



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

March 15, 1995

MEMORANDUM TO: Materials Files

FROM: Michael F. Weber, Radiation Specialist *mfweber*

THRU: John A. Grobe, Chief, Nuclear Materials Inspection Section 2 *John Grobe*

SUBJECT: ADVANCED MEDICAL SYSTEMS, INC.
LICENSE NO. 38-19089-01
DOCKET NO. 030-16055

On March 6-8, 1995, I performed an unannounced inspection at AMS. My activities included the following:

- Overseeing the performance of daily and weekly radiological surveys and equipment checks by the health physics technician, Chris Reed. Copies of the checklists used during the surveys and checks are attached. No problems were identified.
- Performing confirmatory surveys¹ of uncontrolled and controlled areas (excluding high radiation areas) on the first and second floors and roof of the building. The background radiation level was approximately 20 uR/hr. Readings above background are indicated on the attached maps. A small "hot particle" was found on the floor of the 1st floor uncontrolled equipment storage area. (Initially, the inspector measured levels approaching 300 uR/hr in this area. Then the RSO and inspector, using duct tape and a pancake probe, found the removable particle, and measured levels of 5 mrem/hr at 1 cm from the source. The particle was subsequently disposed of in a radioactive waste drum.)
- Performing confirmatory surveys of controlled and uncontrolled areas throughout the grounds outside of the building. Again, the background radiation level was approximately 20 uR/hr. Readings above background are indicated on the attached map. The radiation levels at the site boundary were at background levels.
- Overseeing the replacement of malfunctioning valves on two water storage containers (a third valve was later replaced on March 8).

¹ Meters used: Ludlum Model 19 Micro R Meter, NRC tag 011021, S/N 21567, calibrated 9/13/94, and Bicron RSO-5, NRC tag 042651, S/N B819G, calibrated 12/15/94. Wipe tests of the former low level waste storage room were also performed.

- Interviewing workers (Bob Meschter, RSO; Steve Haddock, Isotope Handler; Chris Reed, HP technician) regarding the upcoming water removal and treatment projects, and many other topics.

No violations of NRC requirements were identified during the course of the inspection.

Tasks for the next inspection include performing a careful, systematic radiological survey of sewer and water pipes in the facility, and investigating further the source of the 200 uR/hr reading found near the pipes in the janitor's closet on the first floor (see attached map).

Smears from former low level waste storage room taken 3/7/95

AMS wellcounter S/N 4896 calibration due 7/5/95

Background 31 cpm efficiency 14.18%

<u>smear</u>	<u>gross cpm</u>	<u>net cpm</u>	<u>dpm</u>
1	31	0	0
2	26	0	0
3	34	3	21
4	44	13	92
5	35	4	28
6	33	2	14
7	29	0	0

ADVANCED MEDICAL SYSTEMS

OPERATING PROCEDURE

TITLE: DAILY CHECKLIST

Procedure No: ISP-5

Revision: 1

Date Issued: 8/28/90

Page 1 of 1

1.0) PURPOSE: To provide a formal checklist for daily routine checks of equipment functions and safety instruments.

2.0) SCOPE: To be performed each working day that Isotope personnel are in facility.

3.0) INSTRUCTIONS:

MON. TUE. WED. THU. FRI. SAT.

3.1) Inspect air monitor chart for abnormal readings.

✓ ✓ ✓ ✓ ✓

3.2) Air monitor time delay @ 5 min.

✓ ✓ ✓ ✓ ✓

3.3) Cell/cell control area manometer reading 0.2 - 0.4;

03/00/90 02/00/90 02/00/90 04/00/90 02/00/90

3.4) Six Alarm board alarm lights are dimly lit. None brightly lit.

✓ ✓ ✓ ✓ ✓

3.5) Green light-cell control area Gamma Alarm.

✓ ✓ ✓ ✓ ✓

() Green light-ISA Gamma Alarm.

✓ ✓ ✓ ✓ ✓

3.7) Boilery A/C systems functioning.

✓ ✓ ✓ ✓ ✓

3.8) Green light-Clean Equ. Room Gamma Alarm.

✓ ✓ ✓ ✓ ✓

3.9) Stack sampler flow & pressure.

4/3 4/3 4/3 4/3 4/3

3.10) Well counter & scaler checks.

✓ ✓ ✓ ✓ ✓

3.11) Inventory check sources.

✓ ✓ ✓ ✓ ✓

Initial:

Date:

dl cr ml el a

7/27/95 7/28/95 7/29/95 3/2/95 3/2/95

CAUTION: IF GAMMA ALARM LIGHT IS FLASHING RED OR AN AUDIBLE ALARM IS HEARD DO NOT ENTER THE AREA UNTIL A SURVEY METER CHECK VERIFIES THE DEGREE AND SOURCE OF RADIATION.

Prepared by

Approval

Revisions

Stephen M. McDermott

Revise 3.4; add 3.10&3.11
Reformat (6 day/page)

CONTROLLED AREA SURVEY DATA SHEET

ISP-2A

LOCATION

RAD LEVEL GCPM CCPM DPM

FIRST FLOOR

1. Top Landing of Front Stairwell	0.1	31	2	14
2. Entrance Level of Stairwell	0.02	27	N/D	N/D
3. Basement Level of Stairwell	0.1	N/A	N/A	N/A
4. Outside Change Room Interlock Door	0.04	30	1	7
5. Manipulator Control Station	0.05	25	N/D	N/D
6. Cell Control Office	0.02	39	10	97
7. Hall in Front of Office	0.03	30	1	7
8. Doorway Outside Shielded Work Room	0.03	29	0	0
9. Conference Room - East	0.02	25	N/D	N/D
10. Conference Room - West	0.02	31	7	14
11. Hallway to Cage Area	0.02	33	6	42
12. Outside Airlock Doors	0.09	33	4	78
13. Outside Counting Room	0.02	28	N/D	N/D
14. South of Counting Station	0.02	33	6	42
15. Counting Station	0.02	30	1	7
16. West Doorway Inside Counting Room	0.02	23	4	28
17. Outside Isotopes Warehouse Overhead Door	0.3	32	3	31
18. Loading Dock Area	0.06	40	11	78
19. Scale Area	0.04	40	11	78
20. Fire Door to Warehouse	0.02	26	N/D	N/D
21. North Side of LLWS Area(when in use)	N/A	N/A	N/A	N/A
22. East of LLWS Area(when in use)	N/A	N/A	N/A	N/A
23. South Side of LLWS Area(when in use)	N/A	N/A	N/A	N/A

Performed by: C Reed Date: 5/4/95

SURVEY METER: AE-1 S/N: 1021 CAL DUE: 5/3/95

COUNTING INST.: Willcoxon S/N: 1096 CAL DUE: 7/5/95

COUNTING EFFICIENCY: 14.18 % BACKGROUND: 29 CPM

ACTION LEVELS: ^{120 cpm} 1000 DPM/100CM²
0.5MR/HR

Reviewed by RSO: R Mersha Date: 7-8-95

CONTROLLED AREA SURVEY DATA SHEET

ISP-2B

LOCATION

RAD LEVEL GCPM CCPM DPM

FIRST FLOOR

1. Change Room Near Lockers
2. Change Room Near Showers
3. Change Room Near Sinks
4. Change Room Entrance to ISA
5. Warehouse Office - East
6. Warehouse Office - Center
7. Warehouse Office - West
8. Cage Area - East
9. Cage Area - Center
10. Cage Area - West
11. Outside Isotope Warehouse

0.02	95	6	42
0.08	40	11	78
0.1	36	2	49
1	39	10	21
0.02	33	4	28
0.02	28	N/D	N/D
0.03	35	6	42
0.1	32	3	31
0.04	27	N/D	N/D
0.02	34	3	35
0.03	25	N/D	N/D

SECOND FLOOR

1. Outside Washroom Door
2. Office at Southeast Corner
3. East Wall Near Stairwell
4. Center of Office Area
5. Northwest Corner of Office
6. Outside Clean Equipment Room

0.3	38	9	63
0.1	39	6	42
0.3	38	9	63
1	35	6	42
0.1	46	17	120
0.04	37	8	56

Performed by: C. Reed Date: 3/7/95

SURVEY METER: ASP-1 S/N: 1021 CAL DUE: 3/5/95

COUNTING INST.: Wellington S/N: 4896 CAL DUE: 7/5/95

COUNTING EFFICIENCY: 14.18 % BACKGROUND: 29 CPM

ACTION LEVELS: 1000 DPM/100CM²
0.5MR/HR

Reviewed by RSO: R. Meredith Date: 3-8-95

SEMI-MONTHLY CHECKLIST

ISP-6A

Period from: _____ to: 3/2/95

INITIALS DATE

Perform Controlled Area Survey (ISP-2)

CK 3/2/95

Test the emergency generator as follows:

Activate generator start circuit and allow generator to run at least five (5) minutes.

CK 3/2/95

Verify alarm response.

CK 3/2/95

Return test switch to normal.

CK 3/2/95

Reset timer to five (5) minutes.

CK 3/2/95

Test battery powered emergency lighting:

Outside Cell Equipment Room

CK 3/2/95

Outside Clean Equipment Room

CK 3/2/95

Cell Control Area

CK 3/2/95

Isotope Shop Area

CK 3/2/95

Isotope Warehouse

CK 3/2/95

Cage Area

CK 3/2/95

COMMENT: ABT slow on return.

