U.S. NUCLEAR REGULATORY COMMISSION

REGION III

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

Docket No. 030-16055

License No. 34-19089-01

Advanced Medical Systems, Inc. (AMS)

1020 London Road Cleveland, OH 44110

Inspection At: AMS

1020 London Road Cleveland, OH 44110

Inspection Conducted: December 4, 1986 through February 18, 1987

Inspectors:

Robert E. Burgin Burgun Senior Radiation Specialist

James L. Lynch / Jah Radiation Specialist

George M. McCann

Senior Licensee Reviewer

Garrel G. Wiedeman, Chief Nuclear Materials Safety

Section 1

Bucch Maltill Bruce S. Mallett, Ph.D., Chief Materials Licensing Section

3/2-/57 Date

3-2-87

3-2-87

Inspection Summary

Approved By:

Inspection on December 4, 1986 through February 18, 1987 (Report

No. 030-16055/87-001(DRSS)) Areas Inspected: This was an announced special safety inspection initiated by an allegation received by NRC Region III representatives in November 1986. The inspection included a review of procedures and records, and interviews of AMS representatives.

Results: The allegation of improper disposal of Cobalt-60 into the sanitary sewers was not substantiated; no violations of NRC requirements were identified.

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DETAILS

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.

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

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:

- 1. Daily: The greater of 10 microcuries total or concentrations not exceeding 1.0×10^{-3} microcuries per milliliter (10 CFR 20.303(b)(1) and (2)); and
- 2. Monthly: Concentrations not to exceed 1.0 x 10-3 microcuries per milliliter (10 CFR 20.303(c)); and
- 3. 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 1.0×10^{-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.

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

ADVANCED MEDICAL SYSTEMS

	OPI	CRATING PROCEDURE		
MITLE: Rele	ease of liquid waste i tary Sewerage System	nto n	Procedure No: Revision: Date Issued: Page 1 of	A 7 - 13 - 79
1.0	PURPOSE: To insure that lice does not exceed	quid waste released in the limits of 10 CFR 2	to the Sanitary Sewe	
2.0	SCOPE: This procedure a it is to be perfor	pplies to all discharge med each time such w	es of contaminated water is discharged.	ater,
3.0	EQUIPMENT REQUIPMENT R	ence standards		
4.0	months sha	PRECAUTIONS: year, the average sew II be computed. This monthly and daily aver	age discharge for th average shall then b	e past 12 be broken s are to be
	used to cal	culate the limits of 10	CFR 20.303	
5.	used to cal 0 INSTRUCTIONS: 5.1 Limits per	10 CFR 20.303 Tre, the limits as calculated used as basis for	ulated in 4.1 calculations	
5.	used to cal INSTRUCTIONS: 5.1 Limits per Record, he Time pe	10 CFR 20.303 Tre, the limits as calculated used as basis for 19 to	calculations 19	n C
5.	Daily: 1 x 10 ⁻³ µ or 10 µ Ci Monthly: 1 x 10 ⁻¹ Yearly: 1 Ci/yea 5.2 Sampling 5.2.1 5.2.2	10 CFR 20.303 Tre, the limits as calculated used as basis for 19 to 19	e solution by turning ven agitator and allow the standard in a valuable to determine the standard in a valuable the standard in a valuable the standard in a valuable	g on owing lve well counter mine the

ADVANCED MEDICAL SYSTEMS

OPERATING PROCEDURE

TITLE:	Release	of liquid waste into
	Sanitary	Sewerage System

Procedure No:	ISP - 12
Revision:	A
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 sanitary sewer system.
- 5.4 Multiple batches of water may be discharged if the total activative 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.

CPM of	Standard	M Ci/ml of Std. Al Ci discharged	
CPM of	Sample		-
Total /	Ci discharged to date		

