



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

FEB 28 1996

Mr. David Cesar, Vice President  
Advanced Medical Systems, Inc.  
121 North Eagle Street  
Geneva, OH 44041

Dear Mr. Cesar:

We have completed our review of your Emergency Plan submitted under letter dated September 21, 1995, and request that you provide clarification and/or additional information on the following topics:

1. AMS Staffing Levels and Offsite Response Personnel

Your response to our previous comment I.A of our June 7, 1995 letter did not provide an assessment of how current staffing levels will be able to fulfill the functions and responsibilities described in the plan, especially during nonworking hours. The following issues should be addressed in the plan:

- a. It appears that the onsite emergency organization is comprised of three individuals during working hours, and the absence of one or more individuals could severely impact the licensee's capability to promptly notify offsite response organizations and coordinate the response to an emergency. The licensee is required by 10 CFR 30.32(i)(3)(viii) to plan the notification and coordination so that unavailability of some personnel will not prevent notification and coordination. The plan should describe how the licensee will compensate for the functions assigned to an absent member of the emergency organization.
- b. Section 4.2 of the plan should clearly state the order in which AMS staff members assume the role of Emergency Manager if the Radiation Safety Officer (RSO) is not available (see previous comment V.C).
- c. It is still difficult to determine which personnel are assigned to each of the functional areas specified in Section 4.2.2 of Regulatory Guide 3.67 (see previous comment V.D). It would be helpful if these functional responsibilities were all specified in one place such as Figure 7.
- d. During nonworking hours, it is unclear whether a fire or other emergency situation will be detected promptly if power lines or phone lines are down. The plan should describe how the alarm system signal is transmitted to ADT Security Systems and how ADT

would detect a loss of contact with the alarm system. Any difference in the response to a loss of contact versus an alarm signal should be described also.

- e. During nonworking hours, it appears that local fire or police units could arrive before AMS staff and it is unclear whether there are adequate provisions to alert offsite response personnel to radiological hazards if no AMS personnel are there to meet them. The plan should describe arrangements with fire, police and rescue personnel regarding how they will fight fires and respond to alarms if AMS personnel are not present when they arrive at the site. The plan should also describe signs and other provisions to prevent offsite response personnel from unknowingly entering areas with elevated radiation levels.

## 2. Engineers Opinion Report

In response to our request for an engineering analysis of the facility structure, the emergency plan refers to an Engineers Opinion Report issued by Neff and Associates dated September 1995. We obtained a faxed copy of the report dated September 22, 1995 (after the date of the emergency plan). We noted a number of deficiencies in the report and a general failure to provide an adequate technical basis to support its conclusions. Most of our concerns regarding the structural integrity of your facility will be addressed in Inspection Report No. 030-16055/95006 which will be transmitted under separate cover. With respect to the emergency plan, the Engineer's Opinion Report does not provide an adequate analysis of the worst case earthquake. The report states that the structure can "withstand seismic forces as great as 5.2 Richter" and "a seismic event greater than 5.2 Richter in this region is highly improbable." Since the Richter scale is a method of classifying the energy released by an earthquake without defining other parameters such as epicentral distance, the statement fails to define the associated seismic forces on the structure. An adequate analysis should state, in appropriate units, the ground acceleration, velocity, and displacement that the worst case earthquake could impose on the structure. The analysis should evaluate how well the various existing structural systems in the building would withstand these seismic effects.

## 3. Facility Description

- a. Section 1.1 contains a brief description of activities formerly conducted at the site, but there is no description of the activities currently authorized or conducted. The plan should describe the current activities.
- b. Section 1.1 and Table 1 describe the amount of licensed material possessed on September 21, 1995. This inventory is subject to change and could increase up to the possession limits stated in

the license. The plan should state the total quantity of radioactive material authorized by the license. Typical quantities possessed at one time may be noted also.