Performed by: CK

Date: 3/2/95

Reviewed by RSO: AG

Date: 3-8-95

FIRST FLOOR

C-19-P-0063

- ① STAIRWELL TO ROOF
- ② HANDS ON ROOF
- ③ SPARKER ROOF
- ④ BOWEN ROOM
- ⑤ SAVED AREA
- ⑥ HALL - HIGH
- ⑦ ISOTOPIC AREA
- ⑧ WASTE STORAGE
- ⑨ WASTE STORAGE
- ⑩ WASTE STORAGE
- ⑪ WASTE STORAGE
- ⑫ WASTE STORAGE
- ⑬ WASTE STORAGE
- ⑭ WASTE STORAGE
- ⑮ WASTE STORAGE
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SAMPLE ROOM
DURING SAMPLING
HOURS

WASTE
STORAGE

HALL
ELECTRICAL
DISTRIBUTION

HALL
ELECTRICAL
DISTRIBUTION

WASTE
STORAGE

WASTE
STORAGE

WASTE
STORAGE

LONDON ROAD

library ~40 μ R/hr

janitor's closet -
pipes behind wall
~200 μ R/hr

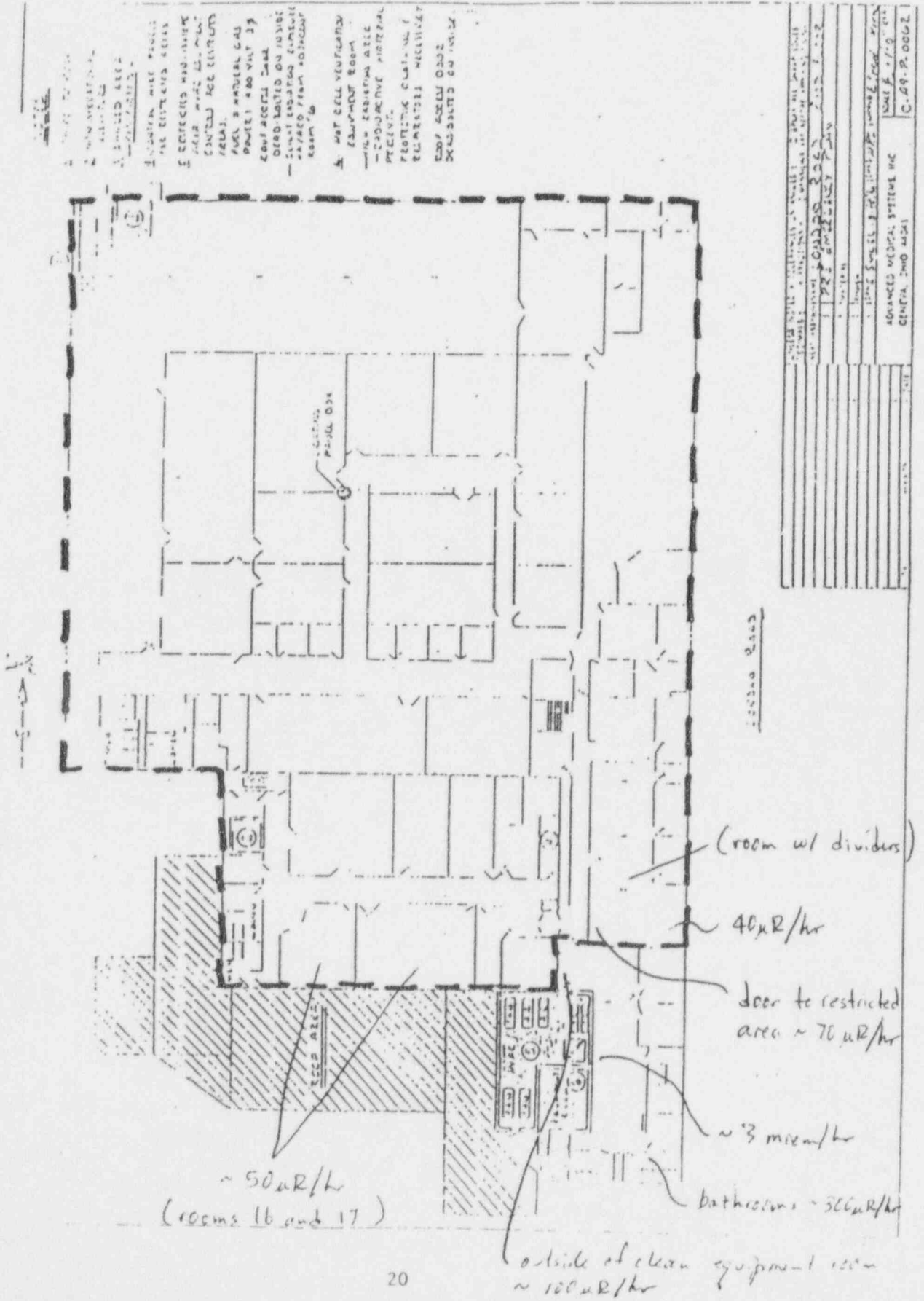
copy machine
room ~40 μ R/hr

change area
~150 μ R/hr

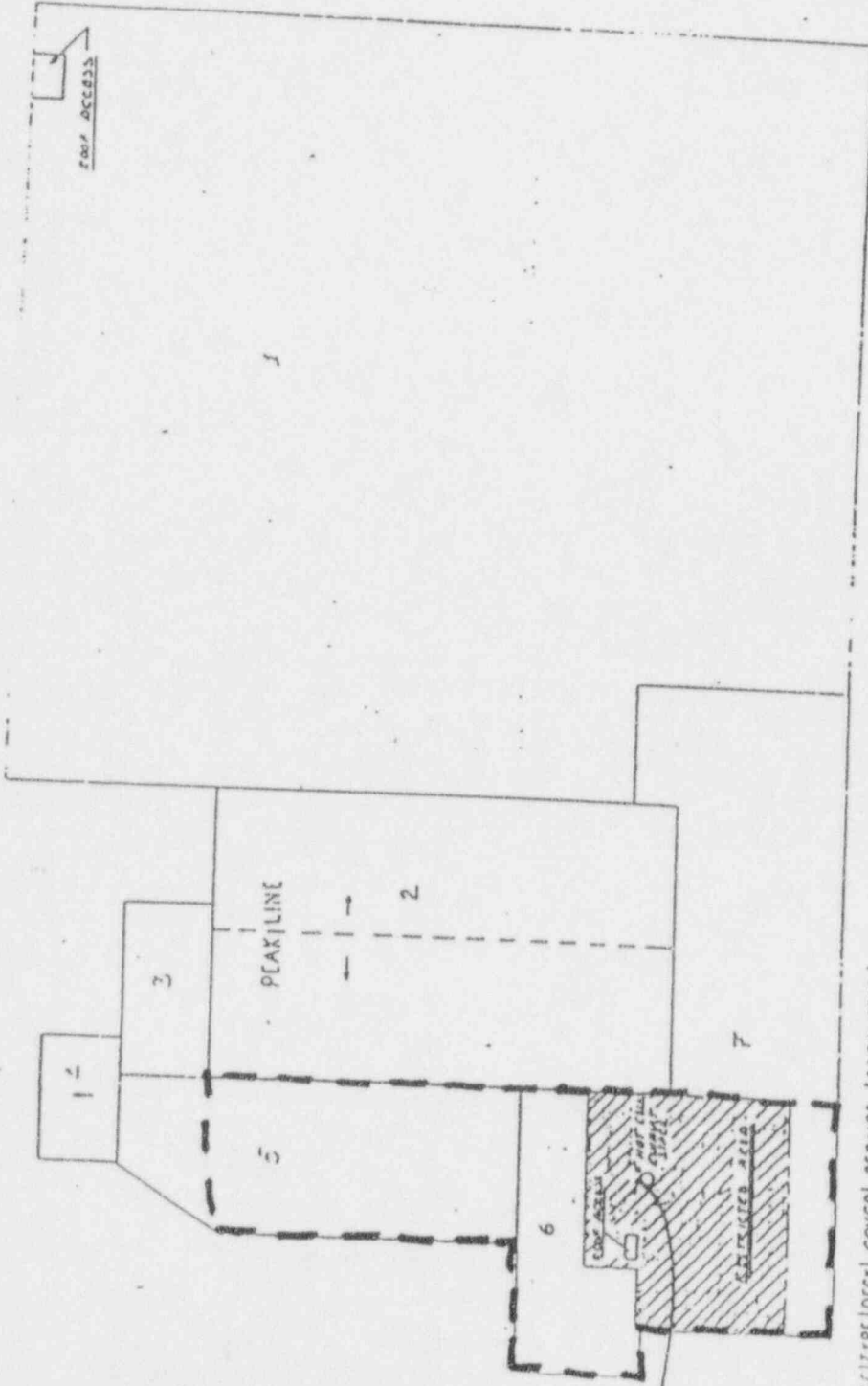
door to waste
storage area
~0.5 mrem/hr

basement (stairs, approx 1m. from water) ~100 μ R/hr

SECOND FLOOR



1/11 2 213



UNITS: 1000'S (1000'S) ON SCALE: 1" = 10'-0"		DATE: 11/11/83	
PROJECT: LONDON ROAD FACILITY		DRAWN BY: [Signature]	
SHEET NO.: 1		TOTAL SHEETS: 1	
DESIGNED BY: ADVANCED MEDICAL SYSTEMS, INC.		SCALE: 1/2" = 1'-0"	
COLUMBIA, OHIO 43041		C-89-R-2212	

NO.	AGE	TYPE	DECK	COVER	REPAIRS	RECOVERED
1	1983	ASPH/FLT	ASPH/FLT	1983	1983	
2	1983	ASPH/FLT	ASPH/FLT	1983	1983	
3	1983	ASPH/FLT	ASPH/FLT	1983	1983	
4	1983	ASPH/FLT	ASPH/FLT	1983	1983	
5	1983	ASPH/FLT	ASPH/FLT	1983	1983	
6	1983	ASPH/FLT	ASPH/FLT	1983	1983	
7	1983	ASPH/FLT	ASPH/FLT	1983	1983	

~ 3 mm/hr

Smears from former low level waste storage room taken 3/7/95

AMS wellcounter S/N 4896 calibration due 7/5/95

Background 31 cpm efficiency 14.18%

<u>smear</u>	<u>gross cpm</u>	<u>net cpm</u>	<u>dpm</u>
1	31	0	0
2	26	0	0
3	34	3	21
4	44	13	92
5	35	4	28
6	33	2	14
7	29	0	0

3/15/95

Jim,

used is documentation of the results of a telephone conversation that I had with the Secretary of the Local Emergency Planning Commission (LEPC) in Cuyahoga County, Mike Kalstrom, on March 2, 1995.

Kalstrom is an emergency planning specialist who works with chemical hazards. He works under the authority of the Superfund Amendment and Reauthorization Act (SARA), Title III, "Emergency Planning and Community Right to Know," and under the jurisdiction of the State Emergency Planning Commission (SERC). Kalstrom works for the Cuyahoga County Board of Commissioners.

