

From: Bruce A. Berson (BAB1), *R111*  
To: JFC, SFC, MHF *Corde's, OGC SCROCKETT, OGC*  
Date: Wednesday, November 23, 1994 8:57 am  
Subject: AMS

I heard from the AMS attorney Henry Billingsley late yesterday afternoon. He will be filing a Touhy request with Karen, Attn: John for live testimony or at least an affidavit from NRC to the effect that NRC has the authority to shut down a licensee if NRC concludes there is an immediate threat to public health and safety from radiological discharges and that based on the information NRC has to date that it has no cause to do so. As you know, the hearing is scheduled for December 9. I also gave him your phone and fax numbers, John.

I told him that I thought it would be doubtful that we would provide a live witness but that an affidavit of some type might be possible. I suggested that he include in his Touhy request a draft of something that he would like to see and told him that should we grant the request we would obviously feel free to modify it to reflect the agency position. Until we see the actual request it will be hard to determine who the appropriate NRC person to execute the affidavit would be, but my initial reaction is that it should be from a regional or HDs NMSS division director.

John, he will also be sending copies of the pleadings to you and me. He stated that he views the TRO and the underlying state court trespass proceeding for damages as preempted and referred to decisions in the 3rd and 7th circuit which he said hold that the Price Anderson Act Amendments bar any state damage proceedings for federally regulated radioactive releases. He has filed a motion to dismiss the underlying trespass proceeding on this basis, but the judge has not ruled. He also expressed the view that that NRC should be concerned that if the sewer district prevails in this case, any sewer district in the country could shut down hospitals etc, all of which make discharges to the sewers.

CC: CJP1, RMB1, RJC1, JAG, WLA

*D/27*

November 29, 1994

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

Dear Mr. Cesar:

This refers to the routine safety inspection conducted by Mr. Wayne Slawinski of the NRC Region III office and Mr. Robert Shewmaker of our headquarters office on October 11-12, 1994, to review certain aspects of your NRC licensed activities authorized by NRC Byproduct Material License No. 34-19089-01. This also refers to the discussion of our findings with Robert Meschter at the conclusion of the site inspection on October 12, 1994 and to the telecon with you on October 21, 1994.

The inspection was limited in scope and included a review of: (1) the implementation of your Radiological Emergency Contingency Plan; (2) information relative to assessing the Waste Holdup Tank (WHUT) room's structural integrity; and (3) recent facility water usage practices. The inspectors also met with Cleveland Fire Department representatives at your facility to discuss their readiness to respond to an event at your facility.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews with personnel. Our assessment of the WHUT room's structural integrity is continuing. Assessment results will be provided under separate cover upon completion of our review.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as specified in the enclosed Notice. In addition to the violations, we also identified the following other concerns during the inspection.

- (1) The only available emergency contact person listed in your Radiological Contingency Plan who provides backup to the RSO is not sufficiently familiar with the plan.
- (2) The Director of Regulatory Affairs has key responsibilities in the implementation of the Radiological Contingency Plan, including being listed as a backup emergency contact; however, this individual has been on leave for more than one year and no other individual has fulfilled the director's role under this plan.
- (3) Your staff has not interfaced sufficiently with the Cleveland Fire Department and other response organizations, to ensure they have an adequate understanding of your Radiological Contingency Plan and the facility.

D128

- (4) While routine radiation and contamination surveys are conducted in the vicinity of the WHUT room area, the specific WHUT room surveillances and radiation surveys described in your February 8, 1988 letter to the NRC have not been conducted.

In addition to your response to the violations, please also respond to the four concerns noted above, indicating your corrective action and actions to prevent recurrence. Of particular concern is the status of your readiness to respond to an emergency. While we believe that your RSO is competent to respond to and support emergency response activities, the available backup for the RSO listed in your contingency plan is not fully cognizant of the plan. It appears that your management oversight of this important aspect of your program has been ineffective. This area requires your prompt attention to ensure you have: (1) a properly trained staff in emergency response positions; (2) appropriate equipment and supplies available; (3) effective audits and exercises to assess emergency response readiness; and (4) a productive relationship with offsite emergency response organizations. Please ensure your response addresses these areas.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice 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.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original signed by John A. Grobe

John A. Grobe, Chief  
Nuclear Materials Inspection Section 2

License No. 34-19089-01

Docket No. 030-16055

- Enclosures: 1. Notice of Violation  
2. Inspection Report No. 030-16055/94004

bcc w/encls: Robert Meschter, AMS  
Capt. Thomas Root, Fire Marshal  
Cleveland Fire Department  
PUBLIC IE07

*JCC ant*

bcc w/encls: C. Jones, NMSS  
J. DiCicco, NMSS  
W. Anelson, *RETI*

DOCUMENT NAME: G:\INSPRPTS\MTLS\030\03016055.941

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy.

