Advanced Medical Systems, Inc. ATTN: Ms. Sherry Stein, Director of Regulatory Affairs 121 N. Eagle Street Geneva, OH 44041 License No. 34-19089-01 Docket No. 030-16055

Dear Ms. Stein:

Thank you for providing this office with copies of recent correspondence which you have had with the Northeastern Ohio Regional Sewer District (NEORSD) concerning the Southerly Wastewater Treatment Plant in Cuyahoga Heights, Ohio.

As noted on page 2 of your March 11, 1993 letter to the Sewer District and as discussed between you and Roy Caniano of my staff on March 13, 1993, your statement that "....the Nuclear Regulatory Commission has informed us that your allegation against us is unsubstantiated" needs to be clarified. This statement leads one to believe that the sewer district was the party that raised the concern to the NRC over negligent discharges from Advanced Medical Systems (AMS) to the sanitary sewer.

As discussed between you and Mr. Caniano and others from this office during a telephone call on March 10, 1993, the NRC had received a concern that AMS had released radioactive materials to the sanitary sewer in the late 1970's and early 1980's in excess of NRC release limits. As a followup to this concern, the NRC performed an assessment of previous AMS discharge operations for the referenced timeframe. The assessment included a review of previous NRC inspection reports, interviews with former AMS employees, and reviews of AMS discharge operation procedures referenced in the AMS NRC license. The assessment did not substantiate the concern.

During the referenced March 10, 1993 telephone call with you and members of my staff, there was no mention that the Sewer District was the party raising the concern to the NRC nor that the allegation from the Sewer District of "negligent discharges" was found to be unsubstantiated by the NRC.

We appreciate your cooperation with this matter and, as we informed you during the March 10, 1993 telephone conversation, we will be providing you with a copy of our assessment regarding your past sewer releases. If you have any guestions, please contact Roy Caniano at 708-790-5500.

ORIGINAL SIGNED BY CHARLES E. NORELIUS

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

cc: NEORSD R. L. Bangart, NMSS

Sreniawski 3/12/93 Caniano/dg 03/17793

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Advanced Medical Systems, Inc. ATTN: Ms. Sherry Stein, Director of Regulator Affairs 121 North Eagle Street Geneva, OH 44041 License No. 34-19089-01 Docket No. 030-16055

SUBJECT: ASSESSMENT OF CONCERNS REGARDING DISPOSAL OF LIQUIDS FROM THE ADVANCED MEDICAL SYSTEMS, INC. (AMS), CLEVELAND, OHIO FACILITY

Dear Ms. Stein:

This refers to a special assessment performed by Region III in response to a concern regarding the disposal of liquids contaminated with cobalt 60 into the sanitary sewer which exceeded NRC limits. This also refers to the March 10, 1993 telephone conversation between you, Messrs. G. McCann, D. Sreniawski and R. Caniano of my staff, regarding the same subject.

The enclosed copy of our report identifies areas examined during the assessment and includes conversations with individuals, review of Region III AMS license files and past NRC inspection reports. Based on our assessment, the concern was not substantiated, and as such, no response to this letter is required.

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

We will gladly answer any questions you have regarding this assessment.

Sincerely.

Portginal Signal by C.S. Moretter

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

Enclosure: As stated

cc w/enclosure: R. N. Connelly, NEORSD E. J. Odeal, NEORSD J. Austin, NMSS/LLWM

bcc w/enclosure: PUBLIC D. Fank, RIII

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McCann

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#### U. S. NUCLEAR REGULATORY COMMISSION

#### REGION III

Docket No. 030-16055

License No. 34-19089-01

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

Assessment Conducted: October 27, 1992 to December 17, 1992

Areas Assessed: Personal Interviews and Records Review

Inspector:

onald Arenawsh Donald J. Srenjawski Senior Radiation Specialist

Approved By:

Roy 2. Caniano, Chief Nuclear Materials Safety Branch

3/12/93 Date

Assessment Summary

Assessment on October 27, 1992 to December 17, 1992

Areas Reviewed: This was a special assessment initiated by concerns received by NRC Region III representatives that AMS was discharging liquid radioactive waste to the sanitary sewer in excess of the reported amounts for several years in the late 1970s and early 1980s.

