



Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 TWX 810-4272-183

May 23, 1988

Nuclear Materials Safety Section I
U. S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Attention: Robert E. Burgin, Senior Radiation Specialist
D. G. Wiedeman, Chief Nuclear Materials Safety Section I

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

Gentlemen:

This letter is in response to the Notice of Violation issued by your office on May 5, 1988. AMS does not deny that in accordance with Regulation 10 CFR 20.105 the unrestricted area (AMS owned sewer system manhole) required redesignation as a restricted area. The data collected by AMS and Nuclear Support Services (AMS consultants) established that a temporary need for redesignation as a restricted area was justifiable and therefore corrective action was taken. Your inspector's findings reconfirmed our actions.

AMS is presently under order by the USNRC to conduct decontamination of the London Road Hot Cell facilities. AMS, as a direct result of the Order Modifying License issued July 23, 1987 and Revised October 30, 1987 by the Confirmatory Order Modifying License, has contracted the services of Nuclear Support Services (NSS) to conduct and direct the phases of decontamination per the directives of the Order.

The NSS decontamination plan (revised 10-30-87) as approved by the USNRC specifically states in paragraph 5.3; "any additional areas or equipment located outside the existing facility controlled areas that are contaminated will be decontaminated to 220 DPM/100cm² or posted and controlled as "RCAs". The AMS Isotope Committee on January 26, 1988 (Attachment A), pursuant to decontamination program, determined that the sewer should be included in our overall program.

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May 23, 1988

We believe that the intent of the NRC is to have AMS and NSS survey and work in a manner to eliminate the unforeseen or difficult-to-access areas. The execution of the decontamination plan has been timely and very effective. The area detected for which the violation pertains (manhole, sewer), was discovered by NSS on January 20, 1988. Additional data was collected by AMS and an action plan was outlined by the AMS Isotope Committee (Attachment A). When the experts from Oak Ridge did their site inspection in 1985 they sampled the sewers but there are no records of radiation level measurements. As a result all parties concerned assumed that there were no undetected radiation levels in unrestricted areas on AMS property. There is no ready access to the sewer because it has a heavy cast iron cover and requires special tools for removal. The radiation areas exist well below the ground level (-10 feet) as part of the sewerage system for AMS. To the best of AMS's knowledge, there has been no access to the sewer during the AMS ownership of the property. Since AMS and the previous owners, Picker International, have been discharging Cobalt-60 contaminated waste water per the regulations 10 CFR 20.303, it was assumed the water was completely discharged from the property. In retrospect it can be seen that there is a possibility for small amounts of material to remain on site from the discharges over the last 30 years.

In conclusion, AMS believes that the NRC approved decontamination plan covered the detection and restriction of the areas of the AMS property which may exceed the permissible levels of radiation in unrestricted areas 10 CFR 20.105 for the purposes of completing the decontamination ordered by the NRC. As part of our facility decontamination program we have identified the sewer as being inclusive. With respect to the above discussions, AMS believes that we have acted expeditiously and in conformance with the decontamination plan. Since this problem was not identified earlier by Oak Ridge survey, we also feel that the information that we have developed should be passed on to provide better insight into a possible weakness in the monitoring of the waste discharge programs of other licensees.

The following are AMS's responses specific to the requirements of 10 CFR 2.201 and the areas/concerns relating to (a) through (d) of your letter attached to the Notice of Violation dated May 5, 1988.

RESPONSES TO 10 CFR 2.201 (a)

1. Corrective Actions and Results Achieved

On January 26, 1988 (Attachment A) at a special meeting of the AMS Isotope Committee, it was agreed that the following actions fell under the scope of the decontamination plan;

The sewer is recognized as a part of the AMS Decon program and has been addressed. The following plan has been followed:

1. Caution signs posted inside the manhole. COMPLETED
2. Restrict access by locking the manhole cover with a bar. COMPLETED

May 23, 1988

3. Develop plan to clean the sewer and propose the plan to NSS. This plan is to be completed as part of the Decon Plan after the basement area has been completed. *→ approximately June*
4. Conduct the Decon operation as part of the decon plan. This work is to be conducted in June, 1988 after the basement has been completed as per the original schedule of activities for decontamination (Attachment B).
5. Enter all records of the operation into the records for the Decon program. This is documented in Attachment C. (AMS Summary of NRC Inspection 4-13-88, recorded 4-15-88).

