January 19, 1995

Mrs. M. Finnigan
885 Rudyard Road
Cleveland, OH 44110

SUBJECT: REPORT REGARDING SURVEYS AND SAMPLING AT THE ADVANCED MEDICAL SYSTEMS, INC. FACILITY (REPORT NO. 030-16055/94003(DRSS))

Dear Mrs. Finnigan:

This refers to the October 25, 1994, telephone conversation between yourself and Michael Kurth of my staff. During this conversation, you requested that information be provided regarding surveys which were conducted during the summer and fall of 1994 outside of the Advanced Medical Systems, Inc. (AMS) facility, 1020 London Road, Cleveland, Ohio. Also discussed was your September 27, 1994, letter to the NRC formally requesting this information.

The enclosed NRC report (Report No. 030-16055/94003(DRSS)) refers to surveys and sampling conducted at the AMS facility from August 17 through October 14, 1994. You agreed during the October 25, 1994, telephone conversation that the information provided in the attached report should satisfy your September 27, 1994, formal request.

If you have questions regarding the report, please contact Michael Kurth of my staff at (708) 829-9869.

Sincerely,

Original Signed By

John A. Grobe, Chief
Nuclear Materials Inspection
Section 2

Enclosure: As stated

cc w/o encl: M. Pearson, RIII

DOCUMENT NAME: B:\CITIZEN.LTR

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OFFICE	RIII	C	RIII	N	RIII	E	RIII	N
NAME	Kurth MK		Snell WGS		Grobe JAG		Strasma AD	
DATE	01/9/95		01/9/95		01/19/95		01/18/95	

OFFICIAL RECORD COPY

B/16

December 6, 1994

Advanced Medical Systems, Inc.
ATTN: Mr. David Cesar, Treasurer
1020 London Road
Cleveland, Ohio 44110

SUBJECT: RESULTS OF NRC RADIOLOGICAL SURVEY AND SAMPLE ANALYSIS OF THE ADVANCED MEDICAL SYSTEMS, INC. (AMS) WASTE WATER PIPING AND ITS OUTFALL INTO THE CITY OF CLEVELAND SEWER (REPORT NO. 030-16055/94003(DRSS))

Dear Mr. Cesar:

This refers to the special inspection conducted by Messrs. Michael Kurth and Edward Kulzer of this office from August 17 through October 14, 1994. The special inspection was conducted to examine the radiological conditions of waste water exiting your facility through your waste water piping and into the City of Cleveland sewers in the vicinity of the sewage outfall from your facility. The inspection was prompted by the identification of exposure rates above background in the City of Cleveland sewer at the Advanced Medical Systems, Inc. (AMS) outfall. The results of this inspection were discussed with you at the conclusion of the inspection.

As described in the enclosed report, extensive radiation surveys and sampling of solid and liquid materials were conducted identifying cobalt-60 in the solid sediment from the city sewers and your waste water piping. Also, cobalt-60 was being carried in the waste water from the AMS outfall into the city sewers. This appears to represent a violation of 10 CFR 20.2003 which permits only the discharge of soluble material or readily dispersible biological material in water. The cobalt-60 emanating from your lateral is neither soluble or readily dispersible biological material.

We plan to meet with you in the near future to discuss these inspection findings. We will contact you at a later date to schedule this meeting. Following our meeting, a decision will be made on the appropriate enforcement action regarding the apparent violation. As such, no Notice of Violation is being issued at this time. While no Notice is being issued and no written response is required, we expect that prompt action has been or will be taken to correct this apparent violation.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosed inspection report will be placed in the NRC Public Document Room.

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

Sincerely,

Original Signed By
R. J. Caniano for

W. L. Axelson, Director
Division of Radiation Safety and Safeguards

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

Enclosure: Inspection Report No.
030-16055/94003(DRSS)

cc w/encl: NEORSD
City of Cleveland

bcc w/encl: J. Turdici, OEDO
J. T. Greeves, NMSS
E. W. Brach, NMSS
J. H. Austin, NMSS
T. C. Johnson, NMSS
M. Nalluswami, NMSS
C. G. Jones, NMSS
R. L. Fonner, OGC
PUBLIC (IE07)

DOCUMENT NAME: B:\AMS94003.DSS

*Concurrence via e-mail

See Previous Concurrences

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OFFICE	RIII		RIII		RIII		RIII		RIII		RIII	
NAME	Kurth		Kulzer		Slawinski		Madera		Grobe		Shear	
DATE	12/ /94		12/ /94		12/ /94		12/ /94		12/ /94		12/ /94	

OFFICE	RIII		NMSS	*	DWM	*	OGC	*	RIII			
NAME	Berson		Paperiello		Knapp		Chandler		Axelson			
DATE	12/ /94		12/ /94		12/ /94		12/ /94		12/6 /94			

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

Sincerely,

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards

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

Enclosure: Inspection Report
No. 030-16055
/94003(DRSS)

cc w/encl: NEORSD
City of Cleveland

bcc w/encl: J. Turdici, OEDO
J. T. Greeves, NMSS
E. W. Brach, NMSS
J. H. Austin, NMSS
T. C. Johnson, NMSS
M. Nalluswami, NMSS
C. G. Jones, NMSS
R. L. Fonner, OGC
PUBLIC (IE07)

DOCUMENT NAME: B:\AMS3.ltr

*Concurrence via e-mail

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OFFICE	RIII	E	RIII	E	RIII	E	RIII	E	RIII	E	RIII	N
NAME	Kurth		Kulzer		Slawinski		Madera		Grobe		Shear	
DATE	12/5/94		12/5/94		12/5/94		12/5/94		12/5/94		12/5/94	

OFFICE	RIII	E	NMSS	*	DWM	*	OGC	*	RIII		OE	E
NAME	Berson		Paperiello		Knapp		Chandler		Axelson		Lieberman	
DATE	12/5/94		12/1/94		12/1/94		12/23/94		12/ /94			

U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-16055/94003(DRSS)

License No. 34-19089-01

Organization: Advanced Medical Systems, Inc. (AMS)
1020 London Road
Cleveland, Ohio

Inspection At: City of Cleveland sewer interceptor (sewer interceptor)
Intersection of sewer interceptor under London Road,
upstream and downstream manholes, and the AMS manhole
Cleveland, Ohio

Inspection Conducted: August 17 through October 14, 1994

Inspectors: _____ 12/5/94
Michael Kurth Date
Radiation Specialist

_____ 12/5/94
Edward Kulzer Date
Radiation Specialist

Reviewed by: _____ 12/5/94
John R. Madera, Chief Date
Materials Licensing Section

Approved by: _____ 12/5/94
John A. Grobe, Chief Date
Nuclear Materials Inspection
Section 2

Inspection Summary

Inspection on August 17 through October 14, 1994 (Report No. 030-16055/94003(DRSS))

Areas Inspected: This was a special inspection conducted to perform surveys of the City of Cleveland sewer interceptor in the location of the AMS facility, Cleveland, Ohio, and in the AMS manhole. The inspection was prompted by the identification of elevated exposure rates on the sewer interceptor surface below the AMS lateral in July 1994. Samples of sewer debris, water effluent, and a series of wipes were collected for analyses.

Results: The NRC inspectors, accompanied by the Northeast Ohio Regional Sewer District (NEORSD), and NEORSD contractors, B. Koh & Associates, Inc.,

identified four areas of elevated exposure rates. These areas are located: (1) below the intersection of the sewer interceptor and the AMS lateral; (2) within the processing drain line in the AMS sewer; (3) within the sanitary inlet into the AMS manhole; and (4) within the sanitary outlet from the AMS manhole into the sewer interceptor. The preliminary results of the sewer debris and wipe test analysis from the August 17, 1994 sampling identified positive cobalt-60 surface contamination levels ranging from 457 disintegrations per minute per 100 cm^2 (dpm/100 cm^2) to 2.7 x 10^6 dpm/100 cm^2, partial levels which exceed the 1,000 dpm/100 cm^2 limit found in NRC's guidance document, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Sources, or Special Nuclear Materials," dated August 1987. Also, between July 5 and October 10, 1994, cobalt-60 was identified, by the NRC and the NEORSD, in the water effluent discharged from the AMS lateral into the sewer interceptor. The September 20, 1994 sampling analysis verified prior indications of cobalt-60 contamination. However, further water discharge samples taken from the location on September 20 and October 4, 1994, did not identify the presence of cobalt-60.

One apparent violation was identified:

> Apparent failure to dispose of licensed material into the sanitary sewerage system that is readily soluble or is readily dispersible biological material in water is an apparent violation of 10 CFR 20.2003, which has been a requirement for this licensee since January 1, 1994 (Section 3. B. of this report).

Also, given that cobalt-60, which is not considered to be readily soluble or readily dispersible biological material in water, was identified in effluent discharged from the AMS lateral and, that cobalt-60 was deemed to be removable within the AMS lateral through the conduct of wipe sampling, the probability exists that future effluent discharges may develop into the disposal of licensed material into the sanitary sewerage system.

DETAILS

1. Persons Contacted

Thomas Lenhart, Assistant General Counsel, NEORSD
* Lawrence English, Assistant General Counsel, NEORSD
* Richard Connelly, Manager Water Quality, NEORSD
* Len Jufko, NEORSD
* William Kasberg, NEORSD
* Theodore Adams, Vice President, B. Koh & Associates, Inc.
#@David Cesar, Treasurer, Advanced Medical Systems, Inc. (AMS)
@ Joseph Michuta, Radiation Safety Officer, AMS
@ Robert Neschter, Senior Radiation Technician, AMS
@ Vincent Rocco, Radiation Technician, AMS

*Denotes those present at interceptor sewer survey conducted August 17. and September 20, 1994.
@Denotes those present at the sewer survey conducted September 20, 1994.
#Denotes those present during the exit interview conducted by telephone on October 14, 1994.

