

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June 8, 1995

Northeast Ohio Regional Sewer District
ATTN: Lawrence K. English
Assistant General Counsel
3826 Euclid Avenue
Cleveland, Ohio 44115-2504

Dear Mr. English:

This responds to your letters dated April 6, 1995 and May 4, 1995, regarding Advanced Medical System's (AMS's) submittal of its radiological emergency plan (EP) to the Northeast Ohio Regional Sewer District (NEORS) for review and comment. Your April 6, 1995 letter informed us that NEORS is a first responder to emergencies including fires, floods and spills. The NEORS's radiological emergency response status was not known to our organization prior to your April 6, 1995 letter.

On May 12, 1995, our office was informed by AMS that its EP was delivered via certified mail to the NEORS on April 26, 1995, and a return receipt was obtained. This information was confirmed in a May 22, 1995 letter from AMS.

Based on your May 22, 1995 telecon with Mr. Madera of my staff, we understand that the NEORS received the AMS EP. Pursuant to 10 CFR Part 30.32(i)(4), AMS is required to allow offsite response organizations, expected to respond in case of an accident, 60 days to comment on its EP. Comments received within the required time frame shall be provided to the NRC. Accordingly, should the NEORS have comments on the AMS EP, please provide them to AMS within 60 days of your receipt of the plan.

If you have any other questions regarding this matter, please do not hesitate to contact Messrs. John Madera or Wayne Slawinski of my staff.

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

See Attached Distribution

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Northeast Ohio Regional
Sewer District

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Distribution

cc w/ltrs dtd 4/6/95; 5/4/95
and 5/22/95:

D. Cesar, Treasurer
Advanced Medical Systems, Inc.
121 N. Eagle Street
Geneva, OH 44041

Marian Zobler
U.S. Nuclear Regulatory Commission
Rockville, MD 20852

Robert Meschter
Radiation Safety Officer
Advanced Medical Systems, Inc.
121 N. Eagle Street
Geneva, OH 44041

Robert E. Owen, Administrator
Department of Health
246 North High Street, 3rd Floor
P.O. Box 118
Columbus, OH 43266

Michael R. White, Mayor
City of Cleveland
601 Lakeside Avenue
Cleveland, OH 44114

Lisa Mehringer
City of Cleveland Law Department
601 Lakeside Avenue, Room 106
Cleveland, OH 44114

Erwin J. Odeal, Executive Director
Northeast Ohio Regional Sewer District
3826 Euclid Avenue
Cleveland, OH 44115

Erv Ball, Deputy Director
Cuyahoga County Board of Health
1375 Euclid Avenue, Suite 524
Cleveland, OH 44115

Michael Kalstrom, Secretary
County of Cuyahoga
Cuyahoga Emergency Management
Assistance Center
1255 Euclid Avenue, Room 102
Cleveland, OH 44115-1807

Jane Harf, Chairperson
Ohio State Emergency Response
Commission
1800 Watermark Drive
P.O. Box 163669
Columbus, OH 43219-3669

bcc:

Cathy Haney, NMSS
PUBLIC IE07
AMS File

E-mail:

Bruce Berson (BAB1)
Bill Brach (EWB)
Jim Caldwell (JLC1)
Fred Combs (FCC)
Donald Cool (DAC)
Steve Crockett (SFC)
Joe DeCicco (JXD1)
Std AMS Distribution

Jack Grobe (JXD1)
Cathy Haney (CXH)
Tim Johnson (TCJ)
John Madera (JRM4)
Kevin Null (KGN)
Cindy Pederson (CDP1)
Josie Piccone (JMP1)

Gary Shear (GLS)
Wayne Slawinski (WJS2)
Mike Stein (MHS)
Mike Weber (MFW1)
Marian Zobler (MLZ)
Bernie Bordenick (BMB)



926 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

ROUTING	
	nao
	-AO

John Grobe, Chief
Nuclear Materials Inspection Section 2
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Failure of Advanced Medical Systems, Inc. to Provide
Emergency Plan to Offsite Response Organizations

Dear Mr. Grobe:

In your March 31, 1995 letter to David Cesar of Advanced Medical Systems, Inc. ("AMS"), you state that you have reached an understanding with AMS regarding their failure to submit their emergency plan to any offsite emergency responders. You then list a number of organizations to which AMS is to send their emergency plan for review and comment. Please take note that the Northeast Ohio Regional Sewer District ("District") is a first responder to emergencies including fires, floods and spills. Accordingly, the District should therefore also receive the emergency plan and the solicitation of comments from AMS.

