

# Advanced Medical Systems, Inc.

## TRAINING AND QUALIFICATIONS OF RADIATION PROTECTION PERSONNEL

Procedure: RSP-006

Revision No.: 000

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Date: March 8, 1996

Approved by (Vice President):

Approved by (RSO):

Approved by (RSC Chair):

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# RADIATION SAFETY PROCEDURE

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## 1 PURPOSE

This procedure details the knowledge, skills, abilities, and training that are necessary to ensure that radiation protection personnel at the Advanced Medical Systems, Inc.(AMS) London Road facility and at field service sites are able to provide effective services.

## 2 SCOPE

This Radiation Safety Procedure (RSP) applies to all AMS personnel performing radiation protection functions at the London Road facility or during work performed by AMS at field service locations. Personnel performing functions that do not pertain to implementation of the Radiation Protection Program Plan are exempt from the requirements of this RSP.

## 3 REFERENCES

- 3.1 Title 10, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports for Workers; Inspection and Investigations"
- 3.2 Title 10, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation".
- 3.3 U. S. Nuclear Regulatory Commission Radioactive Material License Number 34-19809-01.
- 3.4 U. S. Nuclear Regulatory Commission, Regulatory Guide 1.8, "Qualifications and Training of Personnel for Nuclear Power Plants", 1975
- 3.5 U. S. Nuclear Regulatory Commission, Draft Regulatory Guide DG-0008, "Applications for the Use of Sealed Sources in Portable Gauging Devices", May, 1995.
- 3.6 U. S. Nuclear Regulatory Commission, Draft Regulatory Guide and Value/Impact Statement, Division 10, Task FC 411-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Servicing Preregistered Gauges, Measuring Devices, and Sealed Sources Used in Such Devices", June, 1985.
- 3.7 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-001, "Radiation Protection Program Plan".
- 3.8 Advanced Medical Systems, Inc. Radiation Safety Procedure No. RSP-004, "Radiation Protection Records".
- 3.9 Advanced Medical Systems, Inc. "Radiation Protection Technician Training Manual".
- 3.10 Advanced Medical Systems, Inc. "Authorized User Training Manual".

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3.11 Advanced Medical Systems, Inc. "Field Service Technician Training Manual".

#### 4 DEFINITIONS

The definition of terms used in this RSP that may not be commonly understood shall be found in RSP-002, "Definitions".

#### 5 PROCEDURE

##### 5.1 Qualifications of the RSO

5.1.1 The RSO should have an Associate's degree (or equivalent) in the physical or biological sciences, and shall have completed course work and/or have experience with the following:

- 5.1.1.1 Principles and practices of radiation protection;
- 5.1.1.2 Radioactivity measurements, monitoring techniques, and the use of instruments;
- 5.1.1.3 Mathematics and calculations basic to the use and measurement of radioactivity;
- 5.1.1.4 Biological effects of radiation;
- 5.1.1.5 Safety practices applicable to protection from the radiation, chemical toxicity, and other properties of the radioactive materials in use at AMS facilities;
- 5.1.1.6 Conducting radiological surveys and evaluating results;
- 5.1.1.7 Evaluating radioactive material processing facilities for proper operations from a radiological safety standpoint; and
- 5.1.1.8 Applicable USNRC, USEPA, and OSHA regulations, as well as the terms and conditions of any licenses and permits issued to AMS by these agencies.

##### 5.2 Qualifications of the ARSO

5.2.1 The ARSO should have an Associate's degree in the physical or biological sciences (or equivalent).

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5.2.2 The ARSO shall perform work under the direct supervision of the RSO until such time as the ARSO meets the qualifications of the RSO.

#### 5.3 Refresher Training of the RSO and ARSO

5.3.1 The RSO and ARSO should participate in a minimum of 20 hours of refresher training on an annual basis.

5.3.2 Refresher training may consist of a combination of:

5.3.2.1 Attendance at seminars or training courses on radiation protection issues

5.3.2.2 Self development through review of books and literature on radiation protection issues

5.3.2.3 Attendance at scientific meetings where radiation protection issues are discussed

5.3.2.4 Formal education in physics, health physics, statistics, meteorology, radiation biology, industrial hygiene and data base management.

5.3.3 Refresher training shall be documented on a "Refresher Training Documentation" form (Attachment 1).

#### 5.4 Training of Radiation Protection Technicians

5.4.1 Training shall be conducted by the RSO or others designated by the RSO pursuant to the "Radiation Protection Technician Training Manual".

5.4.2 The duration of training shall be 40 hours of classroom instruction, practical demonstration of RSPs, and on-the-job training in the duties of a Radiation Protection Technician.

5.4.3 Each knowledge item required shall be checked off by the RSO on the Performance Verification Sheet for Radiation Protection Technicians (Attachment 2).

5.4.4 The RSO shall evaluate the knowledge of each individual as they receive training, review procedures and reference materials, and become familiar with each subject/task.

**Note:** The evaluation may be in the form of oral and/or written evaluations.

5.4.5 When the RSO is confident that the individual is knowledgeable of the subject/task, the RSO shall sign the Performance Verification Sheet for that task (Attachment 2).



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5.4.6 Unless under the direct supervision of the RSO, personnel shall not perform the activities listed on the Performance Verification Sheet until that activity is signed off.

5.4.7 Personnel shall be considered fully trained when the Performance Verification Sheet has been completed (all checked subjects/tasks are signed off).

5.4.8 Refresher training:

5.4.8.1 Should be conducted:

5.4.8.1.1 A minimum of once a year, and more frequently if a need is identified.

5.4.8.1.2 Whenever major changes are made in operational procedures

5.4.8.1.3 When regulations which affect the radiological aspects of the work take effect

5.4.8.2 Shall include a review of:

5.4.8.2.1 RSPs

5.4.8.2.2 Protection methods (Area 2 of Attachment 2)

5.4.8.2.3 Changes in applicable regulations or license conditions;

5.4.8.2.4 Deficiencies identified during the performance of radiation safety program audits.

5.4.8.3 Shall be documented (Attachment 1 and 6)

5.5 Training of Authorized Users

5.5.1 Authorized Users shall be qualified as Radiation Protection Technicians.

5.5.2 Training shall be conducted by the RSO or others designated by the RSO pursuant to the "Authorized User Training Manual".

5.5.3 Each knowledge item required shall be checked off by the RSO on the Performance Verification Sheet for Authorized Users (Attachment 3).

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5.5.4 The duration of training shall be 40 hours of classroom instruction, practical demonstration of Isotope Shop Procedures, and on-the-job training in the duties of an Authorized User.

5.5.5 The RSO shall evaluate the knowledge of each individual as they receive training, review procedures and reference materials, and become familiar with each subject/task.

**Note:** The evaluation may be in the form of oral and/or written evaluations.

5.5.6 When the RSO is confident that the individual is knowledgeable of the subject/task, the RSO shall sign the Performance Verification Sheet for that task (Attachment 3).

5.5.7 Unless under the direct supervision of the RSO, Authorized Users shall not perform the activities listed on the Performance Verification Sheet until that activity is signed off.

5.5.8 Authorized Users shall be considered fully trained when the Performance Verification Sheet has been completed (all checked subjects/tasks are signed off).

5.5.9 Refresher training:

5.5.9.1 Should be conducted:

5.5.9.1.1 A minimum of once a year, and more frequently if a need is identified.

5.5.9.1.2 Whenever major changes are made in operational procedures

5.5.9.1.3 When regulations which affect the radiological aspects of the work take effect

5.5.9.2 Shall include a review of:

5.5.9.2.1 Changes in applicable regulations or license conditions;

5.5.9.2.2 Deficiencies identified during the performance of radiation safety program audits.

5.5.9.3 Shall be documented (Attachment 1)

5.6 Training of Field Service Technicians

5.6.1 Field Service Technicians shall be qualified as Authorized Users.

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5.6.2 Training shall be conducted by the RSO or others designated by the RSO pursuant to the "Field Service Technician Training Manual".

5.6.3 Each knowledge item required shall be checked off by the RSO on the Performance Verification Sheet for Field Service Technicians (Attachment 4).

5.6.4 The duration of training shall be 40 hours of classroom instruction, practical demonstration of field service procedures, and on-the-job training in field service duties as listed on the "Teletherapy Unit Five Year Inspection & Preventative Maintenance Report" (Attachment 5)

5.6.5 The RSO shall evaluate the knowledge of each individual as they receive training, review procedures and reference materials, and become familiar with each subject/task.

Note: The evaluation may be in the form of oral and/or written evaluations.

5.6.6 When the RSO is confident that the individual is knowledgeable of the subject/task, the RSO shall sign the Performance Verification Sheet for that task (Attachment 4).

5.6.7 Unless under the direct supervision of the RSO, Field Service Technicians shall not perform the activities listed on the Performance Verification Sheet until that activity is signed off.

5.6.8 Field Service Technicians shall be considered fully trained when the Performance Verification Sheet has been completed (all checked subjects/tasks are signed off).

5.6.9 Refresher training:

5.6.9.1 Should be conducted:

5.6.9.1.1 A minimum of once a year, and more frequently if a need is identified.

5.6.9.1.2 Whenever major changes are made in operational procedures

5.6.9.1.3 When regulations which affect the radiological aspects of the work take effect.

5.6.9.2 Shall include a review of:

5.6.9.2.1 Basic knowledge (Area 2, Attachment 4)

5.6.9.2.2 Emergency service (Area 8, Attachment 4)

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5.6.9.3 Shall be documented (Attachment 1).

#### 5.7 Training and Qualifications of RSC

5.7.1 RSC members shall be drawn from those departments and positions that can provide insights into decision-making on radiological issues at the London Road facility.

5.7.2 RSC members shall receive introductory-level training in:

5.7.2.1 Radiation and radioactivity

5.7.2.2 Instrumentation

5.7.2.3 Radiation protection program management

5.7.2.4 Regulations and license requirements

5.7.3 Refresher training shall be conducted a minimum of once per calendar year.

#### 6 EXEMPTION PROVISIONS

6.1 A waiver of training/qualifications requirements for the RSO shall require the approval of the Vice President and the RSC.

6.2 A waiver of training/qualifications of the ARSO shall require the approval of the RSO, the Vice President, and the RSC.

6.3 A waiver of training for Radiation Protection Technicians shall require the approval of the RSO (see Attachment 7).

6.4 A waiver of training for Authorized Users and Field Service Technicians shall require the approval of the RSO, the Vice President, the Director of Engineering and the RSC (see Attachment 7).

6.5 All other variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the Vice President.

#### 7 DOCUMENTATION

7.1 All records associated with implementation of this procedure shall be maintained pursuant to RSP-004.

7.2 Completed Performance Verification Sheets shall be maintained by the RSO.

7.3 Individual employee training records shall be maintained by the Vice President.

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- 7.4 Memoranda detailing waivers (Attachment 7) or exceptions to qualifications stated in this procedure shall be maintained in the individual's training file.
- 7.5 The qualifications of those individuals whose signature appears as an approval authority on a PVS shall be maintained by the RSO.

## 8 ATTACHMENTS

- 8.1 Attachment 1: "Refresher Training Documentation"
- 8.2 Attachment 2: "Performance Verification Sheet for Radiation Protection Technicians"
- 8.3 Attachment 3: "Performance Verification Sheet for Authorized Users"
- 8.4 Attachment 4: "Performance Verification Sheet for Field Service Technicians"
- 8.5 Attachment 5: "Teletherapy Unit Five Year Inspection & Preventative Maintenance Report"
- 8.6 Attachment 6: "Radiation Safety Procedure Review"
- 8.7 Attachment 7: "Waiver of Training"

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Name (Print):

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## ATTACHMENT 2

### PERFORMANCE VERIFICATION SHEET FOR RADIATION PROTECTION TECHNICIANS

NAME OF RADIATION PROTECTION TECHNICIAN:

Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
<b>Area 1 - Basic Radiation Protection</b>			
Radiation Fundamentals (Science/math review; radioactivity; interactions, biological effects quantities and units)			
Measurement Methods (survey instruments, external and internal monitoring systems, environmental monitoring systems)			
Operational Aspects (Protection principles, surveys and inspections, waste management, emergencies)			
Regulations, Standards, Guidelines and Procedures			
Final Examination (Passing Level 80%) and Exam Review			
<b>Area 2 - Protection Methods</b>			
Describe basic radiation protection methods.			
Don and doff anti-C clothing.			
Perform a whole body frisk.			
Demonstrate the procedure for entering and exiting a contamination area.			
Describe and demonstrate the procedure for personnel decontamination.			
Describe and demonstrate the procedure for surface decontamination.			
Identify and explain the meaning of all radiological postings at the facility.			
Describe and demonstrate respirator use			
Describe and demonstrate the use of breathing zone samplers			
Describe and demonstrate the use of personnel dosimeters			



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NAME OF RADIATION PROTECTION TECHNICIAN:			
Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
<b>Area 3 - Instrumentation Use</b>			
Describe the operational procedure of an exposure rate survey instrument.			
Describe the operational procedure of a contamination survey instrument.			
Describe the operational procedure of the smear (well) counter.			
Describe the operational procedure of the gamma spectrometer.			
<b>Area 4 - Performing Surveys</b>			
Perform a contact exposure rate survey and complete the required documentation.			
Perform an ambient exposure rate survey and complete the required documentation.			
Perform a contamination survey and complete the required documentation.			
State the surface contamination limits for AMS.			
Collect and analyze an air sample and complete the required documentation.			
Describe how items being shipped from AMS are surveyed, including documentation.			
Describe how items are received at AMS, including documentation.			
Identify and describe all restricted areas at AMS.			
Describe the procedure for handling and maintaining radiation survey records.			
<b>Area 5 - Radiation Safety Procedures</b>			
Perform the activities described in RSP-008, "Instrumentation and Surveillance".			
Perform the activities described in RSP-009, "Contamination Control".			
Perform the activities described in RSP-011, "Radiological Areas and Posting".			

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### NAME OF RADIATION PROTECTION TECHNICIAN:

Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
Perform three (3) successful demonstrations of receiving radioactive materials as described in RSP-014, "Receipt, Handling and Identification of Radioactive Materials"			
Perform three (3) successful demonstrations of shipping radioactive materials as described in RSP-015, "Packaging and Transportation of Radioactive Materials"			
Perform the activities described in RSP-005, "ALARA Program".			
Perform the activities described in RSP-016, "Emergency Response and Notifications".			
Perform the activities described in RSP-012, "Control of Work"			
Perform the activities described in RSP-013, "Control of radioactive Waste"			
Perform the activities described in RSP-017, "Stop Work Authority"			
Perform three (3) successful demonstrations of data acquisition as described in RSP-018, "Operation of the Gamma Spectrometer"			
Perform three (3) successful demonstrations of the activities described in RSP-019, "Assessment of Radioactivity in Water Samples"			
Perform three (3) successful demonstrations of the activities described in ISP-5.1, "Emergency Generator Test"			
Perform three successful demonstrations of the activities described in ISP-7, "Air Monitor System"			
Perform three successful demonstrations of the activities described in ISP-6, "Gamma Alarm Function"			
Other (describe):			
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## ATTACHMENT 3 PERFORMANCE VERIFICATION SHEET FOR AUTHORIZED USERS

NAME OF AUTHORIZED USER:			
Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
<b>Area 1 - Basic Nuclear Safety</b>			
Complete Radiation Protection Technician Training			
<b>Area 2 - Basic Knowledge</b>			
Review work authorization and RWP requirements.			
Review the use and operation of all emergency devices			
Review and demonstrate the Hot Cell Ventilation System			
Review and demonstrate the Safety Airlock System			
Demonstrate the use of the Source Garden and related equipment.			
Demonstrate the use of the hot cell and related equipment.			
Review and demonstrate Hot Cell maintenance.			
Written Examination (Passing level 80%) and Exam Review			
<b>Area 3 - Operational Procedures</b>			
Successfully leak-test three (3) active sources.			
Perform three (3) active source transfers into Hot Cell.			
Provide three (2) demonstrations of raising Hot Cell floor plug, removing active source, identifying source capsule, replacing source, and replacing floor plug.			
Provide two (2) demonstrations of raising and inserting the floor plug in Bulk Isotope Storage.			
Provide two (2) demonstrations of decontaminating the Hot Cell deck.			
Successfully demonstrate installation and removal of three (3) mock-up sources from machine heads and source exchange containers.			
Successfully demonstrate installation and removal of three (3) active sources from a machine head and source exchange container.			