- c. Section 1.1 states that there are over 60,000 curies of cobalt-60 and 2200 kilograms of depleted uranium in the facility, but it is unclear where this material is typically located. Sections 1.2 through 1.2.12 only identify the location of approximately 34,000 curies of cobalt-60. The typical storage locations for the remaining material authorized by the license should be identified.
- d. The plan still lacks a detailed site drawing showing the exterior features of the building and property described in Section 1.2 of Regulatory Guide 3.67 (see previous comment II.B). A detailed drawing of the exterior features of the site must be provided in addition to the interior floor plans. In addition to detailed information about the licensee's property, the drawing should show the pump house on Mandalay Avenue, the rail line that runs past the facility, and the nearest residents in each direction.
- e. The terminology used to describe areas in the facility is still inconsistent (see previous comment II.D). Section 1.2 refers to a shielded work room on the main floor, but this term does not appear in the following sections or on Figure 3/Appendix B. Section 1.2 refers to a mechanical equipment room and a ventilation system equipment room on the second floor, but these areas are labeled as the clean equipment room and HEPA equipment room in the following sections and Figure 4/Appendix B. Section 1.2 refers to a source storage area and irradiation facility in the basement, but Section 1.2.3 discusses a source garden, and Figure 2/Appendix B does not identify any of these areas in the basement. Consistent terminology should be used and all areas discussed in the text should be indicated on the drawings.
- f. Section 1.2.3 states that there is an L-shaped shield of sand-filled vaults on two sides of the source garden in the basement, but the floor plan in Figure 2/Appendix B does not show the shield. Significant safety features such as the sand shield, the emergency generator, fire pull stations, and storage locations of emergency response kits should be shown on the floor plans. The floor plans should also identify where electrical and natural gas services enter the building.
- g. Section 1.3 states that Figure 5 identifies the facility and its proximity to near-site structures. It states that Figure 5 shows the location of schools, hospitals and fire stations also. Figure 5 appears to be a poor quality copy of a street map and neither the licensee's building nor any structures within 1 mile of the site are clearly identified. Figure 1 does not provide an

adequate picture of the area near the site either. The plan should contain a reasonably detailed drawing of the site area as described in Section 1.3 of Regulatory Guide 3.67 (see previous comment II.F). The plan should also contain a U.S. Geological Survey topographical map (7.5 minute series).

4. Types of Accidents

- a. The discussion on page 2-2 refers to guidance issued by the International Commission on Radiological Protection (ICRP). This guidance is not directly applicable to facilities in the United States. The guidance applicable to protecting the public in this country is contained in the "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" issued by the U.S. Environmental Protection Agency (EPA 400-R-92-001). The plan should refer to this guidance regarding offsite protective action recommendations.
- b. We have a number of concerns regarding the analysis in Section 2.1.1 and Appendix C of potential doses from a fire (see previous comment IV.A). Appendix C states that the source term for the worst case fire was assumed to be 40.4 curies, but the basis for that number is not provided. This does not appear to be a conservative assumption because the revised AMS license application dated October 30, 1995 requests a possession limit of 50 curies for packaged waste and surface contamination, and there is no explanation why the source term should not include bulk quantities of cobalt-60 from containers ruptured by one of the accidents postulated in Chapter 2 such as a gas line explosion, train derailment, or earthquake.

In addition, we disagree with the statement in footnote 40 that a 10-meter release height is a conservative assumption. A ground level release with no plume rise would maximize the offsite dose estimate.

We note that the CAP88-PC computer code is not intended to estimate short term doses resulting from an unplanned release during an emergency. Using a 40-curie source term, we estimated an inhalation dose at 100 meters of 7.7 millirem using the hand calculation in Section 2.1.3 of NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees," January 1988. This estimate is over an order of magnitude greater than the 0.2 millirem dose estimated by the CAP88-PC code. A more detailed and conservative analysis using more appropriate calculational methods should be provided.