2. Corrective Steps Which Will be Taken

AMS and NSS intend to clean the manhole, to the lowest level obtainable, recovering the contaminated waste per 4.1 of the decontamination plan. The manhole will remain posted and maintained as a restricted area. Since this manhole is an integration point between the hygienic sewer lines and the AMS facility, routine surveys of the area will be instituted. AMS has proposed to the NRC the isolation of the WHUT Room. When this proposal, dated February 8, 1988 is approved and AMS has been able to follow up, we will discontinue the disposal of contaminated water per CFR 20.303 from the WHUT Room. This will reduce future discharge of materials to the sewer system.

3. Date When Full Compliance Will be Achieved

AMS expects that the decontamination of the manhole will be completed by mid July, 1988 (Attachment B), which is the scheduled target date for completion of the facility decontamination. As of May 15, 1988, all activities are on schedule with the exception of the delayed WHUT Room isolation approval. Following completion of the decontamination project, final surveys of all areas decontaminated will be submitted to the NRC.

SPECIFIC RESPONSES TO (a) - (d), NRC LETTER OF MAY 5, 1988

a) Characterize the Contents of the Referenced Area Resulting in Elevated Radiation Levels

AMS and Picker, during 30 years of operations, have been batch dischargers of contaminated water waste per allowable controls specified in 10 CFR 20.303. In retrospect, following the discharge of each water dump, it is possible a small amount of water on the surface base of the manhole would evaporate. It would be logical to assume that over the years dry sludge has accumulated containing contaminated residue. In retrospect, the physical properties of Cobalt-60 or any other metal in suspension, could be expected to have this characteristic. Because AMS and Picker International were batch dischargers through a pipe exclusively used for this purpose and leading to the manhole, it is assumed that the surge created by a batch discharge may have left an accumulated residue above the normal sewer flow line. Areas between the manhole and the city sewer and below the normal

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May 23, 1988

sewer effluent flow have been under a constant purge and are expected to demonstrate very little contamination. AMS and NSS expect that the total content of contamination in the manhole will be small.

b) Describe the Means for Maintaining Security of the Area From Approach Via the City of Cleveland (Main) Sewerage System

The line from AMS's manhole to the city sewer line is less than ten (10) inches in diameter and there is no city manhole at the termination of the sewer line. Access by man or equipment from the city sewer is self-secured by the size and location constraints. The sewer cover on our property is secured with a lock and bar and inside the cover is a warning sign. There has been no need identified to maintain additional security.

c) Describe any Plans for Clean-Up (Decontamination) of the Referenced Area

See responses to 10 CFR 2.201 (a) 2. and 3. above. Reference NSS Decontamination Plan for AMS London Road Facility, 10-30-87.

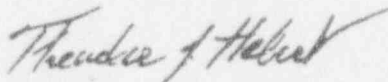
d) Describe any Potential for Release of By-Product Material to the Main Sewerage System

AMS may still discharge contaminated water to the main sewer system within the limits set forth by 10 CFR 20.303 and AMS's ISP-12 issued 8-11-87. However, AMS will discontinue use and has proposed isolation of the WHUT Room. Water from this room was the primary source of the by-product material that is presently in the manhole. AMS does not intend to discharge from this source after the WHUT Room has been isolated. AMS will dismantle all of the equipment previously used to discharge controlled batches of water from the WHUT Room. Further, all of the incoming lines to the WHUT Room will be disabled.

During the decontamination process, a small amount of material from the manhole might be carried out by normal effluent flow from the hygenic system. Of course this material was previously accounted for as part of our normal discharges. Any of the remaining material that may ultimately be released to the sewer system will be quantified and released within the limits set forth by 10 CFR 20.303 as a new discharge.

I hope that the above information on our decon plan for the sewer has answered your questions in your letter dated May 5, 1988 with respect to special safety inspection conducted by Mr. Robert E. Burgin on April 13, 1988. Should you have further questions regarding the above material, please call me at (216) 466-4671.

Sincerely yours,



Theodor J. Hebert
Chairman, Isotope Committee

TJH/dsj

FAX MESSAGE

ADVANCED MEDICAL SYSTEMS, INC.