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## ATTACHMENT 4 PERFORMANCE VERIFICATION SHEET FOR FIELD SERVICE TECHNICIANS

NAME OF FIELD SERVICE TECHNICIAN:			
Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
<b>Area 1 - Basic Nuclear Safety</b>			
Complete Radiation Protection Technician Training			
Complete Authorized User Training			
<b>Area 2 - Basic Knowledge</b>			
Review applicable regulations for foreign and domestic field service.			
Review transportation requirements (10 CFR 71.5, 49 CFR & IAEA Safety Series No. 6).			
Review the theory, operation and service manuals of the Model C-2222 teletherapy unit.			
Review the theory, operation and service manuals of the Model C-9 teletherapy unit.			
Review the theory, operation and service manuals of the Model V-9 teletherapy unit.			
Describe a unit installation (unpacking, assembly, adjustment, equipment/tools, radiation safety, acceptance criteria, documentation requirements, accessory installation/adjustment, laser alignment)			
Describe a unit tear down for shipment (packing, crating, marking, disassembly procedures, documentation)			
Demonstrate blueprint reading capability (mechanical & schematic)			
Describe quality assurance procedures and unit acceptance criteria.			
Describe basic troubleshooting steps for heads, units, tables and controls.			
Perform device Production/Assembly operations (Geneva facility) for a total of 200 hours.			
Written Examination (Passing level 80%) and Exam Review			

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NAME OF FIELD SERVICE TECHNICIAN:

Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
<b>Area 4 - Five-year Inspection and Preventative Maintenance for the Model C-9</b>			
Successfully demonstrate a source head check (Item I of Maintenance Report)			
Successfully evaluate the condition of a collimating device (e.g., calibrate field size indicators, calibrate distance localizer, check collimator accessories and take an x-ray film (Item II of Maintenance Report).			
Successfully determine the unit true isocenter (Item III.A of the Maintenance Report).			
Successfully evaluate the safety modifications (Item III.C of the Maintenance Report).			
Successfully evaluate the treatment timer operation (Item III.D of the Maintenance Report).			
Successfully determine the source transit time (Item III.E of the Maintenance Report).			
Successfully complete all operational tests on the collimator (Item III.F of the Maintenance Report).			
Successfully perform a collimator mechanical inspection (Item III.G of the Maintenance Report).			
Successfully perform an electrical inspection (Item III.H of the Maintenance Report).			
Successfully replace rocker switches on VGB control (rotational units).			
Successfully perform a general safety inspection (Item III.J of the Maintenance Report).			
Successfully evaluate and adjust the table (Item IV of the Maintenance Report).			
Complete and document four (4) full inspections (two at a field site)			
Other (describe):			
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Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
Other (describe):			
Other (describe):			
Other (describe):			
Area 5 - Installation of the Model V-9			
Successfully perform three (3) room layouts (one time at a field site).			
Successfully erect three (3) stands (one time at a field site).			
Successfully install three (3) counterweights (one time at a field site).			
Successfully install three (3) heads (one time at a field site)			
Successfully install three (3) bearing rings (one time at a field site).			
Successfully install three (3) collimator (one time at a field site).			
Successfully performing three (3) wirings and inspections (one time at a field site).			
Perform three (3) successful checkouts and adjustments (one time at a field site).			
Deliver three (3) operator training courses (two times at a field site).			
Other (describe):			
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NAME OF FIELD SERVICE TECHNICIAN:

Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
<b>Area 6 - Five-year Inspection and Preventative Maintenance for the Model V-9</b>			
Successfully demonstrate a source head check (Item I of Maintenance Report)			
Successfully evaluate the condition of a collimating device (e.g., calibrate field size indicators, calibrate distance localizer, check collimator accessories and take an x-ray film (Item II of Maintenance Report).			
Successfully determine the unit true isocenter (Item III.A of the Maintenance Report).			
Successfully evaluate the safety modifications (Item III.C of the Maintenance Report).			
Successfully evaluate the treatment timer operation (Item III.D of the Maintenance Report).			
Successfully determine the source transit time (Item III.E of the Maintenance Report).			
Successfully complete all operational tests on the collimator (Item III.F of the Maintenance Report).			
Successfully perform a collimator mechanical inspection (Item III.G of the Maintenance Report).			
Successfully perform an electrical inspection (Item III.H of the Maintenance Report).			
Successfully replace rocker switches on VG8 control (rotational units).			
Successfully perform a general safety inspection (Item III.J of the Maintenance Report).			
Successfully evaluate and adjust the table (Item IV of the Maintenance Report).			
Complete and document four (4) full inspections (two at a field site)			
Other (describe):			
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Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
Other (describe):			
Other (describe):			
Other (describe):			
<b>Area 7 - Service for the Model C-1000, C-2000, C-3000, C-5000 and C-10000</b>			
Successfully demonstrate a source head check (Item I of Maintenance Report)			
Successfully disassemble and ship three (3) heads and units (one time at a field site).			
Successfully perform a general safety inspection (Item III.J of the Maintenance Report).			
Successfully perform source exchanges as described in Area 8.			
Complete and document four (4) full inspections (two at a field site)			
Other (describe):			
Other (describe):			
Other (describe):			
Other (describe):			
Other (describe):			
<b>Area 8 - Source Exchange</b>			
Describe the radiation safety checklist and the purpose for each item on the list.			
Describe and demonstrate a routine survey at a field site (size and shield wall, top of machine head, leak test)			

# RADIATION SAFETY PROCEDURE

Minor Change

er:

TRAINING AND QUALIFICATIONS OF RADIATION PROTECTION PERSONNEL

No. RSP-006

Rev. No. 000

Date: 03/08/96

Page: 22 of 26

Date: / /

## NAME OF FIELD SERVICE TECHNICIAN:

Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
Perform the activities described in ISP-23, "Source Installation and Exchange Procedures"			
Describe post-exchange actions (dose assessment, records, reports)			
Complete three (3) active source exchanges (two at a field site)			
Other (describe):			
Other (describe):			
Other (describe):			
Other (describe):			
<b>Area 9 - Emergency Service</b>			
Describe and demonstrate pre-service procedures.			
Describe and demonstrate the procedure for closing a stuck shutter.			
Describe and demonstrate the procedure for responding to a radiation accident in the workplace.			
Describe and demonstrate the procedure for containing a leaking source.			
Describe incident reporting requirements.			
Describe and demonstrate post-service actions (dose assessment, records, reports and notifications)			
Complete and document two (2) emergency service calls involving a mock-up source.			
Complete and document two (2) emergency service calls involving an active source.			
Other (describe):			
Other (describe):			

# RADIATION SAFETY PROCEDURE

Minor Change

ver:

TRAINING AND QUALIFICATIONS OF RADIATION PROTECTION PERSONNEL

No. RSP-006

Rev. No. 000

Date: 03/08/96

Page: 23 of 26

Date: / /

NAME OF FIELD SERVICE TECHNICIAN:

Performance Item	Item Required (Check)	Date of Qualification	Signature of RSO or Designee
Other (describe):			
Other (describe):			
Other (describe):			

# RADIATION SAFETY PROCEDURE

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Minor Change

of:

TRAINING AND QUALIFICATIONS OF RADIATION PROTECTION PERSONNEL

No. RSP-006

Rev. No. 000

Date: 03/08/96

Page: 24 of 26

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## ATTACHMENT 5

### TELETHERAPY UNIT FIVE YEAR INSPECTION AND PREVENTATIVE MAINTENANCE REPORT

# RADIATION SAFETY PROCEDURE

Minor Change

ver:

TRAINING AND QUALIFICATIONS OF RADIATION PROTECTION PERSONNEL

No. RSP-006

Rev. No. 000

Date: 03/08/96

Page: 25 of 26

Date: / /

## ATTACHMENT 6 RADIATION SAFETY PROCEDURE REVIEW

Name (Print):			
Signature:			
RSP Number	RSP Title	RSP Date	Date of Review
RSP-001	Radiation Protection Program Plan		
RSP-002	Definitions		
RSP-003	Control of Radiation Safety Procedures		
RSP-004	Radiation Protection Records		
RSP-005	ALARA Program		
RSP-006	Training and Qualifications of Radiation Protection Personnel		
-007	Training in Radiation Protection"		
RSP-008	Instrumentation and Surveillance		
RSP-009	Contamination Control		
RSP-010	Exposure Control		
RSP-011	Radiological Areas and Posting		
RSP-012	Control of Work		
RSP-013	Control of Radioactive Waste		
RSP-014	Receipt, Handling, and Identification of Radioactive Materials		
RSP-015	Packaging and Transportation of Radioactive Materials		
RSP-016	Emergency Response and Notifications		
RSP-017	Stop Work Authority		
RSP-018	Operation of the Gamma Spectrometer		
RSP-019	Assessment of Radioactivity in Water Samples		



# RADIATION SAFETY PROCEDURE

Minor Change

Number:

TRAINING AND QUALIFICATIONS OF RADIATION PROTECTION PERSONNEL

No. RSP-006

Rev. No. 000

Date: 03/08/96

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## ATTACHMENT 7

### WAIVER OF TRAINING

Individual's Name (Print): \_\_\_\_\_

Individual's Signature: \_\_\_\_\_

Training being waived:

- ☐ Radiation Protection Technician Training
- ☐ Authorized User Training
- ☐ Field Service Technicians Training
- ☐ Classroom Training
- ☐ Practical Demonstrations
- ☐ Other (describe) \_\_\_\_\_

Reason for Waiver: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

#### APPROVALS:

*Not all approval signatures are required in all instances. See RSP-006 for instructions.*

Radiation Safety Officer: \_\_\_\_\_  
Signature and Date

Vice President: \_\_\_\_\_  
Signature and Date

Chair, RSC: \_\_\_\_\_  
Signature and Date

Director of Engineering: \_\_\_\_\_  
Signature and Date



# Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

March 18, 1996

Mr. James Taylor  
Executive Director for Operations  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

Re: Request for Action on License #34-19089-01 Pursuant to 10 CFR 2.206

Dear Mr. Taylor:

On August 2, 1993, the Northeast Ohio Regional Sewer District (NEORSD) filed a petition (Prior Petition) with the Nuclear Regulatory Commission (NRC) requesting that the NRC take certain actions regarding NRC License # 34-19089-01 (License). The License is held by Advanced Medical Systems, Inc. (AMS). A copy of the Prior Petition is attached as Exhibit A. The Prior Petition related to operations at the AMS facility at 1020 London Road, Cleveland, Ohio (Facility).

One of the actions requested in the Prior Petition was the modification of the AMS License to include a requirement that AMS provide adequate financial assurance prospectively to cover public liability in the event of nuclear incidents at the Facility. Section 170 of the Atomic Energy Act of 1954 provides the NRC with explicit authority to take such action.

On June 16, 1994, Mr. Robert Bernero issued a Director's Decision (Decision) on behalf of the NRC rejecting the Prior Petition. A copy of the Decision is attached as Exhibit B. The Decision was based on a number of assumptions which have proven incorrect.

## I.

One reason stated by Mr. Bernero for not requiring AMS to provide the requested financial insurance was the condition of the AMS Facility. However, in an eleven-page letter dated February 28, 1996 from Mr. John Madera, Chief, Nuclear Materials Licensing Branch, to AMS, a copy of which is attached as Exhibit C, many of the assumptions regarding the Facility relied upon by Mr. Bernero are called into serious question.

For example, on page 4 of this letter, it is made clear that there is no basis for the 40-curie source term that has been used in estimating potential releases from the Facility and that the proper number, although unknown at this time, is greater. This letter points out many additional deficiencies in the Emergency Plan for this facility, including inadequate assessments of the potential releases

as the result of earthquake or tornado damage. As stated on page 5 of the letter, "it is scientifically certain that a tornado passing over this facility would impose significant structural damage . . ."

Considering that over 60,000 curies of cobalt-60 are located at the Facility (page 3), Mr. Bernero's statement on page 7 of the Decision, "Accordingly, an accidental release of radioactive material from a material licensee's facility will be relatively confined compared to a reactor facility", appears to be unrealistic and inappropriate as it relates to the AMS Facility.

## II.

On page 12 of the Decision, Mr. Bernero suggests a second reason for rejection of the Prior Petition, a Pacific Northwest Laboratory study on sanitary disposal of radioactive materials to be performed under NRC contract. The results of that study have been available for some time and do not support the Director's Decision.

In fact, this study concludes that existing records of discharges of radioactive waste to the sewers "grossly" underestimate the quantity of radioactive materials found at the receiving sewage treatment plants. The study also concludes that there is insufficient information to determine whether sanitary discharges made in compliance with the revised Part 20 requirements would concentrate at sewage treatment facilities in sufficient quantity to be a problem.

Contrary to Mr. Bernero's expectations, the study to which Mr. Bernero referred -- much of which was conducted at NEORSD facilities and with NEORSD cooperation and assistance -- is actually very persuasive evidence in favor of requiring the financial assurance requested in the Prior Petition. That is, since the study demonstrates that contamination of sewage treatment plants due to discharges of licensed materials cannot be ruled out, financial assurance to cover public liability in the event of such a nuclear incident is a reasonable precaution.

## III.

As expressed by Mr. Bernero in both the Decision and his transmittal letter to NEORSD dated June 16, 1994 that accompanied the Decision, NRC's rejection of the Prior Petition was in part based on a revision to 10 CFR Part 20 that, according to Mr. Bernero's letter, ". . . no longer permits non-biological, dispersible material, such as the cobalt-60 used at AMS, to be disposed into the sanitary sewer."

Notwithstanding the revision, recent actions of the NRC have authorized AMS to release such material to the environment in a manner that allows insoluble material to reach the NEORSD sewer system.

Recently, AMS sought to discharge the contents of a 3000-gallon water storage tank, tank number 880, onto the ground at the Facility. It is highly probable that a portion of these contents

Mr. Taylor  
March 18, 1996  
Page Three

would flow overland across the neighboring facility and enter the street catch basin, which leads to the NEORSD system. Testing of the water in this tank 880 by NRC, NEORSD, and even AMS had shown detectable amounts of insoluble cobalt-60.