- c. Section 2.1.2 and Appendix C state that an earthquake could create a 100 millirem/hour dose rate 20 feet beyond the outside wall of the source garden. The plan should state the distance at which the dose rate would drop below 2 millirem/hour and whether that location is in an area accessible to the public. In addition, we attempted to run the Microshield code using the assumptions stated in Appendix C but we could not duplicate the results stated in the plan. The input parameters and assumptions should be described in enough detail to permit us to duplicate and evaluate the calculation.
- d. Section 2.1.3 states that a tornado would not compromise the structural integrity of restricted areas and references the Engineers Opinion Report issued by Neff & Associates. Although this report states that portions of the building contained within the bunker-type construction would not sustain any appreciable distress, it also states "that it is scientifically certain that a tornado passing over this facility would impose significant structural damage" to other parts of the building. Restricted areas on the second floor and in the warehouse areas of the first floor could be completely demolished by a tornado releasing radioactive materials in those areas. Section 2.1.3 should provide a more accurate description of the potential damage from a tornado, and postulate the maximum amount of radioactive material that could be in these areas as a result of routine storage, preparation for shipments, or other operations.

5. Classification and Notification

- a. Section 3.2 is still inconsistent with the notification requirements in the regulations (see previous comment III.A). Pursuant to 10 CFR 30.32(i)(3)(viii), the plan must contain a clear commitment to notify appropriate offsite response organizations promptly after declaring an Alert or Site Area Emergency (SAE). The plan should not differentiate between these classifications or give the impression that the licensee can needlessly wait a full hour before notifying offsite officials of an Alert declaration. In addition, the plan must clearly state that the licensee shall notify NRC immediately after notification of local and State authorities. Simply stating that NRC will be notified within one hour is not sufficient.
- b. Several of the emergency action levels (EALs) in Attachment 1 of Appendix D are defined in terms of potential exposure rates or actual exposures. It is unclear how the Emergency Manager will be able to identify these conditions in a timely manner. It is unacceptable to wait for survey results if it will take more than 15 minutes to get them. EALs must be defined in terms of conditions that are apparent within the first few minutes of an

emergency. This is especially important during nonworking hours. If an alarm goes off and the condition cannot be verified within 15 minutes, the Emergency Manager should act conservatively by declaring an emergency and initiating notification of offsite response organizations. The EALs should be redefined.

- c. The offsite response organizations listed in Attachment 1 of Appendix D to receive a notification vary depending on the event. Each of the organizations identified as a "first responder" should be notified every time an Alert or Site Area Emergency is declared. In addition, all NRC notifications should be made to the NRC Operations Center. The Operations Center coordinates event reports with regional staff.
- d. The plan does not establish the initial recommendations for offsite protective actions that will be included in the initial SAE notification to offsite organizations (see previous comment III.B). If an accident has the potential to require road blocks or other protective actions offsite, the licensee should act conservatively and make initial recommendations to offsite officials until the scope of the accident can be verified. This would include recommendations to stop traffic on the rail line or rope off potentially contaminated areas. Protective action recommendations should be addressed in Sections 3.1.4 and 3.3, and Appendix D.
- e. Section 3.3 should specify the minimum frequency of updates to offsite response organizations after the initial notification (see previous comment IX.B). The response to our previous comment states that Section 8.3 was being modified to include the information, but the revision does not include this information.

## 6. Responsibilities

- a. Section 4.2 states that an environmental consulting firm and a certified health physicist have been retained to assist in all matters relating to radiation safety and environmental issues. Figure 7 only shows the environmental consultant as part of the AMS emergency organization and it is unclear what function either of these parties would perform during an emergency. The roles of the environmental consultant and the certified health physicist should be clarified.
- b. The response to our previous comment V.E states that letters from the hospital, fire department, and police department will be included in the plan. Section 4.3 states that Appendix E contains letters of agreement from "applicable first responders" listed in Table 2 along with information on the agreed upon means of communication and notification with these agencies. Contrary to

these statements, Appendix E only contains letters from the fire department and two State agencies and there is almost no information about methods of communication. Complete documentation that offsite response agencies are aware of, and have agreed to their roles as specified in the plan should be provided.