The assessment consisted of a review of AMS procedures and records, and interviews of former AMS and Picker Co. employees. The assessment did not include onsite inspection effort at AMS.

Results: The concern of improper disposal of cobalt-60 into the sanitary sewers was not substantiated. No violations of NRC requirements were identified.

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### 1. Purpose of Special Assessment

This was a special assessment initiated by a concern that AMS had been releasing cobalt-60 to the sanitary sewer system in excess of NRC limits. It was purported that this practice had occurred during the late 1970s and early 1980s. This concern is similar to an allegation received and reviewed by the NRC on December 4, 1986 through February 18, 1987, which was not substantiated.

#### 2. Relevant Licensed Activities

In addition to the manufacture and servicing of teletherapy units, AMS fabricated the sealed sources used in the teletherapy units for medical treatment of humans. AMS has been licensed since November 1979 when it purchased the London Road facility from Picker Corporation who had performed the same activities. These sources are typically 4,000 to 12,000 curies of cobalt-60; however, some cesium-137 sources had been fabricated. In 1979, AMS was licensed to possess 150,000 curies of cobalt-60 in solid metal form. This possession limit has been retained through the amendment of the license on January 21, 1993. Current source manufacture is limited to training purposes only and does not permit general source distribution.

#### 3. Concern

On September 17, 1992, NRC Region III inspectors received a concern that AMS had released cobalt-60 to the sanitary sewers in excess of NRC limits when discharging liquid waste. The releases had occurred during the late 1970s and early 1980s. Two pathways for contaminated water to reach the sewer in quantities which could exceed NRC release limits were mentioned in the concern and are described below.

- Planned releases from the Holdup Tank were not adequately analyzed for cobalt-60 concentration before the waste water was released to the sewer, and
  - on other occasions, contaminated water from cleanup activities or spilled holdup tanks reached the sewer without being analyzed because the holdup tank was bypassed.

During followup discussions with the individual who had expressed the concerns to the NRC, the first concern was retracted.

#### 4. Followup of Concern

Followup activities to evaluate this concern included a review of past AMS inspection reports and docket file information and telephone interviews with former AMS and Picker employees. Summaries of the activities are described below. Review of Previous Inspection Reports. Since as previously mentioned, the NRC had received an allegation similar to the concern that AMS was releasing cobalt-60 to the sanitary sewers in excess of NRC release limits, the focus of inspection report reviews was Report No. 030-16055/87-001(DRSS), Attachment A, which documents the results of that allegation followup. A review of that report showed that the inspection had covered the same areas needed to evaluate the current concern. The 1986/87 inspection concluded that the allegation that AMS had released cobalt-60 to the sanitary sewer system in excess of NRC limits was not substantiated with no violations of NRC regulations or specific license conditions identified.

a.,

In addition to the 1986/87 special inspection, at least 17 other routine and special inspections were performed during the years 1980 to 1993 of safety aspect of the AMS operations, including liquid waste effluent releases. A review of these reports identified no releases in excess of the one curie of cobalt-60 per year limit permitted by 10 CFR 20.303(d).

The AMS files were also reviewed for information on the construction and use of the sanitary drain system. The current review of the NRC files on AMS showed at least one drain in the basement which released directly to the sanitary sewer, a diagram of its relative (not to scale) position is included as Attachment B. The AMS operating procedures required this drain to be temporarily plugged when the contaminated floor of the basement. area is washed. The wash water was to be vacuumed up and put into the waste holding tank. A review of inspection reports identified two occasions when these recovery procedures were followed. The other connection to the sanitary sewer shown in the diagram is the output from a collection tank in the "clean" side of the basement. This output was installed in the late 1980s, after AMS stopped liquid releases from their cave operations. The operating procedure requires the contents of the collection tank to be sampled before release of contents.

Personnel Interviews. Former Picker and AMS employees were b. interviewed in an attempt to determine what procedures were followed for liquid waste disposals. They stated, during interviews conducted in September and November 1992, that they had followed the AMS operating procedure ISP-12 titled, "Release of Liquid Waste Into Sanitary Sewerage System." This procedure was included as Attachment A to the 1986/87 report and, in summary, requires analysis of all potentially contaminated liquid waste before discharge to the sewer. The interviewed persons were aware of the procedure and stated they used it to prevent unmonitored water from being released from the facility. The persons made the statement without being informed of the procedure by the inspector. They also stated that the volume of water used in cleanings was small, on the order of buckets not streams from a hose.