In a letter dated February 26, 1996, a copy of which is attached as Exhibit D, Mr. Geoffrey Wright, NRC Region III, stated that AMS had been informed that due to the presence of insoluble cobalt-60, dumping such water in a manner that was likely to reach the sanitary sewer would be an apparent violation of 10 CFR 20.2003. Subsequent to this letter, according to Mr. John Madera, AMS claimed to have circulated the contents of tank 880 through a 1 micron filter.

This treatment of the cobalt-60 contaminated water was apparently conducted without prior notice to the NRC, and certainly without prior notice to the Ohio Environmental Protection Agency (OEPA), or the NEORSD. This pretreatment was also conducted without the opportunity for any of these agencies to inspect or observe the treatment equipment.

As stated in the letter dated March 6, 1996 from the OEPA to AMS, a copy of which is attached as Exhibit E, this pretreatment system was in fact installed without required OEPA authorization and any discharge from tank 880 will be deemed a violation. Mr. Madera confirmed by telephone that AMS had detected insoluble cobalt-60 in samples taken from tank 880 following pretreatment.

On March 7, 1996, however, the NEORSD was informed by telephone by Mr. John Madera, NRC Region III, that the NRC was authorizing AMS to discharge the contents of storage tank number 880 onto the ground. Mr. Madera explained the justification for this action by the NRC by telephone to the NEORSD: Because not all of AMS' samples showed insoluble cobalt-60, and there was not a standard sampling protocol in place, NRC could not call the proposed discharge a violation of 10 CFR 20.2003 and successfully uphold that violation in court if AMS sued. So the NRC would do nothing.

The provisions of 10 CFR 20.2003 can be read no other way than to mean zero discharge of insoluble radioactive material, and to place an affirmative duty upon the licensee proposing to discharge to demonstrate that the radioactive material proposed to be discharged is readily soluble. In testing for the presence of insoluble radionuclides at relatively low levels, it is not surprising that not all samples would show positive detects.

Insolubility, practically by definition, indicates the presence of a second material phase that cannot be realistically expected to be precisely uniformly distributed. The very fact that some samples show detects while others do not confirms the insoluble, inhomogeneous character of the radionuclide detected. Mr. Madera nevertheless authorized discharge of this tank, without any confirmatory testing by the NRC.

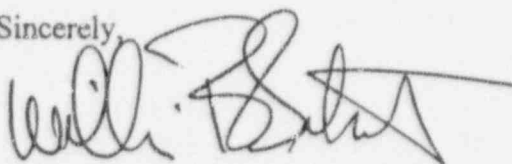
Mr. Taylor  
March 18, 1996  
Page Four

These NRC actions raise serious questions as to the validity of Mr. Bernero's revised Part 20 justification for denying the Prior Petition. Obviously, if the NRC will not enforce its revised regulation unless all samples show positive detects, the revision is an empty gesture.

As set forth above, substantial additional factual information has become available regarding the justification for requiring financial assurance for public liability from AMS subsequent to the date of the Decision. The new information also refutes the assumptions underlying Mr. Bernero's rejection of the Prior Petition.

Therefore, based on the new information presented in this petition, the NEORSD requests that this petition be treated as a new request for action on a license pursuant to 10 CFR 2.206. Please direct any questions regarding this petition to either Thomas Lenhart or Lawrence English, of my legal staff. They may be reached at 216-881-6600.

Sincerely,



William B. Schatz  
General Counsel

encl.

cc: Ramona Travota, USEPA  
Robert Bastian, USEPA  
Michael Cook, USEPA  
Michael Kalstrom, Cuyahoga County LEPC  
Donna Kniss, Ohio EPA  
William Gruber, City of Cleveland  
Erwin Odeal, NEORSD  
Thomas Lenhart, NEORSD  
Lawrence English, NEORSD

EXHIBIT "A"





# Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

August 2, 1993

Mr. James Taylor  
Executive Director for Operations  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

Re: Request for action pursuant to 10 CFR 2.206

Dear Mr. Taylor:

The Northeast Ohio Regional Sewer District ("District") Southerly Wastewater Treatment Center has been contaminated by disposal of Cobalt-60 into the sanitary sewer system. The characterization and remediation of this contamination is ongoing and will cost the District, at a minimum, in excess of one million dollars. The remediation costs could rise into the billions of dollars if off-site disposal is required.

Although the NRC has been cooperative in this remediation effort, the Agency has consistently stated that the costs must be absorbed by the District and its ratepayers, despite the District's innocence in this matter. Chairman Ivan Selin recently stated that the NRC is completely powerless to seek cost recovery from the source of this material regardless of the degree of culpability of the licensee. Mr. Selin further stated that the victim in an off-site contamination case such as the Southerly Treatment Center must rely on state tort law to recover costs from the Licensee. Unfortunately for the victim, tort law will only provide an adequate remedy if a judgment can be obtained against a licensee with the financial resources to pay the judgment. In many situations, the judgment in contamination cases may force the licensee into bankruptcy leaving the victim to cover the remediation costs plus the additional cost of the legal action. The NRC may in such cases be left with an abandoned, contaminated facility.

In addition to requiring financial assurance for site decommissioning, the Atomic Energy Act, in 42 U.S.C. Section 2210,



Mr. James Taylor  
August 2, 1993  
Page 2


permits the NRC to require financial protection to cover public liability claims as a license condition of most licensees. The District has been informed by the NRC, however, that such financial protection has never been required of a licensee other than in the nuclear power industry, where it is mandatory. As a result of this NRC policy, publicly owned treatment works across the nation, as well as other potential victims, may find themselves in a position similar to that of the District and its ratepayers. In the event of an abandoned, contaminated facility, the impact on a municipality could be devastating.

The District therefore requests, pursuant to 10 CFR 2.206, that the NRC require financial protection, available in the form of insurance, of certain of its materials licensees. The amount of such financial protection could vary based upon the risk to the public posed by the licensee. The District specifically requests that adequate financial assurance to cover public liability be required of Advanced Medical Systems, Inc. due to the large volume of evidence indicating prior discharge of Cobalt-60 to the sanitary sewer, and due to the hundreds of curies of loose Cobalt-60 that remain in the London Road facility.

In addition to requiring adequate financial protection, the District also requests that the NRC license of all generators of radiological waste located within Cuyahoga County and Summit County, Ohio, be amended to require that licensees provide not less than 24 hours advance notice to the appropriate sewage treatment plant prior to releasing radioactive material to the sanitary sewer. In a separate petition for rulemaking pursuant to 10 CFR 2.802, the District is requesting that 10 CFR 20.303 (and 10 CFR 20.2003) be revised to require the same notification provision in all licenses issued by the NRC.

Your prompt response to this petition would be appreciated as this is a matter of great concern to the District.

Very truly yours,



William B. Schatz  
General Counsel

WBS/ydm

cc: Richard Bangart  
Philip Olson  
John Martin  
Ken Kirk  
Senator Glenn  
Senator Metzenbaum  
Representative Hoke  
Representative Stokes  
Erwin Odeal  
Thomas Lenhart  
Barry Koh  
Law Director, City of Cleveland

EXHIBIT "B"



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

JUN 16 1994

Docket No. 030-16055  
(10 CFR § 2.206)

William B. Schatz  
General Counsel  
Northeast Ohio Regional Sewer District  
3826 Euclid Avenue  
Cleveland, Ohio 44115-2504

RECEIVED

JUN 22 1994

Legal Department  
N. E. O.

Dear Mr. Schatz:

This letter is in response to your Petition, dated August 2, 1993, on behalf of the Northeast Ohio Regional Sewer District. The Petition requested that the U.S. Nuclear Regulatory Commission take action with respect to Advanced Medical Systems, Inc., (AMS) to modify the AMS license to require, *inter alia*, that AMS provide adequate financial assurance to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended.

Your request was referred to the staff for consideration pursuant to 10 CFR § 2.206 of the Commission's regulations. For the reasons stated in the enclosed "Director's Decision Under 10 CFR § 2.206," the Petition has been denied.

Three items of interest should be noted. First, the revision of 10 CFR Part 20 no longer permits non-biological, dispersible material, such as the cobalt-60 used at AMS, to be disposed into the sanitary sewer. In connection with this revision, the NRC has published an advance notice of proposed rulemaking requesting comment and/or information as to whether an amendment to the new regulations in effect is needed. Second, the Commission has expressed its view that the Atomic Energy Act of 1954 does not prohibit actions by state or local authority on bases other than protection of public health and safety from radiological hazards. This is explained in a letter dated 11/9/93 from M. G. Malsch, NRC, to M. J. Fitzgerald, GAO, and a letter dated 11/9/93 from M. G. Malsch, NRC, to H. B. McFadden, Laramie, Wyoming, City Attorney, both of which are enclosed with this letter and referenced in the enclosed Director's Decision. Third, in a Staff Requirement Memorandum dated June 28, 1993, the Commission has requested the NRC staff to address the issue of rulemaking on the subject of financial assurance for cleanup of an accident for material licensees with a potential for significant contamination.


With regards to the petition dated March 3, 1993, you filed pursuant to 10 CFR § 2.206, we intend to consider your consultant's report on the cobalt-60 characterization at the Southerly Treatment Center, which is currently expected to be completed in June, 1994, before issuing our decision on that Petition. Please forward a copy to me within two weeks after your

consultant submits it to you. Accordingly, we will make a decision on your March 3, 1993, Petition within a reasonable time after receiving your consultant's report.

A copy of the Decision will be filed with the Secretary of the Commission for its review in accordance with 10 CFR § 2.206 of the Commission's regulations. As provided by this regulation, the Decision will constitute the final action of the Commission 25 days after the date of issuance of the Decision unless the Commission, on its own motion, institutes a review of the Decision within that time.

A copy of the Notice which is being filed with the Office of the Federal Register for publication is enclosed.

Sincerely,



Robert M. Bernero, Director  
Office of Nuclear Material Safety  
and Safeguards

Enclosures:

1. Director's Decision DD-94-06
2. Federal Register Notice
3. Ltr dtd 11/9/93 from  
M. Malsch, NRC, to  
M. Fitzgerald, GAO
4. Ltr dtd 11/9/93 from  
M. Malsch, NRC, to  
H. McFadden, Laramie, WY

cc: Advanced Medical Systems, Inc.  
ATTN: Ms. Sherry Stein, Dir.  
of Regulatory Affairs  
1020 London Road  
Cleveland, Ohio 44110

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
Robert M. Bernero, Director

In the Matter of

ADVANCED MEDICAL SYSTEMS, INC.  
(Cleveland, Ohio)

)  
)  
)  
)  
)

Docket No. 030-16055

(10 C.F.R. § 2.206)

DIRECTOR'S DECISION UNDER 10 C.F.R. § 2.206

I. INTRODUCTION

By letter dated August 2, 1993, addressed to Mr. James M. Taylor, Executive Director for Operations, U. S. Nuclear Regulatory Commission ("NRC"), William B. Schatz, on behalf of Northeast Ohio Regional Sewer District ("District"), requested that the NRC take action with respect to Advanced Medical Systems, Inc. ("AMS"), of Cleveland, Ohio, an NRC licensee. The District requested, pursuant to 10 C.F.R. § 2.206, that the NRC institute a proceeding to modify the license of AMS to require AMS to provide adequate financial assurance, available in the form of insurance, to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended. The District alleges the following bases for the request: (1) There is a large volume of evidence indicating prior discharge of cobalt-60 to the sanitary sewer, and (2) hundreds of curies of loose cobalt-60 remain in the London Road facility.

By letter dated November 24, 1993, I formally acknowledged receipt of the

Petition and informed the Petitioner that its request was being treated pursuant to 10 C.F.R. § 2.206 of the Commission's regulations. A notice of the receipt of the Petition was published in the Federal Register on Monday, December 6, 1993 (58 Fed.Reg. 64,341). The NRC staff sent a copy of the letter dated November 24, 1993, with the Petition, to AMS.

I have completed my evaluation of the matter raised by the Petitioner and have determined that, for the reasons stated below, the Petition should be denied.

## II. BACKGROUND

The NRC issued License No. 34-19089-01 to AMS on November 2, 1979. The licensed operation, facilities and equipment had been previously owned and operated by Picker Corporation since 1959. From 1979 to mid-1991, the AMS License authorized the possession of 150,000 curies of cobalt-60 in solid metal form for the purpose of manufacturing of sealed sources for distribution to authorized recipients for use in teletherapy units (used at medical facilities for treatment of medical conditions). The License currently authorizes AMS to possess cobalt-60 in solid metal form in storage and to use this material in training of Licensee personnel in the manufacture of NRC approved sealed sources; the current License does not authorize manufacture of sealed sources for distribution. In addition, the License continues to authorize possession of large quantities of cobalt-60 and cesium-137 in sealed sources, and plated depleted uranium shielding, incident to teletherapy and industrial radiography installation, maintenance, and service. The AMS License currently limits possession to 300,000 curies of cobalt-60 (150,000 curies as solid metal and 150,000 in sealed sources; although the solid metal

can be used to manufacture sealed sources, no manufacturing is authorized at present), 40,000 curies of cesium-137, and 4000 kilograms of depleted uranium. Based on NRC interviews and review of records, AMS stopped releases of processed radioactive liquids to the sewer system in 1989, and since then has generated little radioactive liquid waste, which it holds on site. See US NRC Report No. 030-16055/93002(DRSS) dated July 29, 1993. The facility that houses the licensed material is located on London Road in Cleveland, Ohio.

The Northeast Ohio Regional Sewer District is responsible for operating three wastewater treatment facilities in and around the Cleveland, Ohio, metropolitan area. Its Southerly Wastewater Treatment Center ("SWTC") has been operating since 1927 to remove grit and debris from wastewater generated in the District's service area. This process involves incineration of sludge, transport of the residual ash in a slurry to settlement and evaporation ponds, and eventual transfer of the dried ash to landfills.

In April 1991, the NRC identified cobalt-60 at the SWTC by chance during an aerial radiation survey of an unrelated site, namely, the Chemetron Corporation facility located in Newburgh Heights, Ohio. Surveys were subsequently performed at SWTC in September 1991 and March 1992, by Oak Ridge Institute for Science and Education ("ORISE") at the request of NRC, to determine the extent of the cobalt-60 contamination at the facility. The results of the ORISE surveys are reported in "Radiological Characterization Survey for Selected Outdoor Areas, Northeast Ohio Regional Sewer District, Southerly Wastewater Plant, Cleveland, Ohio," Final Report, August 1992 (hereafter referred to as "ORISE report"). The results of the ORISE surveys



indicated that there were elevated direct radiation readings that were caused by cobalt-60, with elevated soil and sediment sample concentrations. With background averaging 9 microroentgens per hour, exposure rates ranged from 6 to 580 microroentgens per hour. (ORISE report at 6.) The activity of background soil samples was less than 0.2 picocuries per gram; soil and sediment sample activity ranged from less than 0.1 to 9,990 picocuries per gram. (ORISE report at 6.)