		A Commence and a commence of the commence of t			recognition of white	MC
7700	CALLONS	MI PUMPED	SAMPLE CPM	STD CPM	CONSENTRATEN (MS/N) MG PUMPED	YEAR TO. DAT
6.4/4.20	35		8.16×163	5.22×104		0000
5 1.5	0 0		6.36×103	5.04x107		,301
2.16-80	50		8,38×103	5.03×104	196×10-61 11 161	0/37
5. 16. 80 71. 16. 80	00 00	1. 8. 9 8×105	1.16 x 10.	5.06 x 104	31 - 554	2960
08-11-9	50	1.89 X 105	1.14 x 104	5.03 x 101	1,96 x 10 40	5280
08-61-6	50	1.89×700	2.00×10	4.78×104	1,90x 10,2	6984
9-20-80	200	1.89×105	2.47x/04	4.88 N/04		2088
9.20-80	50	1.89 × 135	2.374104	9.72x10+	1.90x10 2 1803	10603
		1861.0				JULE (2)
3-7-81	50	1.89×105	4,21×104	3,18x 10#	1.78×10-2 4453	473
-	550	1.8'9 xº105	2,47×10+	4.19×10+×10	6 10-2 1462	7713
9 5	200	1,891,05	3.41 × 10+	4.21× 10+		94.59
	000	1,89×105	8,47×104	4.19x 10*	1,61×10-2 6157	15616
		2861				
23-4-85 ATTA	50	1.89×105	\times	3.76×10	X 10 4	7304
CHMI		1.89 × 105	1,34 ×/0	3,74×301	× 10 ×	3672
C) () ENT B	00	1.89 X 105	1.76 × 104	3.78×10+	1.578 10-2 1384	5056
361						15/5
1-10-03	220	1,89 ×105		2.7/X107	1000	3025
1-20-3	70 : 0 e	1.89 × 10°	27	2.74×10		4.783
3.3	0 0	1.89 × 105	XX	2.73 X 10*	150	52.86
	<	00		312004	137×10 = 1630	/7/6.

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1.27.83	50	-	1.631104	2.63×104	2	2/x/0	1602	-
1-22-83	20	51,89 x 105	1.60×104	2.66×109		X	1560	1
-	20	1,89 × 105	1.22×104	2.65×104		XX	1192	15670
1. 24.83	20	1,89 × 105	1.17×104	2.67×107		0 / ×	1141	00
1-243	50		1.21×104	2.65×104	1		1181	22
1-24-83	5.0	1 X 68	1.19 × 104	66 X		×	1160	-
1-24-83	(J)	1.89 X 105	1,22×10#	2.66.104		10	1194	20346
i lyn	50	×	8.22 X 103	2.67X104		3	803	21149
10	200	×	1.04×104	2. 70×10+		X	100'5	22154
100	50	× 68	9.60×103			/ × /	921	23075
1-25-83	20	X	8,81×103	87x	*	10	859	33934
1-25-83	20	×	9.36×103	2.66×107		, 01 X	907	2484
3-19-83		X	8.97.103	2.73 X 10"		XIO	852	22673
3-33-83		X	1.06×107	2.74 8/07	289	137 × 10 -2	10.05	26678
4-30-43		7	9.50 X 103	2.90 X 10 Y		10/	824	37522
4-211-83		1.89 x 105	1,17×10,	2.85 X XOY		6 ×	1036	8800
5-11-83		1.89 X 105	7.80×103	2,73 x 10 7		10/4	719	242,
5-19-83		1.89 x 105	7,71,8 10 3	2.70 X 10 Y		0	7/9	20000
6-16-83		1,89 x 103	2	2.75 × 107		1,33 × 10	477	22 423
6-21-83	20	X :	0/ X 6/	2.32 X D		1,33 X 10 -2	2434	22 523
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8-16-83	50	×	X	J. S. X. 10.	500	0/2	1883	27 657
9 27 83	20	1.89 x 10	0 3			2/0		49 927
1.38-83	20	1.84 X 10°	× :	0 :		0/2		52 605
9-39-83	50	1,89 × 105	X 10	2.83 X /0'		X 10	3678	55 221
- 15	5	1.89 x 103	X.10	J.76 110		1,34 × 10 -3	16.16	56 334
10-01-53	50	1.84 × 10-	1,36 X 10:	2.86 x 10.		1.21 × 10	777	