OFFICE	DRSS/RIII	<input checked="" type="checkbox"/> DRSS/RIII	<input checked="" type="checkbox"/> DRSS/RIII	<input checked="" type="checkbox"/>
NAME	POWSLAWSKI:jaw	JMADERA <i>jm</i>	JAGROBE <i>ag</i>	
DATE	11/17/94	11/22/94	11/22/94	

## NOTICE OF VIOLATION

Advanced Medical Systems, Inc.  
Cleveland, Ohio

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

During an NRC inspection conducted on October 11-12, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1994), the violations are listed below:

License Condition 18 requires that the licensee maintain and execute the response measures of their Emergency Plan dated October 25, 1991 and revised January 1992, May 27, 1992 and April 26, 1993.

- A. Item 7.3 of the "Onsite Radiological Contingency Plan For The Cleveland, Ohio Facility," revised May 27, 1992 and April 26, 1993, requires that the licensee conduct a full scale biennial exercise with offsite emergency response personnel.

Contrary to the above, from inception of this requirement in July 1992 to the date of this inspection on October 12, 1994, no full scale exercise involving offsite emergency response personnel has been conducted.

This is a Severity Level IV violation (Supplement VI).

- B. Item 7.5 of the "Onsite Radiological Contingency Plan For The Cleveland, Ohio Facility," revised May 27, 1992 and April 26, 1993, requires that the licensee conduct an annual audit to review the emergency response program, emergency plan procedures, training, equipment and supplies.

Contrary to the above, from inception of this requirement in July 1992 to the date of this inspection on October 12, 1994, no licensee audits of the emergency response program, emergency plan procedures or training has been performed.

This is a Severity Level IV violation (Supplement VI).

- C. Items 6.3 and 6.4 of the "Onsite Radiological Contingency Plan For The Cleveland, Ohio Facility," revised May 27, 1992 and April 26, 1993, list the emergency response equipment and supplies located in the fire pumphouse. Item 7.6 requires that fire pumphouse emergency equipment and supplies be inventoried and checked quarterly, and that inoperable or missing equipment be repaired/replaced as soon as possible.

Contrary to the above, on October 12, 1994, certain emergency response supplies required to be located in the fire pumphouse were not available. Specifically, supplies absent included building keys, a current listing of emergency response personnel and corresponding telephone numbers, and \$3.00 in quarters for pay phone usage.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Advanced Medical Systems, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Lisle, Illinois  
this 29<sup>th</sup> day of November 1994



UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-16055/94004(DRSS)

License No. 34-19089-01

Priority I

Category B

Docket No. 030-16055

Licensee: Advanced Medical Systems, Inc. (AMS)  
1020 London Road  
Cleveland, OH 44110

Inspection At: Advanced Medical Systems, Inc. (AMS)  
1020 London Road  
Cleveland, OH 44110

Site Inspection Conducted: October 11-12, 1994

Inspectors: Wayne Slawinski  
Wayne Slawinski, Senior  
Radiation Specialist, Region III

11/23/94  
Date

Robert Shewmaker  
Robert Shewmaker, Senior Structural  
Engineer, Office of Nuclear Material Safety  
and Safeguards

11/24/94  
Date

Reviewed By: John Madera  
John Madera, Chief  
Materials Licensing Section,  
Region III

11/23/94  
Date

Approved By: John A. Grobe  
John A. Grobe, Chief  
Nuclear Materials Inspection Section 2  
Region III

11/29/94  
Date

Inspection Summary

Inspection on October 11-12, 1994 (Report No. 030-16055/94004(DRSS))

Areas Inspected: Routine, announced inspection to evaluate certain limited aspects of the licensee's NRC-licensed program including a review of: (1) the implementation of the facility Radiological Contingency Plan; (2) information relative to assessing the WHUT room's structural integrity; and (3) recent facility water usage practices. One of the inspectors also met with representatives from the Cleveland Fire Department at the London Road facility to discuss its radiological hazards and the licensee's Radiological Contingency Plan.