2. Background

A. General History

In 1959, the Atomic Energy Commission issued License No. 34-07225-09 to Picker X-Ray Corporation (Picker Corp.), for the operation of an isotope manufacturing facility located at 1020 London Road, Cleveland, Ohio. The Picker Corp. license authorized possession of 150,000 curies of cobalt-60 and 3,000 curies of iridium-192 in solid metal form, and 40,000 curies and 100 curies of cesium-137 and thulium-170 respectively, as sealed sources. These licensed materials were authorized for: (1) processing incident to redistribution to authorized recipients; (2) radiation effects studies; and (3) research and development. The principal operation conducted under this license was the manufacture of cobalt-60 sealed sources for medical teletherapy and industrial radiography units, and subsequent distribution of the sources to authorized recipients throughout the world.

In 1979, the Picker Corp. London Road facility was purchased by Advanced Medical Systems, Inc. (AMS). License No. 34-07225-09 was terminated on November 9, 1979, at which time all licensed material possessed was transferred to AMS.

The NRC issued License No. 34-19089-01 to AMS on November 2, 1979. At this time, the licensed operations, facilities and equipment previously owned and operated by the Picker Corp. were assumed by AMS.

Both operations had released cobalt-60 through the London Road facility lateral into the sanitary sewer under the provisions of 10 CFR 20.303, "Disposal by Release into Sanitary Sewerage Systems," which was in effect through December 31, 1993. The NRC inspection in 1988 confirmed cobalt-60 contamination in the AMS sewer manhole on AMS property. At that time the radiation level ranged as high as 70 milliroentgen per hour (mR/hr) at the bottom of the manhole adjacent to the discharge pipe from the AMS building. The contaminated area was partially decontaminated and covered with a layer of concrete by the licensee. In May 1989, as stated in the NRC Inspection Report No. 030-16055/93002(DRSS), AMS discontinued the discharge of licensed material into the sanitary sewerage system. Also, AMS has not generated liquid waste for several years due to changes in its decontamination methods and termination of source manufacturing operations.

Beginning January 1, 1994, NRC licensees were required to comply with the revised 10 CFR Part 20, which contains more restrictive requirements for sanitary sewer disposal of liquid radioactive waste than previously existed.

The revised 10 CFR 20 specifies, in part, in 20.2003, "Disposal by Release into Sanitary Sewerage," that licensees may discharge licensed material into the sanitary sewerage system only if the material is readily soluble or is readily dispersible biological material in water.

In 1993, as documented in NRC Inspection Report No. 999-90003 /93010(DRSS), an NRC inspector measured the exposure rates in the downstream manhole from the AMS facility in the London Road sewer interceptor. No detectable radiation exposure rates above background were identified. The location where the elevated exposure rate was identified in July 1994 by the NEORSD was inaccessible at the time of the 1993 NRC inspection and the NRC was unaware, in 1993, of the manhole's existence.

B. Specific History Prompting this Special Inspection

On July 5, 1994, surveys were conducted by the Northeast Ohio Regional Sewer District (NEORSD) contractors, B. Koh & Associates, Inc., along the City of Cleveland's interceptor sewer (interceptor sewer) in an area connecting with the AMS lateral under London Road. Elevated exposure rate readings were identified below the AMS lateral on the sewer interceptor brick and iron rungs. The NEORSD reported that the radiation exposure rate measured was approximately 7 mR/hr on contact. Residue deposits on the sewer interceptor brick and iron rungs below the AMS lateral were collected, resulting in the identification of cobalt-60 contamination ranging from 0.084 to 0.12 microcuries per gram. Also, during the performance of the surveys, the NEORSD discovered a manhole directly above the AMS lateral/sewer interceptor

intersection which was buried below the London Road surface. The NEORSD has since raised the level of the manhole to the street surface.

Attachment No. 1 of this report illustrates the pathway and proximity of the AMS lateral in relation to the AMS facility. The approximate length of the lateral from the AMS manhole to the sewer interceptor is 40 feet (12 m). The lateral is made of 4 to 5 foot (122-152 cm) long sections of precast clay/ceramic piping butted together forming the lateral. The lateral is approximately 18 inches (46 cm) in diameter. Attachment No. 2 contains a photograph of the AMS lateral protruding into the City of Cleveland sewer interceptor (sewer interceptor). The sewer interceptor is approximately 5 feet (1.5 m) in diameter and flows to the Easterly Wastewater Treatment Plant.

3. Survey and Sample Analysis Results

A. Survey Results

On August 17 and September 20, 1994, the NRC inspectors, accompanied by NEORSD personnel and NEORSD contractors, conducted a series of surveys in the sewer interceptor outside of the AMS facility under London Road. During those surveys there was a significant flow rate of waste water emanating from the AMS lateral into the interceptor. An assessment of the waste water flow rates is contained in NRC Inspection Report No. 030-16055 /94004(DRSS) issued November 29, 1994. Also, on September 20, 1994, surveys were conducted in both manholes immediately upstream and downstream from the AMS facility along London Road, and in the AMS manhole. The survey instruments used were a Ludlum Model 19 Micro R Meter, NRC Tag No. 014808, a Ludlum Model 12 Count Ratemeter with attached pancake probe, NRC Tag No. 047068, a [1]Bicron MicroRem, Serial No. B709J, and a [2]Ludlum Model No. 2221 Scaler Ratemeter (No Serial No. available) with attached pancake probe.

The background exposure rate measured at the London Road street surface above the AMS lateral/sewer interceptor intersection was 12 [3]microroentgen per hour (μR/hr). The surveys conducted in the sewer interceptor demonstrated elevated exposure rate readings. A sewer interceptor surface area approximately 1.5 feet (46 cm) by 3 feet (91 cm) located directly below the AMS lateral showed elevated readings averaging 1.0 to 10 mR/hr on contact with the sewer interceptor brick. Attachment No. 2 of this report

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[1]This instrument is owned and maintained by B. Koh & Associates, Inc.

[2]This instrument is owned and maintained by B. Koh & Associates, Inc.

[3]Assume that 1 roentgen = 1 Rem.

illustrates the location of the elevated exposure rates in the sewer interceptor. One spot was identified between the iron rungs on the sewer interceptor brick surface showing an exposure rate ranging from 20 to 25 mR/hr on contact. Also, a spot was identified on the rung below the AMS lateral showing an elevated exposure rate of 14 mR/hr on contact. An average exposure rate of 0.5 mR/hr was identified both 3 feet (91 cm) upstream and downstream from the AMS lateral in the center of the sewer interceptor. Also, an exposure rate ranging from 1.5 to 2.0 mR/hr was identified in the center of the sewer interceptor directly across (approximately 61 cm) from the elevated area below the AMS lateral. Attachment No. 3 of this report contains several photographs of the sewer interceptor wall in the area of the AMS lateral.

Surveys conducted of the first manholes immediately upstream and downstream from the AMS facility identified exposure rates ranging from 5 to 9 μR/hr on the surface of London Road next to the manholes. Exposure rates ranging from 14 to 19.5 μR/hr (includes the background rate) were identified in the center of the sewer interceptor and on contact with the interceptor brick in both manholes. The slightly elevated exposure rates were attributed to naturally occurring radioactive materials (NORM) in the sewer brick. (NORM, such as potassium-40, radium-226, and thorium-232, are found in very small quantities in brick.)

Elevated exposure rates were identified in the AMS manhole. Exposure rates ranging from 2 to 3 mR/hr were identified, on contact, approximately 2 to 4 inches (5 to 10 cm) into the processing drain line, and the sanitary inlet and outlet in the AMS manhole. A survey instrument was lowered into the AMS manhole demonstrating exposure rates of 0.5 to 1.0 mR/hr in the center of the AMS manhole.

8. Sampling Analysis Results

On July 5, 1994, the NEORSD collected three sediment samples from the sewer interceptor in the location of the AMS lateral outfall. Also, a water effluent sample was collected from waste water discharging from the AMS lateral. The analytical results of the sediment samples identified positive cobalt-60 concentrations ranging from 0.084 to 0.12 microcuries per gram. The result of the water sample identified a positive cobalt-60 concentration of 29 picocuries per liter (pCi/l).

The NRC collected numerous smears, sewage residues, and water samples on August 17 and September 20, 1994. Table No. 1 identifies the locations and analytical results of the smear and sewage residue samples collected on August 17, 1994. The samples were analyzed using the NRC Region III gamma spectroscopy system. On August 17, 1994, a total 4 smears and 4 sewage residue samples were collected.

As illustrated in Table No. 1, the analysis of the sewage residue samples demonstrated cobalt-60 contamination ranging from 4.29 to 1,230 nanocuries. Two of the 4 smears collected identified cobalt-60 contamination ranging from 2,750 to 103,840 disintegrations per 100 cm^2 (dpm/100 cm^2). Each smear collected was assumed to cover a 100 cm^2 area. The acceptable surface contamination level for removable cobalt-60 is 1,000 dpm/100 cm^2, as stated in the NRC document, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," dated August 1987, which is included as Attachment No. 4 of this report. The water effluent sample collected demonstrated positive indications of cobalt-60 contamination of 35 picocuries per liter (pCi/l).

Table No. 2 identifies the locations and analytical results of the NRC smears collected on September 20, 1994. As illustrated in Table No. 2, a smear result of 16,852 dpm/100 cm^2 removable cobalt-60 contamination was identified on the sewer interceptor wall below the AMS lateral.

On September 20, 1994, smears were also collected from the sewer interceptor walls in the areas of the first sewer interceptor manholes immediately upstream and downstream from the AMS facility along London Road, and the AMS manhole. As illustrated in Table No. 2, general smears of the sewer interceptor walls from the sewer interceptor manholes located immediately upstream and downstream from the AMS facility along London Road did not identify removable cobalt-60 contamination. There was however, a surface contamination level of 97 dpm/100 cm^2 which was identified in the AMS manhole on the AMS lateral exiting into the sewer interceptor.