DATE	501	M. Punpes	Sample CPM	STD CPM	· ·	STD CONCER.	Mc Pumped	r str	Very Contract
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12-31-83	50	1.89 X 105	1,19 x 10 f			1,241/0-2	1113	58329	*
12-22-83	50	1.89 X105	7.70 x 103	2.45 X 109		1,24 1/10-2	736	59 065	
7861									
1-5-84	50	1.89 X 105	3,66 1/03	2148 A10 4	. ~	20		335	
1.5-34	20	5	6.11 X 103	2.49 x 10 Y		1.20 X 10-2	559	24.4	
4-27-84	20	1,89 X 105	1:13 × 105	大小大10%		1.20 ×10 2		11356	
1.17.84	50	1.89 X105	4.41 1107	2.11.8109		1.20 X 10-2		15/31	
48-06-9	200	9.46.X104	3.20x10 4	1.97×10 4		11.16/10-2	33	68	
18.22.84	5.5	2,08×105	1.30×10 4	1.98x 10 *		11.16X10-2		8898/	
10-18-84	0 5	1.89×105	7:33×107	2,15×10 4		1.09×10.	66 59	-	
12-5-84	0,0	1.89×105	2.18×104	L. 13×107		1.09×10 %	3996	37607	
1085			200						
3-6-85	50	1.891/05	4,60×105	1.83×10"	9	1.05.770	4358	12 CON 2000	
12-12-85	10	2.08×10×		18/X/0 V		9.6 X10-3	7528	No dest	
12.3.85	2	2,08 x/0 5		1,73.170	de -	9.6710-3	3723	15.609	
12-13-85	12	2.08 ×10 ×	3,504×10	1, 1670, 1		9.6×10-3	3369	12778	
12-18-85	10	1.512105		1. X2.		9.4x20-3	6955	3	
12-10-85	6	1.89 1105		11:11/110		9.6710-7	7355	00	
12-5-25	w	9.46×10 3			. Dec. 41	9.6×10-3	7053	1/1/2/1/	
1231-15		7.57XV03	9	16041	Local	9.6 X10-3	2.63.6	1577	
					-				
18708 G									
1-8-86	45	1,7X105	6,5 X104	1.41/104		9.4710-3	1362	7:05	
3.12.15	1	265 700	A 8 X/0 F	8.1×10	-	1141.140	7396	85/4/	- (18K
2-28-86	34	115/X105	4,37103	8,25 X10 Y	-	1.41 X10-1	1111	15:170	LG 7AW
22-28-86	20	1,89 X105	3,07X/03	8,24,8104	-	1.41,810"	166	16009	16 Th
2.28-66	15	208 XIOF	279×103	8.19.8101	TALLING AND	1.4/1/10-1	1001	18 21	66 TAN.
2-29-86	55	2.08×105	3.83×103	7.93/10"	олина	3/11/10-1	1415	19:00	LG Thus
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114 Purped 114 X105 2,08 X105 2,08 X105 2,08 X105 2,08 X105 1,35 X105 1,35 X105 1,51 X105 1,51 X105 1,51 X105	3.63×105 7.57×105 3.63×105	
2.28-86 30 3.5-84 30 3.5-84 22 3-13-86 55 5-13-86 55 5-13-86 55 4-10-86 55 4-10-86 55 4-10-86 55 1-16-86 35 1-16-86 90 10-6-96 90	2008 18-11-8 3-11-8 3-11-8	

Water Usage London Road

6/81 -9/81 9/8/ - 14/8/ 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 6/84-10/84 10/54-1/85 1/85 - 3/85 3/85 - 6/85 6/85-10/85 10/55 - 1/86 1/80 - 3/86

4/86 - 6/86

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 26, 800CF * woter to verified that 24,700CF 20,700CF 30,300 CF 25,300 CF 23,100 CF 24,100 CF

9/86 Liquid Waste update Water used 7/85 - 6/86 104,800 CF X 28.32 P/CF = 2,987,936 P Averages are 2,967,936 8/41 8131 P/day 8131 P/day x /40/18 = 8/31 pli/day Set Nucell program limit at 8100pt for

ATTACHMENT D

Sources of waste water	
- hot cell sink	(Small tank)
- Floor Qrains Isotope	shop > (100 gal)

- SINK

- Taundry " " - lockeroom sinks & shower, > (500 gal) Blue tank

Large: small tanks in hot area of basement Blue tank in clean area of basement (since 2/86)

Large tank is probably empty Small tank has some water Bive tank almost empty

Water is pumped from tanks or floor piped to 55 gal drum, mixed (5 ml) sample removed, counted in well counter Standard counted

STATE ASSESSED ASSESS

DATE	GALLONS	MI PUMPED	SAMPLE CPM	STD CPM
5-16-80 5-16-80 5-16-80 5-16-80 5-16-80 6-11-80 9-19-80 9-20-80 9-20-80	25 40 50 50	9.46×10 ⁴ 1.51×10 ⁵ 1.89×10 ⁵	8:16 × 103 6.36 × 103 8.38 × 103 1.16 × 104 1.12 × 104 1.14 × 104 2.00 × 104 2.30 × 104 2.47 × 104	5.22×10 ⁴ 5.04×10 ⁴ 5.03×10 ⁴ 5.03×10 ⁴ 5.06×10 ⁴ 5.04×10 ⁴ 4.78×10 ⁴ 4.88×10 ⁴ 4.88×10 ⁴ 4.88×10 ⁴
9-20-80 3-7-21 10 81	50 50 45 50	1.89 x 105 1.89 x 105 1.89 x 105 1.70 x 105 1.89 x 105 1.89 x 105 1.89 x 105	2.37×10 ⁴ 2.47×10 ⁴ 2.41×10 ⁴ 2.41×10 ⁴ 8.47×10 ⁴	4.72×10 ⁴ 3.18×10 ⁴ 4.19×10 ⁴ 4.20×10 ⁴ 4.21×10 ⁴ 4.19×10 ⁴ 4.19×10 ⁴
3-4-82	50	1.89 × 105 1.89 × 105 1.89 × 105	1.65 × 104 1.34 × 104 1.66 × 104 1.76 × 104	3.76×104 3.74×104 3.78×104 3.78×104
1983 1-20-03 1-20-33 1-20-03	50 50 50	1.89 × 105 1.89 × 105 1.89 × 105 1.89 × 105	1.63 × 104 1.54 × 104 1.45 × 104 1.58 × 104	2.71×104 2.74×104 2.76×104 2.73×104