Results: Three violations of Radiological Contingency Plan (RCP) requirements were identified as described in section 4(b). In addition, several RCP related concerns were noted including licensee personnel familiarity with the plan and a lack of management oversight in the plan's implementation. Similarly, the licensee has not adequately interfaced with local emergency response officials to ensure they are fully cognizant of the facility's hazards and its RCP. The inspection also disclosed that a WHUT room surveillance and radiation survey program has not been implemented in accordance with licensee commitments.

## DETAILS

### 1. Persons Contacted

#### Licensee Representatives

+David Cesar, Treasurer, AMS  
\*Robert Meschter, Radiation Safety Officer, AMS  
Vincent Rocco, Technician, AMS  
++Seymour Stein, Ph.D., President, AMS  
++Edward Svigel, Engineering Manager, AMS

William Muniak, Attorney, Arter & Hadden

#### Cleveland Fire Department Representatives

Reginald Keith, Lieutenant, Pre-Plan Office  
William Little, Captain, Pre-Plan Office  
Thomas Root, Captain & Fire Marshal

The inspectors also met with other members of the Cleveland Fire Department during a meeting with Captain Root at the AMS facility on October 12, 1994.

\*Denotes presence at site exit meeting on October 12, 1994.

+Denotes participation in the exit meeting teleconference on October 21, 1994.

++Denotes telephone contacts only.

### 2. Purpose and Scope of Inspection

This was a limited scope safety inspection conducted primarily to gather information and visually examine accessible areas of the London Road facility relative to assessing the Waste Holdup Tank (WHUT) room's structural integrity. Also reviewed, in part, was the implementation of the licensee's RCP for the London Road facility, including discussions with the Cleveland Fire Department regarding the licensee's plan and related matters. Additionally, the inspectors reviewed the London Road facility's recent water usage and sanitary sewer discharge practices.

### 3. WHUT Room Structural Assessment

As noted above, the primary purpose of this inspection was to assess the structural integrity of the London Road facility's WHUT room. The WHUT room is a poured concrete structure located in the basement of the facility beneath the hot cell, housing two liquid radwaste holdup tanks. The holdup tanks contain unknown quantities of cobalt-60 contaminated liquids and/or sediment. The WHUT room was isolated by the licensee



beginning in 1988 in lieu of its decontamination, as described in the licensee's letter to the NRC dated February 8, 1988. The room's temporary isolation was approved by the NRC in a letter dated October 20, 1988.

To assess the structural integrity of the WHUT room, the inspectors reviewed information relative to the room's design and construction, and visually examined accessible exterior portions of the room and adjacent structures. Original facility blueprints and construction photographs taken in approximately 1960 were also reviewed. Personnel entry into the WHUT room is currently prohibited due to the room's existing radiological condition.

The NRC's assessment of the WHUT room's integrity is continuing. The licensee will be provided the results of the assessment when they become available.

Licensee letter dated February 8, 1988 describes the remedial actions for the WHUT room, including a description of the isolation methods proposed for the room and plans for monitoring the area after its isolation. Section H of the attachment to the February 8, 1988 letter, entitled "Maintenance of the Isolated State," describes a monitoring and surveillance program to ensure the room remains properly isolated. The monitoring program is to include weekly radiological surveys of the accessible exterior surfaces of the room. Specifically, the monitoring program is to consist of radiation level measurements and smears taken in reproducible locations on the exterior walls, and smears of all accessible penetration blocks. Section H further states that procedures addressing the room, its status and other specified information will be included in facility ISP procedures.

The inspection disclosed, however, that the commitments in Section H of the attachment to the February 8, 1988 letter have not been met. For example, as of October 12, 1994, ISP procedures do not address methods for verifying the integrity of WHUT room isolation. In addition, a radiation level measurement and contamination smear survey program has not been implemented for the exterior walls of the WHUT room. Although no deliberate changes to the WHUT room and its contents have been made since the room's isolation in 1988/89, a monitoring and surveillance program is necessary to ensure its continued proper isolation.