## 5. <u>Conclusion</u>

Based upon a review of previous inspection reports and personnel interviews, no new information was identified to indicate that AMS had released cobalt-60 to the sanitary sewers in excess of NRC limits when discharging liquid waste. The concern that AMS had released cobalt-60 to the sanitary sewerage system in excess of NRC release limits was not substantiated.

Attachments:

- A. Inspection Report No. 030-16055/87-001(DRSS)
- B. Diagram of Waste Water System

DMB COPY

MAR 4 - 1987

License No. 34-19089-01

Advanced Medical Systems, Inc. ATTN: Seymore S. Stein President 1020 London Road Cleveland, OH 44110

Gentlemen:

This refers to the special inspection conducted on December 4, 1986 through February 18, 1987, of activities authorized by NRC Byproduct Material License No. 34-19089-01, and to the discussion of our findings with Mr. Howard Irwin, RSO, at the conclusion of the inspection.

This special inspection was initiated as a result of our receipt of an allegation pertaining to releases of radioactive material to the Sanitary Sewage System. A copy of Inspection Report No. 030-16055/87-001(DRSS), which details the allegation and NRC findings, is enclosed.

No violations of NRC requirements or specific license conditions were identified during this special inspection.

Sincerely, when

Darrel G. Wiedeman, Chief Nuclear Materials Safety Section 1

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Enclosure: Inspection Report No. 030-16055/87-001(DRSS)

cc w/enclosure: DCS/RSB (RIDS)

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ATTACHMENT

IED7

### DETAILS

44

#### 1. Persons Contacted

Howard Irwin, Radiation Safety Officer Ted Hebert, Plant Manager Josephine Powell, Secretary, Isotope Handler

### 2. Purpose of Special Inspection

This was an announced special inspection initiated by an allegation that AMS had been releasing.cobalt-60 to the sanitary sewer system in excess of NRC limits. It was purported that this practice had been ongoing for several years.

## 3. Relevant Licensed Activities

In addition to the manufacturing and servicing of teletherapy units, AMS fabricates the sealed sources used in the teletherapy units for the treatment of humans. These sources are typically 4,000 to 12,000 curies of cobalt-60 (Co-60); however, some cesium-137 (Cs-137) sources have been fabricated. AMS is currently\_licensed to possess 300,000 curies of Co-60; 40,000 curies of Cs-137; and depleted uranium (as shielding).

#### 4. Allegation Followup

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Prior to March 1986, all liquid waste from the hot cell, decontamination room, isotope lab, laundry and change room (showers, sinks, etc.) was piped into a 600-gallon steel holding tank, located in a shielded maze in the basement ("hot" side).

Subsequent to March 1986, the system was modified so that water from the change room and laundry goes to a new collection tank on the "clean" side of the basement.

Disposal of liquid waste to the sanitary sewer system is made by batch process. A sample is drawn off the batch tank and counted on a well counter; release quantities are then calculated. AMS' procedure, "Release of Liquid Waste into Sanitary Sewerage System" (included as Attachment A), states "Once each year, the average sewage discharge for the past 12 months shall be computed. This average shall then be broken down into monthly and daily averages. These figures are to be used to calculate the limits of 10 CFR 20.303."

Therefore, daily release concentrations are calculated based on the average daily release of water discharged into the sanitary sewerage system during the previous 12 month period.

AMS' liquid waste disposal log is included as Attachment B (for the period May 15, 1980 through February 11, 1987). This log shows the quantity of cobalt-60 released that day (in microcuries); the year-to-date running total (in microcuries); and the quantity (in gallons) of

the contaminated waste water released. This quantity is the amount of liquid released from the batch tank only; it does not take into account the other water released from the plant that is used to dilute the waste release (and that is used in calculating released concentrations of radionuclides).

The licensee maintains records of total water used at the London Road facility (Attachment C). Using these figures, AMS calculates the maximum releases of radionuclides allowed. For the present, AMS uses the averages for water released during the period July 1985 through June 1986. These averages (Attachment D) are broken down into liters per year, liters per month, liters per day, and ultimately, microcuries releasable per day based on the dilution factors.