Kalstrom is also a member of the City of Cleveland Ad Hoc Task Force on Emergency Planning at Advanced Medical Systems (AMS). Wayne Slawinski and/or I have attended the meetings of that Task Force. Kalstrom has been a very strong and vocal critic of AMS. I have maintained close contact with the other persons and organizations involved in the Task Force and the other participants are comfortable with the progress being made by AMS. The persons involved that I have been touching base with include the Cleveland Director of the Environment (direct report to the Mayor and assigned as Task Force Chairman), the Cleveland Fire Chief, the Cleveland Law Department, the Ohio Emergency Management Agency, and the Ohio Department of Health. I last personally met with the Task Force Chairman on 2/21. Kalstrom appears to be in a different position from the remainder of the Task Force.

On February 7, Kalstrom on behalf of the LEPC petitioned the SERC to grant a variance from regulations governing the operation of the LEPC to designate AMS as an "additional facility" under the Ohio Revised Code giving the LEPC authority over the hazards assessment and emergency planning at AMS. In that letter, Kalstrom makes sweeping and unsupported harsh criticisms of the NRC's oversight of AMS. Prior to that letter, I had spoken with Kalstrom twice and responded to one letter from him and thought that he had no significant outstanding problems.

After I met with the Ad Hoc Task Force Chairman on 2/21, I intended to meet with Kalstrom to explore and resolve his concerns expressed in the 2/7 letter. Prior to my opportunity to do that, on 2/27 we became aware from the Ohio State Liaison Officer, Jim Williams, of a meeting that Kalstrom scheduled that afternoon with the SERC. We were unable to attend the SERC meeting due to the lack of notice, but shared our observations with Williams. Williams view was that he perceived potential regulatory overlap problems between SERC and NRC if the SERC got involved directly in AMS.

The SERC heard Kalstrom at the meeting on 2/27 but postponed a decision on his petition until a future meeting. Kalstrom had Larry English, an attorney with NEORS, with him at the SERC meeting. This seemed unusual since the sewer district does not have emergency planning responsibilities.

We offered to Williams to meet both with the LEPC and SERC. The meeting was scheduled with the SERC on 3/9, and was subsequently postponed by the SERC to 3/27 due to scheduling difficulties. Kalstrom is scheduled to be in attendance at that SERC meeting.

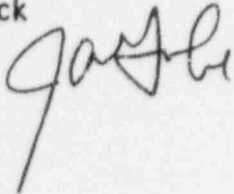
Because the LEPC is a petitioner for a hearing on the AMS license renewal, we

3/9/8

decided to proceed any meeting with Kalstrom with a phone call. Enclosed is documentation of the results of that call. As an action item from the call, I agreed to send Kalstrom some guidance and technical documents supporting NRC emergency response regulations and licensing practices on fuel cycle facilities. It was further concluded after discussing the results of my call with DRSS and NMSS management that the best way to prepare the SERC for their decision was to proceed with the meeting directly with the SERC with Kalstrom in attendance, and not schedule a separate meeting with Kalstrom.

If you have any questions, please call me.

Jack

A handwritten signature in dark ink, appearing to be 'Jack' or 'J. Jack', written in a cursive style.

Meeting Minutes
March 15, 1995

Subject: AMS

Attendees:

OGC: M. Malsch
S. Burns
L. Chandler
M. Zobler
J. Cordes
J. Goldberg

NMSS: D. Cool
C. Haney
F. Combs
C. Paperiello

RIII: C. Pederson
J. Grobe
J. Caldwell
W. Slewinski

Issues Discussed and Proposed Action:

1. Status of the 2.206 Petition

OGC has prepared Commission Paper that discusses various options of addressing the petition. This document should be available for review by NMSS in the near future.

2. Disposition of Sources

RIII will draft an order that instructs AMS to prepare a plan to reduce the source inventory at the London Road facility. This plan will include a time table for any proposed actions. The order should be prepared within the next 6 to 8 weeks.

3. Current Water Issues

RIII has prepared an confirmatory order that addresses the current water problems at AMS. The order is currently under review by staff in OGC and NMSS. RIII would like to issue this document ASAP. AMS will be prepared to act on the order after March 17, 1995.

OGC expressed a concern that NEORS should be made aware of the items that the order would impose on AMS. A decision was made to discuss the nature of the order with NEORS on March 16.

B/100

March 15, 1995

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. Michael F. Weber of this office on March 6 through 8, 1995, of activities authorized by NRC Byproduct Material License No. 39-19089-01.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Specifically, the inspector's activities included: (1) overseeing the performance of daily and weekly radiological surveys and equipment checks by your health physics technician; (2) performing confirmatory surveys of controlled and uncontrolled areas on the first and second floors and roof of your facility; (3) performing confirmatory surveys of controlled and uncontrolled areas throughout the grounds outside of your facility; (4) overseeing the replacement of malfunctioning valves on two of the water storage containers; and (5) interviewing workers regarding the upcoming water removal and treatment project.

No violations of NRC requirements were identified during the course of this inspection.

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

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

Sincerely,

Original Signed By

John A. Grobe, Chief
Nuclear Materials Inspection Section 2

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

See Attached Distribution

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OFFICE	RIII	C	RIII	E	RIII		RIII	
NAME	Weber:dp		Grobe					
DATE	03/15/95		03/15/95		03/ /95		03/ /95	

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Distribution

Robert Meschter
Radiation Safety Officer
Advanced Medical Systems, Inc.
121 N. Eagle Street
Geneva, OH 44041

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:

Cathy Haney, NMSS
John A. Grobe, RIII
Marian Zobler, OGC

PUBLIC IE07

E-mail:

Bill Axelson (WLA)
Bruce Berson (BAB1)
Bernie Bordenick (BM8)
Bill Brach (EWB)
Jim Caldwell (JLC1)
Fred Combs (FCC)
John Cordes (JFC)
Steve Crockett (SFC)

Joe DeCicco (JXD1)
Jack Goldberg (JRG1)
Jack Grobe (JAG)
Cathy Haney (CXH)
Tim Johnson (TCJ)
Steve Lewis (SHL)
John Madera (JRM4)
Kevin Null (KGN)

Donald Cook (DAC)
Josie Piccone (JMP1)
Gary Shear (GLS)
Wayne Slawinski (WJS2)
Mike Stein (MHS)
Mike Weber (MFW1)
Marian Zobler (MLZ)

March 16, 1995

City of Cleveland
Department of Public Health
Environment Division
ATTN: Robert O. Staib
Acting Director
1925 St. Clair Avenue
Cleveland, Ohio 44114

Dear Mr. Staib:

This refers to your letter dated February 16, 1995, and the meeting I and others of my staff had with you at your office in Cleveland, Ohio on February 21, 1995, concerning the Advanced Medical Systems, Inc. (AMS) facility located in Cleveland. The purpose of our meeting was to discuss the water problems at the AMS facility, address the concerns expressed in your letter and describe the NRC oversight activities at AMS.

Our responses to the six questions listed in your February 16, 1995 letter are provided below.

Question No. 1: Does the contaminated water currently in the basement of the AMS facility pose any risk to the public health of the citizens of Cleveland?

Response: The contaminated water in the AMS facility basement does not pose a risk to the health of the citizens of Cleveland. The contaminated water is contained in the facility basement. Precautions have been taken to retain the water in the basement. Should conditions develop that would result in the release of the basement water to the environment, there would likely be significant levels of soil contamination in the immediate vicinity of the London Road facility basement.

Question No. 2: Does the contaminated water currently in the basement of the AMS facility pose any risk to workers in the building or to city inspectors who may need to enter the site?

Response: The water flooding the facility basement does not pose a radiological risk to workers in the building or to others who may visit the site, provided individuals exercise standard safety precautions should access into the basement be necessary. The basement has been safely accessed by AMS workers and NRC staff equipped with conventional water-proof gear consisting of rubber hip waders and gloves.

④

4503270062

B/103

Question No. 3: How and where will this water be disposed of?

Response: AMS has proposed a plan to treat the contaminated water. The plan involves a vendor supplied and operated water treatment system. The system includes portable filtration and ion exchange demineralization equipment. Similar systems have been successfully used to cleanup contaminated water at nuclear power plants. AMS proposes to reduce the cobalt-60 concentration in the wastewater to below 200 pCi/l and then evaporate the waste water.

Question No. 4: What is the timetable for the remediation of this water?

Response: Due to concerns for the structural integrity of the building foundation, the risk of which is exacerbated by the spring thaw and rains, AMS has agreed to initiate its pump and treat operations during mid March pending NRC approval of their treatment plan.

Question No. 5: What likelihood is there that contaminated water will leach out of the basement into the surrounding soil and water table?

Response: It is unlikely that contaminated water will leach out of the basement based on the licensee's actions to maintain hydrologic conditions as described in Confirmatory Action Letter (CAL) No. RIII-94-008(DRSS), Revision 1, dated February 1, 1995. Those conditions should prevent water leaching. The NRC monitors water conditions at the facility on a daily basis.

Question No. 6: What is the potential that the water in the basement will cause the basement floor to crack or break?

Response: NRC hydrogeology and structural engineering experts have evaluated the AMS facility situation through analyses and on site visual inspection and evaluation on February 1 and 2, 1995, and concluded that the basement floor slab is not in imminent risk of failure. Nevertheless, licensee commitments confirmed in our CAL have been implemented to control ground water hydrostatic pressure and thereby provide additional assurance that the basement integrity will be maintained.

We will continue to closely monitor AMS activities to ensure that appropriate radiological controls are exercised during the treatment and remediation operations. As discussed during our meeting, I have initiated on March 10, 1995, a biweekly telephone conference with you and your staff to discuss the status of activities at AMS. I will work through the Cleveland Law Department to schedule the next teleconference for March 24, 1995, and will anticipate continuing these calls until the AMS situation stabilizes and water treatment is underway.

As you requested, enclosed are several recent documents from AMS concerning its action plan and proposals for dealing with the facility water problems. We will continue to provide your office with all documents we receive from AMS as well as those we issue to them.

City of Cleveland

-3-

If I can be of further assistance to you, please do not hesitate to contact me at (708) 829-9806.