- c. The response to our previous comment V.G concerning the capabilities of offsite organizations and rumor control arrangements stated that the plan would be modified to address these items. The plan does not include this information. In addition to other capabilities, Section 4.4 should specifically address whether local fire or police personnel have the capability to conduct radiation surveys.
- d. Section 4.4 fails to describe some of the organizations listed in Table 2. A description of the responsibilities and capabilities of each of these organizations should be provided.
- e. In Table 2, the organizations do not appear to be listed in the order they would be called. The NRC Operations Center should be notified immediately after appropriate local and State organizations. Table 2 and Attachments 2 and 3 of Appendix D should be revised to prevent confusion.

#### 7. Response Measures

- a. The terms used for accidents are still inconsistent (see previous comment IV.B). The plan should establish the terms for accidents in Chapter 2 and these terms should be used consistently throughout the rest of the plan. The terms we found are listed below:

<u>Chapter 2</u>	<u>Chapter 5</u>	<u>Appendix D</u>
Fire	Fire	Loss or Theft
Earthquake	Natural Phenomenon	Unauthorized Entry
Tornado	Tornado	Power Failure
Vandalism	Vandalism	Minor Spill or Release
Flood	Flood	Major Spill or Release
Industrial Facility Impact		Minor Fire
Underground Gas Line Explosion		Significant Exposure
Transportation Accident		Fire, Explosion or Other Major Emergency

- b. We disagree with the statement in Section 5.3 that no actions can be taken to mitigate the consequences of a tornado or flood. When there is advance warning of severe weather conditions, we would expect the licensee to take reasonable steps to secure the facility and minimize releases. If a tornado warning is issued for the site area, we would expect the licensee to declare an alert and take immediate steps to secure licensed materials especially in the warehouse portions of the facility. Section 5.3 and Appendix D should address the mitigating actions that will be taken if a severe weather warning is issued.
- c. Section 5.4.1 states that evacuated personnel will assemble at the designated muster area, however the location of the muster area is not specified and it is not shown on any of the drawings. The location of the muster area should be identified.
- d. Section 5.4.1 does not describe provisions for search and rescue operations if the RSO cannot account for all personnel. This issue should be addressed.
- e. Section 5.3 states that licensee staff will assist the fire department by conducting surveys during fire fighting efforts. Footnote 25 on page 5-2 states that in the event of a fire, only self-contained breathing apparatus (SCBA) should be worn, and full- or half-face respirators are not permitted. Section 6.4 states that respirators are maintained in the building and Table 3 indicates that a respirator is maintained at the pump house. Please indicate what types of respirators are maintained in the building and the pump house. SCBAs should be available in the building and the pump house to respond to a fire.
- f. Section 5.5 still does not address informed consent (see previous comment VI.A). The plan should describe how the Emergency Manager will verify that a volunteer is aware of the health risks before authorizing emergency exposures exceeding 25 rem.
- g. Issuing dosimeters to firemen is not addressed in section 5.11 of Appendix D. This issue should be addressed in the implementing procedure.
- h. Section 5.5 states that personnel will be monitored for contamination, but there is no description of the procedures for decontaminating personnel if contamination is found. This issue should be addressed.

- i. Section 5.6 states that the Cleveland Emergency Medical Service personnel receive annual training, but it is unclear who conducts this training. In addition, there is no letter of agreement confirming that this organization has agreed to transport contaminated individuals. The training issue should be clarified and a letter of agreement should be provided.
- j. Sections 5.6 and 5.7 state that the University Hospital of Cleveland is capable of diagnosing and treating radiation injuries, and has a Radiation Safety Officer who will perform surveys and control contamination. There is no letter of agreement from the hospital verifying its capabilities and confirming its agreement with these statements (see previous comment VI.D). A letter of agreement should be provided.