Table No. 3 identifies the dates, locations, and analytical results of the water effluent collected by the NRC and the NEORSD. As illustrated in Table No. 3, water effluent samples taken from the upstream and downstream manholes, and from the AMS manhole, did not demonstrate positive indications of cobalt-60. However, water effluent collected from the outfall of the AMS lateral into the sewer interceptor on July 5, August 17, September 28, October 1, and October 10, 1994, demonstrated positive concentrations of cobalt-60 ranging from 13 to 306 pCi/l. Given that removable cobalt-60 was identified on the surface of the AMS lateral, it appears that the water effluent flowing through the AMS lateral sloughed the cobalt-60 from the lateral causing the release of licensed material into the sanitary sewerage system. The discharge of licensed material, cobalt-60, which is not readily soluble or is readily dispersible biological material in water into the sanitary sewerage system is an apparent violation of 10 CFR 20.2003 which has been a requirement for this licensee since January 1, 1994.

One apparent violation of NRC requirements was identified.

4. Exit Meeting

During the performance of surveys and sample collecting, the preliminary findings were provided to those individuals present during the August 17 and September 20, 1994, on-site inspections, as identified in Section 1 of this report. A summary of the areas surveyed and the forthcoming letter were discussed. Also, on October 14, 1994, the results of this inspection were discussed in a telephone conversation between Mr. Cesar and Mr. Caniano. The AMS and NEORSD employees did not identify any information provided during the inspection as proprietary.

Attachments:
1. Illustration of pathway of AMS lateral into sewer interceptor
2. Diagram of sewer interceptor
3. Series of photographs of sewer
4. Guideline for the Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source,or Special Nuclear Material

TABLE NO. 1

NRC SEWER SAMPLE RESULTS

SEWER SAMPLES FROM THE CITY OF CLEVELAND INTERCEPTOR
IN THE IMMEDIATE AREA OF THE AMS LATERAL ON LONDON RD

SAMPLES TAKEN AUGUST 17, 1994

	SAMPLE LOCATION	RESULT ± 2σ
1.	Debris and sludge from left (upstream) of rungs below the AMS lateral	°4,290 pCi ± 32 pCi
2.	Black debris off of top rung below the AMS lateral	°434,000 pCi ± 3,000 pCi
3.	Black debris off of brick wall below the AMS lateral	°1,230,000 pCi ± 7,000 pCi
4.	Red debris off of rung above the AMS lateral	°1,630 ± 20 pCi
5. a.	Smear: Rung immediately below the AMS lateral	less than 41 'dpm
5. b.	Smear: NEORSD Sewer wall (sewer brick) below the AMS lateral	103,840 dpm ± 167 dpm
5. c.	Smear: NEORSD Sewer wall (sewer brick) above the AMS lateral	2,756 dpm ± 52 dpm
5. d.	Smear: Inside the AMS lateral	457 dpm ± 138 dpm

'Note: The reported uncertainty refers only to counting statistics.

°Note: Additional analysis error will be introduced due to the unique geometry associated with the debris. The geometry error is estimated to be less than 10 percent.

'Note: disintegration per minute = dpm. Also, each smear result is estimated to be averaged over a 100 cm^2 area.

TABLE NO. 2

NRC SMEAR RESULTS
SEWER SAMPLES FROM THE CITY OF CLEVELAND SEWER INTERCEPTOR
IN THE AREA OF THE AMS FACILITY ON LONDON ROAD
AND THE AMS SEWER

SAMPLES TAKEN SEPTEMBER 20, 1994

*	LOCATION		RESULT ± 2σ
1	Smear:	Iron Rung Directly Below the AMS Lateral	*717 ± 17 dpm
2	Smear:	Sewer Interceptor Brick Directly Below the AMS Lateral (between lateral and 1st rung	16,852 ± 264 dpm
3	Smear:	Sewer Interceptor Brick Directly Above the AMS Lateral	< 16 dpm
4	Smear:	Approximately 1 foot inside the AMS Lateral between the positions of 12:00 and 3:00	56 ± 4 dpm
5	Smear:	Outer Surface of the AMS Lateral between the positions of 12:00 and 3:00	< 23 dpm
6	Skipped No. 6		
7	Smear:	Outer Surface of the AMS Lateral at the 6:00 position	490 ± 143 dpm
8	Smear:	Inside the AMS Lateral Approximately 1 foot at the 5:00 position (as close to water line as possible)	161 ± 7 dpm
9	Smear:	General Wipe of Upstream Sewer Interceptor	< 13 dpm
10	Smear:	General Wipe of Downstream Sewer Interceptor	< 14 dpm
11	Smear:	AMS Sewer- Floor of AMS Sewer	< 13 dpm
12	Smear:	AMS Sewer- Outlet from Processing Drain (East Drain near waterline)	< 16 dpm
13	Smear:	AMS Sewer- General Wipe of Sewer Wall	< 22 dpm
14	Smear:	AMS Sewer- South Inlet to Manhole (near waterline)	< 23 dpm
15	Smear:	AMS Sewer- AMS Sewer Outlet to Interceptor (near waterline)	97 ± 6 dpm

'Note: The reported uncertainty refers only to counting statistics.

*Note: Disintegrations per minute = dpm. Also, each result is estimated to averaged over a 100 cm^2 area.

TABLE NO. 3

NRC AND THE NEORSD WATER EFFLUENT SAMPLE RESULTS

	SAMPLE	DATE COLLECTED - LOCATION	RESULT ± *2σ
1	NEORSD	July 5, 1994 - AMS lateral outflow to sewer interceptor	29 pCi/l
[1]2	NRC	August 17, 1994 - AMS lateral outflow to sewer interceptor	35 pCi/l ± 0.4 pCi/l
3	NEORSD	August 17, 1994 - AMS lateral outflow to sewer interceptor	33 pCi/l
4	NRC	September 20, 1994 - AMS lateral outflow to sewer interceptor	˙< 10.3 pCi/l
5	NEORSD	September 20, 1994 - AMS lateral outflow to sewer interceptor	˙< 20 pCi/l
6	NRC	September 20, 1994 - AMS manhole	˙< 9.3 pCi/l
7	NRC	September 20, 1994 - Upstream manhole	˙< 8.9 pCi/l
8	NRC	September 20, 1994 - Downstream manhole	˙< 9.1 pCi/l
9	NEORSD	September 28, 1994 - AMS lateral outflow to sewer interceptor	13 pCi/l
10	NEORSD	October 1, 1994 - AMS lateral outflow to sewer interceptor	86 pCi/l
11	NEORSD	October 4, 1994 - AMS lateral outflow to sewer interceptor	˙< 0.1 pCi/l
12	NEORSD	October 10, 1994 - AMS lateral outflow to sewer interceptor	306 pCi/l

*Note: The reported uncertainty refers only to counting statistics.

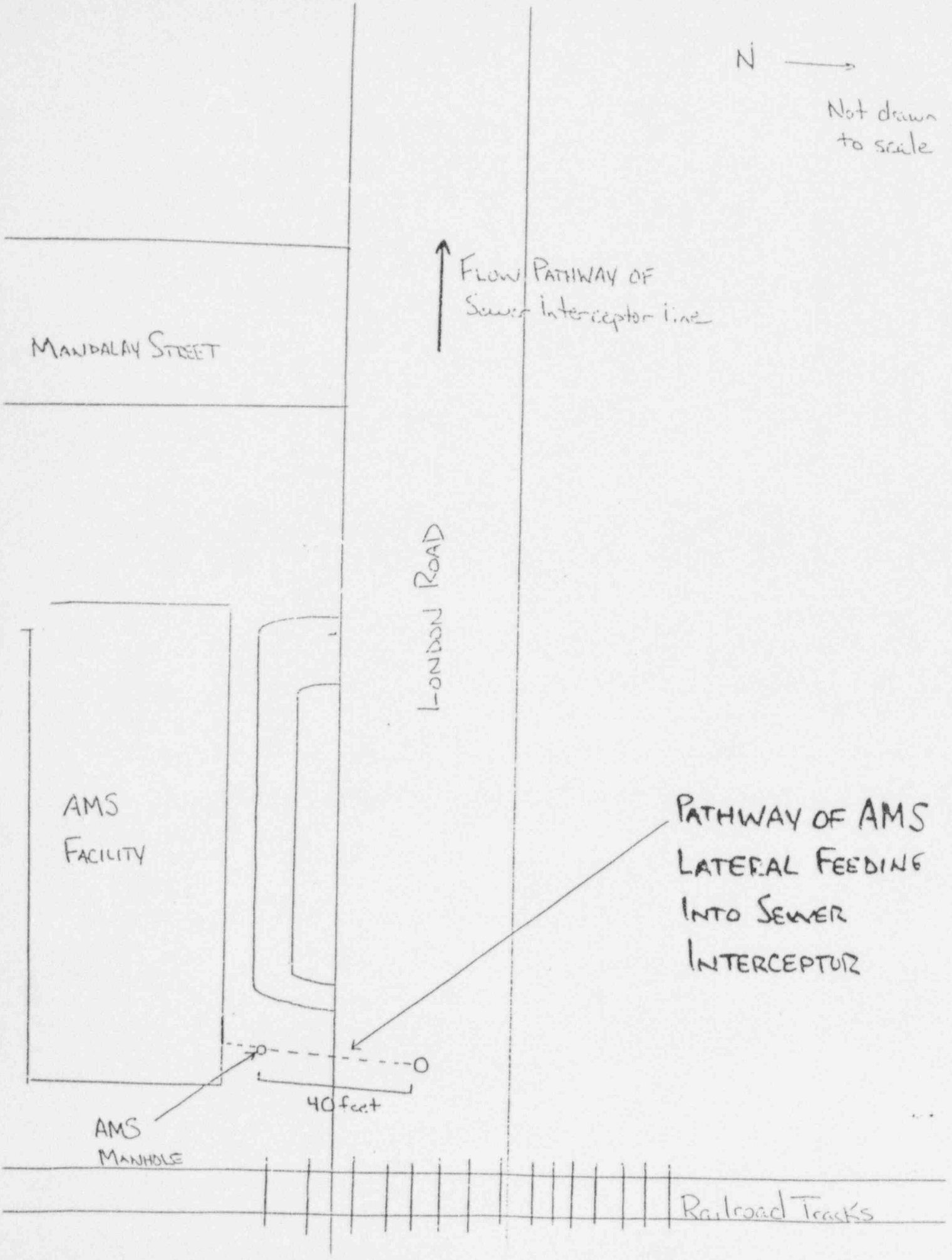
˙Note: The analytical results demonstrating the less than symbol, "<", indicates that no measurable activity was identified below the minimum detectable level derived for that sample. The minimum detectable level for each sample in which no measurable activity was detected is recorded in the "RESULT" column.