Subsequent to the inspection, the licensee performed radiation measurements on exterior portions of the WHUT room's walls. No evidence of WHUT room integrity problems were identified.

No violation of regulatory requirements was identified; however, one concern was noted.

4. Radiological Contingency Plan (RCP)

a. Background Information

In 1991, the licensee developed a RCP for its London Road Cleveland, Ohio facility, pursuant to 10 CFR 30.32(i). A RCP dated October 5, 1991, was submitted by the licensee for NRC review, reportedly after incorporating comments/suggestions from the Cleveland Fire Department, Police Department and Emergency Medical Services Agency. The RCP outlines licensee and certain offsite response organization responsibilities and describes its emergency plan for responding to fire, explosion or other events that could result in a release of radioactive material.

The RCP developed by the licensee was reviewed and approved by the NRC and incorporated into License No. 34-19089-01 via Amendment No. 25, dated July 30, 1992. License Condition No. 18 currently requires that the licensee maintain and execute the response measures of their Emergency Plan dated October 25, 1991 and revised January 1992, May 27, 1992 and April 26, 1993.

b. Plan Implementation

Portions of the RCPs implementation were evaluated during this inspection. Additionally, the plan and the London Road facility's radiological hazards were discussed with Cleveland Fire Department representatives during a meeting at the facility on October 12, 1994.

The inspection showed that the RCP has not been implemented as required. The inspection also disclosed licensee management involvement and oversight of the plan's implementation to be weak, particularly within the last year since the licensee's Regulatory Affairs Director has been on leave. Problems have been compounded by continued turnover in radiation safety officer staff. The inspection identified several RCP implementation violations and related concerns, as described below.

Item 7.3 of the "Onsite Radiological Contingency Plan For The Cleveland, Ohio Facility," revised May 27, 1992 and April 26, 1993, requires that the licensee conduct a full scale biennial exercise with offsite emergency response personnel. As described above, the RCP was incorporated into License No. 34-19089-01 on July 30, 1992.

As of October 12, 1994, no full scale exercise involving offsite emergency response personnel has been conducted by the licensee. Failure to conduct a full scale exercise is a violation of License Condition 18 which references the RCP.

In a letter to the NRC dated September 22, 1993, the licensee informed the Commission of its intent to conduct the required exercise in December 1993. However, according to licensee representatives, the exercise was not conducted.

Item 7.5 of the RCP requires that the licensee conduct an annual audit to review the emergency response program, and emergency plan procedures, training, equipment and supplies.

As of October 12, 1994, no licensee audits of the emergency response program, emergency plan procedures or training have been conducted.

Items 6.3 and 6.4 of the RCP list the licensee's emergency response equipment and supplies located in the fire pumphouse located approximately 300 feet west of the London Road facility. Item 7.6 of the RCP requires that fire pumphouse emergency equipment and supplies be inventoried and checked quarterly, and that inoperable or missing equipment be repaired/replaced as soon as possible.

During the inspection on October 12, 1994, certain emergency response supplies required to be located in the fire pumphouse were not available. Specifically, supplies absent included London Road facility building keys, a current listing of emergency response personnel and corresponding telephone numbers, and \$3.00 in quarters.

In addition to the violations described above, other concerns related to RCP implementation were identified. These concerns are described below.

- (1) Appendix A of the RCP includes a list of licensee "Emergency Contact Personnel." The list was revised in September 1994 and includes the name of the RSO, Engineering Manager and Director of Regulatory Affairs. Inspector conversation with the Engineering Manager revealed only a cursory familiarity with the RCP. Also, the revised emergency contact list failed to include the correct telephone number for the NRC Operations Center and Region III office.
- (2) The Regulatory Affairs Director has several responsibilities in the RCPs implementation. However, the director has been on leave for over one year and no other individual(s) has fulfilled the director's RCP responsibilities.

- (3) An October 12, 1994 meeting with Cleveland Fire Department representatives revealed that the licensee has not interfaced sufficiently with fire department personnel, to develop a thorough familiarity with the RCP and the licensee's facility. Subsequent to the inspection, the NRC learned that the fire department has classified the AMS facility as an Extremely Hazardous Substances (EHS) facility. According to the Cleveland Fire Department, EHS facilities warrant an emergency pre-plan, detailing fire department procedures and planned actions for responding to facility emergencies.