8. Equipment and Facilities

- a. Section 6.2 does not describe any communications capability at the alternate command center (the pump house). Both the primary and alternate command center should have a telephone or other means of communication with offsite organizations.
- b. Section 6.4 states that dosimeters and survey meters are stored in the "instrument calibration room" shown in Figure 3, and that protective clothing and respirators are stored "in the locker room or storage room." There is no instrument calibration room indicated on Figure 3 and the storage location for the protective clothing is too vague. It is unclear whether these locations would be accessible during postulated accidents. Section 6.4 should use terminology that is consistent with the labels on the drawings. It would be helpful if the command center, equipment storage locations, first aid kits, emergency generator and other features related to emergency response were specifically indicated on the drawings.
- c. Section 6.4 and Table 2 only list pocket dosimeters. While pocket dosimeters are useful for real-time dose assessment, they are not very accurate. The licensee should provide more accurate dosimeters (e.g., film badges or TLDs) that can be used to verify personnel exposures after an emergency is brought under control.
- d. Table 3 indicates that only one respirator and two pocket dosimeters are maintained at the pump house. This does not appear to be sufficient to equip the licensee's staff and offsite rescue personnel that may need to enter the building. The pump house should contain enough respirators and dosimeters to equip the licensee's emergency staff, and enough additional dosimeters to monitor hose crews, search and rescue teams, or other offsite rescue personnel.

- e. Table 3 indicates that only one frisker and one survey meter are maintained at the pump house. We believe that at least one additional survey meter should be provided at this location for backup. The range of the survey meters should be specified also.

9. Maintaining Emergency Capabilities

- a. Section 7.2 should specifically state that the risks of emergency doses will be covered in the training of offsite rescue personnel so they can decide in advance what risks they would be willing to accept during lifesaving operations. Numerical estimates of health risks are provided in the EPA Manual of Protective Action Guides.
- b. Section 7.3 should state that the exercise objectives and scenario shall be provided to NRC in advance (typically 60 days) to allow NRC to review and comment on the exercise.
- c. Sections 7.4 and 7.5 should specify who is responsible for tracking findings from critiques and audits, and verifying that the findings are closed out.
- d. Section 7.5 states that there will be periodic audits. The plan should clearly state that there will be annual audits.
- e. Section 7.6 should state that the shelf-life of protective clothing and other degradable materials shall be tracked and changed out on a regular basis. In addition, provisions for calibration of the stack monitor and testing of the emergency generator should be described.

10. Records

Section 8.1 should specify that records of incidents shall be permanently retained with the licensee's decommissioning records.

11. Format

- a. The plan still does not have a list of effective pages that a reader can use to verify his copy is complete and up-to-date (see previous comment XII). A list of effective pages should be provided.
- b. Although Figures 2, 3, 4, and 5, and Appendix B have cover pages that are numbered, the actual drawings are not numbered or identified as part of the emergency plan. The drawings can be removed from the plan without creating any gaps in the page numbers. Every page of the plan, including the drawings, must be identified with a page number and a revision number/date.

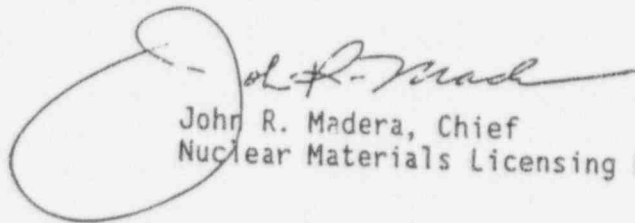
D. Cesar

-11-

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 98538.

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

Sincerely,

A handwritten signature in cursive script, appearing to read "John R. Madera", is written over a large, loopy circular mark.

John R. Madera, Chief  
Nuclear Materials Licensing Branch

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

EXHIBIT "D"



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

February 26, 1996

RECEIVED

FEB 28 1996

Legal Department  
N. E. O.