121 North Eagle Street, Geneva, OH 44041

Telephone: (216) 466-4671

FAX: (216) 466-0186

TO: USNRC
Region III

FROM: SJ Sker
Reg Affairs

ATTN: Ray Caniano

NO.: (708) 790-5665

DATE: March 12, 1993

Attached please find the correspondence regarding the Northeast Ohio Regional Sewer District's demand for compensation

Don
F T I
Ray

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4871 • TWX 4332-195 ATC UI • FAX (216) 466-0188

March 11, 1993

VIA CERTIFIED U.S. MAIL

Mr. Thomas E. Lenhart
Assistant General Counsel
Northeast Ohio Regional Sewer District
3826 Euclid Avenue
Cleveland, Ohio 44115-2504

RE: Your Letter Dated March 4, 1993

Dear Mr. Lenhart:

We are in receipt of your letter dated March 4, 1993, wherein you renew your demand for compensation. As you are aware, you have still failed to provide a basis for this demand, other than to state that AMS should "[r]est assured that the District has conducted a thorough investigation prior to contacting your company". We do not consider this bold statement to provide any basis for your demand, especially since your letter of February 22, 1993, alleges that our Geneva facility was somehow responsible for negligent discharges to the Southerly Wastewater Treatment Plant.

You are, therefore, requested to provide full and accurate details of your allegation. Specifically:

- (1) The dates of your alleged investigation of AMS, the name(s) of the investigator(s), and the outcomes therefrom;
- (2) The reason(s) why you failed to provide AMS with notice of these investigations, and/or the outcomes therefrom;
- (3) The specific regulations you claim that AMS violated, and the reason(s) why AMS was not previously notified of these alleged violations if you claim any such violations exist;
- (4) The list of other facilities discharging radioactive materials into the sanitary sewer system that are pumped to the Southerly Wastewater Treatment Plant, the dates of your investigation into those facilities, and the outcome of those investigations;

Mr. Thomas E. Lenhart

-2-

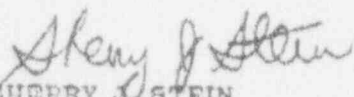
March 11, 1993

- (5) Whether any contamination was detected at the Easterly Plant, where as you admit, AMS' wastewater is sent, the specific levels of this contamination, if you allege any to exist, and the reason(s) why AMS was never notified of any such alleged contamination.

Your prompt response to the above requests for substantiation is requested.

Finally, given the fact that there is no evidence to substantiate your allegation, and the fact that the Nuclear Regulatory Commission has informed us that your allegation against us is unsubstantiated, we will continue to consider your demand that we financially compensate your District to be without basis in fact and nothing short of harassment.

Sincerely,


SHERRY J. STEIN
Director of Regulatory Affairs

SJS/cs



Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

March 4, 1993

RECEIVED MAR - 5 1993

Ms. Sherry J. Stein
Director of Regulatory Affairs
Advanced Medical Systems, Inc.
121 North Eagle Street
Geneva, Ohio 44014

Re: Southerly Wastewater Treatment Plant
Cuyahoga Heights, Ohio

Dear Ms. Stein:

We are in receipt of your letter of February 23, 1993, and wish to respond to clear up any misunderstanding you may have. The District believes that the radioactive materials were discharged from your facility at 1020 London Road, Cleveland, Ohio. Although the London Road facility discharges to the Easterly Wastewater Treatment Plant, the solids from Easterly are pumped to the Southerly Wastewater Treatment Plant for further processing including incineration.

Rest assured that the District has conducted a thorough investigation prior to contacting your company. The District's prior letter to your company was intended to notify you of our claim and demand for compensation. The District intends to proceed immediately to litigation should Advanced Medical not respond in a favorable manner towards resolution of the matter.

The District recommends a copy of this letter also be forwarded to your insurance carrier(s), and your company seriously reconsider the District's demands. The District is open to an amicable resolution of this matter should Advanced Medical care to rationally discuss it.

Very truly yours,

Thomas E. Lenhart
Assistant General Counsel

TEL/ydm

cc: E. J. Odeal
W. B. Schatz
S. J. Fagnilli
R. J. Connelly

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4871 • TWX 4332-135 ATC UJ • FAX (216) 466-0186

February 23, 1993

VIA CERTIFIED U.S. MAIL

Mr. Thomas E. Lenhart
Assistant General Counsel
Northeast Ohio Regional Sewer District
3826 Euclid Avenue
Cleveland, Ohio 44115-2504

RE: Advanced Medical Systems, Inc.
121 North Eagle Street
Geneva, Ohio 44041

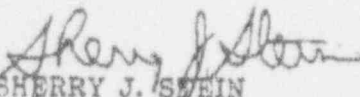
Dear Mr. Lenhart:

In response to your letter alleging, without basis in fact, that our facility negatively discharged radioactive material into the sanitary sewer system tributary to the Southerly Wastewater Treatment Plant. Please be advised that this facility does not possess radioactive material. Further, we are two counties away, discharging to the Geneva Wastewater Treatment Plant located at 141 North Avenue, Geneva, Ohio. You may verify this by contacting them at 466-4228.