Sincerely,

Original Signed by John A. Grobe

John A. Grobe, Chief
Nuclear Materials Inspection Section 2

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

- Enclosures:
1. 01/27/95 Letter
Re: Action Plan For
London Road Facility
 2. 02/02/95 Letter
w/encls Re: Treatment
of Water at the London
Road Facility
 3. 02/10/95 Letter
Re: Treatment of Water
at the London Road Facility
 4. 02/14/95 Letter
Re: Treatment of Water
at the London Road Facility
 5. 03/01/95 Letter
Re: Application to Amend
License No. 34-19089-01
 6. 03/03/95 Letter
Re: Supplement 2 to Application
to Amend License No. 34-19089-01
 7. 03/08/95 Letter
Re: License No. 34-19089-01
 8. 03/10/95 Letter
Re: License No. 34-19089-01

SEE DATED
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FOR
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See Attached Distribution

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NAME	Slawinski:dp		Weber		Cool		Goldberg		Grobe	
E	03/16/95		03/16/95		03/16/95		03/13/95		03/16/95	

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Radiation Safety Officer
Advanced Medical Systems, Inc.
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Geneva, OH 44041

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City of Cleveland
601 Lakeside Avenue
Cleveland, OH 44114

Lisa Mehringer
City of Cleveland Law Department
601 Lakeside Avenue Room 106
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1255 Euclid Avenue, Room 102
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bcc:

Cathy Haney, NMSS
John A. Grobe, RIII
Marian Zobler, OGC

PUBLIC IE07

E-mail:

Bruce Berson (BAB1)
Bernie Bordenick (BMB)
Bill Brach (EWB)
Jim Caldwell (JLC1)
Fred Combs (FCC)
Donald Cool (DAC)
Steve Crockett (SFC)
Joe DeCicco (JXD1)
Jack Grobe (JAG)

Cathy Haney (CXH)
Tim Johnson (TCJ)
John Madera (JRM4)
Kevin Null (KGN)
Cindy Pederson (CDP1)
Josie Piccone (JMP1)
Gary Shear (GLS)
Wayne Slawinski (WJS2)
Mike Stein (MHS)

Mike Weber (MFW1)
Marian Zobler (MLZ)

March 17, 1995

Advanced Medical Systems, Inc.
ATTN: Seymour S. Stein, Ph.D.
President
121 North Eagle Street
Geneva, OH 44041

SUBJECT: AMENDMENT NO. 32 TO LICENSE NO. 34-19089-01 AUTHORIZING
WASTE WATER TREATMENT ACTIVITIES

Dear Dr. Stein:

The enclosed amendment is being issued to confirm your plans and schedules for: (1) dealing with the accumulation of ground water in and around the Advanced Medical Systems, Inc. (AMS) facility basement and that stored in above ground tanks; (2) immobilizing and/or remediating contamination that has collected in below ground sewer piping and manholes; and (3) processing ground water that may build up around the facility in the future. The amendment requires that these activities begin immediately and be completed within ninety (90) days.

This amendment supersedes the commitments documented in the Confirmatory Action Letter (Revision 1) issued February 1, 1995. However, please be aware that while the activities authorized by this amendment are being accomplished, we expect that you will take all actions necessary to ensure an appropriate positive hydrostatic pressure is maintained from outside to inside the facility's basement to prevent the migration of basement contamination to the environment and minimize hydrostatic pressure on the basement floor slab.

Please note that License Conditions 20.H. does not address the following activities: (1) evaporation of treated water or its discharge to the sanitary sewer system; (2) installation of a composite sampler and flow gauge in the newly installed manhole and lateral; (3) conventional disposal of excavated soils exhibiting cobalt-60 concentrations greater than 8 picocuries per gram; and (4) re-connection of foundation footer drains to a proposed new manhole/lateral system.

Failure to comply with the provisions of this amendment, other license conditions, and representations in your license may result in enforcement action in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Should you be unable to complete the activities authorized by this amendment within 90 days, an amendment to your license for an extension must be granted in writing by the Commission.

If you have any questions or require clarification regarding any aspect of this amendment, please contact me at (708) 829-9806.

~~9503310135~~ ②

B/104

Advanced Medical Systems, Inc.

-2-

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

Original Signed by John A. Grobe

John A. Grobe, Chief
Nuclear Materials Safety Section 2

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

Enclosure: Amendment No. 32

See Attached Distribution

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Mike Weber (MFW1)
Marian Zobler (MLZ)

MATERIALS LICENSE

ursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with letter dated March 1, 1995,	
1. Advanced Medical Systems, Inc.		3. License Number 34-19089-01 is amended in its entirety to read as follows:	
2. 1020 London Road Cleveland, OH 44110		4. Expiration Date December 31, 1994	
		5. Docket or Reference No. 030-16055/040-08764/030-17154	
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A. Cobalt-60	A. Solid Metal	A. 150,000 curies	
B. Cobalt-60	B. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	B. 135,000 curies (no single source to exceed 13,700 curies)	
C. Cesium-137	C. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	C. 40,000 curies (no single source to exceed 2,200 curies)	
D. Depleted Uranium	D. Nickel Plated	D. 4,040 kilograms	
E. Cobalt-60	E. Sealed Sources	E. 15,000 curies	

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Amendment No. 32

6. Byproduct, source, and/or special nuclear material

F. Cobalt-60

7. Chemical and/or physical form

F. Sealed Sources
(any sealed source approved by the NRC or an Agreement State)

8. Maximum amount that licensee may possess at any one time under this license

F. 15 millicuries

9. Authorized Use:

- A. For storage only incident to waste disposal or transfer to an authorized recipient. This license does not authorize the manufacture of sealed sources.
- B. For installation, maintenance of, dismantling and servicing of Picker Corporation and Advanced Medical Systems, Inc. teletherapy units and Picker Model 6145 radiography units possessed by licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State. For installation and removal of sealed sources into Picker Corporation, Advanced Medical Systems, Inc. and Keleket Barnes teletherapy units of licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State. For training Hospital or Clinic personnel for in-house service operations on teletherapy equipment, on unit model per course, in accordance with letter dated August 15, 1988 and September 29, 1988.
- C. For installation, maintenance, dismantling and servicing of Picker Corporation and Advanced Medical Systems radiography and teletherapy units of licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State.
- D. Shielding material in Picker Corporation and Advanced Medical System, Inc., radiography and teletherapy devices.
- E. For storage only, those non-NRC approved sources in the possession of the licensee prior to the issuance of this amendment.
- F. For use in devices (including Tech OP Model 571 Calibrator described in application dated November 12, 1984) approved by the Nuclear Regulatory Commission or an Agreement State to calibrate radiation survey instruments.

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CONDITIONS

10. Licensed material in Items 6.A., 6.E. and 6.F. shall be used only at the licensee's facility at 1020 London Road, Cleveland, Ohio. Licensed material in Items 6.B. and 6.C. shall be used only at 1020 London Road, Cleveland, Ohio and at facilities of customers who possess a specific license from the NRC authorizing possession of the licensed material. Licensed material in Item 6.D. shall be used only at the licensee's facilities at 1020 London Road, Cleveland, Ohio or 121 North Eagle Street, Geneva, Ohio, and at facilities of customers who possess a specific license from the NRC authorizing possession of the licensed material.

11. A. The Radiation Protection Officer for service operations described in Subitems 9.B. and 9.C. and routine health physics activities is Robert Meschter.

The licensee shall not perform service operations described in Subitems 9.B. and 9.C. until Robert Meschter has completed the required training.

- B. Licensed material shall be used by, or under the supervision of and in the physical presence of users listed in the table below. The users are only authorized to perform the indicated services on the teletherapy or radiography units specified in the table below:

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

	CS 600	C 1000	C 2000	C 3000	C 5000	C 10,000	C4	C8	C9	C12	Cyclops
USER											
Curtis Perry				3	1,2	1,2	1,2	1,2	1,2		1,2
Haddock	5	5	5	5	5	5	5	5	5	5	5

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

	V 1000	V 2000	V 3000	V 10,000	C V4	C V9					
USER											
Curtis Perry		1,2	1,2	1,2	1,2	1,2					
Haddock	5	5	5	5	5	5					

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11. (Continued)

1. Authorizes the servicing of AMS/Picker units, excluding source exchange.
2. Authorizes sealed source exchange.
3. Authorizes removal of unit and head from customer sites only.
4. Authorizes the training of AMS personnel in the manufacture of AMS/Picker sealed sources.
5. Authorizes the handling of sealed sources only.

12. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transfer or indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.
- (3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.
- B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designated for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.
- D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in what the sealed source is permanently or semi-permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

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12. (Continued)

- E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action.
13. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
14. Inventory Requirements:
- A. An inventory system will be established that accounts for the receipt, movement, transfer and disposal of all radioactive material possessed under this license. Records of inventories will be maintained for 10 years from the date of each inventory.
- B. A complete examination of records will be completed every six months to confirm the location of all radioactive material and ensure that possession is within the limits specified in this license.
- C. A physical inventory of all radioactive material possessed under this license will be conducted on or before June 1, 1993. Thereafter, a physical inventory of all radioactive material possessed under this license will be completed within 60 months of the previous physical inventory.
15. The licensee's field service audits (as described in the ATC Medical Group Management Plan, revised April 1, 1989, and submitted with letter dated April 17, 1989) shall be performed unannounced by the Radiation Protection Officer (i.e., Radiation Safety Officer).
16. The licensee shall follow the recommended survey frequencies outlined in Regulatory Guide 8.21, Revision 1, October 1979, in work areas where radioactive materials are handled or used.
17. The licensee shall maintain records of information important to safe and effective decommissioning at 1020 London Road, Cleveland, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