It was originally deduced (memorandum for Carl J. Paperiello, Deputy Regional Director from Loren J. Hueter, Radiation Specialist on the subject of Report on Trip to General Chemical Corporation (Non-licensee) 5000 Warner Road, Cleveland, Ohio and to Northeast Ohio Regional Sewer District, 6000 Canal Road, Cleveland, Ohio (Docket No. 030-18276; License No. 34-17726-02) dated June 13, 1991), based on the history and analysis of layers of incinerator ash in the fill areas, that the cobalt-60 began entering the treatment facility in the late 1970's or early 1980's. The history of SWTC revealed that, after renovation of the incinerators between 1975 and 1978, the current ponds were put into use for the first time. The ponds were then cleaned for the first time from December 1982 to March 1983, and all the excavations placed in the north fill area. The ash from the evaporation ponds was removed in vertical sections, and spread horizontally in the fill areas. The only timing sequence that can be determined is that cobalt-60 contamination entered SWTC prior to the 1982 cleaning. The contamination apparently originated from discharges to the sewer system in the Cleveland area that is serviced by the District.

The District removes ash from the ponds every few years so that the facility

can continue to use the ponds and continue its water treatment process. The District has transferred the dried ash from the evaporation ponds to an onsite fill area at SWTC. The NRC approved the site characterization strategy for the ash removal and has conducted confirmatory surveys along with ORISE following the transfer of ash from the evaporation ponds. Radiological characterization of the facility is ongoing to better determine the amount of cobalt-60 that is actually present on the SWTC site.

### III. DISCUSSION

The District's petition requests the NRC to require AMS to provide adequate financial assurance, available in the form of insurance, to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended, to cover any contamination that might be caused by loss of control of radioactive material by AMS. While applying to any contamination resulting from a future release from the AMS operation, the request in the Petition also appears to apply to the contamination already present at the District's SWTC. The NRC has treated the request in broad terms, i.e., as applying to possible future events resulting in offsite contamination as well as the currently existing contamination on the AMS site. (The District had filed a petition (dated March 3, 1993) pursuant to 10 C.F.R. § 2.206, requesting that the NRC require AMS to assume all costs resulting from the off-site release of cobalt-60 that has been deposited at the SWTC. That Petition is currently pending before the NRC.) The concerns which form the bases for the Petitioner's request and the evaluation of the staff are provided below.

A. Regulatory Framework.

1. Summary of Price-Anderson provisions

The Petitioner requests that the NRC apply the provisions of section 170 of the Atomic Energy Act of 1954, as amended ("Act"), 42 U.S.C. § 2210 ("Price-Anderson provisions"), to require AMS to obtain insurance for public liability. Section 170a. in part provides that:

Each license issued under section 103 and 104 and each construction permit issued under section 185 shall, and each license issued under section 53, 63, or 81 may, for the public purposes cited in section 21., have as a condition of the license a requirement that the licensee have and maintain financial protection of such type and in such amount as the [Commission] in the exercise of its licensing and regulatory authority and responsibility shall require in accordance with subsection [170]b. to cover public liability claims.

Thus, section 170a. provides that the Commission must require all of its power reactor licensees to have and to maintain financial protection (e.g., liability insurance) to cover public liability claims. Nuclear reactors are licensed pursuant to either section 103 or 104 of the Act. Reactors at nonprofit educational institutions are exempt from the provisions of section 170a., but are subject to the provisions of 170k. Section 170a., however, also authorizes the Commission to exercise its discretion to determine whether materials licensees should be required to have and maintain financial protection.

2. Commission Application of Price-Anderson to Material Licensees

Because the Commission issued the AMS License under section 81 of the Act, the Commission may exercise its discretion under the Price-Anderson provisions, as discussed above, in determining whether to require AMS to have and to maintain

financial protection (i.e., liability insurance). As a matter of policy, the Commission generally has chosen not to require financial protection of a licensee whose license has been issued pursuant to sections 53, 63, or 81 of the Act. The rationale for this policy rests on the NRC's determination that the magnitude of compensation for potential personal injury or property damage associated with activities conducted under materials licenses is significantly less than that associated with the operation of facilities licensed pursuant to sections 103 or 104 of the 1954 Act (i.e., nuclear reactors). Not only is the quantity of radioactive material much less for material licensees than that contained in the inventories at reactor sites, but there are other significant differences. For example, the material licensee's radioactive material is in a non-pressurized, ambient-temperature state compared to a reactor's inventory, which is maintained in a highly energized condition or environment, characterized by high temperature and pressure. Accordingly, an accidental release of radioactive material from a material licensee's facility will be relatively confined compared to a reactor facility. This, in turn, leads to much lower potential for the need for involvement of offsite support for a material licensee's accidental release, as compared to an accidental release from a reactor.

In 1976, however, the Commission determined that there was a significant radiological hazard associated with the operation of some "plutonium processing and fuel fabrication plants." (Compare the definition of "plutonium processing and fuel fabrication plant" in 10 C.F.R. § 70.4 with that in 10 C.F.R. § 140.3(h). Not all such plants licensed pursuant to 10 C.F.R. Part 70 are required to have financial protection pursuant to

10 C.F.R. § 140.13a.) The Commission exercised its discretionary authority under the Price-Anderson provisions to require licensees of "plutonium processing and fuel fabrication plants" (as defined in 10 C.F.R. 140.3(h)), licensed under section 53 of the 1954 Act, to have financial protection in an amount equal to the maximum amount of liability insurance available from private sources. (See 10 C.F.R. §§ 70.4, 140.3(h), and 140.108.) Currently, no person holds a license to operate such a facility.

Finally, in order to assure that all licensees within a particular class are treated uniformly, it has been the policy of the Commission, in implementing the Price-Anderson provisions, to impose requirements upon a defined class of licensees by promulgating regulations of general applicability, rather than issuing orders to individual licensees. Notwithstanding the above, the Commission requires that licensees, and not the public, bear the burden of prompt cleanup of accidental contamination from releases in violation of Commission requirements.

#### B. Application of Price-Anderson to Existing Conditions

That discharge of cobalt-60 to the sanitary sewer has occurred is well established. Records of licensees in the District service area that were licensed for cobalt-60 indicate that licensees were authorized to discharge cobalt-60 to the sanitary sewerage under controlled conditions.

Insurance coverage in general, and under Price-Anderson in particular, however, is *prospective*, and does not cover pre-existing conditions such as

property damage that has already occurred. Any insurance required now could not be used to satisfy a claim by the District to pay for cleanup of the cobalt-60 contamination now on the District's site. Accordingly, the imposition of financial protection requirements (e.g., liability insurance) pursuant to section 170 on AMS would not provide the District with a remedy for the bases it asserts. Likewise, any contamination on the AMS site is also a pre-existing condition and would not be covered by any insurance required pursuant to section 170. Accordingly, the District's bases for its request do not warrant the NRC granting the request.

Moreover, with respect to AMS' onsite contamination, the scope of the Price-Anderson coverage is limited to claims for public liability, i.e., legal liability arising out of or resulting from a nuclear incident or precautionary evacuation except, *inter alia*, claims for loss of, or damage to, or loss of use of property which is located at the site and used in connection with the licensed activity (See section 11.w of the Act, 42 U.S.C. § 2014(w)); it does not provide funds for cleanup *per se*. (In general, a "nuclear incident" means any occurrence causing bodily injury, sickness, disease, or death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of source, special nuclear, or byproduct material. See section 11.q of the Act, 42 U.S.C. § 2014(q).) With regard to the onsite contamination alleged by the District, therefore, requiring insurance pursuant to section 170 would be to no avail. In view of the foregoing, even if it were not a pre-existing condition, the contamination on the AMS site in and of itself does not provide a basis for requiring insurance pursuant to Price-Anderson.



In exercising its authority to protect the public health and safety pursuant to section 161 of the Act, 42 U.S.C. § 2201, the Commission has imposed requirements on its licensees to provide financial assurance for decommissioning which require the licensees to set aside funds to pay for remediation of any onsite contamination prior to license termination. See 10 C.F.R. § 30.35. With regard to the contamination on the AMS site and AMS' continued possession of byproduct material, funding of onsite cleanup is covered by the Commission's decommissioning funding plan requirements, which provide adequate protection for the public health and safety. On July 7, 1992, AMS provided decommissioning financial assurance by certification as permitted by 10 C.F.R. 30.35(c)(2), and will be required to include a decommissioning funding plan in its next application for license renewal; the current AMS license expires in December 1994. In view of the above, the District has not provided a basis for imposing additional requirements under Price-Anderson on AMS with regard to existing contamination on the AMS site or at the District's SWTC.

C. Possible Future Public Liability Claims

The possibility remains, nevertheless, that the contamination existing on the site might be spread to areas offsite or that future operations could result in offsite contamination. As set forth below, however, the District has not provided a basis for granting its request.

As discussed above, the Commission has adopted a policy of exercising its discretionary authority to apply the Price-Anderson provisions with respect to



classes of licensees rather than to individual licensees. The circumstances presented by the possibility of offsite contamination by AMS do not provide sufficient justification to deviate from that policy. The likelihood of accidental release of cobalt-60 from the AMS facility has diminished and continues to do so for several reasons, including the following: First, AMS is no longer authorized to manufacture sealed sources, and the use of raw material for this process has ceased. Second, efforts are being made by AMS to contain and dispose of loose radioactive material presently at the facility, decreasing their inventory substantially. Third, AMS is listed on the Site Decommissioning Management Plan, which provides for heightened NRC attention toward an objective of timely decontamination of the site to unrestricted use criteria and the eventual removal of the site from the list. Fourth, present disposal regulations allow disposal of only soluble radioactive material into the sanitary sewer, as discussed further below. In addition, the bases the District alleges in support of the Petition do not distinguish AMS from other materials licensees for the purposes of application of the Price-Anderson provisions. The District has not provided sufficient information, nor are we aware of information at this time, which would warrant extension of Price-Anderson to all materials licensees similar to AMS. In view of the above, the District's request concerning Price-Anderson coverage is denied. Moreover, because the Commission requires each licensee to be responsible for any remediation of offsite contamination resulting from a release of byproduct material in violation of regulations or license conditions, no action is required to modify the AMS License as requested by the District. In view of the foregoing, the District has presented no basis warranting the granting of its request.

The NRC notes that the 1991 revision to 10 C.F.R. Part 20, which became mandatory January 1, 1994, included several revised criteria for permissible release of radioactive material into the sanitary sewer. Since insoluble material was involved in a number of sewage treatment facility cases, the new rule eliminates the options to release either insoluble, or readily dispersible material, unless it is biological material, into a sanitary sewer system. Revised Part 20 also lowers allowable concentrations of radionuclides released into the sanitary sewer. Because a 1992 NRC study demonstrated that, under certain conditions, the potential to exceed the Part 20 public dose limit exists, NRC has contracted with Pacific Northwest Laboratory to perform additional studies on possible mechanisms at sewage treatment facilities that could lead to reconcentration of radionuclides. This multi-task contract began in October 1993; a report is due later this year. In connection with this study, the Commission has issued an advanced notice of proposed rulemaking in which the Commission has requested comments on whether an amendment to the current regulations governing the release of radionuclides from licensed nuclear facilities to sanitary sewer systems is needed. (59 Fed. Reg. 9146 (Feb. 25, 1994)). The facts regarding the District's SWTC were one set of circumstances prompting the Commission to issue the notice.<sup>1</sup>

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<sup>1</sup> The Commission recently expressed its views that although the Atomic Energy Act of 1954 preempts dual Federal-State regulation of radiation hazards, it does not prohibit actions by state or local authority on bases other than protection of public health and safety from radiological hazards. See letter dated 11/9/93 from M. Malsch, NRC to M. Fitzgerald, GAO; and letter dated 11/9/93 from M. Malsch, NRC, to H. McFadden, Laramie, Wyoming, City Attorney. The above matters do not provide a basis for granting the District's request, nor change the results of the analysis in this Decision.

Finally, it should be noted that the Commission has requested the NRC staff, in a Staff Requirement Memorandum dated June 28, 1993, to address the issue whether financial assurance for materials licensees for cleanup of an accident with the potential for significant contamination should be required. The staff will recommend that rulemaking be initiated if it appears that the benefit of such requirements outweighs the costs.

#### IV. CONCLUSION

The staff has carefully considered the request of the Petitioner. In addition, the staff has evaluated the bases for the Petitioner's request. For the reasons discussed above, I conclude that no substantial public health and safety concerns warrant NRC action concerning the request.

As provided by 10 C.F.R. § 2.206(c), a copy of this Decision will be filed with the Secretary of the Commission for the Commission's review. The Decision will become final action of the Commission twenty-five (25) days after issuance unless the Commission on its own motion institutes review of the Decision within that time.

Dated at Rockville, Maryland, this 16<sup>th</sup> day of June 1994.

FOR THE NUCLEAR REGULATORY COMMISSION



Robert M. Bernero, Director  
Office of Nuclear Material Safety  
and Safeguards

U.S. NUCLEAR REGULATORY COMMISSIONDOCKET NO. 030-16055ADVANCED MEDICAL SYSTEMS, INC.ISSUANCE OF DIRECTOR'S DECISION UNDER 10 C.F.R. § 2.206

Notice is hereby given that the Director, Office of Nuclear Material Safety and Safeguards, has issued a decision concerning a Petition dated August 2, 1993, submitted by the Northeast Ohio Regional Sewer District regarding Advanced Medical Systems, Inc. (AMS).

By letter dated November 24, 1993, the NRC staff formally acknowledged receipt of the Petition and informed the Petitioner that their Petition would be treated as a request under 10 CFR § 2.206. The Petition requested the U.S. Nuclear Regulatory Commission to take action to require AMS to provide adequate financial assurance to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended.

The Director of the Office of Nuclear Material Safety and Safeguards has determined to deny the Petition. The reasons for this Decision are explained in a "Director's Decision Under 10 CFR § 2.206" (DD-94-06), which is available for public inspection in the Commission's Public Document Room located at 2120 L Street, NW, DC 20555, and at the Local Public Document Room, Perry Public Library, 3735 Main Street, Perry, Ohio 44081.

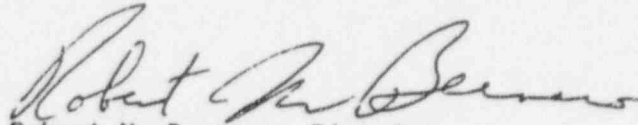
A copy of this Decision will be filed with the Secretary for the Commission's review in accordance with 10 CFR § 2.206. As provided by this regulation, the

ENCLOSURE 2

Decision will constitute the final action of the Commission 25 days after the date of issuance of the Decision unless the Commission on its own motion institutes a review of the Decision within that time.

Dated at Rockville, Maryland, this 16<sup>th</sup> day of June 1994.

FOR THE NUCLEAR REGULATORY COMMISSION

A handwritten signature in cursive script, appearing to read "Robert M. Bernero".

Robert M. Bernero, Director  
Office of Nuclear Material Safety  
and Safeguards



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

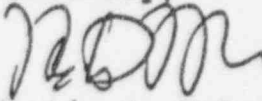
NOV 09 1993

Martin J. Fitzgerald, Esq.  
Associate General Counsel  
United States General Accounting Office  
Washington, D.C. 20548

Dear Mr. Fitzgerald:

In your letter of October 6, 1993, addressed to the General Counsel of the Nuclear Regulatory Commission, you requested our response to a number of questions regarding the concentration of radioactive materials in publicly owned treatment works. Your questions and our responses are contained in the enclosure to this letter. If you have further questions, please call me at (301) 504-1740, or Robert L. Fonner at (301) 504-1643.