Further, you are well aware of the fact that our Cleveland facility, not mentioned in your letter, discharges to the Easterly Wastewater Treatment Plant, located at 14021 Lake Shore Boulevard, not to the Southerly Wastewater Treatment Plant in Cuyahoga Heights. This may be verified by your own organization.

Since you have failed to provide any form of evidence to substantiate your allegation, we find your demand that we financially compensate your District for any costs to be nothing short of harassment. You are, therefore, formerly requested to cease and desist your demands for compensation immediately.

Cordially,


SHERRY J. STEIN
Director of Regulatory Affairs

SJS/cs



Northeast Ohio Regional Sewer District

326 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

RECEIVED FEB 23 1993

VIA CERTIFIED MAIL RETURN RECEIPT
REQUESTED AND ORDINARY U.S. MAIL

February 22, 1993

Dr. Seymour S. Stein
President
Advanced Medical Systems
121 North Eagle Street
Geneva, Ohio 44041

Re: Southerly Wastewater Treatment Plant
Cuyahoga Heights, Ohio

Dear Dr. Stein:

As you undoubtedly know, the Northeast Ohio Regional Sewer District has investigated Cobalt-60 contamination at the District's Southerly Wastewater Treatment Plant. The District believes that Advanced Medical Systems negligently discharged radioactive materials into the sanitary sewer system tributary to the Southerly Plant causing the District substantial damage. The District believes that your company is strictly liable for such damage.

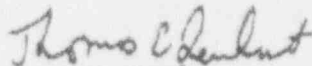
As a result of the contamination, the District has and will continue to incur substantial costs for remediation of the Southerly site. The District hereby demands that your company participate financially to compensate the District for the costs it has and will continue to incur.

Unless an acceptable response and settlement is received from Advance Medical Systems within twenty-one (21) days of the date of this letter, the District will pursue all remedies available to it, including litigation. Furthermore, if you carry or carried insurance for this type of loss, please forward a copy of this letter to your carrier(s) immediately, and have their representatives contact the undersigned immediately.

Dr. Seymour S. Stein
Advanced Medical Systems
February 22, 1995
Page Two

Please contact the undersigned with your company's response.

Very truly yours,


Thomas E. Lenhart
Assistant General Counsel

TEL/td

cc: E. J. Odeal
W. B. Schatz
S. J. Fagnilli
R. Connelly



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

LICENSE FILE
AMS 94-19089-01

MAR 10 1993

Northeastern Ohio Regional Sewer District
ATTN: Mr. Richard N. Connelly, Manager
Water Quality and Industrial
Surveillance
4747 East 49th Street
Cuyahoga Heights, OH 44125-1011

Dear Mr. Connelly:

We have received your letter dated February 8, 1993, requesting that a joint inspection be conducted at Advanced Medical Systems (AMS) consisting of members of the Nuclear Regulatory Commission (NRC) and investigators from your staff. The basis for your request was that you believe our inspection staff could provide meaningful insights regarding AMS discharge operations and also provide information on safety hazards which may be present at the facility. For the reasons set forth below, we would welcome an accompaniment by members of your staff during a future NRC inspection, but do not believe a joint inspection is warranted.

BACKGROUND

The NRC has inspected the AMS facility on numerous occasions since the 1960's when the facility was operating under the license issued to the Picker Corporation. In November of 1979, the Picker facility was sold to AMS and AMS acquired the NRC license. Until 1987, Picker and AMS manufactured numerous multi-curie cobalt 60 sources for use in medical teletherapy units. Since 1987, AMS limited its source production to only a few sources. In May of 1991, the AMS license was amended to preclude any source manufacturing for distribution. At that time AMS activities were limited to possession and service operations only. Over the past few years AMS has been upgrading its facilities, conducting inventories and training staff.

When AMS and Picker were actively manufacturing cobalt-60 sources and discharging to the sanitary sewer system, the NRC routinely assessed operations to determine whether the facility was in compliance with effluent release limits set forth in 10 CFR Part 20. Inspection results, which you have reviewed, concluded that the licensee's releases met regulatory requirements.