STANDARD CONCENTRATION (MG/M)	MC PUMPED	YEAR TO DATE	
1.76×10-2 1.96×10-2 1.96×10-2 1.96×10-2 1.96×10-2 1.96×10-2 1.90×10-2 1.90×10-2 1.90×10-2	290 374 617 856 823 840 1480 1704 1818 1803	290 664 1281 2137 2960 3800 5280 6984 8802 10605	
1.72×10-2 1.6.×10-2 1.6.×10-2 1.6/×10-2	4453 1798 1462 1746 6157	4453 6251 7713 9459 15616	
1.57 × 10-2 1.57 × 10-2 1.57 × 10-2 1.57 × 10-2	1.1303	1304 2369 3672 5056	
137 10 -2 × 10 -2 × 10 -2 137 × 10 -2	1565 1460 1358 1503	1565 3025 4783 6286 7916	

		de la company de		
DATE	GAL	MLPUMPED	SAMPLE CPM	STO CPM ST.
1.21.83	50	1.89 x 105	1.72×104	2,65 X/04
1-21.83		1.89 × 105	1.73×104	2.62×104
1-22-23		1.89 × 105	1.63X104	2.63×104
1= 22-83		1.89 × 105	1.60×104	2.66×104
1-24-83		1.89 × 105	1,22×104	2.65×104
1-24-83		1.89 × 105	1.17×104	2.67×104
1-28-23		1.89 X 105	1.21×104	2.65×104
1-24-83		1.89 × 105	1.19 × 104	2.66×104
1-24-83		1.89 X /0 ⁵	1.22×104	2.66104
1-25-83		1.89 × 105	8.22×103	2.67X104
1-25-83		1.89 × 105	1.04×104	2.70×104
1-25-83		1.89 × 105	9.60 x 103	2.66×104
1-25-83		1.89 × 105	8,81×103	2.67×104
1-25-83		1.89 X 105	9.36×103	2.66×104
3-19-83		1.89 X 105	8.97×103	2.73 × 104
3-23-83	50	1.89 X 105	1.06×104	2.74 \$104
4-30-83	1	1.89 × 105	9.50 X 10-3	2,90 x 10 9
4-51-83	a company	1.89 x 105	1,17×10 4	2.85 × 104
5-11-83	50	1.89 × 105	7.80×103	2,73 , 104
5-19-83	50	1.89 × 105	7.71 × 103	2.70 X 10 4
6-16-83	50	1,89 × 105	1.06 × 104	2.75 × 104
6-21-83	50	1,89 × 105	2.74 X 104	2.82 × 104
8-11-83	.50	1.89 × 105	1.18 × 104	2.82 XNY
8-16-83	50	1,89 × 103	2.18 × 104	2.81 × 104
-27-83		1.89 × 103	8.11 × 10 4	2.71 × 104
: 28-8-3	50	1.89 × 105	8.15 X 10 4	2.72×104
9-29-83	50	1,89 × 105	4.39 X 104	2.83 × 104
10-20-83	50	1.89 × 105	2.04 × 104	J.96 X104
10-21-33	50	1.89 X 105	1,36 × 104	3.86×104

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1.37×10 ⁻²	u
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1.37×10-2 1/94 1.37×10-2 803	i
1.37x 10-2 803	
1.37×10-2 1005	
1,37×10-2 921	-
4 1.37 × 10-2 859	
1.37×10-2 907	
1,37 x 10-2 852	
1.37 × 10 -2 10.05	
1/33 / /	
1.33 × 10 -2 1036 1.33 × 10 -2 719	
1,33 × 10 -2 719	
1/33 × 10 -2 974	
1,33 × 10 2 2452	
1.28 × 10 -2 101	
1.28 × 10 - 1883	
1 nd V 10 -2 725/	
128 × 10 1 /2.70	
1,28 × 10 3678	
1,24 × 10 16.16	
1711 1113	alkan