Please call me at (216) 881-6600 if you have any questions about the foregoing. Thank you in advance for your prompt attention to this oversight.

Sincerely,

Lawrence K. English
Assistant General Counsel

cc: Martha McCorkle
Robert Staib
Michael Kalstrom
Henry Billingsley, II
Dwight Miller
William Axelson
Roland Lickus
Richard Connelly

APR 1 1995

The mission of the Northeast Ohio Regional Sewer District is to enhance public health and welfare through the efficient, cost-effective conveyance and treatment of wastewater. This is accomplished by an organization dedicated to professionalism, fairness and consistency that anticipates and responds to the changing environmental needs of the community.

~~9512220121~~ 1p.



Northeast Ohio Regional Sewer District

326 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

May 4, 1995

Mr. John Madera
U. S. Nuclear Regulatory Commission
Region III
901 Warrenville Road
Lisle, Illinois 60532-4351

Re: Advanced Medical Systems, Inc. Emergency Plan

Dear Mr. Madera:

Confirming our discussion on the telephone today, it does not appear that as of this date the Northeast Ohio Regional Sewer District ("District") has received a copy of the proposed emergency plan from Advanced Medical Systems, Inc. As we also discussed, I will let you know when the District actually does receive the subject plan.

Sincerely,

Lawrence K. English
Assistant General Counsel

cc: Erwin Odeal
Richard Connelly
William Schatz
Sara Fagnilli
Thomas Lenhart

RECEIVED

MAY 08 1995

REGION III

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041

(216) 466-4371 FAX (216) 466-0186

May 22, 1995

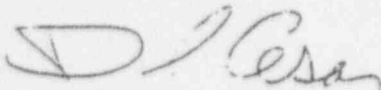
Mr. Wayne Slawinski
U. S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-9820

Dear Mr. Slawinski:

Per your request for a copy of the certified, signed, return receipt from the Northeast Ohio Regional Sewer District, attached please find copies of the return receipt and correspondence verifying that the Sewer District received Advanced Medical Systems, Inc.'s Emergency Plan on April 26, 1995.

If you have any questions, please contact me.

Sincerely,



DAVID CESAR
Treasurer

DC/cs
Enclosures

9 copies

Is your RETURN ADDRESS completed on the reverse side?

SENDER:

- Complete items 1 and/or 2 for additional services.
- Complete items 3, and 4a & b.
- Print your name and address on the reverse of this form so that we can return this card to you.
- Attach this form to the front of the mailpiece, or on the back if space does not permit.
- Write "Return Receipt Requested" on the mailpiece below the article number.
- The Return Receipt will show to whom the article was delivered and the date delivered.

I also wish to receive the following services (for an extra fee):

1. ☐ Addressee's Address

2. ☐ Restricted Delivery

Consult postmaster for fee.

3. Article Addressed to:

Northeast Ohio Regional
Sewer District
3826 Euclid Ave.
Cleveland, OH 44115-2504

4a. Article Number

P 416 193 631

4b. Service Type

☐ Registered ☐ Insured

☒ Certified ☐ COD

☐ Express Mail ☐ Return Receipt for Merchandise

7. Date of Delivery

APR 26 1995

Signature (Addressee)

6. Signature (Agent)

8. Addressee's Address (Only if requested and fee is paid)

PS Form 3811, December 1994

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ADVANCED MEDICAL SYSTEMS, INC.

121 North Eagle Street
Geneva, Ohio 44041

ATTN D CESAR