---

[1]This sample was analyzed by the NRC. After conducting the analysis, the sample was provided to the NEORSD for analysis (Sample Result No. 3 of this table). Therefore, Sample Nos. 2 and 3 were the same samples analyzed independently.

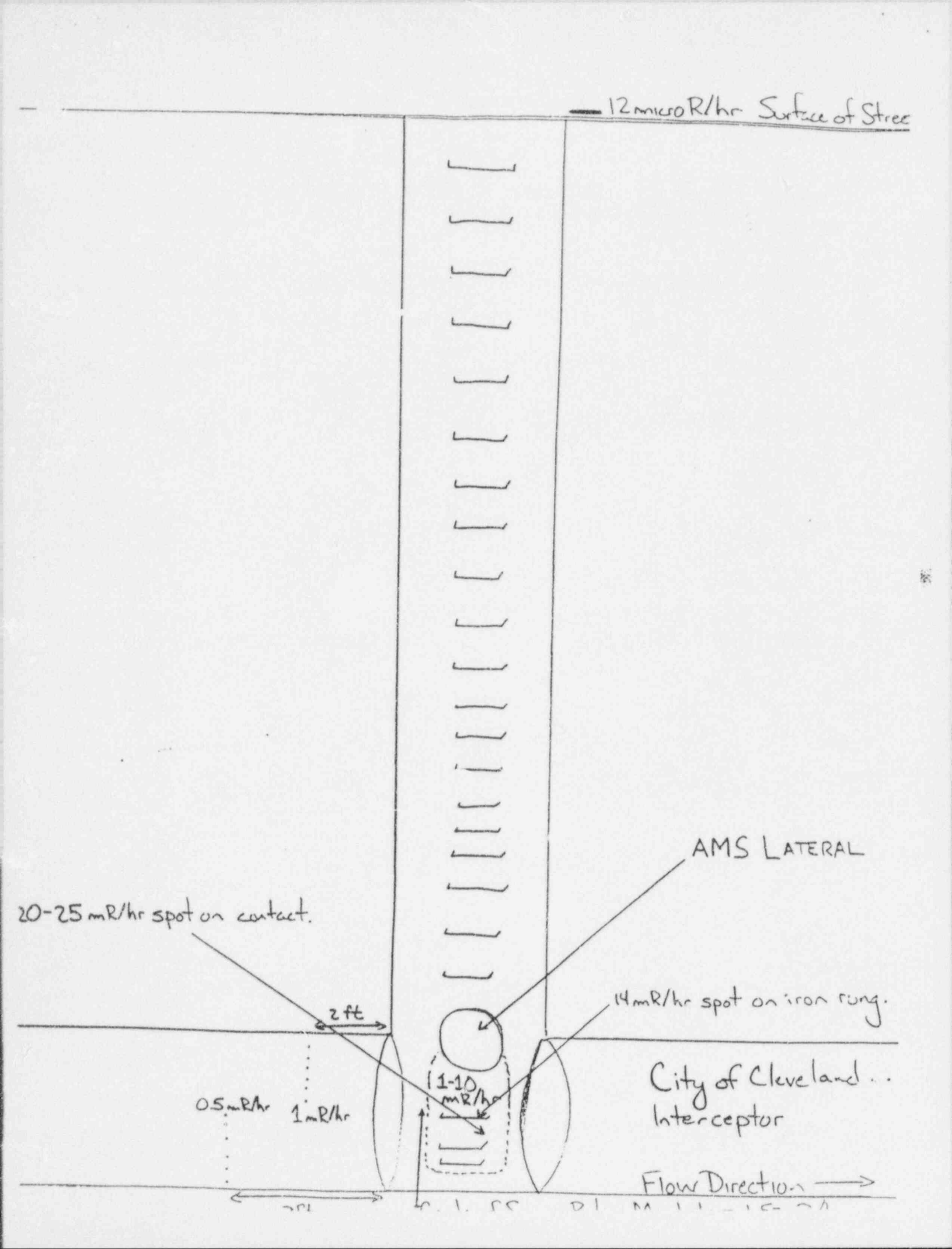
ATTACHMENT NO. 1

ILLUSTRATION OF PATHWAY OF AMS LATERAL
INTO SEWER INTERCEPTOR


N
Not drawn to scale
FLOW PATHWAY OF Sewer Interceptor line
MANDALAY STREET
LONDON ROAD
AMS FACILITY
PATHWAY OF AMS LATERAL FEEDING INTO SEWER INTERCEPTOR
40 feet
AMS MANHOLE
Railroad Tracks

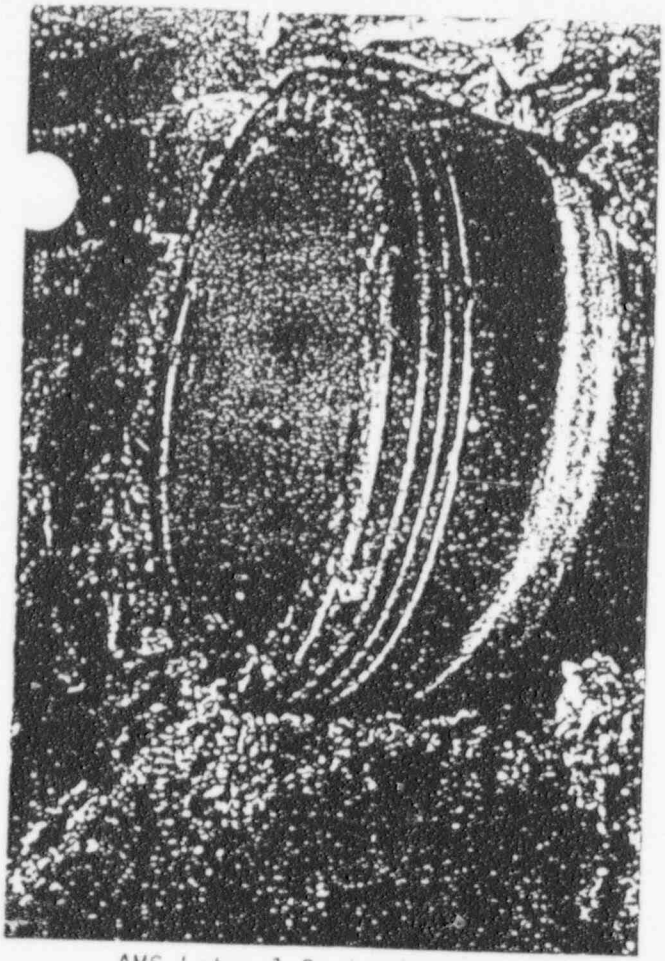
ATTACHMENT NO. 2

DIAGRAM OF SEWER INTERCEPTOR


12 micro R/hr Surface of Stree
AMS LATERAL
20-25 mR/hr spot on contact.
14 mR/hr spot on iron rung.
2 ft
1-10 mR/hr
0.5 mR/hr
1 mR/hr
City of Cleveland . .
Interceptor
Flow Direction

ATTACHMENT NO. 3

SERIES OF PHOTOGRAPHS OF SEWER



AMS Lateral Protruding Out into the City of Cleveland Sewer Interceptor

Sewer Interceptor and Iron Rungs Below the AMS Lateral

Pathway of the AMS Lateral from the Interceptor into the AMS Building

ATTACHMENT NO. 4

GUIDELINE FOR THE DECONTAMINATION OF FACILITIES AND EQUIPMENT PRIOR TO RELEASE FOR UNRESTRICTED USE OR TERMINATION OF LICENSES FOR BYPRODUCT, SOURCE, OR SPECIAL NUCLEAR MATERIAL

GUIDELINES FOR DECONTAMINATION OF FACILITIES AND EQUIPMENT PRIOR TO RELEASE FOR UNRESTRICTED USE OR TERMINATION OF LICENSES FOR BYPRODUCT, SOURCE, OR SPECIAL NUCLEAR MATERIAL

U.S. Nuclear Regulatory Commission
Division of Industrial and
Medical Nuclear Safety
Washington, DC 20555

August 1987

The instructions in this guide, in conjunction with Table 1, specify the radionuclides and radiation exposure rate limits which should be used in decontamination and survey of surfaces or premises and equipment prior to abandonment or release for unrestricted use. The limits in Table 1 do not apply to premises, equipment, or scrap containing induced radioactivity for which the radiological considerations pertinent to their use may be different. The release of such facilities or items from regulatory control is considered on a case-by-case basis.