UC YEAR TO DATE
9597
1/316
12918
14478
15670
16811
17992
19152
20346
21149
22154
23075
23934
24841
25693
26698
27522
28558
29277
29996
30 970
33 523
35 406
42 657
49 9 27 53 605
55 221
56 334
2022

DATE	GAL	ML PUMPED	Sample CPM.	STD CPM
12-20-83	50	1.89 ×105	9.47×103	2.52 X104
12-21-83	50	1.88 × 105	1,19 × 10 4	2.51 × 104
12-22-83	50	1.89 × 105	7.70 × 103	2.45 × 104
1984				
1-5-84	.50	1.89 X 105	3.66 × 103	2.48 ×10 4
1-5-84	50	1.89 × 105	6.11 × 103	2.49 1 10 4
2-27-84	50	1.89 × 105	1.13 × 105	2.4 × 104
2-27-84	50	1.89 × 105	4,41 X104	2.76 × 104
6-20-84	25	9.46 × 104	3.20×10 4	1.97× 10 4
6.22.84	55	2.08×105	1.20×10 4	1.98X 10 7
-10-18-34	50	1.89×105	7.22×104	2.15 X 16.4
12-5-84	50	1.89× 105	2.18×104	1.13×10 4
13.55				/
3-6-85	50	1.89X105	4.00×105	1.83×104
12-12-85	- 55	2.08 405	6.81 X/0 V	1.81 x 10 4
12:13:85	55	2,08 X/05	3.3/ X/04	1.73/12
:-12-13-85	55	Z.08 X/0 5	3,04×104	1. 1/4/0"
-12-18-85	10	1.517105	7,05 X/0 V	-1: X/2
- 12-20-85		1.89 X105	6.454104	1.59/10
-12-34-85	3	9.46×103	1,29×10 6	- Z-Six
:_12-31-85	2	7.571/03	1,38 ×10 6	1.6641
And the second second second		commence and the first of		
1986	-			
1-8-86	45	1,7×105	6.5 X/04	1.41×10 ×
2-27-86	7	2.65 X10 V	1.6X/05	81/X/0 4
2-28-86	40	1151 X105	4,31/03	8,25×10 4
12-28-86	50	1.89 X105	3,07 × 10 3	8,24×104
2-28-86	55	2.08 X105	2.79×103	8119×104
2-28-86	55	2.08 X105	3.83×103	7.93×10 1
A:		2017.272		

Walter Street

	STD CONCEN,	D	uc Year	
· M	" MC / ML	MC Pumped	To Date	7 12,7 L 1 - 1 1
4	1.24×10-2	882	57216	
4	1 1,24/10-2	1113	58329	
4	1,24 × 10-2	736	59 065	
W.	1.20 × 10 -2	335	335	
4	1,20 × 10-2	559	894	
Ny y	1.20 × 10-2	10462	11356	
4	1,20 × 10-2	4075	15431	
	1.16×10-2	1792	17223	
	11.16× 10-2		18683	
	1.091102	6929	1.5613	
	1.09×10-2	3996	129609	
	1.07%	3770	,,,,,,	
	1.05 × 102	4358	4358	
	9.6 X10-3	7528	11886	
	9.64/0-3	3723	15609	
	9.6×10-3	3369	12 278	
	19.6×10-3	6955	2: 733	
	9.6×10-7	7355	1 388	
		7053	11 341	
	9.6×10-3	5636	12 777	
	1 4.0 XIO	3630		
	_3	40/-	77167	
	9,41/0-3	7362	7:62	Floor
	141 X10-1	7396	14:58	Floor
	1.41×10-1	1/12	15:170	LG TANK
	1.41×10-1	994	16864	LG-TANK
	1.41×10-1	1001	17805	LG TANK
	1.41×10-1	1415	19:00	LG-TANK
•	7	435.5		
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DATE	GAL	ML Pumped	SAMPLE CPM	STD CPH
2-28-84	30	1.14×105	3,63×103	8 1104
3.5-86	2.2.	8,331/04	5.15 X/04	8,25×10×
3-/3-86	55	2,08 ×105	9,66 X103	8,1 1/0 4
3-13-86	55	2.08 NO5	2,79×103	8.1×10 ×
3-14-86	55	2.08/105	2.85 ×103	8.12×104
3-14-86	55	2.08 X10 "	1,5 X/03	B1/2/10
3-34-86	35	1.32 410 3	1,7X/02	1.83 8/45
4-10-86	53	2.08 ×105	4,77/103	1.418102
4-10-86	55	21084105	114×103	1.541105
4-16-86	19	7.10×104	5,09 X/0	1.87×100
6-25-86	42	1.59 X10 5	5.9 % x 10-	122105
7-16-86	36	1.35 × 105	3.95 X 102	1.84x 10 5
9-11-86	. 90	3.41×105	5,26 X103	2,71205
10-6-86	40	1.51+105	7.85 710 2	2.65 10
			2	
21987				
1-2-87	80	3.03×105	2,29 X/03	2.5 ×105
1-19-87	200	7.57×105	1.31 × 103	2.96×105
2-11-87	96	3.63 x105	1.20x104	2.53×105
			Construction of the Construction of	
				THE WAY