Sincerely,

  
Martin G. Malsch  
Deputy General Counsel for  
Licensing and Regulation

Enclosure: As stated

cc: W. Parler  
R. Bernero

Enclosure 3

QUESTION 1. Does the NRC have the authority to require publicly-owned treatment works (POTWs) to test for concentrations of radioactive materials subject to the jurisdiction of the Atomic Energy Act? If so, under what authority? Would the POTWs be responsible for the payment for such tests?

ANSWER

Sections 161b. and 161i. of the Atomic Energy Act of 1954, as amended, authorize the NRC to promulgate rules and issue such orders as the Commission may deem necessary to protect health and safety with regard to regulated radioactive materials. This authority may be applied to unlicensed persons if necessary (see 10 CFR 2.202). The POTWs would be responsible for the payment for such tests if ordered. The NRC has no appropriated funds to pay for licensee or nonlicensee testing.

QUESTION 2. Under what authority and on what conditions does the NRC test for concentrations of radioactive materials subject to regulation under the Atomic Energy Act at POTWs? Who is responsible for the payment for such tests? Please explain.

ANSWER

The NRC may itself conduct sampling and testing under the authority of 161c. of the Atomic Energy Act of 1954, as amended. Such



sampling and testing may be done as the consequence of an inspection where the NRC inspectors take samples in order to ascertain regulatory compliance or need for regulatory action. The NRC inspectors use standard sampling techniques and normally split samples with the affected person. The stimuli for such inspections or investigations are varied. They may be routine, stem from allegations, or result from survey overflights based upon other evidence of contamination in the area being surveyed. The NRC bears the cost of its own testing, unless, in the case of licensees, the underlying inspection is subject to a fee pursuant to 10 CFR Part 170.

QUESTION 3. Does the NRC have the authority to require that the POTWs periodically report to the NRC any buildup of radioactive materials at their facilities? If so, under what authority?

ANSWER

The NRC has authority under section 161c. of the Atomic Energy Act of 1954, as amended, to obtain such information as the Commission may deem necessary to assist it in exercising any authority under the Act, enforcement or administration of the act, or any regulation or order issued thereunder. Pursuant to 10 CFR 2.204 a Demand For Information may be issued to a licensee or an unlicensed

person. If the POTW is a licensee, section 1610. also provides authority to require reports.

QUESTION 4. Does the NRC have any authority to regulate the concentration of radioactive materials subject to the Atomic Energy Act at a POTW if the concentration of such materials is not of a licensable amount? Please explain.

ANSWER

The NRC has no general regulations establishing de minimis quantities or concentrations of material not subject to regulation. However, certain kinds and quantities of radioactive materials have been exempted by rule from regulation when possessed by unlicensed persons. For example, 10 CFR 40.13 establishes exemptions for source material when it does not exceed .05% by weight of the compound or mixture in which it is found, in bulk untreated ore, in gas lamp mantles, and certain metallurgical alloys and counterweights. Exempt quantities and concentrations of byproduct material are limited to specific items, such as smoke detectors, which are manufactured or distributed under license. In these cases, the safety of the product in the hands of unlicensed persons has been carefully evaluated. Thus, the concept of "licensable amount" is inappropriate. The circumstances of each situation have to be reviewed against the codified regulations to determine if the regulatory requirements for exemption have been met. If those

requirements have not been met, the material remains subject to regulation.

QUESTION 5. Does the NRC have the authority to require that its licensees notify the POTWs prior to the disposal of any radioactive materials? If so, under what authority? What are the pros and cons of such a requirement?

ANSWER

The NRC has authority under section 1610. of the Atomic Energy Act of 1954, as amended, to require licensees to submit such reports as may be necessary to effectuate the purposes of the Act. It is not possible without considerable study of the implications of such a reporting requirement to identify meaningful pros and cons. However, the agency must comply with the requirements of the Paperwork Reduction Act in establishing the need for such reporting. One example may illustrate the complexity of the issue. Currently excreta from patients undergoing diagnostic or therapeutic treatment with isotopes (e. g. iodine 131 for certain thyroid conditions) may be flushed to sanitary sewers without restriction. Implementation of a reporting requirement for such occurrences may be difficult to achieve.

QUESTION 6. What authority, if any, do the POTWs have to refuse to allow NRC licensees to make disposals of radioactive materials into their systems? Please explain.

ANSWER

A recent letter to the city attorney for Laramie, Wyoming, discusses the issue raised in this question. A copy of the letter is attached. As the letter explains, a POTW may under certain circumstances refuse to allow disposals of radioactive materials into the treatment system.

QUESTION 7. To address the problem of excessive concentrations of radioactive materials at POTWs, how should the NRC and the Environmental Protection Agency coordinate their efforts?

ANSWER

The NRC and the EPA have established a coordinating committee of senior officials to discuss matters of mutual concern on an ongoing basis. A Memorandum of Understanding between the agencies, dated March 16, 1992, establishes the basic charter for cooperation between the agencies. A copy of the MOU is attached. This matter has not been the subject of discussions by the coordinating committee and there is no reason to believe that lack of coordination has contributed to the type of problem suggested.

Nonetheless, both NRC and EPA have a regulatory interest in waste water treatment sludges and incinerator ash and this matter will be placed on the committee's agenda.



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

NOV 09 1993

Hugh B. McFadden, Esq.  
Laramie City Attorney  
Corthell and King  
221 South Second Street  
P. O. Box 1147  
Laramie, Wyoming 82070

Dear Mr. McFadden:

In your letter to the NRC of September 9, 1993 you requested an expression of views on the following question: "Can a municipality lawfully regulate or prohibit the discharge of radioactive materials into its wastewater treatment system, with or without an industrial pretreatment program mandated by EPA?" We understand the context of your question to be a city plan to begin producing sludge in 1996, and the related facts that Laramie has a hospital with a nuclear medicine department and that the University of Wyoming does some research with radioisotopes.

By necessity our response has to be general, limited to the principles of law that govern this agency and its relationships with states and municipalities. The primary legal principle is that the Atomic Energy Act of 1954, as amended, occupies the field with respect to issues of radiation protection in the use of source, byproduct, and special nuclear material, as these terms are defined in the Act. If, however, the basis for the state or local governmental action is something other than the protection of workers and public from the health and safety hazards of regulated materials, the action is not preempted. See, e.g. Pacific Gas and Electric Co. v. State Energy Resources Conservation and Development Commission, 461 U. S. 190 (1983). As a consequence of the Atomic Energy Act occupying the field dual Federal-State regulation of the radiation hazards associated with use of these materials is not allowed. See 10 C.F.R. 8.4 and 10 C.F.R. Part 150.

However the extension of these general Federal preemption principles to actions of State or Local government entities in their proprietary capacity (say as owners of POTWs) raises additional issues which have not been resolved definitely. More important here, however, is that if the city of Laramie were to have sound reasons, other than radiation protection, to require pretreatment of wastes from the hospital or university to eliminate or reduce radioactivity, such pretreatment would not fall afoul of the Atomic Energy Act. Thus, NRC regulations that allow users of regulated materials to discharge to sanitary sewers do not compel a waste water treatment operator to accept those radioactive materials. We note, however, that the materials regulated by this agency are exempted from regulation under the Federal Water

Enclosure 4



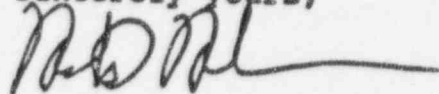
Pollution Control Act and the Resource Conservation and Recovery Act. Thus pretreatment to eliminate or reduce the regulated isotopes would not be required by these environmental statutes.

In January of 1994 new rules take effect in 10 C.F.R. Part 20 that will limit the discharge to sanitary sewer systems to only those licensed materials which are soluble in water or which are readily dispersible biological material (such as may be found in a university research laboratory), see 10 C.F.R. 20.2003. Finally, there is no limit on radioactivity that may be discharged to a sanitary sewer in excreta from patients undergoing medical diagnosis or therapy. You may wish to consult with the radiation safety officers of the hospital and university to gain an understanding of the technical characteristics of the isotopes used in these institutions and their fate in waste water treatment.

The problem of certain radioactive materials ending up in the sludges from waste water treatment, or in ash from the incineration of sludges, is well known to the staff of the NRC. A generic study is underway to understand the dimensions of the issue and whether it poses a particular health and safety matter that needs to be dealt with by more specific regulation. The Atomic Energy Act encourages the useful and beneficial uses of radioisotopes in medicine and research, at the same time the NRC is highly cognizant of the health risks to third parties that may result from such uses. We believe that our regulation is appropriately balanced between the need to protect the public from the undue hazards of the regulated materials and also to allow their beneficial use in a controlled manner.

I hope that this response will be helpful to you. If you have any further questions you may call either me at area code 301-504-1740, or Robert L. Fonner at area code 301-504-1643.

Sincerely yours,



Martin G. Malsch  
Deputy General Counsel for  
Licensing and Regulation



# GUIDING PRINCIPLES FOR EPA/NRC COOPERATION AND DECISIONMAKING

## Introduction

The Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC), in recognition of a mutual commitment to the effective and efficient protection of public health and safety and the environment, have developed this Memorandum of Understanding in order to establish a basic framework within which EPA and NRC will endeavor to resolve issues of concern to both agencies that relate to the regulation of radionuclides in the environment.

## Goal

The goal of this Memorandum of Understanding is to foster cooperation in fulfilling the responsibilities of each agency to ensure protection of the public health and safety and the environment in accordance with existing agency responsibilities and authorities.

## Principles

EPA and NRC, in carrying out the respective responsibilities of the two agencies in the regulation of radionuclides, will strive to:

1. Base regulatory decisions on a determination that such actions will result in a substantial reduction of significant risk to the public health and safety and the environment, and in making such decisions consider, to the extent permitted by law, the importance of the risk reductions to be achieved when compared to other radiological risks already subject to existing regulations, the overall economic impact on NRC licensees of additional regulatory requirements to achieve such reductions, and pursue the most efficient, cost-effective course in the regulation of those licensees.
2. Focus agency priorities on those significant safety and environmental problems subject to the authority of both agencies that offer the greatest potential for substantial risk reduction;
3. Avoid unnecessary duplicative or piecemeal regulatory requirements for NRC licensees, consistent with the legal responsibilities of the two agencies, and ensure that standards and regulations, when issued, can be effectively implemented; and

4. Effectively and responsibly carry out the provisions of Reorganization Plan No. 3 of 1970. Under the Plan, EPA issues generally applicable environmental limits on radiation exposure or levels, or concentrations or quantities of radioactive materials, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive materials, and NRC implements these standards by the use of its licensing and regulatory authority.

### Implementation Guidance

#### A. Scope

For certain facilities or materials licensed or regulated by the NRC, EPA is required by statute to develop environmental standards for radionuclides which are applicable directly to NRC-regulated facilities or materials. For example, EPA is required to develop generally applicable environmental standards for offsite releases from radioactive material in high-level waste repositories under the Nuclear Waste Policy Act. For other program activities, such standards are authorized but, depending sometimes on the circumstances, are not legally required. With the exception of Section C, below, this Memorandum of Understanding is intended to address issues associated with both types of standards. Section C applies according to its terms where EPA standards are not legally mandated. This MOU does not apply to matters arising under RCRA or CERCLA.

#### B. General

Each agency will keep the other generally informed of its relevant plans and schedules regarding such activities, will respond to the other agency's requests for information to the extent reasonable and practicable, and will strive to recognize and ameliorate to the extent practicable anticipated problems with regard to implementation and consistency with other program activities.

Each agency will deal with the other in a spirit of cooperation to achieve the goals of this Memorandum of Understanding. Agency management will endeavor, to the maximum possible extent, to resolve informally and in a timely manner those differences identified as a result of the procedures contained in this Memorandum of Understanding. If differences cannot be resolved, the respective General Counsels of each agency will arrange for the matter to be presented by the necessary parties to the heads of both agencies for resolution.

Each agency will keep the other fully informed of its priorities for the development of regulations and will endeavor to develop a common understanding of the priorities and schedules for resolution, with the highest priorities accorded to initiatives which offer the greatest potential for significant risk reduction.

If both agencies agree, in accordance with these principles and guidance, that duplicative regulation in a particular area is undesirable, but nevertheless is required by law, then the agencies will cooperate in considering and, if appropriate, supporting legislative changes.

### C. Governing Criteria and Procedures

This Section applies to the issuance of regulations for releases applicable to NRC regulated facilities or activities for releases into the environment of source, byproduct or special nuclear materials under the Clean Air Act. It also applies to the issuance of such regulations under the Atomic Energy Act and other provisions of law which may give rise to duplication of effort and overlapping regulation of NRC regulated facilities or activities, but only to the extent issuance of such standards is authorized but not legally mandated. Subject to the above, EPA and NRC agree as follows:

#### 1. Criteria

- EPA's decisions not to impose emission standards for hazardous air pollutants under the Clean Air Act for NRC licensed materials or facilities will, in accordance with 112(d)(9) of the Clean Air Act, be based upon a determination that NRC's regulatory program provides an ample margin of safety to protect the public health. Similarly, EPA's decisions to impose or not impose other regulations regarding NRC licensed materials or facilities will be based upon a determination as to whether NRC's regulatory program achieves a sufficient level of protection of the public health and environment. This determination may be influenced by particular risk reduction or risk prevention goals being pursued and this Memorandum of Understanding does not reflect agreement on such goals at this time. Ideally, agreement on risk reduction or prevention goals for radionuclides will be reached pursuant to paragraph D. below but in a particular case where EPA and NRC cannot agree on such goals, this Memorandum of

Understanding is without prejudice to EPA deciding to proceed with regulation, without NRC concurrence, based upon an EPA inability to find that NRC's program provides a sufficient level of protection.

- EPA and NRC will jointly seek to minimize unnecessary duplication of effort and overlapping regulation of NRC-licensed materials and facilities.

2. Procedures: In developing regulations in accordance with its authorities, if EPA, after finding that NRC's regulatory program fails to provide a sufficient level of protection of the public health and safety or the environment, identifies an area where it believes that EPA regulation applicable to NRC licensees regarding radionuclides may be necessary, EPA will, before developing and proposing rules in the Federal Register, informally and promptly inform the NRC of the basis for its position. If EPA believes that such direct regulation of its licensees by EPA is unnecessary, the two agencies will endeavor to resolve any issues, including consideration of information from NRC regarding the level of protection achieved by NRC regulatory programs and any necessary modifications to NRC's regulatory program, so that duplicative regulation and implementation are avoided. Decisions rendered pursuant to this paragraph will fully consider the implementation of existing regulatory programs in assessing the level of protection being achieved by regulated facilities. Final EPA conclusions on whether EPA will impose regulations applicable to NRC-licensed materials or facilities, and final NRC conclusions on whether NRC will develop modifications to its program, will be accomplished in a public process based upon a full and public record. Any decision made pursuant to this memorandum is subject to review and modification based upon actual experience with its implementation.

Similarly, if NRC undertakes the development of new regulations that would affect the level of protection of public health and safety and the environment related to an area where EPA has authority to issue regulations applicable to NRC licensees, or if NRC undertakes any rulemaking or other regulatory activity to fulfill its agreements made pursuant to this Memorandum of Understanding, NRC will promptly and informally notify and consult with EPA before developing and proposing rules in the Federal Register, and before any final decision by the Commission on the proposal.