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

Dear Mr. English:

I am writing in response to your facsimiles dated January 31, February 1, February 5, February 7, and February 12, 1996, as well as the recent telephone conversations between you and members of my staff, regarding the discharge of water at Advanced Medical Systems, Inc. (AMS). In these communications, you expressed concern about the presence of insoluble cobalt-60 (Co-60) in the water from AMS' underdrain system and manhole which had been pumped into storage Tanks 877, 222, and 880.

Your facsimiles list the results of the solubility tests performed by your contract laboratory. The January 31, 1996 facsimile documented that your laboratory had measured a cobalt-60 (Co-60) activity of  $2.7 \pm 2.0$  picocuries (pCi) on the filter from water held in AMS Tank 877. Likewise, the February 5, 1996 facsimile reported a measurement of  $4.0 \pm 1.9$  pCi on the filter from water held in AMS Tank 222, and the February 12, 1996 facsimile reported a measurement of  $39.3 \pm 12.0$  pCi on the filter from water held in AMS Tank 880. Since Co-60 was detected on these filters, Northeast Ohio Regional Sewer District (NEORS) considers the Co-60 in Tanks 877, 222 and 880 to be insoluble. In as much as 10 CFR 20.2003 requires that licensed material which is discharged into a sanitary sewerage system be readily soluble in water, NEORS requested that NRC prohibit AMS from discharging the water from these tanks.

On January 31, 1996, we asked AMS to postpone the discharge of Tank 877 until NRC's investigation was complete. On February 5, 1996, we made the same request for Tank 222. AMS complied with our requests.

By facsimile dated February 2, 1996, AMS indicated that its contract laboratory, Lockheed Analytical Services, had measured the Co-60 concentration in a water sample from Tank 877 and found no detectable Co-60 (the minimum detectable activity (MDA) for this analysis was 4.1 picocuries per liter (pCi/l)). A solubility test on this water sample was not performed. By facsimile dated February 7, 1996, AMS indicated that its laboratory had measured the Co-60 concentration and performed a solubility test of a water sample from Tank 222. Co-60 was not detected on the filter (the MDA for this analysis was 3.5 pCi).

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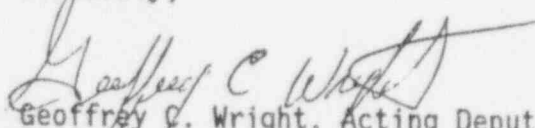
In response to your first three facsimiles, on February 6, 1996, an NRC inspector and I went to AMS and took six 0.5 liter water samples from Tanks 877 and 222. The water in the tanks had been recirculating for approximately 20 hours. In the Region III laboratory, each water sample was tested for solubility. Co-60 was not detected on these filters; thus, the NRC analysis did not confirm that the water in these tanks contained insoluble Co-60. These results were transmitted to AMS, and AMS subsequently discharged the water from the two tanks. (The analysis results are summarized in the enclosure.)

In response to your February 12, 1996 facsimile, on February 13, 1996, an NRC inspector went to AMS and took seven 0.5 liter water samples from Tank 880. Four samples were obtained from the top of the tank while the water was being recirculated. (The water in the tank had been recirculating for approximately 24 hours.) Based on our discussions with you regarding NEORSD's sampling technique, three samples were obtained from the tank's bottom outlet valve one hour after the recirculation pump had been turned off. Prior to taking the samples, approximately two liters of water were drained from the bottom outlet valve and returned to the tank.

The analysis of the samples from Tank 880 is still in progress. To date, two samples from the top and two samples from the bottom of the tank have been filtered. No Co-60 was detected on the filters from the top samples, but Co-60 was detected on the filters from the bottom samples. (The analysis results are summarized in the enclosure.) Based on these results: (1) on February 16, 1996, we informed AMS that insoluble cobalt-60 had been detected in the water from Tank 880, and therefore, a discharge of Tank 880 would be an apparent violation of 10 CFR 20.2003, and (2) we are currently reviewing the adequacy of AMS' sampling and analysis procedures.

Once our analysis of samples from Tank 880 is complete, you will be provided the complete results. In the meantime, please do not hesitate to contact me should you have any further questions regarding AMS.