The amount of cobalt-60 released by AMS per year follows:

1980 - 10.605 millicuries 1981 - 15.616 millicuries 1982 - 5.056 millicuries 1983 - 59.065 millicuries 1984 - 29.609 millicuries 1985 - 45.777 millicuries 1986 - 51.157 millicuries 1987 - 2.861 millicuries (through February 11, 1987)

10 CFR 20.303 limits the total quantities and concentrations of radionuclides releasable to the sanitary sewage system. These limits for Co-60 are:

- Daily: The greater of 10 microcuries total or concentrations not exceeding 1.0 x 10<sup>-3</sup> microcuries per milliliter (10 CFR 20.303(b)(1) and (2)); and
- Monthly: Concentrations not to exceed 1.0 x 10<sup>-3</sup> microcuries per milliliter (10 CFR 20.303(c)); and
- Annually: Not to exceed one curie (10 CFR 20.303(d)).

AMS' daily releases exceed the 10 microcurie limit; however, they are lower than the 1.0 x 10-3 microcuries per milliliter allowable concentration. Based on calculations of total water released (Attachment D), AMS may release 8,131 microcuries of Co-60 per day. The maximum actually released based on the above calculations has been 2,084 microcuries (greater total quantities have been released on a daily basis in previous years; however dilution factors applicable to that time period have also been greater).

AMS' maximum total annual release has been approximately 60 millicuries (in 1983), compared to one curie allowable.

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A special inspection was conducted on October 21-24, 1985, with the assistance of Oak Ridge Associated Universities (ORAU), an NRC contractor. Part of this inspection included analysis of sludge from the sanitary sewer to determine reconcentration of radionuclides in the sewerage system. Results of the analysis showed < 4 picocuries/gram of Cs-137 and < 1.7 picocuries/gram of Co-60.\*

- \* 1 picocurie = 1/1,000 of a microcurie
  - 4 picocuries/gram and less are of no regulatory significance.

### 5. Findings/Conclusions

The allegation that AMS has released cobalt-60 to the sanitary sewerage system in excess of NRC limits was not substantiated; no violations of NRC regulations or specific license conditions were identified.

## Attachments:

- A. AMS Operating Procedure: Release of Liquid Waste into Sanitary Sewerage System
- B. AMS Liquid Waste Log (May 15, 1980 through February 11, 1987)
- C. AMS Water Usage Log for London Road
- D. AMS Worksheet for Liquid Waste Releases

O PER	ATING	PROCI	DURE

ALVANCEL MILLAN

	Procedure No: ISP - 12
TITLE: Release of liquid waste into	Revision: A
Sanitary Sewerage System	Date Issued: 7 - 13 - 79
	Page 1 of 2

1.0 PURPOSE:

To insure that liquid waste released into the Sanitary Sewer System does not exceed the limits of 10 CFR 20.303

2.0 SCOPE:

This procedure applies to all discharges of contaminated water, it is to be performed each time such water is discharged.

3.0 EQUIPMENT REQUIRED:

Batch tank, reference standards Well counter Film badge Sample collector, log book

4.0 REQUIREMENTS & PRECAUTIONS:

4.1 Once each year, the average sewage discharge for the past 12 months shall be computed. This average shall then be broken down into monthly and daily averages. These figures are to be used to calculate the limits of 10 CFR 20.303

- 5.0 INSTRUCTIONS:
  - 5.1 Limits per 10 CFR 20.303

Record, here, the limits as calculated in 4.1 Time period used as basis for calculations 19 to 19

Daily:  $1 \times 10^{-3} \mu$  Ci/ml x \_\_\_\_\_ liters/day x  $10^3$  ml/liter = \_\_\_\_  $\mu$  Ci or 10 p Ci, whichever is greater

Monthly:  $1 \times 10^{-3} \mu$  Ci/ml x \_\_\_\_\_ liters/mon x  $10^3$  ml/liter = \_\_\_\_  $\mu$  Ci Yearly: 1 Ci/year

5.2 Sampling procedure per batch

- 5.2.1 Fill batch tank
  - 5.2.2 Thoroughly agitate the solution by turning on the electric motor driven agitator and allowing it to run for 5 minutes
  - 5.2.3 Draw off a sample through the sample valve
  - 5.2.4 Count the sample and the standard in a well counter
  - 5.2.5 A computer program is available to determine the

number of gallons that may be discharged per day.