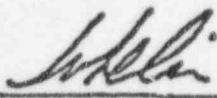
Where either agency is developing new regulations for radionuclides in an area not covered by an existing regulatory program, the agencies will, before proposing new regulations, consult concerning what the proper division of responsibility should be.

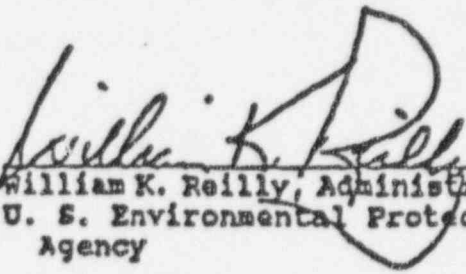
D. Risk Assessment

In carrying out this Memorandum of Understanding, the agencies will actively explore ways to harmonize risk goals and will cooperate in developing a mutually agreeable approach to risk assessment methodologies for radionuclides.

E. Other Provisions

1. Nothing in this Memorandum of Understanding limits the authority of either agency to exercise independently its authorities with regard to matters that are the subject of this Memorandum of Understanding.
2. Nothing in this Memorandum of Understanding shall be deemed to establish any right nor provide a basis for any action, either legal or equitable, by any person or class of persons challenging a government action or a failure to act.
3. This Memorandum of Understanding will remain in effect until terminated by the written notice of either party submitted six months in advance of termination.

  
\_\_\_\_\_  
Ivan Selin, Chairman  
U. S. Nuclear Regulatory  
Commission

  
\_\_\_\_\_  
William K. Reilly, Administrator  
U. S. Environmental Protection  
Agency

March 16, 1992

EXHIBIT "C"



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

FEB 28 1996

Mr. David Cesar, Vice President  
Advanced Medical Systems, Inc.  
121 North Eagle Street  
Geneva, OH 44041

Dear Mr. Cesar:

We have completed our review of your Emergency Plan submitted under letter dated September 21, 1995, and request that you provide clarification and/or additional information on the following topics:

1. AMS Staffing Levels and Offsite Response Personnel

Your response to our previous comment I.A of our June 7, 1995 letter did not provide an assessment of how current staffing levels will be able to fulfill the functions and responsibilities described in the plan, especially during nonworking hours. The following issues should be addressed in the plan:

- a. It appears that the onsite emergency organization is comprised of three individuals during working hours, and the absence of one or more individuals could severely impact the licensee's capability to promptly notify offsite response organizations and coordinate the response to an emergency. The licensee is required by 10 CFR 30.32(i)(3)(viii) to plan the notification and coordination so that unavailability of some personnel will not prevent notification and coordination. The plan should describe how the licensee will compensate for the functions assigned to an absent member of the emergency organization.
- b. Section 4.2 of the plan should clearly state the order in which AMS staff members assume the role of Emergency Manager if the Radiation Safety Officer (RSO) is not available (see previous comment V.C).
- c. It is still difficult to determine which personnel are assigned to each of the functional areas specified in Section 4.2.2 of Regulatory Guide 3.67 (see previous comment V.D). It would be helpful if these functional responsibilities were all specified in one place such as Figure 7.
- d. During nonworking hours, it is unclear whether a fire or other emergency situation will be detected promptly if power lines or phone lines are down. The plan should describe how the alarm system signal is transmitted to ADT Security Systems and how ADT



would detect a loss of contact with the alarm system. Any difference in the response to a loss of contact versus an alarm signal should be described also.

- e. During nonworking hours, it appears that local fire or police units could arrive before AMS staff and it is unclear whether there are adequate provisions to alert offsite response personnel to radiological hazards if no AMS personnel are there to meet them. The plan should describe arrangements with fire, police and rescue personnel regarding how they will fight fires and respond to alarms if AMS personnel are not present when they arrive at the site. The plan should also describe signs and other provisions to prevent offsite response personnel from unknowingly entering areas with elevated radiation levels.

## 2. Engineers Opinion Report

In response to our request for an engineering analysis of the facility structure, the emergency plan refers to an Engineers Opinion Report issued by Neff and Associates dated September 1995. We obtained a faxed copy of the report dated September 22, 1995 (after the date of the emergency plan). We noted a number of deficiencies in the report and a general failure to provide an adequate technical basis to support its conclusions. Most of our concerns regarding the structural integrity of your facility will be addressed in Inspection Report No. 030-16055/95006 which will be transmitted under separate cover. With respect to the emergency plan, the Engineer's Opinion Report does not provide an adequate analysis of the worst case earthquake. The report states that the structure can "withstand seismic forces as great as 5.2 Richter" and "a seismic event greater than 5.2 Richter in this region is highly improbable." Since the Richter scale is a method of classifying the energy released by an earthquake without defining other parameters such as epicentral distance, the statement fails to define the associated seismic forces on the structure. An adequate analysis should state, in appropriate units, the ground acceleration, velocity, and displacement that the worst case earthquake could impose on the structure. The analysis should evaluate how well the various existing structural systems in the building would withstand these seismic effects.

## 3. Facility Description

- a. Section 1.1 contains a brief description of activities formerly conducted at the site, but there is no description of the activities currently authorized or conducted. The plan should describe the current activities.
- b. Section 1.1 and Table 1 describe the amount of licensed material possessed on September 21, 1995. This inventory is subject to change and could increase up to the possession limits stated in

the license. The plan should state the total quantity of radioactive material authorized by the license. Typical quantities possessed at one time may be noted also.

- c. Section 1.1 states that there are over 60,000 curies of cobalt-60 and 2200 kilograms of depleted uranium in the facility, but it is unclear where this material is typically located. Sections 1.2 through 1.2.12 only identify the location of approximately 34,000 curies of cobalt-60. The typical storage locations for the remaining material authorized by the license should be identified.
- d. The plan still lacks a detailed site drawing showing the exterior features of the building and property described in Section 1.2 of Regulatory Guide 3.67 (see previous comment II.B). A detailed drawing of the exterior features of the site must be provided in addition to the interior floor plans. In addition to detailed information about the licensee's property, the drawing should show the pump house on Mandalay Avenue, the rail line that runs past the facility, and the nearest residents in each direction.
- e. The terminology used to describe areas in the facility is still inconsistent (see previous comment II.D). Section 1.2 refers to a shielded work room on the main floor, but this term does not appear in the following sections or on Figure 3/Appendix B. Section 1.2 refers to a mechanical equipment room and a ventilation system equipment room on the second floor, but these areas are labeled as the clean equipment room and HEPA equipment room in the following sections and Figure 4/Appendix B. Section 1.2 refers to a source storage area and irradiation facility in the basement, but Section 1.2.3 discusses a source garden, and Figure 2/Appendix B does not identify any of these areas in the basement. Consistent terminology should be used and all areas discussed in the text should be indicated on the drawings.
- f. Section 1.2.3 states that there is an L-shaped shield of sand-filled vaults on two sides of the source garden in the basement, but the floor plan in Figure 2/Appendix B does not show the shield. Significant safety features such as the sand shield, the emergency generator, fire pull stations, and storage locations of emergency response kits should be shown on the floor plans. The floor plans should also identify where electrical and natural gas services enter the building.
- g. Section 1.3 states that Figure 5 identifies the facility and its proximity to near-site structures. It states that Figure 5 shows the location of schools, hospitals and fire stations also. Figure 5 appears to be a poor quality copy of a street map and neither the licensee's building nor any structures within 1 mile of the site are clearly identified. Figure 1 does not provide an

adequate picture of the area near the site either. The plan should contain a reasonably detailed drawing of the site area as described in Section 1.3 of Regulatory Guide 3.67 (see previous comment II.F). The plan should also contain a U.S. Geological Survey topographical map (7.5 minute series).

#### 4. Types of Accidents

- a. The discussion on page 2-2 refers to guidance issued by the International Commission on Radiological Protection (ICRP). This guidance is not directly applicable to facilities in the United States. The guidance applicable to protecting the public in this country is contained in the "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" issued by the U.S. Environmental Protection Agency (EPA 400-R-92-001). The plan should refer to this guidance regarding offsite protective action recommendations.
- b. We have a number of concerns regarding the analysis in Section 2.1.1 and Appendix C of potential doses from a fire (see previous comment IV.A). Appendix C states that the source term for the worst case fire was assumed to be 40.4 curies, but the basis for that number is not provided. This does not appear to be a conservative assumption because the revised AMS license application dated October 30, 1995 requests a possession limit of 50 curies for packaged waste and surface contamination, and there is no explanation why the source term should not include bulk quantities of cobalt-60 from containers ruptured by one of the accidents postulated in Chapter 2 such as a gas line explosion, train derailment, or earthquake.

In addition, we disagree with the statement in footnote 40 that a 10-meter release height is a conservative assumption. A ground level release with no plume rise would maximize the offsite dose estimate.

We note that the CAP88-PC computer code is not intended to estimate short term doses resulting from an unplanned release during an emergency. Using a 40-curie source term, we estimated an inhalation dose at 100 meters of 7.7 millirem using the hand calculation in Section 2.1.3 of NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees," January 1988. This estimate is over an order of magnitude greater than the 0.2 millirem dose estimated by the CAP88-PC code. A more detailed and conservative analysis using more appropriate calculational methods should be provided.

- c. Section 2.1.2 and Appendix C state that an earthquake could create a 100 millirem/hour dose rate 20 feet beyond the outside wall of the source garden. The plan should state the distance at which the dose rate would drop below 2 millirem/hour and whether that location is in an area accessible to the public. In addition, we attempted to run the Microshield code using the assumptions stated in Appendix C but we could not duplicate the results stated in the plan. The input parameters and assumptions should be described in enough detail to permit us to duplicate and evaluate the calculation.
- d. Section 2.1.3 states that a tornado would not compromise the structural integrity of restricted areas and references the Engineers Opinion Report issued by Neff & Associates. Although this report states that portions of the building contained within the bunker-type construction would not sustain any appreciable distress, it also states "that it is scientifically certain that a tornado passing over this facility would impose significant structural damage" to other parts of the building. Restricted areas on the second floor and in the warehouse areas of the first floor could be completely demolished by a tornado releasing radioactive materials in those areas. Section 2.1.3 should provide a more accurate description of the potential damage from a tornado, and postulate the maximum amount of radioactive material that could be in these areas as a result of routine storage, preparation for shipments, or other operations.

5. Classification and Notification

- a. Section 3.2 is still inconsistent with the notification requirements in the regulations (see previous comment III.A). Pursuant to 10 CFR 30.32(i)(3)(viii), the plan must contain a clear commitment to notify appropriate offsite response organizations promptly after declaring an Alert or Site Area Emergency (SAE). The plan should not differentiate between these classifications or give the impression that the licensee can needlessly wait a full hour before notifying offsite officials of an Alert declaration. In addition, the plan must clearly state that the licensee shall notify NRC immediately after notification of local and State authorities. Simply stating that NRC will be notified within one hour is not sufficient.
- b. Several of the emergency action levels (EALs) in Attachment 1 of Appendix D are defined in terms of potential exposure rates or actual exposures. It is unclear how the Emergency Manager will be able to identify these conditions in a timely manner. It is unacceptable to wait for survey results if it will take more than 15 minutes to get them. EALs must be defined in terms of conditions that are apparent within the first few minutes of an



emergency. This is especially important during nonworking hours. If an alarm goes off and the condition cannot be verified within 15 minutes, the Emergency Manager should act conservatively by declaring an emergency and initiating notification of offsite response organizations. The EALs should be redefined.

- c. The offsite response organizations listed in Attachment 1 of Appendix D to receive a notification vary depending on the event. Each of the organizations identified as a "first responder" should be notified every time an Alert or Site Area Emergency is declared. In addition, all NRC notifications should be made to the NRC Operations Center. The Operations Center coordinates event reports with regional staff.
- d. The plan does not establish the initial recommendations for offsite protective actions that will be included in the initial SAE notification to offsite organizations (see previous comment III.B). If an accident has the potential to require road blocks or other protective actions offsite, the licensee should act conservatively and make initial recommendations to offsite officials until the scope of the accident can be verified. This would include recommendations to stop traffic on the rail line or rope off potentially contaminated areas. Protective action recommendations should be addressed in Sections 3.1.4 and 3.3, and Appendix D.
- e. Section 3.3 should specify the minimum frequency of updates to offsite response organizations after the initial notification (see previous comment IX.B). The response to our previous comment states that Section 8.3 was being modified to include the information, but the revision does not include this information.

## 6. Responsibilities

- a. Section 4.2 states that an environmental consulting firm and a certified health physicist have been retained to assist in all matters relating to radiation safety and environmental issues. Figure 7 only shows the environmental consultant as part of the AMS emergency organization and it is unclear what function either of these parties would perform during an emergency. The roles of the environmental consultant and the certified health physicist should be clarified.
- b. The response to our previous comment V.E states that letters from the hospital, fire department, and police department will be included in the plan. Section 4.3 states that Appendix E contains letters of agreement from "applicable first responders" listed in Table 2 along with information on the agreed upon means of communication and notification with these agencies. Contrary to

these statements, Appendix E only contains letters from the fire department and two State agencies and there is almost no information about methods of communication. Complete documentation that offsite response agencies are aware of, and have agreed to their roles as specified in the plan should be provided.

- c. The response to our previous comment V.G concerning the capabilities of offsite organizations and rumor control arrangements stated that the plan would be modified to address these items. The plan does not include this information. In addition to other capabilities, Section 4.4 should specifically address whether local fire or police personnel have the capability to conduct radiation surveys.
- d. Section 4.4 fails to describe some of the organizations listed in Table 2. A description of the responsibilities and capabilities of each of these organizations should be provided.
- e. In Table 2, the organizations do not appear to be listed in the order they would be called. The NRC Operations Center should be notified immediately after appropriate local and State organizations. Table 2 and Attachments 2 and 3 of Appendix D should be revised to prevent confusion.