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18. The licensee shall maintain and execute the response measure of their Emergency Plan dated October 25, 1991 and revised January 1992, May 27, 1992 and April 26, 1993. The licensee shall make no change in the emergency plan submitted pursuant to 10 CFR [30.32(i), 40.31(j), 70.22(i)] that would decrease the effectiveness of the plan without prior Commission approval. The licensee may make changes to its Emergency Plan without prior Commission approval if the changes do not decrease the effectiveness of the plan. The licensee shall maintain records of changes that are made to the plan without prior approval for a period of three years from the date of the changes and shall furnish the Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and the appropriate NRC Regional Office specified in Appendix D of 10 CFR 20, a report, within six months after the change is made, containing a description of each change.
19. The licensee is authorized to begin the following activities no sooner than March 17, 1995, and must complete them within 90 days after March 17, 1995 in accordance with letters dated January 27, February 2, 10, and 14, and March 1, 3, 8, and 10, 1995, wherein the licensee proposed and clarified its plans and schedules for: (1) dealing with the accumulation of ground water in and around its facility basement; (2) immobilizing and/or remediating contamination that has collected in below ground sewer piping and manholes; and (3) processing future ground water that builds up around the facility. These plans and schedules address the following actions the licensee will take.
- A. Process water that is currently stored outside its facility in above-ground tanks.
- i. Tanked water will be processed in-situ using a submersible water treatment system that includes filtration and ion-exchange demineralization as described in letters dated March 1, 3, 8, and 10, 1995.
- ii. Water will be treated until it contains no detectable non-soluble cobalt-60 and less than 200 pCi/l of soluble cobalt-60 as determined by a contract analytical laboratory. The treated water will subsequently be pumped to 25,000 gallon storage containers located in the facility warehouse, as described in letters dated March 3, 8 and 10, 1995.
- B. Simultaneously pump and process water currently residing in the sewer manhole and lateral, building sump pit and basement.
- i. Pumping will be sequenced as described in letter dated March 1, 1995, to ensure a positive hydrostatic pressure is maintained from outside to inside the facility's basement.
- ii. Water in the sewer manhole, lateral, building sump pit, and basement will be pumped to a radiologically controlled area of the facility and processed using a skid mounted, multi-stage filtration and ion-exchange system as described in letters dated March 1, 3, 8 and 10, 1995. Spill procedures and radiological controls will be implemented as described in letter dated February 14, 1995, and Attachment 2 to letter dated March 1, 1995.

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19. (Continued)

- iii. Water removed from the sewer manhole, lateral, building sump pit, and basement will be treated to contain no detectable non-soluble cobalt-60 and less than 200 pCi/l soluble cobalt-60 as determined by a contract analytical laboratory. The treated water will subsequently be pumped to 25,000 gallon storage containers located in the facility warehouse, as described in letters dated March 3, 8, and 10, 1995.
- C. Water sampling and analytical protocols will be as described in letter dated February 2, 1995, as clarified in letters dated February 14, and March 3, 1995. Solubility of cobalt-60 in samples containing detectable activity will be demonstrated in accordance with the reference in Supplement 2 to letter dated March 3, 1995. All solid radwaste generated from the water processing activities, including filter and demineralizer resin wastes, will be collected and stored at the London Road facility pending its ultimate disposal as radioactive waste.
- D. Excavate areas around the facility to allow: (i) access to the radioactively contaminated four-inch waste discharge line; and (ii) the radiological evaluation of the facility's underdrain system and surrounding soils.
- i. Excavate the soil in the vicinity of the building's four-inch waste discharge line and underdrains and disconnect these drains as described in letter dated March 1, 1995. Evaluate the radiological contamination status of the underdrain system and remediate or replace the system. Reconnect the underdrain system to the building sump pit and pump, test and process the underdrain system waters as described in letter dated March 1, 1995. The testing and processing of water pumped from the underdrain system will continue until sampling of the water consistently reveals no detectable non-soluble cobalt-60 and less than 200 pCi/l soluble cobalt-60.
- ii. Evaluate the radiological status of the soil in the vicinity of the underdrain system and building sump pit as described in the letter dated March 1, 1995.
- E. Immobilize the radioactive contamination present in the sewer manhole, lateral and four-inch discharge line.
- i. Completely grout-in the radioactively contaminated four-inch sewer discharge line and the manhole and lateral up to the sewer interceptor as described in "Issue 4" of letter dated January 27 and letter dated March 1, 1995. The grouting will render the existing sewer discharge piping system inoperable and immobilize (fix) the radioactive contamination that resides in the system.
- ii. Develop and implement a sub-surface radiological monitoring program to assess contamination migration as described in letter dated February 10, 1995. The program must be submitted in writing and approved by the NRC.

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- F. Remediate the London Road interceptor in the vicinity of the abandoned lateral, as described in letter dated January 27, 1995. The remediation activities will be coordinated with the Northeast Ohio Regional Sewer District.
20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated November 12, 1984;
- B. Letters dated November 12, 1984 (excluding Item 4), February 12, 1985, June 7, 1985 (excluding letter Item 4), September 6, 1985 (excluding change to Page 29 of ISP-1 manual);
- C. Letters dated May 29, 1986 (Response to Enclosure A, Significant Licensing Deficiencies of NRC letter dated March 7, 1986);
- D. Letter dated July 23, 1986 (Response to Enclosure B, Additional Licensing Issues for Renewal Applications of NRC letter dated March 7, 1986) excluding approval of the licensee's in-house training program;
- E. Letters dated August 22, 1986, October 28, 1986, November 13, 1986, November 14, 1986 and December 4, 1986 (with Revised ISP-1 Manual, Appendices A and B attached), May 7, 1987, August 3, 1987, December 31, 1987, January 15, 1988 (Item V only), August 15, 1988 (with attached course manual), September 29, 1988 (with attachments) and November 21, 1988; and
- F. Letters dated March 29, 1989 (except Section 3.4 "Hot Cell Entry and Action Levels"), April 7, 1989, August 25, 1989 (except Item B(4)), July 23, 1990 (except Sections 3.0 and 5.0 of ISP-14 procedure), March 1, 1991 (with attachments), March 27, 1991 (with attachments), May 9, 1991, May 14, 1991, February 27, 1992, February 28, 1992, March 2, 1992, and March 5, 1992.
- G. Letters dated April 16, 1992 (with enclosures), June 15, 1992 (with attachments), August 10, 1992, September 18, 1992, December 29, 1992 (with enclosures), January 20, 1993, March 30, 1993, March 31, 1994 (with enclosure), April 11, 1994, and September 21, 1994.

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Amendment No. 32

20. (Continued)

- H. Letters with attachments dated January 27, 1995, February 2, 10, and 14, 1995, and March 1, 3, 8, and 10, 1995.

Notwithstanding any reference to the specific activities in the above listed letters, the following activities are not addressed by this license.

- i. The evaporation of treated water or its discharge to the sanitary sewer system.
- ii. Installation of a composite sampler and flow gage.
- iii. Conventional disposal of excavated soils exhibiting cobalt-60 concentrations greater than 8 pCi/g.
- iv. Re-connection of the foundation underdrain system to the proposed new manhole and lateral.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

March 17, 1995

By

Cassandra F. Grier
Materials Licensing Section, Region III

March 20, 1995

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

Dear Mr. Cesar:

Enclosed is the legal brief that Advanced Medical Systems, Inc. (AMS) submitted to the NRC staff during our meeting on March 7, 1995. It is being transmitted to you to formally incorporate the document into the docket file for your license.

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

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

Sincerely,

Original Signed by John A. Grobe

John A. Grobe, Chief
Nuclear Materials Inspection Section 2

Enclosure: As stated

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

See Attached Distribution

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D R A F T

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

NORTHEAST OHIO REGIONAL)	CASE NO. 1:94CV2555
SEWER DISTRICT)	
)	JUDGE WHITE
Plaintiff)	
)	
v.)	BRIEF OF SEPARATE DEFENDANT
)	ADVANCED MEDICAL SYSTEMS,
ADVANCED MEDICAL SYSTEMS,)	INC. ON PREEMPTION
INC., et al.,)	
)	
Defendants)	

I. INTRODUCTION

Advanced Medical Systems, Inc. ("AMS") is licensed by the Nuclear Regulatory Commission ("NRC") to possess Cobalt 60, a nuclear byproduct material as defined by the Atomic Energy Act and NRC regulations. See 42 U.S.C. 2014(e); 10 C.F.R. 30.71 (1944) and 10 C.F.R. 33.100 (1944). From 1979 through 1989 AMS was engaged in the business of manufacturing teletherapy source devices using Cobalt 60, pursuant to its NRC license. Similar work had been done at the site by Picker Corporation, a previous owner of the facility since the late 50's. During this 30 year period, NRC regulations at 10 C.F.R. 20.303 authorized AMS (and its predecessor) to dispose of Cobalt 60, within specified limits, into the sanitary sewer.

Current NRC regulations at 10 C.F.R. 20.2003 still authorize disposal of soluble Cobalt 60 (or Cobalt 60 in readily dispersible biological material) into the sewer.

AMS ceased teletherapy source manufacturing operations in 1989 and since that time has not discharged any Cobalt 60. Without question traces of this Cobalt 60 discharged in the period prior to 1989 remained in the sewer lines connecting the facility to the sewer system operated by plaintiff, NEORSD. After this time period, any Cobalt 60 that flowed from AMS's site into the treatment works of the Northeast Ohio Regional Sewer District ("NEORSD") via the sewer system was residual material released from the wastewater piping and lateral sewer line that runs from AMS's London Road facility to the sewer interceptor.

The presence of residual traces of Cobalt 60 in the sewer does not constitute a violation of the NRC regulation that defines the currently permissible discharges, 10 C.F.R. 20.2003. The NRC has stated that no "emergency action" is required to eliminate this residual material. Notwithstanding, NEORSD, has prevailed upon this Court to issue a temporary restraining order blocking the connection between AMS's London Road facility and the sewer system and now seeks to obtain an injunction to continue this blockage. The justification offered for this is that the presence of even one atom of Cobalt 60 in the effluent from AMS constitutes an interference with the operation of NEORSD's water treatment works under its Pretreatment Regulations. NEORSD, however, has yet to

offer a shed of evidence to support this claim. Further NEORSD has continued to operate its sewage treatment plants during this time.

An examination of the applicable law against this factual background demonstrates that there is no sound legal basis upon which a preliminary injunction can be justified. Enforcement of NEORSD's regulations would violate the Supremacy Clause of the United States Constitution in this case. Further, the within public liability action filed by NEORSD, pursuant to the Price Anderson Amendments Act, provides NEORSD with its sole vehicle for recovery. As will be shown, injunctive relief in this case is inconsistent with federal law and therefore is not an available remedy. Finally, NEORSD is unable to demonstrate the existence of any of the factors that would justify injunctive relief. Indeed granting the injunction sought will vastly increase rather than ameliorate the potential for harm to the public.