STANDERD concentration ME/ML	uc Pumped	To Date	
1.41/40-1	726	20 006	FLOUR
	7324	27330	FLOOR
1.41 ×10	3496	30826	LARGE TANK
1.41 X/0-1	1011	3/ 837	LARGE TANK
1.45 ×10-1	1037	32 874	LARGE
1,9240-1	545	33,419	LARREC
1.4240-1	17	33,436	BLUE
191110	908	34,344	LARGE
1,36 X/0	213	34,557	LARGE
1.36 × 0-1	26	34583	BLUE
1.36 ×10-1	71	34654	Blue
1.36 × 10 - 1	33	34887	Blue
	8/2	35529	6/47
1,28×10-1	73	35,602	Blue
1,28×10		595×1	
	355	355	BCUE
1.28 40	422	777	Blue
1.24 ×10-1	2084	2861	Blue
1,21x10-1	200		
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and the same of	And the second second		

NUCLEAR REGULATORY COMMISSION

REGION III

Special Inspection Report No. 030-16055/87-002(DRSS)

Docket No. 030-16055

License No. 34-19089-01

Licensee: Advanced Medical Systems, Inc. (AMS)

1020 London Road Cleveland, Ohio

Inspection Conducted On: April 29-30, 1987

Sample Analysis Completed: May 26, 1987

Inspection Conducted At: Northeastern Ohio Regional Sewer District

Cleveland, Ohio

Inspectors:

R. E. Burgin Lynch for Senior Radiation Specialist

M A Kunowsh M. A. Kunowski

Radiation Specialist

Approved By: D. G. Wiedeman, Chief for

Nuclear Materials Safety Section 1

Date

6-3-87 Date

Inspection Summary

Inspection Conducted on April 29-30, 1987 (Report No. 030-16055/87-002(DRSS)) Areas Inspected: This was an unannounced special inspection conducted in accordance with Temporary Instruction 2800/9, "Reconcentration of Radionuclides in Sanitary Sewerage Systems," issued March 25, 1987. The special inspection consisted of sampling/analysis of settled solids and filter cake (treated dry waste) from the Northeastern Ohio Regional Sewer District for evidence of reconcentration of cobalt-60 and/or cesium-137 from the Advanced Medical Systems, Inc. facility in Cleveland, Ohio.

Results: The samples were analyzed (gamma spectroscopically) using a Region III multi-channel analyzer. The samples showed no detectable presence of cobalt-60

nor cesium-137.

DETAILS

1. Contacts

James F. Weber, Manager, Northeastern Ohio Regional Sewer District (NEORSD)
Richard N. Connelly, Supervisor, Industrial Waste Section, NEORSD

James T. Laheta, Investigator, Industrial Waste Section, NEORSD

2. Purpose of Special Inspection

In accordance with Temporary Instruction 2800/9, "Reconcentration of Radionuclides in Sanitary Sewerage Systems," samples of untreated settled solids and filter cake (treated dry waste) were collected from the Northeastern Ohio Regional Sewer District for evidence of reconcentration of cobalt-60 (Co-60) and cesium-137 (Cs-137) from the Advanced Medical Systems' (AMS') cobalt-60 and cesium-137 teletherapy source fabrication facility in Cleveland, Ohio.

3. Results

The raw settled solids and filter cake were analyzed gamma-spectroscopically in Region III's multi-channel analyzer. The results indicate no presence of cobalt-60 nor cesium-137 (and therefore no apparent reconcentration of these radionuclides at the sanitary sewerage treatment plant as a result of source fabrication operations at Advanced Medical Systems, Cleveland, Ohio).

MAY 5 - 1988

Advanced Medical Systems, Inc. ATTN: Seymore S. Stein, Ph.D. President 121 North Eagle Street Geneva, OH 44041 License No. 34-19089-01

Gentlemen:

This refers to the special safety inspection conducted by Mr. Robert E. Burgin of this office on April 13, 1988, of activities authorized by NRC Byproduct Material License No. 34-19089-01.

The inspection was initiated following our review of AMS' February 8, 1988 letter (with enclosures) proposing isolation of the Waste Hold Up Tank (WHUT) room at the London Road facility. Section J of Nuclear Support Services' (NSS) report, "Remedial Actions for the Waste Hold Up Tank Room at the London Road Facility," enclosed with the above-referenced letter, included results of surveys performed on January 21, 1988, in an unrestricted area in the sewerage system within AMS property lines. The survey indicated the presence of radiation levels as high as 70 millirem per hour.