As of November 18, 1994, the fire department's first response units have toured the facility and been instructed by the licensee in its radiological hazards. The department's hazardous materials unit plans to tour the facility in the near future. The fire department anticipates development of its emergency pre-plan by the end of 1994.

Three violations of regulatory requirements and several concerns were identified.

#### 5. Water Usage and Disposal Practices

The inspectors reviewed City of Cleveland water billing records for the London Road facility and discussed recent water usage practices with the licensee.

According to the current AMS facility RSO, no liquid radwaste has been discharged into the sanitary sewer system since his employment initiated in July 1994. The RSO further stated that no liquid radwaste has been generated, other than on August 22, 1994, when an employee showered to remove a small quantity of facial contamination. The facial contamination occurred during the decontamination of lead blankets in the isotope shop. Approximately 2-3 gallons of water was reportedly used by the employee while showering in one of the facility's designated decontamination showers. The decontamination showers drain to a 200-gallon plastic tank located in the front basement of the facility. The liquid generated during the shower remained in the tank and has since evaporated.

The licensee receives water billing and consumption information on a quarterly basis. Quarterly records for the London Road facility were reviewed by the inspectors for the period July 1992 through June 1994. The records show, with one exception, quarterly water usage to range from about 45,000 ft<sup>3</sup> during the fourth quarter of 1992 to 83,000 ft<sup>3</sup>



for the first quarter of 1994. This equates to a volume range of 3740 to 6900 gallons per day. The exception occurred during the second quarter of 1993, when only 6000 ft<sup>3</sup> (500 gallons/day) was used. Billing records show total water usage for the 12-month period July 1993 through June 1994, to be nearly twice that used during a corresponding period in 1992-1993. The licensee attributes the increased usage in mid-1993 to mid-1994 to escalating plumbing problems in the facility. The reason for the relatively small volume of water used during the second quarter of 1993 is unknown.

According to the licensee, facility water usage is primarily limited to general use of toilets, sinks and urinals for sanitary and consumption purposes. Since the facility is normally occupied by only two or three individuals for a single shift, typical daily water usage is expected to be only about 100-200 gallons. As noted above, the licensee's water usage over the last two years has been significantly greater than expected. According to the licensee, plumbing problems have plagued the facility for several years and have been allowed to continue unrepaired. According to the licensee, the plumbing problems were continuous, however, their severity could fluctuate day-to-day. The problems have worsened over the last 6-10 months. NRC inspectors have been aware of some of these plumbing problems for over one year, including a continually flushing toilet and leaking urinal flush mechanism in the men's lavatory.

During an NRC inspector London Road facility site visit on July 7, 1994, the inspector observed unexpectedly large quantities of water discharging into the sewer system, when viewed from the manhole area just outside the facility. The July 1994 discharges were, at the time, attributed by the licensee to the aforementioned plumbing problems. This explanation was plausible since a stuck flush mechanism on the men's toilet was known to be a continuing problem.

A standard toilet continuously flushing at about 50% of its normal capacity can use roughly three gallons of water per minute or 4300 gallons per day. Therefore, the London Road facility's unusually large water usage since 1992 appears to correlate with the plumbing problems.

On or about September 29, 1994 and continuing the week of October 3, 1994, a contractor repaired the plumbing problems known to exist at the facility. The work included installation of two new urinals to existing flush valves, and repair of a toilet flush valve. As a result of the repairs, facility water usage beginning the fourth quarter of 1994 should be significantly reduced. During the inspection on October 12, 1994, the inspectors removed the manhole cover where discharges to the sanitary sewer system exit the London Road facility, and verified that discharges had ceased. The inspectors also observed the new plumbing fixtures and plumbing contractors billing record.

No violations of regulatory requirements were identified.

6. Exit Meeting

The inspectors met with the licensee's RSO at the conclusion of the site inspection on October 12, 1994, and summarized the scope and findings of the inspection. On October 21, 1994, a teleconference was conducted between Mr. Roy Caniano and other NRC Region III staff and Mr. David Cesar of AMS. The inspection findings, NRCs planned enforcement action and the licensees corrective action options were discussed during the teleconference.

The licensee did not indicate that any of the information reviewed during the inspection was considered proprietary.