II. LAW AND ARGUMENT

A. NEORSD's regulations are preempted by federal law.

NEORSD's pretreatment Regulations are preempted by the federal Atomic Energy Act, 42 U.S.C. 2011 et seq. ("AEA") and regulations promulgated thereunder. These regulations specifically authorize releases of Cobalt 60 into the sewer. Enforcement of NEORSD's regulations in this case via injunctive relief would violate Article VI, Clause 2, of the United States Constitution (the Supremacy Clause). "[S]tate law that conflicts with federal law is without effect." Cipollone v. Liggett Group, Inc., 112 S.Ct.

2608, 2616-2617 (1992), quoting, U.S. CONST. Art VI, cl. 2 and Maryland v. Louisiana, 451 U.S. 725, 746 (1981). Accordingly, NEORSD's regulations are unenforceable in this case.

It is undisputed that the NRC is the federal agency charged with regulating the use, handling and disposal of nuclear materials. 42 U.S.C. 5841. Pursuant to its authority, the NRC "established by regulation maximum permissible releases of source, byproduct, and special nuclear materials into the environment by licensees."¹ Train v. Colorado Public Interest Research Group, Inc., 426 U.S. 1, 6 (1976) citing 10 C.F.R. 20.106 and App. B, Table II (1976). "Federal regulations issued by agencies have "no less pre-emptive effect than federal statutes." Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 699 (1984). See also Feikama v. Texaco, Inc., 16 F.3d 1408, 1415-1416 (4th Cir. 1994); Brayman v. Baxter Healthcare Corp., 842 F.Supp. 747, 751 (S.D.N.Y. 1994) quoting, Louisiana Public Service Com'n v. F.C.C., 476 U.S. 355, 369 (1986) (holding that preemption may result from federal agencies acting within the scope of their authority).

¹ Train, the Atomic Energy Act and NRC regulations at 10 C.F.R. 20.2003, inter alia, demonstrate that federal law authorizes releases "into the environment" - obviously an "off site" location. Further, the plain language of the statute that authorizes the within public liability action is designed for "off site" plaintiffs, i.e. members of "the public." See 42 U.S.C. 2014 (hh); O'Conner v. Commonwealth Edison Co., 13 F.3d 1090 (7th Cir. 1994), cert. denied, 114 S.Ct. 2711 (1994); In re TMI Cases Consolidated II, 940 F.2d 832, 854 (3rd Cir. 1991), cert. denied, 112 S.Ct. 1262 (1992). Accordingly, NEORSD's argument in its brief on preemption that the NRC may only regulate "on site" releases is a red herring and entirely without legal support.

The NRC regulations at 10 C.F.R. 20.2003 and former 10 C.F.R. 20.303 expressly authorize disposal of Cobalt 60 "by release into sanitary sewerage." 10 C.F.R. 20.2003 expressly provides, in pertinent part:

§20.2003 Disposal by release into sanitary sewerage

(a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble (or is readily dispersible biological material) in water; and

(2) The quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of appendix B to §§20.1001-20.2401; and . . .

(4) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, and 1 curie (37 GBq) of all other radioactive materials

10 C.F.R. 20.2003 (formerly 10 C.F.R. 20.303) (Emphasis added).²

Prior to 1993, 10 C.F.R. 20.2003 was set forth at 10 C.F.R. 20.303 that provided:

² Table 3 of Appendix B to 10 C.F.R. 20.1001-20.2401 states a maximum average monthly concentration of Cobalt 60 that can be released into a sewer. This maximum concentration, after conversion, is 30,000 pCi per liter of effluent.

§20.303 Disposal by release into sanitary sewerage systems.

No licensee shall discharge licensed material into a sanitary sewerage system unless:

(a) it is readily soluble or dispersible in water; and

(b) the quantity of any licensed or other radioactive material released into the system by the licensee in any one day does not exceed the larger of paragraphs (b)(1) or (2) of this section. . . .

10 C.F.R. 20.303.

The NRC retains all authority with respect to the handling and disposal of byproduct material as provided in 42 U.S.C. 2021(c). Although the states may exercise authority over non-radiation aspects of nuclear materials, "the Federal Government maintains complete control of the safety and 'nuclear' aspects" Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n, 461 U.S. 190, 212 (1983).³

Generally federal law preempts state law where state law conflicts with federal law, or "if federal law so thoroughly occupies a legislative field as to make reasonable the inference

³ In Pacific Gas, the Court held that a California statute with an avowed economic purpose was not preempted unlike NEORSD's regulatory purpose of health and safety, pursuant to the federal Clean Water Act, as discussed below. Further the state action in Pacific Gas did not have an impermissible regulatory effect on NRC action since there was no NRC regulation applicable to the "future storage" issue presented in Pacific Gas. There is a NRC regulation that is "right on point" with regard to the issue presented in this case.

that Congress left no room for the States to supplement it." Cipollone v. Liggett Group, Inc., 112 S.Ct. 2608, 2617. Moreover, if compliance with both state and federal law is impossible, federal law must control. United Nuclear Corp. v. Cannon, 553 F.Supp. 1220, 1229 (D.R.I. 1982), quoting, Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963). See also International Paper Co. v. Ouellette, 479 U.S. 481, 493, 495 (1987).

In this specific field of atomic regulation, the Supreme Court has refined the preemption analysis. Federal law preempts state law if the purpose of the state law is health and safety or if the state law has "some direct and substantial effect on the decision" of the licensee and the NRC "concerning radiological safety levels." Pacific Gas, 461 U.S. 190, 212-213; English v. General Electric Co., 496 U.S. 72, 84-85 (1989).⁴ Application of the Supreme Court's "preemption test" establishes that NEORSD's regulations are without effect in this case to prohibit any Cobalt 60 due to alleged harm from its radioactive nature.

⁴ Silkwood v. Kerr McGee Corp., 464 U.S. 238, 256 (1984) upon which NEORSD relies, also recognizes this preemption test of purpose or effect. Silkwood is distinguishable from the instant case because it did not construe a state law with an avowed health or safety purpose. Moreover, Silkwood's award of punitive damages was overruled by statute. 42 U.S.C. 2210(s); O'Connor v. Commonwealth Edison Co., 13 F.3d. 1090, 1105 n.13 (7th Cir. 1994), cert. denied, 114 S.Ct. 2711 (1994).

First, the purpose of NEORSD's regulations is health and safety. The avowed purpose of Title II of NEORSD's Pretreatment Regulations is:

Purpose and Policy - These Pretreatment Regulations set forth uniform pretreatment requirements for discharges into the Northeast Ohio Regional Sewer District's wastewater collection and treatment system, and enables the District to protect public health in conformity with all applicable Local, State and Federal laws relating thereto.

Northeast Ohio Regional Sewer District Code of Regulations, Title II, Pretreatment Regulations, section 2.0103 at page II-2.

NEORSD's regulations also provide that they are promulgated pursuant to the Federal Clean Water Act. See Northeast Ohio Regional Sewer District code of regulations, Title II, pretreatment regulations, Section 2.0103(a), referencing the "purpose/goal" as "to satisfy the State and Federal requirements in compliance with the Clean Water Act. . . ."

In Train v. Colorado Public Interest Research Group, Inc., 426 U.S. 1, 15, 25 (1976), a unanimous Supreme Court held that effluent limitations or standards promulgated by any agency pursuant to the Clean Water Act may not regulate materials that are encompassed in the Atomic Energy Act's definition of source, byproduct, or special nuclear materials. (citations omitted). (Emphasis provided). See also Northern States Power Co. v. State of Minnesota, 447 F.2d 1143, 1147-1150 (8th Cir. 1971), affirmed, 405 U.S. 1035 (1972) (AEA preempts a state attempt to impose more stringent limitations on the radioactive effluents of a licensed facility). NEORSD's

protestations to the contrary, it is clear that NEORSD's regulations are promulgated pursuant to the Clean Water Act with a primary purpose to "protect public health."⁵

Local agencies are prohibited from regulating in order to address public health and safety concerns or radiological hazards. Pacific Gas, 461 U.S. 190, 210; Train, 426 U.S. 1, 15, 25; English, 496 U.S. 72, 84. The purpose of NEORSD's pretreatment regulations as set forth in Title II of its code is safety and public welfare - a purpose within the "prohibited field" as stated in Pacific Gas and Train. Accordingly, NEORSD's regulations are without effect in this case.

Second, NEORSD regulations are preempted because their enforcement in this case has "some direct and substantial effect on the decisions" of AMS and the NRC "concerning radiological safety levels." English v. General Electric Co., 496 U.S. 72, 85. "[S]tate regulation of matters directly affecting . . . radiological safety . . . 'even if enacted out of nonsafety concerns, would nevertheless infringe upon the NRC's exclusive

⁵ Moreover, if, NEORSD now chooses to ignore its own stated purpose in order to avoid preemption and allege an economic purpose then violation of the regulation could only cause economic harm -- precluding injunctive relief. It is well established that speculative allegations of economic harm are insufficient to justify the extraordinary relief requested here. Warner v. Central Trust Co., N.A., 715 F.2d 1121, 1123 (6th Cir. 1983) (where the threat of harm is speculative and even if established, only financial, plaintiff will not suffer irreparable injury as a matter of law).

authority." English, 496 U.S. 72, 84 quoting in part, Pacific Gas, 461 U.S. 190, 212.

Even if this Court could ignore the avowed purpose of NEORSD's regulations, the regulations still are preempted because enforcement of NEORSD's regulations would directly and substantially infringe upon the NRC's authority to regulate the handling and disposal of Cobalt 60 by effectively nullifying 10 C.F.R. 20.2003. It also would become impossible for any licensee to comply with NEORSD's regulations, mandating "zero Cobalt", in the sewers and the NRC regulation allowing the discharge of Cobalt up to 30,000 pCi per liter to the sewer. Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963). This result is impermissible and would hold the NRC regulations and NRC licensees hostage to the whims of the NEORSD, or any other local sewer authority in the country.