1. The licensee shall make a reasonable effort to eliminate residual contamination.

2. Radioactivity on equipment or surfaces shall not be covered by paint, plating, or other covering material unless contamination levels, as determined by a survey and documented, are below the limits specified in Table 1 prior to the application of the covering. A reasonable effort must be made to minimize the contamination prior to use of any covering.

3. The radioactivity on the interior surfaces of pipes, drain lines, or ductwork shall be determined by making measurements at all traps, and other appropriate access points, provided that contamination at these locations is likely to be representative of contamination on the interior of the pipes, drain lines, or ductwork. Surfaces of premises, equipment, or scrap which are likely to be contaminated but are of such size, construction, or location as to make the surface inaccessible for purposes of measurement shall be presumed to be contaminated in excess of the limits.

4. Upon request, the Commission may authorize a licensee to relinquish possession or control of premises, equipment, or scrap having surfaces contaminated with materials in excess of the limits specified. This may include, but would not be limited to, special circumstances such as razing of buildings, transfer of premises to another organization continuing work with radioactive materials, or conversion of facilities to a long-term storage or standby status. Such requests must:

   a. Provide detailed, specific information describing the premises, equipment or scrap, radioactive contaminants, and the nature, extent, and degree of residual surface contamination.

   b. Provide a detailed health and safety analysis which reflects that the residual amounts of materials on surface areas, together with other considerations such as prospective use of the premises, equipment, or scrap, are unlikely to result in an unreasonable risk to the health and safety of the public.

TA

ACCEPTABLE SURFACE CONTAMINATION LEVELS

NUCLIDES[a]	AVERAGE[b c f]	MAXIMUM[b d f]	REMOVABLE[b e f]
U-nat, U-235, U-238, and associated decay products	5,000 dpm α/100 cm^2	15,000 dpm α/100 cm^2	1,000 dpm α/100 cm^2
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	100 dpm/100 cm^2	300 dpm/100 cm^2	20 dpm/100 cm^2
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	1000 dpm/100 cm^2	3000 dpm/100 cm^2	200 dpm/100 cm^2
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5000 dpm $\beta\gamma$/100 cm^2	15,000 dpm $\beta\gamma$/100 cm^2	1000 dpm $\beta\gamma$/100 cm^2

[a] Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

[b] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[c] Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

[d] The maximum contamination level applies to an area of not more than 100 cm^2.

[e] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

[f] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr at 1 cm and 1.0 mrad/hr at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

5. Prior to release of premises for unrestricted use, the licensee shall make a comprehensive radiation survey which establishes that contamination is within the limits specified in Table 1. A copy of the survey report shall be filed with the Division of Industrial and Medical Nuclear Safety, U. S. Nuclear Regulatory Commission, Washington, DC 20555, and also the Administrator of the NRC Regional Office having jurisdiction. The report should be filed at least 30 days prior to the planned date of abandonment. The survey report shall:

   a. Identify the premises.

   b. Show that reasonable effort has been made to eliminate residual contamination.

   c. Describe the scope of the survey and general procedures followed.

   d. State the findings of the survey in units specified in the instruction.

   Following review of the report, the NRC will consider visiting the facilities to confirm the survey.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
GENERAL COUNSEL

Grobe
(Bernero + Madera have)

April 12, 1995

Marshall E. Miller
Presiding Officer
1920 South Creek Boulevard
Spruce Creek Fly-In
Daytona Beach, FL 32124

Dr. Harry Foreman
Special Assistant
1564 Burton Avenue
St. Paul, MN 55108

In the Matter of
ADVANCED MEDICAL SYSTEMS, INC.
Material License No. 34-19089-01
Docket No. 30-16055-ML-REN

Dear Administrative Judges:

Pursuant to 10 C.F.R. §§ 2.1231 and 2.1203(c), I am forwarding to you and the parties copies of the documents set forth in the attached Index which comprise, as of this date, the hearing file for this proceeding. Please note that the Staff's review of the application for license renewal submitted by Advanced Medical Systems, Inc. (AMS) is not complete. At this time the Staff currently estimates that its review of the application will be completed within three to six months. The Staff will update the hearing file in accordance with 10 C.F.R. § 2.1231(c).

Sincerely,

Marian L. Zobler

Marian L. Zobler
Counsel for NRC Staff

Enclosures: As stated

cc w/encls: Service List

B/17

APR 20 1995

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AMS HEARING FILE INDEX

April 12, 1995

1. Materials License Number 34-19089-01, as amended, September 27, 1994.

2. Letter to Mr. John R. Madera, Section Chief for Licensing, U.S. Nuclear Regulatory Commission from David Cesar, Treasurer, Advanced Medical Systems, Inc., Re: Application for Renewal of Material License No. 34-19089-01, November 29, 1994.

3. Letter to Advanced Medical Systems, Inc., Attn: David Cesar, Treasurer from John A. Grobe, Chief, Nuclear Materials Inspection Section 2, Re: Application for Renewal of NRC License No. 34-19089-01, December 22, 1994 (without attachments).

4. Letter to Mr. Jack Grobe, Nuclear Materials Inspection, Section 2, U.S. Nuclear Regulatory Commission from David Cesar, Treasurer, Advanced Medical Systems, Inc., Re: Response to Letter dated December 22, 1994, December 29, 1994.

5. Letter to John A. Grobe, Chief, Nuclear Materials Inspection, Section 2, U.S. Nuclear Regulatory Commission from David Cesar, Treasurer, Advanced Medical Systems, Inc., Re: Application for Renewal of NRC License No. 34-19089-01, Control No. 397891, enclosing application for renewal of NRC License, January 26, 1995, with enclosed application (three parts). Please note that section 3, Decommissioning Cost Estimate for the London Road Site in Cleveland, Ohio, has been withheld, pursuant to the proprietary statement contained in the document until the Staff makes a determination with respect to the applicant's request to withhold this document. The Presiding Officer and parties will be promptly notified of the Staff's determination.

6. Telefacsimile to John A. Grobe, Chief, Nuclear Materials Inspection, Section 2, U.S. Nuclear Regulatory Commission from David Cesar, Treasurer, Advanced Medical Systems, Inc., Re: W.H.U.T. Room report, March 6, 1995.

7. Letter to John A. Grobe, Chief, Nuclear Materials Inspection, Section 2, U.S. Nuclear Regulatory Commission from David Cesar, Treasurer, Advanced Medical Systems, Inc., Re: enclosing two copies of W.H.U.T. Room Survey, with enclosed Survey, March 8, 1995.

8. Letter to Advanced Medical Systems, Inc., Attn: David Cesar, Treasurer from John A. Grobe, Chief, Nuclear

Materials Inspection Section 2, Re: Review of Decommission Funding Plan, March 13, 1995.

9. Materials License No. 34-19089-01, as amended, March 17, 1995.

10. Letter to Advanced Medical Systems, Inc., Attn: David Cesar, Treasurer from John A. Grobe, Chief, Nuclear Materials Inspection Section 2, Re: Cost Estimate for Decommissioning, March 30, 1995.

11. Letter to Advanced Medical Systems, Inc., Attn: David Cesar, Treasurer from John A. Grobe, Chief, Nuclear Materials Inspection Section 2, Re: Emergency Plan and Notice of Violation, March 31, 1995.

12. Letter to Distribution List from David Cesar, Treasurer, Advanced Medical Systems, Inc., Re: Enclosing copies of AMS' Emergency Plan, March 31, 1995.

13. Letter to Mr. John A. Grobe, Chief, Nuclear Materials Inspection, Section II, U.S. Nuclear Regulatory Commission From David Cesar, Treasurer, Advanced Medical Systems, Inc., Re: Modified and Restated Decommissioning Trust, March 31, 1995 (with enclosures). Please note that this document is a facsimile copy, a copy of the original document will be forwarded to the Presiding Officer and the parties as soon as possible.

BUTTER INPUT 1/20/95

On January 19, 1994, the Deputy Director, Division of Radiation Safety and Safeguards, Region III, and members of the Region III staff conducted a site visit and inspection at the Advanced Medical Systems, Inc. facility in Cleveland, Ohio. The local sewer district has plugged thae facility sewer piping to the sewer interceptor due to concern over the discharge of cobalt-60 to the sewers. The purpose of the visit was to evaluate the resuongoing problems the facility is experiencing with ground water infiltration into the contamianted facility basement and to sample water that has accumulated in various locations within the facility, in above ground tanks, and in an on site man hole and sump pit.

8/18

January 20, 1995

Cuyahoga Emergency Management
Assistance Center
ATTN: Michael S. Kalstrom, Secretary
Cuyahoga County Local Emergency
Planning Committee
1255 Euclid Avenue Room # 102
Cleveland, Ohio 44115-1807

Dear Mr. Kalstrom:

This responds to your December 29, 1994 letter to me regarding the Advanced Medical Systems, Inc. (AMS) facility at 1020 London Road, Cleveland, Ohio and its Radiological Contingency Plan (RCP). Specifically, you questioned the adequacy of the existing RCP and expressed concern that the plan has not been properly implemented. In addition, you pointed out that the NRC's Fire Protection Safety Evaluation Report (fire safety assessment) for the AMS facility did not include a complete hazards analysis of the AMS facility and possible community impacts from a major fire, explosion, tornado or other disaster. The committee which you represent requested that the NRC conduct a thorough review of the risks posed by the facility, including a survivability assessment and hazards analysis of the hot cell, waste holdup room and other contaminated areas. You also requested a review of the RCP and its implementation.

As background information, in 1985, the Radiological Assessment Program of Oak Ridge Associated Universities (ORAU) was contracted by the NRC to evaluate the AMS radiological and fire protection programs. A second similar ORAU evaluation was conducted in 1988. In June 1990, the NRC developed a fire safety assessment, documenting NRC staff's evaluation of the fire protection and emergency planning programs for the AMS facility, and consolidating NRC fire protection recommendations. Our fire safety assessment was not a detailed hazards analysis of the entire AMS London Road facility.