Sincerely,



Geoffrey C. Wright, Acting Deputy Director  
Division of Nuclear Materials Safety

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

Enclosure: NRC Analysis

See Attached Distribution

Distribution

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Cleveland, OH 44115

Michael Kalstrom, Secretary  
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Marian Zobler  
U.S. Nuclear Regulatory Commission

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C. Jones, NMSS  
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AMS File

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Ohio State Emergency Response  
Commission  
1800 Watermark Drive  
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# ENCLOSURE

## RESULTS OF NRC'S ANALYSIS OF FILTERS FROM TANKS 877, 222 AND 880

AMS Tank Number	Filter Number	Activity (pCi)	MDA (pCi)	Count Time (hours)
877	1	< MDA	2.0	12.7
877	2	< MDA	1.8	16.0
877	3	< MDA	1.8	13.3
222	1	< MDA	2.3	10.4
222	2	< MDA	1.7	16.1
222	3	< MDA	1.7	17.1
880 top	2	< MDA	1.7	15.7
880 top	3	< MDA	2.3	11.0
880 bottom	1	$17.2 \pm 1.2$	1.5	24.4
880 bottom	2	$19.6 \pm 2.0$	2.4	7.2

NOTES: (1) MDA stands for minimum detectable activity.

EXHIBIT "E"



State of Ohio Environmental Protection Agency

Northeast District Office

2110 E. Aurora Road  
Twinsburg, Ohio 44087-1969  
(216) 425-9171  
AX (216) 487-0769

George V. Voinovich  
Governor

March 6, 1996

RE: Advanced Medical Systems  
NEORSD  
Pretreatment

David Cesar  
Advanced Medical Systems  
121 North Eagle Street  
Geneva, OH 44041

Dear Mr. Cesar:

The Ohio EPA has recently discovered that Advanced Medical Systems (AMS) is processing water prior to discharge to NEORSD. AMS is allowed to discharge water collected in tanks from the footer drain system provided the soluble Cobalt-60 concentration is less than 100 pCi/l. Analysis of a tank of collected water revealed an insoluble Cobalt-60 concentration. Recently, NEORSD was requested to approve the discharge of this same tank of water after the water had been treated in some undocumented manner.

The Ohio EPA, NRC, and NEORSD have agreed that while the NRC has authority to regulate radiological discharges, OEPA and NEORSD have the authority to regulate discharges if those discharges can result in an interference of POTW operations. The Ohio EPA has also informed NRC and AMS that Permit to Install regulations found in OAC 3745-31 would be invoked if a pretreatment system was installed in order to reduce Cobalt-60 concentrations to a level that would not cause interference.

From the limited amount of information supplied to this office, it appears that AMS has constructed a pretreatment system that is intended to remove Cobalt-60 in order to prevent interference with NEORSD operations. AMS installed this system without first obtaining a Permit-to-Install, which is a violation of OAC 3745-31-02(A)(1) and ORC 6111.45. Please provide a response to this office by March 15, 1996 that provides a schedule for submittal of a Permit-to-Install to the Ohio EPA Northeast District Office.

If you have any questions or comments, please contact me at 216-963-1285.

Sincerely,

*Donna J. Kniss*

Donna J. Kniss  
Environmental Engineer  
Division of Surface Water  
Northeast District Office

DK:cfh

cc: James Payne, AGO  
Richard Connelly, NEORSD  
Dwight A. Miller, Stavole and Miller  
Henry E. Billingsley, Arter and Hadden  
John Madera, U. S. NRC Region III

(10 C.F.R. § 2.206)

William B. Schatz, Esq.  
General counsel  
Northeast Ohio Regional Sewer District  
3826 Euclid Avenue  
Cleveland, Ohio 44115-2504

Dear Mr. Schatz:

This letter acknowledges receipt of your March 18, 1996, correspondence sent on behalf of the Northeast Ohio Regional Sewer District (NEORSO) requesting action with regard to License #34-19089 held by American Medical Systems, Inc. Your request is being treated as a Petition under 10 C.F.R. § 2.206 of the Commission's regulations.