Even if NEORSD raises some other non-safety purpose, the regulations are still preempted. If there are two objectives of a regulation -- one safety related and one non safety related -- the objectives are inseparable and the regulation is preempted. See e.g., English v. General Electric Co., 496 U.S. 72, 84 (the preempted field is defined "by reference to the motivation behind the state law"); Brown v. Kerr-McGee Chemical Corp. (7th Cir. 1984), 767 F.2d 1234, 1240 (7th Cir. 1984), cert. denied, 475 U.S. 1066 (1986); Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n, 461 U.S. 190, 210 (AEA's "savings clause" only allows state regulation where it does not

conflict with federal law and does not address safety quoting, 42 U.S.C. 2021(k) (state regulation only for purposes other than radiation hazards); and 42 U.S.C. 2018 (state and local agencies have no authority to regulate NRC). Accordingly, this court should deny enforcement of NEORSD's regulations via injunctive relief because enforcement violates the Supremacy Clause.

- B. Injunctive relief is not an available remedy in a public liability action where it is inconsistent with federal law.

NEORSD's situation and alleged grievances are not unique. Congress afforded claimants such as NEORSD the sole remedy of a federal public liability action pursuant to the Price Anderson Amendments to the Atomic Energy Act. 42 U.S.C. 2014(hh), (w), (q). O'Conner v. Commonwealth Edison Co., 13 F.3d 1090 (7th Cir. 1994), cert. denied, 114 S.Ct. 2711 (1994); In re TMI Litigation Consolidated Cases II, 940 F.2d 832 (3rd Cir. 1991), cert. denied, 112 S.Ct. 1262 (1992) (public liability action is sole cause of action). The public liability action provides a state law remedy where such remedy is not inconsistent with federal law. 42 U.S.C. 2014(hh); Pacific Gas, 461 U.S. 190, 205 (1983); Coley v. Commonwealth Edison Co., 768 F.Supp. 625, 628 (N.D. Ill. 1991). Compensatory damages may be available to NEORSD upon proof that AMS violated a federal duty of care.⁶ Injunctive relief via

⁶ Federal regulations must define the duty of care in this case because NEORSD's regulations of "zero Cobalt" are more restrictive than 10 C.F.R. 20.2003 and inconsistent with
(continued...)

enforcement of NEORSD's regulations is inconsistent with federal law and not an available remedy.

The cases upon which NEORSD relies, Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984) and English v. General Electric Co., 496 U.S. 72 (1990), provided that where the federal duty of care was violated damages were not inconsistent with federal law. Silkwood's award of punitive damages, however, was later overruled by statute. 42 U.S.C. 2210(s); O'Conner v. Commonwealth Edison Co., 13 F.3d 1090, 1105 n.13 (7th Cir. 1994), cert. denied, 114 S.Ct. 2711 (1994). Goodyear Atomic Corp. v. Miller, 486 U.S. 174 (1988), did not decide the issue of preemption under the AEA, but relied instead on a separate federal statute, 40 U.S.C. 290, which was expressly excepted from application of the Price Anderson Amendments Act by 42 U.S.C. 2014(w)(i). Goodyear, 486 U.S. 174, 182 (1988). Neither the purpose nor effect of 40 U.S.C. 290, addressing the rights of states to enact worker's compensation laws, has anything to do with radiation hazards. In addition, none of these cases considered state laws with an avowed safety purpose.

⁶(...continued)

federal law. See e.g. O'Conner v. Commonwealth Edison Co., 13 F.3d 1090, 1105 (7th Cir. 1994), cert. denied, 114 S.Ct. 2711 (1994), quoting, In re TMI Litigation Consolidated Cases II, 940 F.2d 832, 859 (3rd Cir. 1991), cert. denied, 112 S.Ct. 1262 (1992); Lamb v. Martin Marietta Energy Systems, Inc., 835 F.Supp. 959, 965 (W.D. Ky. 1993); Coley v. Commonwealth Edison Co., 768 F.Supp. 625, 628-629 (N.D. Ill. 1991); Restatement (2d) of Torts, §286 (1965). As a result, pursuant to 42 U.S.C. 2014(hh), NEORSD's standard cannot provide the duty of care.

Finally, none of these cases considered the extraordinary remedy of injunctive relief.

Several jurisdictions have held that injunctive relief based on state law is inconsistent with federal law and therefore not available in circumstances similar to this case.

In Jersey Central Power and Light Co. v. Township of Lacey, 772 F.2d 1103 (3rd Cir. 1985), cert. denied, 475 U.S. 1013 (1986) the Third Circuit denied plaintiffs injunctive relief and held that a local township ordinance that prohibited local storage of radioactive waste was preempted by the AEA. The court considered the identical issue as that before this Court:

We are dealing with a fundamental conflict between the locality's interest in the exercise of its police power for public health and safety purposes and an established federal regulatory scheme. The questions posited are whether there has been federal preemption and whether the local regulation conflicts with federal law.

772 F.2d 1103, 1109.

The Township argued that its ordinance "had an avowed economic purpose" and therefore put it "outside the occupied field of nuclear safety regulation and within the ambit of 'the states' exercise of their traditional authority over land use." 772 F.2d 1103, 1112. In rejecting the Township's argument, the Court stated:

The avowed purpose of the Township ordinances, however, is to protect 'the public good' based on 'a local legislative determination that an acceleration of nuclear waste storage within the Township is contrary to the general welfare of its inhabitants.'

772 F.2d 1103, 1112.

The court held that the Township's ordinances were not distinguishable from cases in other circuits holding that enforcement of state laws to prohibit the storage of nuclear waste violate the Supremacy Clause and, therefore, are without effect. 772 F.2d 1103, 1112, citing, People of State of Illinois v. General Electric Co., 683 F.2d 206, 215 (7th Cir. 1982), cert. denied, 461 U.S. 913 (1983). Washington State Bldg. & Const. Trades Council AFL-CIO v. Spellman, 684 F.2d 627, 630 (9th Cir. 1982), cert. denied, 461 U.S. 913 (1983); Annot., 82 A.L.R.3d 751 (1978). See also, County of Will v. Chem-Nuclear Systems, Inc. (Oct. 7, 1987), N.D. Ill. No. 87 C 1478, unreported, 1987 WL 18362 (holding that a local ordinance requiring a special use permit was preempted and therefore could not be applied to the defendant, a facility that compacted low level nuclear waste); Natural Resources Defense Council, Inc. v. Zeller, 688 F.2d 706, 710-711 (11th Cir. 1982) (holding that court lacks jurisdiction to enjoin valid actions taken pursuant to NRC and EPA regulations and agreements and that regulations themselves cannot be challenged in district court).

In United States v. City of New York, 463 F.Supp. 604 (S.D.N.Y. 1978) Columbia University operated its nuclear reactor in accordance with its Atomic Energy Commission license (now the NRC). New York City amended a section of its health code to require Columbia University to obtain a certificate of health and safety from the City before operating its nuclear reactor. 463 F.Supp. 604, 606. The City argued that its requirements focused on the

cost of cleaning up and protecting the public from any nuclear accident. Id. at 607.

Despite that Columbia University had a federal license, complied with federal regulations, and had the AEC's blessing, the City rejected Columbia's application for the certificate, thereby preventing Columbia from operating its reactor.

The United States and trustees of Columbia University brought an action for declaratory relief claiming that New York City's refusal to give Columbia a certificate was unconstitutional under the Supremacy Clause and that the regulatory ordinance was void under the doctrine of preemption. The court held that despite the City's alleged economic purpose, the ordinance resulted in impermissible regulation of a radiation hazard and, therefore, was preempted. Enforcement of the ordinance, the court determined, would impermissibly infringe on the NRC's authority.

Finally, in Brown v. Kerr-McGee Chemical Corp., 767 F.2d 1234 (7th Cir. 1985), cert. denied, 475 U.S. 1066 (1986) the court held that federal law preempted and barred off-site property owners' request for injunctive relief ordering an NRC licensee to alternatively dispose of nuclear waste.

In reaching this holding the court stated that "an injunction ordering Kerr-McGee to remove the byproduct material from the West Chicago site would, in effect, substitute the judgment of the district court for that of the NRC as to whether on-site encapsulation is the best method of storing this byproduct material." 767 F.2d 1234, 1242. Significantly, the court reached

this conclusion even though there were several alternate methods of disposal which met with the NRC's approval. Id.⁷

The plaintiffs' request for injunctive relief was "preempted because, if granted, the injunction would stand 'as an obstacle to the accomplishment of the full purposes and objectives' of federal regulation of radiation hazards." 767 F.2d 1234, 1242. (citations omitted). See also Feikama v. Texaco Inc., 16 F.3d 1408, 1416 (4th Cir. 1994) (injunctive relief preempted by federal regulations).

Injunctive relief via NEORSD's regulations is not available in this case because it is inconsistent with federal law. Accordingly, NEORSD's request for injunctive relief should be denied.

C. NEORSD has not established any of the factors that would justify injunctive relief.

Additional and independent grounds warrant denial of NEORSD's request for injunctive relief. The extraordinary relief of a preliminary injunction can be justified only upon a showing, by clear and convincing evidence, of the following four (4) factors:

- (1) plaintiff has a strong or substantial likelihood of succeeding on the merits of its case;

⁷ Similarly, NEORSD's argument that alternative disposal methods exist is unavailing. NEORSD cannot substitute its judgment for that of the NRC.

- (2) plaintiff is substantially likely to suffer clear and irreparable harm if the relief is not granted;
- (3) granting the relief sought will not cause substantial harm to defendant or others;
- (4) the public interest will be better served by granting the injunctive relief, rather than by not doing so.

Cabot Corp. v. King, 790 F.Supp. 153, 155, (N.D. Ohio 1992), citing, Mason County Medical Ass'n v. Knebel, 563 F.2d. 256, 261 (6th Cir. 1977).

In addition, plaintiff must show that it has no adequate remedy at law. CSX Transp. v. Tennessee Bd. of Equalization, 964 F.2d 548, 551 (6th Cir. 1992), citing, EBSCO Indus. v. Lilly, 840 F.2d 333, 335-336 (6th Cir. 1988), cert. denied, 488 U.S. 825 (1988). See also Economou v. Physicians Weight Loss Centers, 756 F. Supp. 1024, 1038 (N.D. Ohio 1991) quoting, Sampson v. Murray, 415 U.S. 61 (1974) Beacon Theaters, Inc. v. Westover, 359 U.S. 500, 506-507 (1959) ("the basis of injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies.").