	Approval	Revisions	
Prepared by		A 7 - 83 Format Change	
		ATLACHMENT A	

# ADVANCED MEDICAL SYSTEMS

# OPERATING PROCEDURE

	Procedure No: ISP - 12
MITLE: Release of liquid waste into	riocedure nov 104 12
	Revision: A
Sandtary Sewerage System	Date Issued: 7 - 13 - 79
	Page 2 of 2

# 5.0 INSTRUCTIONS: cont'd.

- 5.3 If the activity is within the limits of 10 CFR 20.303 (see5.1) then the batch tank drain plug is removed and the specified amount of water is discharged into the senitary sewer system.
- 5.4 Multiple batches of water may be discharged if the total activ ity does not exceed the limits of 10 CFR 20.303.
  - Each batch must be sampled per 5.2

# 5.5 Recordkeeping

For each batch of contaminated water released, the following data must be recorded in the log book.

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Total µ Ci discharged to date	

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12-29-66	22	2.08 1/05	3.83×10	7.93×10	- 14/ K10	-1405-		
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Date	6.01	MI Purrel	SAMPLE OPM	610 11 PH	Fides Stevenso		al i
2.28.80	30	1,144105	3,63,×103	5 Mi	1 Mrsh	Le Pumped	Lev
3.5-86	22	8,33×104	5.15 X104	Sie Syn Y	- 1.91/No-1	726	20 000
3-/3-86	53	2,08 X/10 5	9.06 ×10 3	8.1×10 4	- 1.81 K10 -	-7324	27330
3-13-86	55	2.08×05	2,77410.3.	R. IXIN	1. 1 UI VII -1		30.9.26
3-14-86	55	2.08×105	2.85×103	B.12 X10 Y		101	
3-14-86	55	~, 0.8 X10 "	1.5×103.	B./12/20	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	1.00/	32. BZV
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18-91-1	-19-	7.10×10 5	5,09,10	1.57×10	136 ×18-1		31551
. 6-25-86	42	0/X FC.1	01X11.C	1	1.36 × 10-1	12	101 CIL
1-16-86	26	1.357 10 3	5.355/0	O/ YLY-I	1.33×10-1	33	34 887 -
10-1-00	00	X41×10	2 2/ 85 / 13 2	2.01.200	252811 1.27×10-1	2/2	35529
0		6.4104T	6.2		1.28×10-1	73	35.602
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12-2-1	80	503×105	* 01× 62'2.	2.5 ×105		-	
18-61-1	38	7.57×105	1,31 × 10 <sup>7</sup>	2.96×105	128,400	355	355
2-11-87	960	3,63×105	· 1. 20×104	2.53×105	1- 14 X/0-1	442	177
d an > R					1.21 ×10	×034	2861
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Water Usop London Road

6/81 - 9/81 9/8/ - 12/8/\_\_\_ 12/81-3/82 3/82 - 6/82 6/82-9/82\_\_\_\_ 9/82=12/82 \_\_\_ 12/82-3/83 3/83-6/83 6/83=9/83\_\_\_\_ 9/83 -12/83 12/83 - 3/84 3/84 - 6/84 6/54- 10/84 10/54- 11.85 1/85 - 3/85 3/85 - 6/85 6/55 -10/85 14/25 - 1/86 1/50 - 3/86 4186 - 6186

172,000 CF - 75,000 CF 48000 CF 99000 CF 137,000 CF 75000 CF 13000 CF 1000 CF 78000 CF 140,000 CF 17,000 CF 11,000 CF 25,300 CF \* Water to verified that meter working progrady 26, 800 CF 24,700CF 20,700CF 30,300 CF 25,300 CF. 23,100 CF 24,100 CF

.9/84 Liquid Waste upclate Water used 7/85 - 6/86 104,800 CF X 28.32 P/CF = 2,967,936 R Averages are 2,967, 36 - 1/4c .... 247,328 e/mm 8131 P/day 8131 l/day × 14C/ 2 = 8131 µCi/day Set Nucell program limit at 8100pC for person Through 6/87 日本なったわけっちいう A STATE AS STREET, ST.