DISCUSSION

During the years when Picker and AMS were conducting source manufacturing operations, routine NRC inspections were conducted by qualified staff. These inspections included reviews of discharge operations including the licensee's program for monitoring materials released to the sanitary sewerage system as well as reviews of equipment, discussions with employees, observations of operations and reviews of records.

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A/S

MAR 10 1993

In addition to the routine inspections, from December 4, 1986 through February 18, 1987, in response to an allegation that materials had been released to the sanitary sewerage system in excess of the limits in 10 CFR Part 20, a special inspection was conducted. Based on a review of the documents available and discussions with staff who were involved with the operations, a determination was made by the NRC that the releases to the sanitary sewerage system for the period May 15, 1980 through February 11, 1987 were within the regulatory limits. In 1988, NRC Region III performed a special inspection of, and reviewed licensee reports of, changes in the systems to eliminate routine discharges through the floor drain and the hot cell. In addition, NRC reviewed the plans for a new holding tank for shower and sink drainage from the "clean" side of the operation. This tank must be sampled prior to release of its contents but any contamination found would be expected to be below NRC release limits. Any releases would be reviewed as part of our ongoing inspection program.

Recent NRC inspections at AMS have focused on facility improvements, inventories of radioactive materials, remediation activities, and training of staff. The lack of inspections of discharge operations is primarily because AMS has not been manufacturing any sources for distribution and that drains from the hot cell and basement have been capped to prevent any discharges from those areas. Those areas contain the majority of contamination. Furthermore, AMS has held any liquids resulting from remediation activities for ultimate disposition and therefore, there have been no releases to the sanitary stream from the remediation operations.

Based on our past inspections as described above, and because of the unlikely discovery of records or personal recollections that would provide more complete or new information, we do not plan to perform further reviews of past AMS discharge operations. If you wish to pursue this area, we recommend that you independently contact AMS to arrange for an inspection by your staff. AMS health physics staff will guide you and provide you with radiation monitoring devices if any radiologically controlled areas are entered within the AMS facility. This should alleviate your concern for safety of your investigators.

However, we do wish to cooperate with you to the extent possible. We will furnish you with the results of any future inspections. Your staff is welcome to accompany our inspectors during future inspections at AMS. These inspections may include assessments of any releases of radioactive materials, for example, from remediation activities. If such an accompaniment were desired, you would be requested to independently contact AMS and obtain the company's approval for access to their facility. You would be requested to follow specific guidance required of other governmental agencies who periodically accompany the NRC on inspection activities. Such guidance is attached for your information.

Northeastern Ohio Regional
Sewer District

2

MAR 10 1993

If you have any questions regarding our past inspections or wish to make arrangements for an accompaniment, please contact me or Roy Caniano of my staff at 708-790-5500.

Sincerely,

Charles E. Norelius

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

Attachment: As stated

cc w/attachment:
AMS License File
34-19089-01
DCD/DCB (RIDS)
S. Stein
Ohio Dept. of Health

OBSERVATION OF NRC INSPECTIONS

NRC Protocol

- NRC will process requests which are communicated in writing to the Regional Administrator through the State Liaison Officer. Requests should identify the type of inspection activity and facility.
- Limits on scope and duration of the observation period may be imposed if, in the view of the Regional Administrator, they compromise the efficiency or effectiveness of the inspection.
- Region will make it clear that only NRC has regulatory authority for inspection findings and enforcement actions regarding radiological health and safety.

Observer Protocol

- Observer will make advance arrangements with the licensee for required site access training prior to the actual inspection.
- Normally, only one individual will be allowed to observe the NRC inspection.
- The observer's communication with the licensee will only be through an NRC inspector.
- When informed of an unannounced inspection, observer must not release any information including its time and purpose.
- The observer will remain with NRC escorts throughout the inspection.
- The observer will not be provided with proprietary information. Observers will not remove any material from the site without NRC or licensee approval.
- The observer, in accompanying the NRC inspectors, does so at his or her own risk. NRC will not be responsible for injuries or exposures to harmful substances which may occur to the accompanying individual during the inspection and will assume no liability for any incidents associated with the accompaniment. Individuals accompanying NRC inspectors agree to waive all claims of liability against the Commission.
- The observer will be expected to adhere to the same conduct as NRC inspectors during an inspection accompaniment.
- Observer communications regarding these inspections should not be released to the public or the licensee before they are made known to the NRC and the inspection report is issued.

Signature of Observer

Date