Further, the "plaintiff's burden is greater at the preliminary injunctive stage because the plaintiff bears the burden of demonstrating the probability of success on a claim by a 'strong' or 'substantial' likelihood of success on the merits." Cabot Corp. v. King, 790 F.Supp. 153, 156. As discussed above, NEORS has very little chance of prevailing on the merits since its regulations are unenforceable in this case.

1. NEORSD has not shown that it is substantially likely to suffer clear and irreparable harm.

Injunctive relief may not be granted unless the plaintiff demonstrates that it will suffer clear and certain irreparable injury without such relief. Garlock, Inc. v. United Seal, Inc., 404 F.2d 256, 257 (6th Cir. 1968); SED, Inc. v. City of Dayton, 515 F.Supp. 737, 742 (S.D. Ohio 1981) supplemented, 519 F.Supp. 975 (S.D. Ohio 1981). "A plaintiff must always demonstrate some irreparable injury before a preliminary injunction may issue." Friendship Materials, Inc. v. Michigan Brick, Inc., 679 F.2d 100, 104 (6th Cir. 1982) (Emphasis by the Court). See also Cripps v. Seneca County Bd. of Elections, 629 F.Supp. 1335, 1340 (N.D. Ohio 1985).

NEORSD "must produce some evidence of both a past injury and the likelihood of future injury in order to support [its] claim of irreparable harm." Michigan Coalition v. Griepentrog, 945 F.2d 150, 154 (6th Cir. 1991), citing, Sampson v. Murray, 415 U.S. 61 (1974), rev'd on other grounds, 954 F.2d 1174 (6th Cir. 1992).

NEORSD's conclusory allegations that Cobalt 60 is deleterious or constitutes an interference with its wastewater treatment facilities are insufficient to demonstrate irreparable harm as a matter of law. Id. NEORSD alleges, without any evidentiary support, that the discharge of any radioactive Cobalt into the sewer system impairs its wastewater treatment processes. NEORSD's

allegations fall far short of a substantial showing of irreparable harm.

Moreover, the facts belie any alleged harm. NEORSD has been and is accepting and processing wastewater containing low level radioactive materials for literally decades with no detriment to its operations. NEORSD's expert, B. Koh & Associates, has concluded in a site characterization report that the presence at Southerly of Cobalt 60 previously released "poses no threat to the health and safety of the nearest residents or other members of the public. . . ." AMS's expert witness, Carol Berger, also stated that nothing coming from AMS's lateral poses a hazard or an impediment to the operation of the Southerly wastewater treatment plant.

NEORSD has failed to demonstrate by clear and convincing evidence the critical element for an injunction: a substantial likelihood of irreparable harm for which an adequate remedy at law is unavailable. Accordingly, NEORSD's request for injunctive relief should be denied.

2. Granting injunctive relief would continue to substantially harm AMS and poses very significant potential for harm to the public.

When considering whether to grant the extraordinary relief of an injunction or temporary restraining order, the Court must give due consideration to the rights of all parties and not just the party seeking the injunction. American Fed. of Musicians v. Stein, 213 F.2d 679, 682-84 (6th Cir. 1954) cert. denied, 348 U.S.

873 (1954) (injunction should issue only if the resulting harm to the defendant will be slight or inconsiderable).

The effect of granting the injunction sought by NEORSD would be to place the structural integrity of the AMS facility at risk. The placement of a plug in the sewer drains from the facility has directly resulted in the flooding of the basement -- an area containing significantly higher levels of Cobalt 60 than any area outside the plant. Water accumulating around the foundation drains of the facility, with no route of drainage away from the building because of the sewer blockage, has penetrated the foundation. This has placed high levels of stress on the foundation walls and floor of the building and resulted in the accumulation of an estimated 60,000 gallons of water in the interior of the facility. As the spring thaw progresses and the seasonal rains come the stresses on the building will increase, endangering the structural integrity of the building. A breach in the structure caused by a rapid build up of water pressure from a sudden storm or warm spell could cause the floor of the basement to heave or the foundation walls to collapse, allowing the free communication of ground water between the interior and exterior of the building. The consequences of such an event could be catastrophic to the facility and dangerous to the general public.

Further, in the event that this occurred AMS would be unable to call upon sufficient financial resources to address much less solve the problem. The costs of treating and discharging the water now confined in the basement are conservatively estimated to be in

excess of \$250,000. There is no way to predict the amount of water that will enter the basement, pick up Cobalt 60, and escape to the soil and water table if the current situation persists and the foundation or floor of the building fails.

NEORSD's ill advised foray into the regulation of nuclear materials -- a field in which it has no expertise, already has resulted in needless loss and damage to AMS and no benefit to anyone. Indeed, there was no health or safety problem represented by AMS's operations before the meddling of NEORSD. The situation is now significantly worse and, more important, now has the potential to be a catastrophe, in which a real public safety risk will be created at the same moment that AMS is financially ruined.

3. **Granting injunctive relief would pose a substantial harm to the public.**

In the circumstances of this case, the potential harm to the public if this Court were to award the relief NEORSD requests is directly proportioned to the harm to AMS. "Before resorting to this extraordinary remedy, a court must balance the interests of the parties giving particular attention to the public consequences of a decree." Charter Tp. of Huron, Mich. v. Richards, 997 F.2d 1168, 1175 (6th Cir. 1993), citing, Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982).

As stated, the relief already granted NEORSD has caused a threat to the public safety. Prior to NEORSD's plugging of AMS's lateral, there was no threat at all.

The NRC has determined that the regulation promulgated at 10 C.F.R. 20.2003 best serves the public interest. The NRC is required, as a federal regulatory agency, to consider effects on the public and environment when enacting its regulations. "Congress instructed the NRC to ensure 'that the management of any byproduct material . . . is carried out in such a manner as . . . the Commission deems appropriate to protect the public health and safety and the environment from radiological and nonradiological hazards' associated with the possession of byproduct material." Brown v. Kerr-McGee Chemical Corp., 767 F.2d 1234, 1242 (7th Cir. 1985), cert. denied, 475 U.S. 1066 (1986) quoting, 41 U.S.C. 2114(a)(1). (Emphasis by the court). It is not for NEORSD to usurp the NRC's determination.⁸

The NRC regulations governing disposal of nuclear byproduct material are based upon the NRC's expert determination that disposal into the sewer system was and is an appropriate method for licensees to dispose of low level radioactive byproduct material, including Cobalt 60. The relief requested by NEORSD is not authorized by federal law and would impose upon the public a substantially greater likelihood of harm. Accordingly, NEORSD's request for injunctive relief should be denied.

⁸ NEORSD's allegations of harm to the public directly contradict its position on preemption, namely, that NEORSD is not seeking to protect public health or safety. NEORSD cannot have it "both ways."

4. NEORSD has an adequate remedy at law.

NEORSD has an adequate remedy at law and is pursuing it. Claims of financial loss are "readily compensable in damages at law." Montgomery v. Carr, 848 F.Supp. 770, 777 (S.D. Ohio 1993). "[M]onetary harm is not generally the type of irreparable harm which warrants a preliminary injunction." Id. "The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm." Sampson v. Murray, 415 U.S. 61, 90 (1974).

In addition to the within action, NEORSD is petitioning the NRC for a change in the regulations at 10 C.F.R. 20.2003. See Exhibit I, 10 C.F.R. 2.802 and 2.803. NEORSD has also initiated the following proceedings relating to releases of Cobalt 60 into the sewer:

1. A petition to the U.S. Nuclear Regulatory Commission ("NRC") for an order directing AMS to take financial responsibility for any operations that may be necessary to address alleged Cobalt 60 contamination in incinerated sewage sludge ash located at the Southerly Wastewater Treatment Plant. This petition was filed on March 3, 1993 (Exhibits A and B);
2. A complaint for injunctive relief and compensatory and punitive damages filed in State Court in April of 1993 and later dismissed by the State Court. (Exhibits C and D);
3. A notice of intent to sue under the Federal Water Pollution Control Act, dated October 14, 1994. (Exhibit F).

Further, NEORSD is vigorously pursuing its opportunities to submit public comment to the NRC on several issues, including the renewal of AMS's NRC license and the NRC regulations that currently authorize the discharge into sewers of Cobalt 60.

NEORSD's request for injunctive relief is, in effect, an impermissible, collateral attack on the NRC regulation found at 10 CFR 20.2003 and an attempt to circumvent the administrative procedures of the NRC. Public Serv. Co. v. U.S. Nuclear Regulatory Com'n, 582 F.2d 77, 82-83 (1st Cir. 1978), cert. denied, 439 U.S. 1046 (1978), citing, Power Reactor Devel. Co. v. International Union, 367 U.S. 396, 408 (1961).⁹ The NRC's determination that 10 C.F.R. 20.2003 properly considers all competing interests is entitled to the greatest deference. Id. The proper forum for contesting the NRC's determination is the NRC.

NEORSD can appeal the NRC's final decision through proper administrative channels. See 10 C.F.R. 2.714 (intervention in agency proceedings); 42 U.S.C. 2239(a) (requiring NRC to grant a hearing upon request of interested parties); 10 C.F.R. 2.786 (appeals of NRC decisions). Finally, after all administrative

⁹ The NRC has primary jurisdiction regarding construction and application of its regulations. Primary jurisdiction is a doctrine that applies "whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case, the judicial process is suspended pending referral of such issues to the administrative body for its views." United States v. Western Pacific Railroad Co. (1956), 352 U.S. 59, 64. This court should defer to the NRC's primary jurisdiction.

remedies have been exhausted - which is not the case here - appeal may be taken to the United States Circuit Courts. 42 U.S.C. 2239(b). See also 28 U.S.C. 2342. NEORSD clearly has many adequate remedies available at law including the within action for compensatory damages. Accordingly, NEORSD's request for injunctive relief must be denied.

III. CONCLUSION

For the foregoing reasons and authorities, NEORSD's Application for Preliminary Injunction and Motion for Temporary Restraining Order must be denied in all respects.

Respectfully submitted,

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