#### 7. Response Measures

- a. The terms used for accidents are still inconsistent (see previous comment IV.B). The plan should establish the terms for accidents in Chapter 2 and these terms should be used consistently throughout the rest of the plan. The terms we found are listed below:

##### Chapter 2

Fire  
Earthquake  
Tornado  
Vandalism  
Flood  
Industrial Facility  
Impact  
Underground Gas Line  
Explosion  
Transportation  
Accident

##### Chapter 5

Fire  
Natural Phenomenon  
Tornado  
Vandalism  
Flood

##### Appendix D

Loss or Theft  
Unauthorized Entry  
Power Failure  
Minor Spill or  
Release  
Major Spill or  
Release  
Minor Fire  
Significant  
Exposure  
Fire, Explosion or  
Other Major  
Emergency

- b. We disagree with the statement in Section 5.3 that no actions can be taken to mitigate the consequences of a tornado or flood. When there is advance warning of severe weather conditions, we would expect the licensee to take reasonable steps to secure the facility and minimize releases. If a tornado warning is issued for the site area, we would expect the licensee to declare an alert and take immediate steps to secure licensed materials especially in the warehouse portions of the facility. Section 5.3 and Appendix D should address the mitigating actions that will be taken if a severe weather warning is issued.
- c. Section 5.4.1 states that evacuated personnel will assemble at the designated muster area, however the location of the muster area is not specified and it is not shown on any of the drawings. The location of the muster area should be identified.
- d. Section 5.4.1 does not describe provisions for search and rescue operations if the RSO cannot account for all personnel. This issue should be addressed.
- e. Section 5.3 states that licensee staff will assist the fire department by conducting surveys during fire fighting efforts. Footnote 25 on page 5-2 states that in the event of a fire, only self-contained breathing apparatus (SCBA) should be worn, and full- or half-face respirators are not permitted. Section 6.4 states that respirators are maintained in the building and Table 3 indicates that a respirator is maintained at the pump house. Please indicate what types of respirators are maintained in the building and the pump house. SCBAs should be available in the building and the pump house to respond to a fire.
- f. Section 5.5 still does not address informed consent (see previous comment VI.A). The plan should describe how the Emergency Manager will verify that a volunteer is aware of the health risks before authorizing emergency exposures exceeding 25 rem.
- g. Issuing dosimeters to firemen is not addressed in section 5.11 of Appendix D. This issue should be addressed in the implementing procedure.
- h. Section 5.5 states that personnel will be monitored for contamination, but there is no description of the procedures for decontaminating personnel if contamination is found. This issue should be addressed.



- i. Section 5.6 states that the Cleveland Emergency Medical Service personnel receive annual training, but it is unclear who conducts this training. In addition, there is no letter of agreement confirming that this organization has agreed to transport contaminated individuals. The training issue should be clarified and a letter of agreement should be provided.
- j. Sections 5.6 and 5.7 state that the University Hospital of Cleveland is capable of diagnosing and treating radiation injuries, and has a Radiation Safety Officer who will perform surveys and control contamination. There is no letter of agreement from the hospital verifying its capabilities and confirming its agreement with these statements (see previous comment VI.D). A letter of agreement should be provided.

8. Equipment and Facilities

- a. Section 6.2 does not describe any communications capability at the alternate command center (the pump house). Both the primary and alternate command center should have a telephone or other means of communication with offsite organizations.
- b. Section 6.4 states that dosimeters and survey meters are stored in the "instrument calibration room" shown in Figure 3, and that protective clothing and respirators are stored "in the locker room or storage room." There is no instrument calibration room indicated on Figure 3 and the storage location for the protective clothing is too vague. It is unclear whether these locations would be accessible during postulated accidents. Section 6.4 should use terminology that is consistent with the labels on the drawings. It would be helpful if the command center, equipment storage locations, first aid kits, emergency generator and other features related to emergency response were specifically indicated on the drawings.
- c. Section 6.4 and Table 3 only list pocket dosimeters. While pocket dosimeters are useful for real-time dose assessment, they are not very accurate. The licensee should provide more accurate dosimeters (e.g., film badges or TLDs) that can be used to verify personnel exposures after an emergency is brought under control.
- d. Table 3 indicates that only one respirator and two pocket dosimeters are maintained at the pump house. This does not appear to be sufficient to equip the licensee's staff and offsite rescue personnel that may need to enter the building. The pump house should contain enough respirators and dosimeters to equip the licensee's emergency staff, and enough additional dosimeters to monitor hose crews, search and rescue teams, or other offsite rescue personnel.

- e. Table 3 indicates that only one frisker and one survey meter are maintained at the pump house. We believe that at least one additional survey meter should be provided at this location for backup. The range of the survey meters should be specified also.

9. Maintaining Emergency Capabilities

- a. Section 7.2 should specifically state that the risks of emergency doses will be covered in the training of offsite rescue personnel so they can decide in advance what risks they would be willing to accept during lifesaving operations. Numerical estimates of health risks are provided in the EPA Manual of Protective Action Guides.
- b. Section 7.3 should state that the exercise objectives and scenario shall be provided to NRC in advance (typically 60 days) to allow NRC to review and comment on the exercise.
- c. Sections 7.4 and 7.5 should specify who is responsible for tracking findings from critiques and audits, and verifying that the findings are closed out.
- d. Section 7.5 states that there will be periodic audits. The plan should clearly state that there will be annual audits.
- e. Section 7.6 should state that the shelf-life of protective clothing and other degradable materials shall be tracked and changed out on a regular basis. In addition, provisions for calibration of the stack monitor and testing of the emergency generator should be described.

10. Records

Section 8.1 should specify that records of incidents shall be permanently retained with the licensee's decommissioning records.

11. Format

- a. The plan still does not have a list of effective pages that a reader can use to verify his copy is complete and up-to-date (see previous comment XII). A list of effective pages should be provided.
- b. Although Figures 2, 3, 4, and 5, and Appendix B have cover pages that are numbered, the actual drawings are not numbered or identified as part of the emergency plan. The drawings can be removed from the plan without creating any gaps in the page numbers. Every page of the plan, including the drawings, must be identified with a page number and a revision number/date.

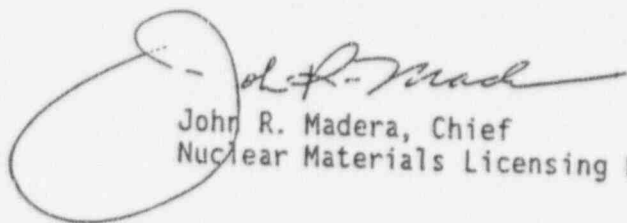
D. Cesar

-11-

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 98538.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 829-9887.

Sincerely,

A handwritten signature in cursive script, appearing to read "John R. Madera". The signature is written in dark ink and is positioned above the printed name and title.

John R. Madera, Chief  
Nuclear Materials Licensing Branch

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

EXHIBIT "D"



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

February 26, 1996

RECEIVED

FEB 28 1996

Legal Department  
N. E. O.

Lawrence K. English  
Assistant General Counsel  
Northeast Ohio Regional  
Sewer District  
3826 Euclid Avenue  
Cleveland, Ohio 44115-2504

Dear Mr. English:

I am writing in response to your facsimiles dated January 31, February 1, February 5, February 7, and February 12, 1996, as well as the recent telephone conversations between you and members of my staff, regarding the discharge of water at Advanced Medical Systems, Inc. (AMS). In these communications, you expressed concern about the presence of insoluble cobalt-60 (Co-60) in the water from AMS' underdrain system and manhole which had been pumped into storage Tanks 877, 222, and 880.

Your facsimiles list the results of the solubility tests performed by your contract laboratory. The January 31, 1996 facsimile documented that your laboratory had measured a cobalt-60 (Co-60) activity of  $2.7 \pm 2.0$  picocuries (pCi) on the filter from water held in AMS Tank 877. Likewise, the February 5, 1996 facsimile reported a measurement of  $4.0 \pm 1.9$  pCi on the filter from water held in AMS Tank 222, and the February 12, 1996 facsimile reported a measurement of  $39.3 \pm 12.0$  pCi on the filter from water held in AMS Tank 880. Since Co-60 was detected on these filters, Northeast Ohio Regional Sewer District (NEORS) considers the Co-60 in Tanks 877, 222 and 880 to be insoluble. In as much as 10 CFR 20.2003 requires that licensed material which is discharged into a sanitary sewerage system be readily soluble in water, NEORS requested that NRC prohibit AMS from discharging the water from these tanks.

On January 31, 1996, we asked AMS to postpone the discharge of Tank 877 until NRC's investigation was complete. On February 5, 1996, we made the same request for Tank 222. AMS complied with our requests.

By facsimile dated February 2, 1996, AMS indicated that its contract laboratory, Lockheed Analytical Services, had measured the Co-60 concentration in a water sample from Tank 877 and found no detectable Co-60 (the minimum detectable activity (MDA) for this analysis was 4.1 picocuries per liter (pCi/l)). A solubility test on this water sample was not performed. By facsimile dated February 7, 1996, AMS indicated that its laboratory had measured the Co-60 concentration and performed a solubility test of a water sample from Tank 222. Co-60 was not detected on the filter (the MDA for this analysis was 3.5 pCi).

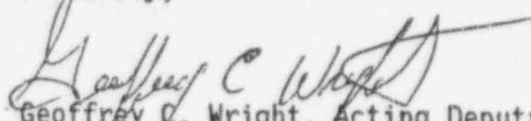
In response to your first three facsimiles, on February 6, 1996, an NRC inspector and I went to AMS and took six 0.5 liter water samples from Tanks 877 and 222. The water in the tanks had been recirculating for approximately 20 hours. In the Region III laboratory, each water sample was tested for solubility. Co-60 was not detected on these filters; thus, the NRC analysis did not confirm that the water in these tanks contained insoluble Co-60. These results were transmitted to AMS, and AMS subsequently discharged the water from the two tanks. (The analysis results are summarized in the enclosure.)

In response to your February 12, 1996 facsimile, on February 13, 1996, an NRC inspector went to AMS and took seven 0.5 liter water samples from Tank 880. Four samples were obtained from the top of the tank while the water was being recirculated. (The water in the tank had been recirculating for approximately 24 hours.) Based on our discussions with you regarding NEORSD's sampling technique, three samples were obtained from the tank's bottom outlet valve one hour after the recirculation pump had been turned off. Prior to taking the samples, approximately two liters of water were drained from the bottom outlet valve and returned to the tank.

The analysis of the samples from Tank 880 is still in progress. To date, two samples from the top and two samples from the bottom of the tank have been filtered. No Co-60 was detected on the filters from the top samples, but Co-60 was detected on the filters from the bottom samples. (The analysis results are summarized in the enclosure.) Based on these results: (1) on February 16, 1996, we informed AMS that insoluble cobalt-60 had been detected in the water from Tank 880, and therefore, a discharge of Tank 880 would be an apparent violation of 10 CFR 20.2003, and (2) we are currently reviewing the adequacy of AMS' sampling and analysis procedures.

Once our analysis of samples from Tank 880 is complete, you will be provided the complete results. In the meantime, please do not hesitate to contact me should you have any further questions regarding AMS.

Sincerely,



Geoffrey C. Wright, Acting Deputy Director  
Division of Nuclear Materials Safety

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

Enclosure: NRC Analysis

See Attached Distribution

Distribution

Robert Meschter  
Radiation Safety Officer  
Advanced Medical Systems, Inc.  
1020 London Road  
Cleveland, OH 44110

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

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

Michael Kalstrom, Secretary  
County of Cuyahoga  
Cuyahoga Emergency Management  
Assistance Center  
1255 Euclid Avenue, Room 102  
Cleveland, OH 44115-1807

Marian Zobler  
U.S. Nuclear Regulatory Commission

bcc:

C. Jones, NMSS  
PUBLIC IE07  
AMS File

E-mail:

Bruce Berson (BAB1)  
Cynthia Jones (CGJ)  
Tim Johnson (TCJ)  
John Madera (JRM4)  
Kevin Null (KGN)  
Cindy Pederson (CDP1)

Bill Brach (EWB)  
Mike Stein (MHS)  
Mike Weber (MFW1)  
Marian Zobler (MLZ)  
Bernie Bordenick (BMB)  
Josie Piccone (JMP1)

Joe DeCicco (JXD1)  
Jim Caldwell (JLC1)  
Fred Combs (FCC)  
Donald Cool (DAC)  
Steve Crockett (SFC)  
Geoffrey Wright (GCW)

Robert E. Owen, Administrator  
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Columbus, OH 43266

Lisa Mehringer  
City of Cleveland Law Department  
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Cleveland, OH 44114

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

Jane Harf, Chairperson  
Ohio State Emergency Response  
Commission  
1800 Watermark Drive  
P.O. Box 163669  
Columbus, OH 43216-3669



# ENCLOSURE

## RESULTS OF NRC'S ANALYSIS OF FILTERS FROM TANKS 877, 222 AND 880

AMS Tank Number	Filter Number	Activity (pCi)	MDA (pCi)	Count Time (hours)
877	1	< MDA	2.0	12.7
877	2	< MDA	1.8	16.0
877	3	< MDA	1.8	13.3
222	1	< MDA	2.3	10.4
222	2	< MDA	1.7	16.1
222	3	< MDA	1.7	17.1
880 top	2	< MDA	1.7	15.7
880 top	3	< MDA	2.3	11.0
880 bottom	1	17.2 $\pm$ 1.2	1.5	24.4
880 bottom	2	19.6 $\pm$ 2.0	2.4	7.2

NOTES: (1) MDA stands for minimum detectable activity.

EXHIBIT "E"



State of Ohio Environmental Protection Agency

Northeast District Office

2110 E. Aurora Road  
Twinsburg, Ohio 44087-1969  
(216) 425-9171  
FAX (216) 487-0769

George V. Voinovich  
Governor

March 6, 1996

RE: Advanced Medical Systems  
NEORSD  
Pretreatment

David Cesar  
Advanced Medical Systems  
121 North Eagle Street  
Geneva, OH 44041

Dear Mr. Cesar:

The Ohio EPA has recently discovered that Advanced Medical Systems (AMS) is processing water prior to discharge to NEORSD. AMS is allowed to discharge water collected in tanks from the footer drain system provided the soluble Cobalt-60 concentration is less than 100 pCi/l. Analysis of a tank of collected water revealed an insoluble Cobalt-60 concentration. Recently, NEORSD was requested to approve the discharge of this same tank of water after the water had been treated in some undocumented manner.

The Ohio EPA, NRC, and NEORSD have agreed that while the NRC has authority to regulate radiological discharges, OEPA and NEORSD have the authority to regulate discharges if those discharges can result in an interference of POTW operations. The Ohio EPA has also informed NRC and AMS that Permit to Install regulations found in OAC 3745-31 would be invoked if a pretreatment system was installed in order to reduce Cobalt-60 concentrations to a level that would not cause interference.

From the limited amount of information supplied to this office, it appears that AMS has constructed a pretreatment system that is intended to remove Cobalt-60 in order to prevent interference with NEORSD operations. AMS installed this system without first obtaining a Permit-to-Install, which is a violation of OAC 3745-31-02(A)(1) and ORC 6111.45. Please provide a response to this office by March 15, 1996 that provides a schedule for submittal of a Permit-to-Install to the Ohio EPA Northeast District Office.

If you have any questions or comments, please contact me at 216-963-1285.

Sincerely,

*Donna J. Kniss*

Donna J. Kniss  
Environmental Engineer  
Division of Surface Water  
Northeast District Office

DK:cph

cc: James Payne, AGO  
Richard Connelly, NEORSD  
Dwight A. Miller, Stavole and Miller  
Henry E. Billingsley, Arter and Hadden  
John Madera, U. S. NRC Region III



Printed on recycled paper

- NOESID good points re: readily soluble -  
general arguments.
- coordinate w. NAAS on our letters.
- current documentation re: readily soluble
- analysis re: Bernier's 2.206 response? validity  
of assumptions -- alleged contradictions?
- status of AMS actions -- letter on integrated plan?