The 1990 assessment concluded that AMS's previously developed emergency preplan was inadequate and should be expanded to address those items outlined in 10 CFR 30.32. 10 CFR 30.32(i) is the regulation that addresses, in part, emergency plan requirements for domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended. In January 1992, AMS developed an RCP which addressed the items in 10 CFR 30.32(i). The plan was approved and incorporated into the AMS license through Amendment No. 25, dated July 30, 1992. This plan continues to be referenced in License No. 34-19089-01.

License No. 34-19089-01 expired on December 31, 1994. A timely renewal application was submitted to the NRC prior to the license expiration date. Preliminary review of that application revealed that it was not adequate to meet our expectations. A deficiency letter was sent to the licensee and a revised renewal package is due to be submitted by the end of January. Hazards assessment information is required to be submitted by the licensee in its license renewal application, along with an emergency plan that meets the

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current criteria of 10 CFR 30.32(i)(3)(ii). As part of the license renewal process, the adequacy of the updated RCP will be reviewed for compliance with current emergency plan criteria of 10 CFR 30.32 and NRC standard review plan guidance (NUREG-0810).

We agree with your concern regarding AMS's implementation of its existing RCP. A routine NRC inspection of the AMS facility on October 11 and 12, 1994, revealed several weaknesses with the plan's implementation. The results of our inspection were forwarded to the licensee in a letter dated November 29, 1994, and included three violations related to RCP implementation, three other specific concerns and an overall concern with inadequate AMS management oversight in the emergency planning area. These problems are currently being addressed by the licensee. A copy of our November 29, 1994 correspondence is enclosed for your information.

On December 12, 1994, we met with representatives of the Cleveland Department of the Environment, other state and local officials, and you to discuss the AMS facility and its emergency plan. On January 3, 1995, AMS representatives met with you and other state and city of Cleveland officials to further discuss emergency planning issues. As a result of these meetings, we understand that a radioactive material source term has been derived for the AMS facility and will be used by the Ohio EPA to assess offsite radiological impacts under various accident scenarios. We further understand that you will be a continuing participant in these meetings to review and evaluate the AMS emergency planning capability.

In response to your concern regarding contaminated water runoff potentially resulting from fire fighting activities at the facility, we understand that the fire pre-plan being developed by the Cleveland Fire Department and AMS will include provisions for use of dry chemicals to fight fires in contaminated areas of the facility, as a preferred fire fighting technique in lieu of water. Nevertheless, should water be necessary to extinguish a fire in the hot cell portion of the facility, this water would likely drain into the basement of the facility, which has no direct flow path to the sewer system or the environment. This water would need to be collected and disposed of pursuant to NRC regulations.

We appreciate your concern and interest in the AMS emergency plan. We will continue to cooperate with the committee you represent and other interested parties in resolving emergency planning concerns. Cuyahoga County is now on routine distribution of documents exchanged between NRC and AMS. I can assure you that the license for the AMS facility will not be renewed unless an emergency plan meeting the current criteria of 10 CFR 30.32(i) is in place. Implementation of the plan will continue to be reviewed during NRC inspections of the AMS operations.

Please do not hesitate to contact me with any further questions.

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

Enclosure: Letter and Notice of
Violation dtd 11/29/94

See Attached Distribution

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NAME	Slawinski:dp		Combs		Goldberg		Grobe	
DATE	01/20/95		01/20/95		01/20/95		01/20/95	

OFFICIAL RECORD COPY

Distribution

cc w/enclosure:
Michael R. White, Mayor
City of Cleveland
601 Lakeside Avenue
Cleveland, OH 44114

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

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

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

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

bcc w/enclosure:
Mike Stein, OGC
Cyndi G. Jones, NMSS
John A. Grobe, RIII
PUBLIC IE07

E-mail:
Bill Axelson (WLA)
Bill Brach (EWB)
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Josie Piccone (JMP1)
Kevin Null (KGN)
Mike Stein (MHS)
Steve Lewis (SHL)
Tim Johnson (TCJ)
Wayne Slawinski (WJS2)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

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.

(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,

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

November 29, 1994

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

Dear Mr. Cesar:

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(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.

(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

bcc w/encl: C. Jones, NMSS
J. D. Cicco, NMSS
W. Axelson, RIII

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NAME	WSLAWINSKI:jaw		JMADERA		JAGROBE			
DATE	11/21/94		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 29th 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 11/23/94
Wayne Slawinski, Senior Date
Radiation Specialist, Region III

John C. Shewmaker 11/29/94
Robert Shewmaker, Senior Structural Date
Engineer, Office of Nuclear Material Safety
and Safeguards

Reviewed By: J. K. Madera 11/23/94
John Madera, Chief Date
Materials Licensing Section,
Region III

Approved By: John C. Grobe 11/29/94
John A. Grobe, Chief Date
Nuclear Materials Inspection Section 2
Region III

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 rooms 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^3 during the fourth quarter of 1992 to 83,000 ft^3

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 ft³ (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.

Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland Ohio 44115-2504 216 • 881 • 6600 FAX 216 • 881 • 8716

January 20, 1995

Ms. Cynthia Jones
U.S. Nuclear Regulatory Commission
Mail Stop T-8F5
Washington, DC 20555

Re: Proceeding Transcript and Appellate Brief

Dear Cindy:

It was very nice meeting you at the Region III Headquarters. I am glad we had the opportunity to discuss areas of mutual concern, and look forward to working with you toward their resolution.

Per your request of January 11, 1995, enclosed please find copies of the transcripts of proceedings of December 13, 1994 before the Honorable George W. White, U.S. District Judge, Northern District of Ohio, Eastern Division. You may be particularly interested in several of the assertions by counsel for Advanced Medical Systems (AMS) contained therein.

For example, at page 8, it asserted that the Waste Hold-Up Tank (WHUT) room may be compromised if further water enters the basement. Counsel for AMS further asserts at page 29 that the compression plug in the AMS lateral "has the effect of making it impossible for us to do something about the accumulated water in our foundation" and that "there is a possibility that there will be a structural failure or structural damage to that building if that compromises that WHUT room". Further, at page 41-42, AMS counsel quotes an engineer as stating that the WHUT room is going to flood.

These statements are in distinct contrast to the assurances provided by Mr. Grobe at the January 11, 1995 meeting.

At page 20, counsel for AMS asserts that there are a number of licensees in the Greater Cleveland area that have been discharging Cobalt-60 into the sewer system. This is in direct contradiction to the statements contained in the November 7, 1994 NRC memorandum from Roy J. Caniano to W.L. Axelson.

At page 28, counsel for AMS asserts that, as far as Cobalt-60 content is concerned, that the water in the AMS lateral meets safe drinking water standards. This assertion appears to be contradicted by Mr. Grobe's comments at the January 11, 1995 meeting.

B/20

3PP.

These contradictions between the stated positions of the NRC and AMS concern us greatly.

We are further concerned that the NRC has left the evaluation of how to handle the present contamination to AMS, and will provide only a post-facto review of the evaluation presented by AMS. Mr. Grobe made it clear at the January 11, 1995 meeting that NRC would not be providing additional suggestions for programs to be reviewed for effectiveness, cost-efficiency, man-Rem exposure, and so on. This appears to limit the options available to the NRC to those suggested by AMS. It also appears that this creates a suggestion of the homeowner to ask the raccoon how best to keep his garbage in his garbage cans.

Counsel for AMS states at page 32 that if the water from AMS is required by the NRC "to be filtered or processed, or something else," that AMS will comply. AMS counsel further states at page 42 that the NRC has the authority to make AMS "do anything." We would urge you to take all appropriate steps to unilaterally ensure that all available treatment methods including 0.45 micron filtration, ion exchange, and evaporation -- are indeed explicitly evaluated.

Also per your request, enclosed please also find a copy of the NRC Office of the General Counsel Brief for Respondents filed in the Sixth Circuit Court of Appeals. In this October 1, 1993 document, it is asserted by the NRC General Counsel that the AMS facility (with the exception of the WHUT room) was completely decontaminated in 1989. See, e.g., page 5, footnote 2. If that was indeed true, then, apparently, re-contamination of the facility has occurred since 1989.

According to the NRC Brief, "If AMS allowed its facility again to become contaminated with radiation, it would be subject to a new order requiring cleanup based on the new contamination." Counsel for AMS has conceded that the AMS lateral is indeed contaminated, and NRC has established areas in the AMS facility other than the WHUT room which are contaminated. Please let us know when the new order requiring cleanup will be implemented.

Please call me at (216) 881-6600 if you have any questions or comments about the foregoing.

Very truly yours,

Lawrence K. English
Assistant General Counsel

encl.
cc: Sara J. Fagnilli (w/o encl.)
Thomas E. Lenhart (w/o encl.)

Grobe

CONVERSATION RECORD

TIME: 3:40 p.m. DATE: 1/20/95

O VISIT O CONFERENCE X TELEPHONE

O INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Larry English	NEORSD	216-881-6600

SUBJECT
Public meeting and Excavation at AMS

SUMMARY
I spoke with Larry English about the postponement of the public meeting regarding AMS. I also thanked him for the 1/13/95 letter informing us of the excavation work at AMS. I informed Larry about the difficulties that AMS is experiencing from the 3 & 1/2 inch rain and the subsequent influx of water into the basement. I shared with Larry that I was onsite last Wednesday and inspected the excavation, indicating to Larry that the licensee was constructing a separate under drain sump pit independent of the manhole. Larry was appreciative of the call and requested that we notify the NEORSD when the meeting was rescheduled.

ACTION REQUIRED
File in AMS License File.