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, interviews with personnel, independent measurements and the collection of water and sludge samples subsequently analysed in our Region III laboratory.

During this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

In addition to the response required pursuant to 10 CFR 2.201, you are directed to address the following specific areas/concerns related to the violation:

- a. Characterize the contents of the referenced area resulting in elevated radiation levels.
- b. Describe your means for maintaining security of the area from approach via the City of Cleveland (main) sewerage system.
- c. Describe any plans for clean-up (decontamination) of the referenced area.
- d. Describe any potential for release of type duct material to the main sewerage system.

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MAY 5 - 7330 Advanced Medical Systems, Inc. We will gladly discuss any questions you have concerning this inspection. D. G. Wiedeman, Chief Buclear Materials Safety Section 1 Enclosures: 1. Notice of Violation 2. Inspection Report No. 030-16055/88001(DRSS) cc w/enclosures: DCD DCB (RIDS) Burgin

NOTICE OF VIOLATION

Advanced Medical Services

License No. 34-19089-01

As a result of the inspection conducted on April 13, 1988, and in accordance with 10 CFR Part 2, Appendix C - General Statement of Policy and Procedure for NRC Enforcement Actions (1987), the following violation was identified:

10 CFR 20.105, "Permissible levels of radiation is unrestricted areas," states in paragraph (b):

Except as authorized by the Commission pursuant to paragraph (a) of this section, no licensee shall possess, use or transfer licensed material in such a manner as to create in any unrestricted area from radioactive material and other sources of radiation in his possession:

- (1) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour, or
- (2) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 100 millirems in any seven consecutive days.

Contrary to the above, AMS licensed material (cobalt-60) in an unrestricted area (sewerage system) created radiation levels of 80 millirem per hour. The duration of this condition is not known at this time.

This is a Severity Level IV Violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each violation: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

MAY 5 - 1988

Dated

D. G. Wiedeman, Chief

Nuclear Materials Safety Section 1

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-16055/88001(DRSS)

Docket No. 030-16055

License No. 34-19089-01

Licensee: Advanced Medical Systems, Inc. (AMS)

1020 London Road

Cleveland, OH 44110

Inspection Conducted: April 13-21, 1988

Inspection At: AMS' London Road Facility

Inspector:

Approved By:

G. Wiedeman, Chief

Nuclear Materials Safety

Section 1

Inspection Summary

Inspection on April 13, 1988 (Report No. 030-16055/88301(DRSS)) Areas Inspected: This was an unannounced special safety inspection initiated following the NRC's review of survey records submitted with AMS! February 8. 1988 proposal to isolate the Waste Hold Up Tank Room at its London Road facility. These records indicated the presence of elevated radiation levels (as much as 70 millirem per hour) in an unrestricted area in the sewerage system within AMS property lines. The inspection consisted of a selective examination of procedures and representative records, observations, interviews with personnel, independent measurements and the collection of water and sludge samples subsequently analysed in the NRC Region III laboratory. Results: Of the areas inspected, one violation was identified -10 CFR 20.105(b)(2); radiation levels existed in an unrestricted area which, if an individual were continuously present, could have resulted in his receiving a dose in excess of 100 millirems in any seven consecutive days (Section 5).

DETAILS

1. Persons Contacted

*Robert A. Jucius, Principal Physicist

*Howard R. Irwin, Radiation Safety Officer

*Denotes those present at Exit Interview on April 13, 1988.

2. Licensed Activities

AMS is licensed by the NRC to possess up to 300 kCi of cobalt-60, 40 kCi of cesium-137 and 9,000 pounds of depleted uranium. License Number 34-19089-01 authorizes AMS to perform research, development, and processing of sealed sources for distribution to authorized recipients; to install, dismantle, service and maintain picker Corporation and AMS teletherapy units, and Picker radiography units; to remove, install or exchange sources in Picker corporation, AMS Inc., and Keleket-Barnes teletherapy equipment; to develop and demonstrate equipment containing sealed sources; and to leak test sealed sources installed in Picker Corporation and AMS, Inc. devic. 3.

3. Purpose of Special Inspection

The inspection was initiated following NRC Region III's review of AMS February 8, 1988 letter (with enclosures) proposing isolation of the Waste Hold Up Tank (WHUT) room at the London Road facility. This letter (with enclosures) is included as Attachment A.