REGION III  
ACTION ITEM CONTROL FORM

*Cindy*

YEAR

96

NUMBER

0129

DATE INITIATED

040196

REQUESTED BY

PEDERSON

REQUESTING DIVISION

DNMS

PUBLIC RESPONSIVENESS CORRESPONDENCE (Y OR N)

N

DESCRIPTION

NEORSD - REQUEST FOR ACTION  
NON LIC 34 - 19089 - 01

ASSIGNED TO

MADERA

DIVISION

DNMS

DUE DATE

040896

CLOSEOUT ACTION

CLOSED DATE

REMARKS

PRIORITY ROUTING

First	Second
RA	RC
DRA	EIC
DRF	SGA
DHS	OI
DNMS	PAO
DRMA	

EDO Principal Correspondence Control

FILE

ATS

me to Madara

Due 4/8

"W assessment"

- Goff
- Madara
- Weber
- me

Post original  
Thank you

ROM:

DUE: 04/12/96

EDO CONTROL: GT96170

DOC DT: 03/18/96

FINAL REPLY:

William B. Schatz  
Northeast Ohio Regional Sewer District

TO:

James Taylor

OR SIGNATURE OF :

\*\* GRN \*\*

CRC NO:

DESC:

ROUTING:

2.206 PETITION FOR ACTION ON LICENSE #34-19089-01  
HELD BY ADVANCED MEDICAL SYSTEMS, INC.

Taylor  
~~Milhoan~~  
Thompson  
Blaha  
Paperiello, NMSS  
Lieberman, OE  
Miller, RIII

DATE: 03/22/96

ASSIGNED TO:

CONTACT:

OGC

CYR

SPECIAL INSTRUCTIONS OR REMARKS:

Ref. EDO 9221

March 18, 1996

Ruth H. Vandegrift, Supervisor  
Contaminated Site Section  
Ohio Dept. of Health  
P.O. Box 118  
Columbus, OH 43266-0118

Dear Ms. Vandegrift:

I am writing in response to your January 30, 1996 letter to Mr. Hubert Miller, Regional Administrator, Region III, regarding contaminated soil at Advanced Medical Systems, Inc. (AMS) London Road facility.

We have been following the issues at AMS for some time. On September 17, 1995, we issued a Demand for Information (DFI) to AMS, requesting the licensee to prepare a comprehensive prioritization and schedule of intended action to be taken to reduce the overall risk posed by radioactive materials present at the facility. AMS responded to our DFI with its Strategic Plan for the London Road Facility (Plan), dated January 15, 1996. In its Plan, AMS designated the offsite disposal of wastes as a low priority item, with a scheduled completion date within the next three to five years.

In our December 6, 1995 response to AMS (copy attached), we indicated that we consider the offsite disposal of wastes to be a high priority action, with a scheduled completion date within the next year, given that: (1) these wastes are the only radioactive material at AMS which are in a potentially dispersible form, and (2) offsite disposal of wastes is now possible due to the recent reopening of the licensed low-level waste disposal facility at Barnwell, South Carolina.

AMS' reply to our response is due on April 15, 1996. At that time, we will determine if AMS' response is acceptable, and take appropriate action, if necessary, to ensure compliance with NRC regulations.

Should you have further questions regarding AMS, please do not hesitate to contact me.

Sincerely,

Original signed by

Geoffrey C. Wright, Acting Deputy Director  
Division of Nuclear Materials Safety

Enclosure: As stated

See Attached Distribution

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December 6, 1995

Advanced Medical Systems, Inc.  
ATTN: David Cesar  
Vice President  
121 North Eagle Street  
Geneva, OH 44841

Dear Mr. Cesar:

This letter refers to: (1) the matters discussed at the exit meeting between NRC and AMS on August 29, 1995, (2) the Demand for Information (DFI) subsequently issued by NRC on September 17, 1995, and (3) your response to the DFI, dated October 11, 1995.

We have completed our preliminary review of your response to the DFI, and find that we need additional information and/or clarification on several issues.

We note that your response discussed several initiatives which were not raised in the DFI. Examples of these initiatives include auditing the AMS radiation protection program and upgrading the standard operating procedures. We are encouraged by these positive initiatives.

At the exit meeting, both NRC and AMS were in agreement that definite emphasis should be placed on the reduction of the radioactive material inventory located at the AMS facility. This requires that AMS restore its hot cell to operability for inventory reduction efforts. In your response, you designated the recovery of the capabilities of the hot cell, and the subsequent reduction of sealed source and bulk cobalt 60 inventory, as intermediate priority actions, to be completed within the next one to three years in accordance with your priority scheme. We consider that a higher priority should be given to these actions. Furthermore, given the importance of the inventory reduction, we request estimated completion dates rather than the "TBD" stated in Table 3 of your response. In addition, you should describe the actions taken to date and planned, to identify a market for the sealed and bulk sources.

We also regard the training of the offsite emergency response personnel in AMS' Emergency Plan, and the subsequent emergency exercise, as high priority actions. We expect this training to take place expeditiously after NRC approves the Emergency Plan, as you stated in your response, and the exercise to follow within two months after the training is completed. Therefore, you should designate these actions as high priority actions.

Regarding Item A.2. of the DFI (offsite disposal of wastes), we consider this action to be a high priority action, given that: (1) these wastes are the only radioactive material at AMS which are in a potentially dispersible form, and (2) offsite disposal of wastes is now possible due to the recent reopening of the licensed low-level waste disposal facility at Barnwell, South Carolina. Please note that for materials licensees, NRC does not consider storage as a

substitute for disposal (see Information Notice 90-09). Low level waste should be stored only when disposal capacity is unavailable and for no longer than is necessary. The only exception to this is storage for decay, which is generally authorized for radionuclides with half-lives of 120 days or less. This issue has direct bearing on your Decommission Funding Plan, and will be addressed, with comments regarding the "Conceptual Decommissioning Plan," in a separate correspondence from Region III.

We request specific justification if the actions discussed in the above three paragraphs are not designated as high priority actions with specific schedules assigned.

Regarding Item B (inventory), we agree that the health and safety significance of reducing the inventory of sealed and bulk sources, which requires the use of the hot cell, outweighs the health and safety significance of removing the stuck plug of the hot cell's front storage well and completing the physical inventory. However, the further postponement of the removal of the plug and the subsequent completion of the physical inventory necessitates that AMS request an amendment to License Condition 14. The new completion date for the physical inventory should expeditiously follow the completion date for the reduction of the inventory of sealed and bulk sources, and must not extend past June 30, 1998, the date of the next required physical inventory.

Regarding Item D (decommissioning/decontamination of the WHUT room), your response did not address these issues. Please describe your plan of action for the decommissioning/decontamination of the WHUT room.

Regarding Item E (decontamination of the facility), in your response you state: "AMS is not operating under a decommissioning order, therefore this item is not applicable. Further, the contamination in the referenced areas is adequately controlled such that workers and members of the public do not incur 'avoidable risks' merely by its presence." As we stated in the DFI, 10 CFR 20.1101(b) requires a licensee to use, to the extent practicable, procedures and engineering controls to achieve radiation doses to workers and members of the public that are as low as is reasonably achievable (ALARA). Moreover, AMS is required, by License Condition 22, to decontaminate restricted areas if surface contamination levels exceed 40,000 disintegrations per minute per 100 square centimeters (dpm/100 cm<sup>2</sup>).<sup>1</sup> Consistent with ALARA principles, your plan should address steps that will be taken to further reduce contamination levels and permit a greater degree of worker safety and accessibility throughout the facility. Therefore, you should re-address this issue and describe your plan of action for the decontamination of the AMS facility.

Regarding the disposition of the 100,000 gallons of treated water, we note that this is a low priority action. Please provide us information regarding the expected long term (3-5 years) integrity of the collapsible storage tanks.

<sup>1</sup> Letter from S. J. Stein to NRC, dated July 23, 1990.

We also wish to inform you that the structural integrity inspection conducted by R. Shewmaker of NRC Headquarters has been completed. We will forward the complete inspection report to you as soon as it is available. The inspection revealed several concerns which may have an effect on several issues discussed in the DFI (e.g., the Emergency Plan, and the Decommissioning Funding Plan). Therefore, in your response to this letter, please address the issues discussed in the structural integrity inspection report.

A response to this letter is requested within thirty days after receiving the aforementioned structural integrity inspection report.

Questions concerning this letter should be addressed to Mr. James L. Caldwell, Deputy Director, Division of Nuclear Materials Safety, Region III, who can be reached at (708) 829-9801.

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

Sincerely,

Original signed by  
Hubert J. Miller  
Regional Administrator

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

See Attached Distribution

March 19, 1996

Robert Meschter  
Radiation Safety Officer  
Advanced Medical Systems, Inc.  
1020 London Road  
Cleveland, OH 44110

Dear Mr. Meschter:

In my February 22, 1996 letter, I indicated that NRC's analysis of water samples obtained on February 13, 1996, from Advanced Medical Systems, Inc. (AMS) Tank 880, was still in progress. This letter is to provide you with the final results on those water samples. The results, summarized in the enclosure, do not differ qualitatively from the preliminary results, in that they show that: (1) samples taken from the bottom of tank 880 contained insoluble cobalt-60, and (2) samples taken from the top of the tank did not contain detectable cobalt-60.

Please do not hesitate to contact me should you have further questions.

Sincerely,

Original signed by  
Geoffrey C. Wright, Acting Deputy Director  
Division of Nuclear Materials Safety

Enclosure: As stated

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# ENCLOSURE

## Results of NRC's Analysis of Water and Filters from Tank 880

### Water Samples

Top or Bottom	Sample Number	Filtered or Unfiltered	Count Time (hours)	Activity (pCi/l)	MDA (pCi/l)
bottom	1	unfiltered	17.4	176 ± 13	19
bottom	1	filtered	26.8	30.6 ± 5.3	13
bottom	2	unfiltered	15.8	162 ± 16	24
bottom	2	filtered	56.9	14.0 ± 5.5	12
bottom	3	unfiltered	25.9	80.5 ± 8.2	15
top	1	unfiltered	2.6	< MDA	53
top	2	unfiltered	17.2	< MDA	22
top	3	unfiltered	24.8	< MDA	18
top	4	unfiltered	23.5	< MDA	16

### Filter Samples

Top or Bottom	Sample Number	Count Time (hours)	Activity (pCi)	MDA (pCi)
bottom	1	24.4	17.2 ± 1.2	1.5
bottom	2	24.6	20.6 ± 1.3	1.6
top	1	14.4	< MDA	2.1
top	2	15.7	< MDA	1.7
top	3	11.0	< MDA	2.3
top	4	22.6	< MDA	1.7

#### NOTES:

(1) MDA stands for minimum detectable activity.



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03211

David Cesar, Vice President  
Advanced Medical Systems, Inc.  
121 North Eagle Street  
Geneva, Ohio 44041

Dear Mr. Cesar:

We have reviewed your letter dated October 20, 1995 with its accompanying "Conceptual Decommissioning Plan" (Plan). The letter and Plan were submitted in response to our August 17, 1995, deficiency letter.

The purpose of this letter is to summarize our review of your response. We will address: (1) the requirement for decommissioning financial assurance, (2) our August 17 letter and your response, and (3) the AMS Plan - SAFSTOR vs. DECON.

As you are aware, decommissioning financial assurance for the possession of byproduct material is required pursuant to 10 CFR Part 30, Section 35. This regulation requires certain licensees to submit a decommissioning funding plan (DFP), which includes a cost estimate and a financial assurance instrument, to cover the costs of future decommissioning in the event that decommissioning is required at the present time. In other words, the cost estimate and financial assurance instrument must cover the decommissioning costs if decommissioning began today, as opposed to a projected decommissioning date in the future. The amount of financial assurance required is based upon the quantity of material authorized on a license.

Our August 17 letter primarily discussed two issues which pertain to the cost estimate AMS submitted in support of decommissioning financial assurance. To summarize, the issues are: (1) NRC's request that AMS revise its facility characterization to include an assessment of the radiological conditions of the soil under the basement and WHUT room floors, and (2) incorporation of the current disposal costs at Barnwell into AMS' DFP. In your October 20 letter, you did not address issue (1). As stated in our letter, we are not confident that the three core samples taken through the basement slab prior to the flood are representative of the current radiological conditions of the soil under the basement and WHUT room floors. The presence of radioactivity under the floor would presumably increase the quantity of licensed material and therefore, increase the cost estimate for decommissioning financial assurance. Enclosed is a copy of our August 17 letter. Please submit an evaluation of the radiological conditions of the soil under the basement and WHUT room floors, or justify why the three core samples should be considered representative of the current radiological conditions.

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Contained within your Plan is a description of two methods for decommissioning the AMS facility - SAFSTOR and DECON, and the associated costs required for each method (910,000 dollars for the SAFSTOR option, and approximately 3.3 million dollars for the DECON option). After comparing and contrasting these two options, AMS proposes to establish approximately 910,000 dollars financial assurance based on a SAFSTOR approach using a 50 year storage period. The deferment of decommissioning through implementation of SAFSTOR is only applicable to power reactors. The Statement of Considerations for the 1988 decommissioning rulemaking (53 FR 24018) states, "The intent of the rule is to provide the necessary guidelines with regard to use of decommissioning alternatives in a manner which protects the public health and safety." In the 1988 rulemaking, provisions for deferring dismantlement are applicable only to power reactors where up to a 60 year period is specifically allowed. Deferred decommissioning for materials licensees and non-power reactors is not specifically allowed.

The supporting analyses in the "Generic Environmental Impact Statement on Decommissioning Nuclear Facilities" (GEIS), NUREG-0586, indicates that there may be cases for materials licensees where deferred decommissioning may be the most protective of public health and safety. In Chapter 14 of the GEIS, it is stated that deferred dismantlement could be a preferred option for source manufacturers which use short-lived nuclides that decay within a few weeks or months. However, longer SAFSTOR periods are not discussed as being suitable. In comparison to the utilities, the financial stability of many materials licensees is uncertain. Therefore, by providing decommissioning financial assurance below a level that would fund complete remediation of the facility at any time during the SAFSTOR period, the public taxpayer would be forced to accept a decommissioning obligation that substantially exceeds the proposed level of funding.

As presented in your plan, SAFSTOR is equivalent to decay-in-storage. Current NRC policy limits authorization for decay-in-storage to radionuclides with half-lives no greater than 120 days. NRC considers storage of radioactive waste with half-lives greater than 120 days as extended interim storage. Extended interim storage requires specific authorization. Furthermore, NRC policy states that extended interim storage of low level waste should not be a substitute for disposal to a licensed waste facility if access is available.

Therefore, unless a materials licensee does not have access to a disposal facility, all radioactive waste with half-lives exceeding 120 days should be shipped off-site. As stated in our October 31, 1995, letter regarding your application for renewal, we feel strongly that AMS should take the opportunity to ship its radioactive waste to Barnwell.

Table 3 to your Conceptual Decommissioning Plan entitled "Manpower and Cost Estimates" lacks the specificity the NRC needs to verify your cost estimate. A cost estimating table that organizes and provides an acceptable format to

D. Cesar

-3-

the NRC for determining decommissioning cost components and activities is illustrated in Appendix F to Regulatory Guide 3.66 (enclosed). It provides an extensive checklist of decommissioning activities that must be included in a decommissioning cost estimate. Resubmit your cost estimating table using the format provided in Appendix F.

We will continue our review of your application upon receipt of the information requested in this letter. Please reply in duplicate, within 30 days, and refer to Control Number 98507.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 829-9887.

Sincerely,

Original Signed By  
John R. Madera, Chief  
Nuclear Materials Licensing Branch

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

Enclosures: As stated

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