NAME OF PERSON DOCUMENTING CONVERSATION: John A. Grobe
SIGNATURE: John A. Grobe
DATE: 1/23/95

ACTION TAKEN
Filed in License File. Distributed to AMS team.

SIGNATURE: John A. Grobe TITLE Chief, Materials Sup., Section 2 DATE 1/23/95

B/21

GLS 1/19/95
JHG

Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland, Ohio 44115-2504 216 • 881 • 6600 FAX: 216 • 881 • 9709

January 13, 1995

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

Re: Excavation at 1020 London Road

Dear Mr. Grobe:

Upon my return to Cleveland, I learned that there were excavation activities ongoing at 1020 London Road. It appeared that the footers along the building's southeast wall were being dug up with a backhoe. This work had apparently begun earlier this week.

At the time these activities were observed, the AMS Radiation Safety Officer was not present. The trenches, which are now covered over with boards or planks, appeared to be approximately four (4) feet deep.

I wanted to bring this to your attention, inasmuch as these activities were not mentioned during our January 11, 1995 meeting, nor do they appear to be contemplated by any of the documentation you have provided to us.

Please call me if you have any questions about the foregoing.

Very truly yours,

Lawrence K. English

Lawrence K. English
Assistant General Counsel

January 24, 1995

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

Dear Mr. Cesar:

This is in response to the letter dated December 20, 1994, from Mr. Robert Meschter of your staff requesting information on NRC Region III contacts.

Please be advised that I will be your principal contact at the NRC Region III office concerning emergency planning and all other issues regarding your licensed activities. Messrs. John R. Madera and Wayne J. Slawinski will be alternate contacts if I am unavailable.

If you have any questions regarding this matter, please contact me at (708) 829-9806.

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

See Attached Distribution

DOCUMENT NAME: G:\LTRS2LIC\MTLS\030\95316055.L04

B/22

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OFFICE	RIII		RIII		RIII		RIII	
NAME	Grobe:dp							
DATE	01/24/95		01/ /95		01/ /95		01/ /95	

OFFICIAL RECORD COPY

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Distribution

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

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

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

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

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3826 Euclid Avenue
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Bill Brach (EWB)
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Jack Grobe (JAG)
Tim Johnson (TCJ)
Cyndi Jones (CGJ)
Steve Lewis (SHL)
John Madera (JRM4)
Kevin Null (KGN)
Carl Papperiello (CJP1)
Josie Piccone (JMP1)
Wayne Slawinski (WJS2)
Mike Stein (MHS)

Grobe

Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland, Ohio 44115-2504 216 • 881 • 6600 FAX: 216 • 881 • 9709

January 25, 1995

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

Re: Cancellation of January 23, 1995 Meeting

Dear Mr. Grobe:

Thank you for informing us late last Friday afternoon that the meeting scheduled for Monday (January 23, 1995) was canceled. If I understood you correctly, the meeting is now scheduled for February 6, 1995. Please advise us as to whether that is a firm date.

You mentioned that the reason for the cancellation of the scheduled meeting was that Advanced Medical Systems had eighteen (18) inches of water in its basement. Inasmuch as the Nuclear Regulatory Commission has been aware of the detailed configuration of the drainage about the facility at 1020 London Road since at least the time of your dye-testing thereof in Spring 1993 (see, e.g., page 15 of NRC Report No. 030-16055/93002(DRSS)), it concerns us greatly that the NRC has neither developed nor implemented alternative water administration methods over the last couple of months.

Despite the ostensible seriousness of the water level in the AMS basement, it is apparently not so serious as to occasion any overtime efforts by the AMS personnel. The last worker appears to depart the 1020 London Road facility by 3:30 p.m. On the date of your call, for example, District personnel observed that no AMS personnel remained at the 1020 London Road facility beyond regular closing time.

You also mentioned that you were not aware of the excavation ongoing at the southeast corner of the AMS facility. You stated that you personally had been out to the site on Wednesday, January 18, 1995, but did not mention the shed that has now been built in the approximate location of the excavation. This shed was also not mentioned during our January 11, 1995 meeting, nor does it appear to be contemplated by any of the documentation you have provided to us.

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This also concerns us. This licensee is excavating the foundation of a building whose basement and interconnected sewer lines are known to harbor loose Cobalt-60 and to be subject to infiltration by water from the outside. It is reasonable to assume that any wall that allows infiltration can also allow exfiltration. Hence, it is possible that the soil excavated may also contain Cobalt-60. Notwithstanding this obvious possibility, it does not appear that any of the soil removed from around the contaminated basement has been analyzed. Certainly, inasmuch as you were not aware of the excavation itself, the licensee is not under NRC orders to conduct such analysis. The soil is presently in a pile, exposed to the elements. It is not in any way protected from runoff.

This raises once again the issue of the lack of ongoing oversight of this licensee. That the licensee could be conducting outdoor excavation of potentially contaminated soil with a backhoe without the knowledge of the NRC forces us to wonder what other, possibly smaller scale operations may be ongoing at this facility.

These activities also hignlight the necessity of unilateral, affirmative requirements by the NRC of this licensee, and for rigorous oversight thereof. As the NRC's present posture is to merely review the proposals of the licensee for the handling of this contaminated facility, it now appears possible and even likely that the licensee will merely not inform you of operations it doubts will find your approval, operating on the assumption that these activities will not be independently discovered by the NRC.

Please let us know if the February 6, 1995 meeting is confirmed. As always, please call me if you have any questions about the foregoing.

Very truly yours,

Tom Lahst for LKE

Lawrence K. English
Assistant General Counsel

cc: Richard N. Connelly
Sara J. Fagnilli
Thomas E. Lenhart

Advanced Medical Systems, Inc.

th Eagle Street • Geneva, Ohio 44041
66-4671 FAX (216) 466-0186

January 26, 1995

Mr. John A. Grobe, Chief
Nuclear Materials Inspection
Section II
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: Application for Renewal of NRC License No. 34-19089-01
Control No. 397891

Dear Mr. Grobe:

Enclosed are two (2) copies of our Application for Renewal of our above-referenced NRC License. The enclosed information describes all aspects of Advanced Medical Systems' licensed operations, Radiation Safety Program and Procedures.

Advanced Medical Systems' operations have changed significantly since the last renewal five (5) years ago. The introduction discusses the Business Plan and Management Organization for Advanced Medical Systems given its current operations.

Your correspondence dated December 22, 1994 requested that we address specific issues when submitting our License Renewal. This information is enclosed in the Application for License Renewal.

The one item I did not address in this Application for License Renewal is the situation with water in the basement of the facility. This is an abnormal situation and is being addressed as a singular event. As such, I do not feel it is appropriate for it to be a part of the License.

If you have any questions or require clarification on any of the information contained within the Application for License Renewal, please contact me at (216) 466-4671.

Sincerely,

DAVID CESAR
Treasurer

DC/mz
Enclosures

B/24

9502170064 7PP

TABLE OF CONTENTS

MANAGEMENT ORGANIZATION AND DISCUSSION OF BUSINESS PLAN

INTRODUCTION
DISCUSSION OF BUSINESS PLAN AND MANAGEMENT ORGANIZATION

Business Plan

Advanced Medical Systems' operations have changed since the last License Renewal. Since its founding, when certain assets were acquired from Picker Corporation, Advanced Medical Systems has manufactured sealed sources, performed service work and manufactured a variety of teletherapy and radiography units.

Advanced Medical Systems' market has changed significantly as the domestic medical device field for teletherapy and radiography units has moved to more advanced technology - principally, linear accelerators. The domestic market for Advanced Medical Systems' products has significantly reduced. As the domestic market has shrunk, the export market has realized significant gains. Advanced Medical Systems has always sold and provided services for export primarily to developing countries.

Advanced Medical Systems has recently completed a reevaluation of its distributor base in various countries around the world and has made several changes. This evaluation is paying immediate gains. The company currently has Irrevocable Letters of Credit for six (6) machines with commitments of an additional eight (8) tender offers by the end of the year. Based upon sales projections provided by our distributors, we anticipate a 400% sales increase within the next several years.

Along with the change in marketing strategy, the company has also made the decision back in 1990 to no longer manufacture its own sealed sources. Accordingly, the company has plans to transfer to an authorized third party its current inventory of sealed sources and bulk cobalt. The authorized third parties that have already accepted shipments of existing inventory are Neutron Products and J.L. Shepherd, both of whom are NRC licensees. In addition, several foreign countries have expressed an interest in accepting the donation of low-level sources.

The termination of Advanced Medical Systems' source manufacturing operations drastically simplifies its operations. Advanced Medical Systems will purchase sealed sources from Theratronics and Neutron Products for use in its teletherapy units. These sources, when they are received at the facility located at 1020 London Road, would have their source strength verified and then if they are going into a unit, installed and surveyed prior to shipment.

As Advanced Medical Systems' sales are principally derived from exporting complete units, domestic service will no longer be ordinarily handled internally. It is anticipated the majority of domestic service will be contracted out. Export service is accomplished principally by our distributors and agents who have been trained on Advanced Medical Systems' equipment and Advanced Medical Systems' personnel provide support on an as-needed basis.

In addition, Advanced Medical Systems will maintain its service technicians' training program to train service engineers from foreign countries.