Your Petition requests that the U.S. Nuclear Regulatory Commission (Agency or NRC) institute a proceeding to modify the license of Advanced Medical Systems, Inc. (AMS) to require that AMS provide adequate financial assurance to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2210.

As you noted in your letter, NEORSO filed a petition pursuant to 10 C.F.R. § 2.206 (Prior Petition) on August 2, 1993, requesting the Agency take this same action. In the Prior Petition, NEORSO also made two other requests for action, neither of which is referenced in the current Petition. On June 16, 1994, NRC issued a Director's Decision (DD-94-6) denying the petition, concluding that no substantial public health and safety concerns warranted NRC action concerning the request.

As the basis for NEORSO's current Petition, you claim that substantial additional factual information has become available since the Director's Decision was issued on June 16, 1994, regarding the justification for requiring financial assurance for public liability from AMS. You further assert that this "new" information refutes the reasons underlying the Agency's denial of the Prior Petition.

The information which you offer in support of NEORSO's Petition is comprised of the following documents and events: (1) a February 28, 1996, letter from John Madera, NRC Region III, to David Cesar of AMS, requesting additional information in connection with AMS' Emergency Plan; (2) the results of a Pacific Northwest Laboratory study on the sanitary disposal of radioactive materials; and (3) the NRC staff's March 1996 allowance of AMS to discharge the contents of storage tank 880 onto the ground, notwithstanding the 1991 revision to 10 C.F.R. Part 20.

Regarding Mr. Madera's letter, you state that this letter now casts doubt upon one of the Director's bases for denying NEORSO's Prior Petition, "the condition of the AMS Facility". You claim that Mr. Madera's letter points out deficiencies in AMS' Emergency Plan which were either unknown or nonexistent at the time of the Prior Petition. You believe this information calls into question the Director's application of the Price-Anderson provisions to materials licensees in general and to AMS in particular.

William B. Schatz, Esq.

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Regarding the Pacific Northwest Laboratory study, you assert that its results do not support the Director's Decision and thus undermine a second reason for the Director's denial of the Prior Petition, the actual performance of this study. You believe the results of this study constitute new information since they were not available when the Director's Decision was issued. In particular, you state that the study shows that the amount of discharged radioactive waste found at sewage treatment plants is grossly underestimated by existing records. As such, you claim that this study supports your position that offsite contamination as it relates to the AMS Facility is a realistic possibility and thus warrants a deviation from NRC's policy of not applying the Price-Anderson provisions to individual materials licensees.

Regarding the staff's conclusion that it did not appear to be a violation of 10 C.F.R. § 20.2003 for AMS to discharge the contents of storage tank 8' into the ground in March 1996, you claim that this NRC action weakens a basis for the Director's denial of the Prior Petition, the revision of 10 C.F.R. Part 20. Specifically, you assert that 10 C.F.R. §20.2003 should be read such that no discharge of insoluble radioactive material is allowable. Thus, you claim that the staff's allowance of AMS to discharge some samples of insoluble radioactive material out of storage tank 880 renders invalid the Director's use of the rule revision as a justification for denying the Prior Petition.

Your Petition has been referred to me pursuant to 10 C.F.R. § 2.206 of the Commission's regulations. As provided by section 2.206, action will be taken on your request within a reasonable time. I have enclosed for your information a copy of the Notice that is being filed with the Office of the Federal register for publication.

Sincerely,

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

Enclosure: As stated

cc: Advanced Medical Systems, Inc.

Agency's denial of the Prior Petition. Accordingly, Petitioner has submitted a new request for action regarding AMS' License No. 34-19089-01.

A copy of the Petition is available for inspection and copying in the Commission's Public Document Room, 2120 L Street, N.W., Washington, D.C. 20555.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

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

dated at Rockville, Maryland

this \_\_\_\_ day of \_\_\_\_\_ 1996.