Section J of Nuclear Support Services' (NSS) report, "Remedial Actions for the Waste Hold Up Tank Room at the London Road Facility," enclosed with the above-referenced letter, included results of surveys performed on January 21, 1988, in the sewerage system within AMS property lines. The survey indicated the presence of radiation levels as high as 70 millirem per hour in an unrestricted area.

4. NRC Followup

On April 13, 1988, the special inspection was conducted on-site and included a review of selected records, observations, interviews of licensee representatives, independent measurements and the collection of water and sludge samples subsequently analyzed in the NRC Region III Laboratory (counting results of the collected samples are discussed in Section 4.b).

a. Interview of Robert A. Jucius, Principal Physicist

Mr. Jucius was interviewed on April 13, 1988, and provided the following information:

During the performance of radiation level surveys outside the AMS London Road facility on January 20, 1988, Mr. Leland Schroeder Nuclear Support Services (NSS) identified a sewer (manhole) cover

reading 50k counts per minute. This survey was performed to determine the environmental impact of AMS' Waste Hold Up Tank (WHUT), and is documented in NSS' report enclosed with AMS' February 8, 1988 letter to the NRC (Attachment A).

Upon review of the NSS survey documents by AMS representatives, the high reading was observed on Mr. Schroeder's January 20, 1988 survey report (Attachment B). On January 21, 1988, Mr. Robert A. Jucius performed "verification surveys" in and around the manhole. Survey results (documented in Attachment C) indicated radiation levels as high as 70 millirem per hour (mrem/hr) at the bottom of the sewer pipe directly below the manhole. Smear (wipe) sample results of bottom sediment measured with a spectroscaler converted to 121,770 dpm/100 cm² (not enough sediment could be obtained to fit a good counting geometry on the more sophisticated quantification equipment).

Mr. Judius stated that he placed a "Caution-Radiation Area" sign and contact instructions on the ladder inside the manhole, informing any individual entering the sewerage system from AMS property to contact AMS prior to entry (this posting was observed during the April 13, 1988 special inspection). While warning notices were placed in the manhole, access to the sewerage system was not restricted for another $1-1\frac{1}{2}$ months, according to Mr. Judius, when a locking bar was welded to the outer manhole pipe (a metal rod secured with a padlock).

When questioned about notifications possibly made in regard to the high radiation levels identified in the unrestricted area, Mr. Jucius stated that the topic was discussed with AMS' Radiation Safety Committee, and the decision was made not to report the situation to the NRC at that time (the information was provided to the NRC in the form of environmental surveys, Attachment C).

b. NRC Independent Measurements

On April 13, 1988, the NRC inspector performed radiation level surveys and collected water and sludge samples from the sewerage system. Radiation levels at the bottom of the AMS manhole ranged from 60-80 mR/hour, increasing in the direction of the facility. Levels off-site (at the mid-London Road manhole) were background.

A water sample (still) from the AMS sewerage system measured 8.855E-6 microcuries per milliliter*; the sludge sample measured 6.187E-2 microcuries per milliliter (both for cobalt-60). The main (City of Cleveland) sewer system water sample (fast moving) did not contain measurable amounts cobalt-60.

^{*10} CFR 20, Appendix B, allows cobalt-60 concentrations in unrestricted areas (water) of 3.0E-5 and 5.0E-5 uCi/ml for insoluble and soluble forms, respectively.

The NRC survey/sampling locations and results are identified in Attachments D and E, respectively. The sample analysis was completed by NRC laboratory representatives on April 21, 1988.

5. Apparent Violation

10 CFR 20.105, "Permissible levels of radiation in unrestricted areas," states in paragraph (b):

Except as authorized by the Commission pursuant to paragraph (a) of this section, no licensee shall possess, use or transfer licensed material in such a manner as to create in any unrestricted area from radioactive material and other sources of radiation in his possession:

- (1) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour, or
- (2) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 100 millirems in any seven consecutive days.

Contrary to the above, AMS licensed material (cobalt-60) in an unrestricted area (sewerage system) created radiation levels of 80 millirem per hour. The duration of this condition is not know at this time.

6. Exit Interview

A brief exit interview was held at the conclusion of this special inspection which included a discussion of the apparent violation and AMS corrective actions to date (posting inside the manhole and securing the manhole from non-AMS entry; even Cleveland Water Works employees would need to contact AMS to get into the manhole from AMS property).

Also briefly discussed were possible means to post and secure the 80 mR/hr area from entry via the main sewer system.

Sampling results (Section 4.b.) were not available at the time of the inspection.

Attachments:

- A. AMS letter dated February 8, 1988 (w/enclosure)
- B. NSS survey sheet dated January 20, 1988
- C. NSS survey sheet dated January 21, 1988
- D. NRC survey/sampling location schematic
- E. NRC Confirmatory Measurements