ADVANCED MEDICAL SYSTEMS, INC.
MANAGEMENT PLAN
ORGANIZATION OF OPERATIONS

Description of Management Controls and Operation

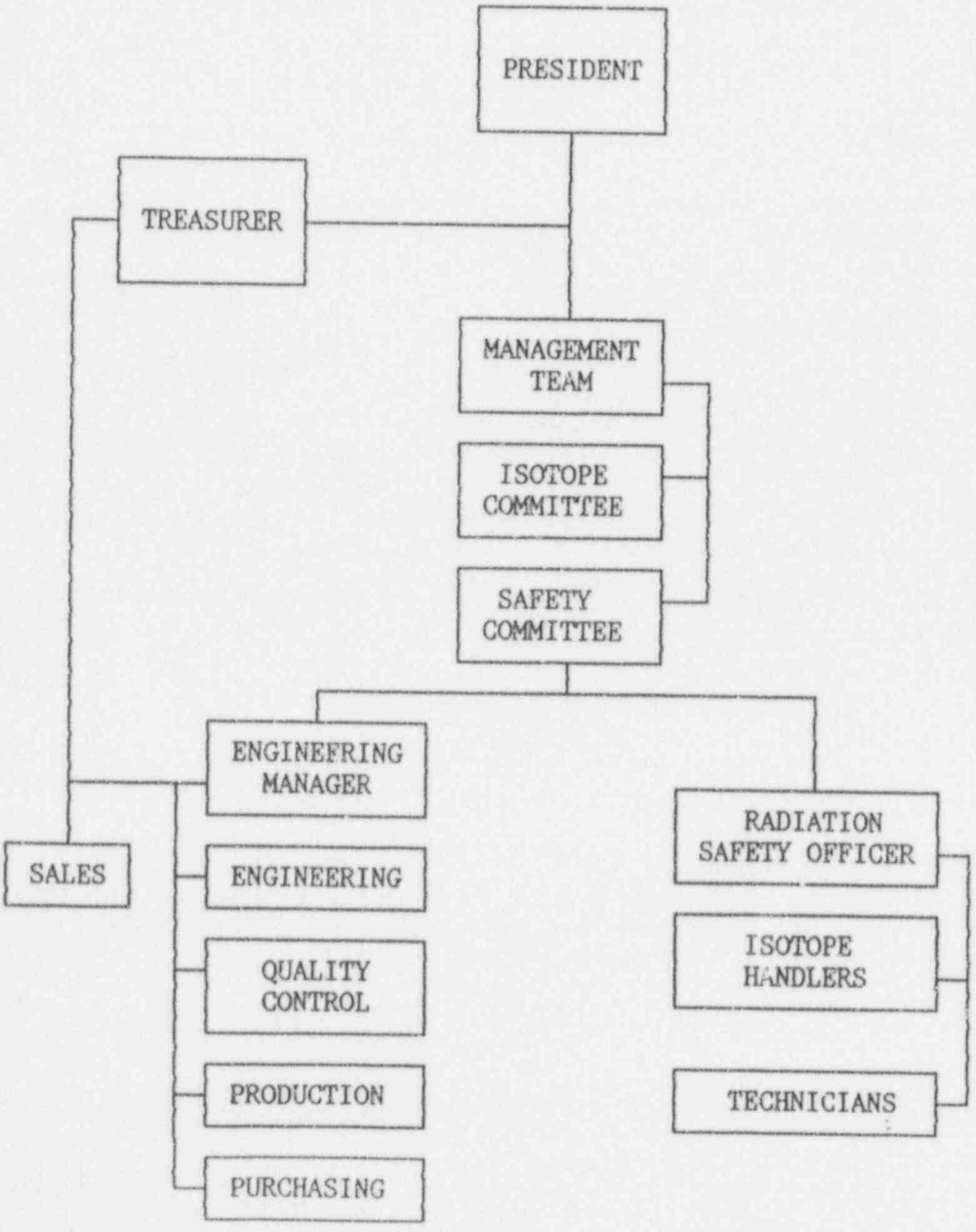
Advanced Medical Systems, Inc. currently has two locations. These are as follows:

121 North Eagle Street
Geneva, Ohio 44041

1020 London Road
Cleveland, OH 44110

The operations at the Geneva location include Engineering, Quality Control, Production, Purchasing and Sales. The operations at the London Road facility include Isotope handling, source surveys and receipt and shipment of sources.

The Company's two facilities operate autonomously. Each department/facility head has the authority to manage their respective department/location. The Advanced Medical Systems Organization Chart is as follows:



Management Team

The Management Team of Advanced Medical Systems is responsible for the operations of the Company. The Management Team consists of the following department heads: Radiation Safety Officer, Engineering Manager and Treasurer. This Team may change as the Company changes and different situations arise.

The Radiation Safety Officer (RSO) occupies a position on the Management Team as he is responsible for all operations at the Isotope Laboratory which is the principal licensee on the NRC's Material License and is also responsible for compliance with regulatory matters.

The Engineering Manager occupies a position on the Management Team as he is responsible for all medical device manufacturing, quality assurance and compliance with FDA regulations.

The Treasurer occupies the third position on the Management Team and is responsible for overseeing sales and all financial functions of the Company.

Each of these individuals brings their own area of expertise to effectively make operating decisions regarding Advanced Medical Systems.

Isotope Committee

The Isotope Committee is responsible for overseeing all regulatory affairs of Advanced Medical Systems with the Nuclear Regulatory Commission. The Isotope Committee is to meet on a quarterly basis and review the operations of the Isotope Facility and compliance with current regulations. The Isotope Committee is chaired by the company's Radiation Safety Officer.

Safety Committee

The Safety Committee is to meet quarterly and is chaired by the Engineering Manager. All safety issues regarding the medical devices manufactured by Advanced Medical Systems are to be discussed.

Facility Managers

The Engineering Manager is responsible for the operations in Geneva. The Radiation Safety Officer is responsible for the operations at the Cleveland facility. As such, the RSO has complete authority and autonomy to manage the facility. Certain financial controls are in position to require approval from the Treasurer for all non-emergency expenditures in excess of $1,500. In emergency situations, corporate approval is not required.

When a service call is received, the Engineering Manager will make the determination to send an AMS service technician or contract the service request to a third party. It is anticipated the majority of the calls will be contracted. All Customer Service will require approval by the Engineering Manager.

The purpose of this structure of the service organization will allow for the selection of the best-suited individual or entity to be assigned the work. Engineering also serves as a checkpoint for specific service problems.

An AMS employee will, upon completion of AMS performed service activity, record in detail a service report, the type and nature of the work assigned.

Upon completion of each assignment, each Service Report for domestic service will be reviewed by the Engineering Manager and initialed.

For domestic service involving teletherapy equipment with radioactive material, the review and initials of the RSO is required. During regular Isotope and Safety Committee Meetings, the results of the audits on all domestic Service Reports are reviewed.

When the Company subcontracts service work, the Company is acting solely as a sales representative and has no control over the third party's work.

AMS Service Technicians will be audited according to the following schedule if AMS utilizes each individual:

"FIELD SERVICE AUDITS"

Summary of Internal Service Audits

A. Field Service Audits

On an annual basis, the RSO will audit the procedures and activities of each licensed service engineer as he performs his duties during a simulated service call or source exchange. An outline of the audit parameters to be considered are attached. (The RSO may, in his discretion, alternatively or additionally audit the procedures and activities of each licensed service engineer as he performs his duties during a field service call.)

B. Service Report Audits

Conducted by the Engineering Manager and RSO as domestic service reports are generated. Audit results will be entered on each domestic service report and signed.

C. Customer Unit Functions and Service Report Evaluation

Conducted by a qualified member of the customer's staff for each domestic service call. This document will be attached to the AMS Service Report. In addition, a service evaluation questionnaire will be mailed to the facility following each service call. Any adverse comments will immediately be brought to the attention of the Engineering Manager.

D. Safety Committee Meetings

These meetings are held quarterly. The members include the AMS Engineering Manager, Radiation Safety Officer and corporate representative (Treasurer). Field Service Reports are reviewed. In addition, any incident reported during the quarter is also reviewed. NOTE: Special Safety Committee Meetings will be held to review incident reports as necessary.

E. Isotope Committee Meetings

These meetings are held quarterly. The members include the Engineering Manager, Radiation Safety Officer and corporate representative. Domestic Service Reports involving Cobalt unit installation, dismantling and maintenance are reviewed. In addition, any pending issues relating to the operation of the Isotope Facility or the manufacture of teletherapy equipment will be discussed. Records are maintained as Minutes of the Meeting. NOTE: Special Isotope Committee Meetings will be held to review incident reports as necessary.

SPECIAL NOTE: A corporate representative may or may not be present at any meeting held within the Management Team. A copy of all documents and actions recommended are forwarded to the corporate representative for review. A copy initialed by all members of the Isotope Committee will be placed on permanent file.

External Audits of Service Activities and Documents: The company will engage an external consulting group every two (2) years to review all service documents unless performed by contractors. Although this two-year audit will encompass a complete review of records and documents, this audit deals specifically with the service function.

Training and Qualifications of Service Engineers Involving Radioactive Materials and Teletherapy Devices: The RSO will maintain a continuing training program in the areas of radiation safety and hazards to complement the existing medical device, mechanical and electrical, expertise presently in house. This program will follow the USNRC-authorized AMS training program (Section 1.9 of Materials License Application package). The purpose of this program is to ensure AMS-licensed service engineers are qualified to conduct service work on Cobalt-60 teletherapy units. Under this plan, all service involving the handling of or direct exposure to radioactive materials in teletherapy units will be conducted only by or in the presence of a licensed person. It is equally important that each service engineer has proven his knowledge of the mechanical and electrical systems of the medical device.

Service of units who do not contain radioactive material sources and service of teletherapy units not involving licensed activity will be conducted by service engineers who have been thoroughly trained either by previous experience or within Advanced Medical Systems, Inc. These units do not require a service engineer licensed by the NRC.

Audits and Audit Control System: Audits and audit controls are described under separate cover. The types of audits conducted are listed below. See attachment.

Primary:
1. Customer unit function and Service Report Evaluation.
2. Service Report Audits.
3. Field audits by RSO.

Final:
1. Safety Committee Meeting audits.
2. Isotope Committee Meeting audits.

External audits by outside consultant.