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

OFFICE OF THE
GENERAL COUNSEL

August 6, 1996

Marshall E. Miller
Presiding Officer
877 Heatherstone Avenue Apt. 606
Mountain View, CA 94040

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

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

Dear Administrative Judges:

Pursuant to 10 C.F.R. § 2.1231(c), attached please find the following documents to be included in the hearing file for this proceeding.

67. Letter to Mr. David Cesar, Vice President, Advanced Medical Systems, Inc. from Cynthia D. Pederson, Director, Division of Nuclear Materials Safety, Region III, U.S. Nuclear Regulatory Commission, re: May 7, 1996 meeting regarding disposal of cobalt-60 and waste, May 23, 1996.

68. Letter to Ms. Cynthia D. Pederson, Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission from David Cesar, Vice President and Treasurer, Advanced Medical Systems, Inc., re: Building Recovery Project, Advanced Medical Systems, Inc. (License No. 34-19089-01), June 10, 1996, with attachment, Building Recovery Project.

69. Letter to Mr. Hubert Miller, Regional Administrator, Region III, U.S. Nuclear Regulatory Commission from Robert Meschter, RSO, Advanced Medical Systems, Inc., re: Strategic Plan (USNRC License No. 34-19089-01), June 7, 1996.

70. Letter to Mr. J.R. Madera, Chief, Nuclear Materials Licensing Section, Region III, U.S. Nuclear Regulatory Commission from Robert Meschter, RSO, Advanced Medical Systems, Inc., re: Advanced Medical Systems Inc. (License No. 34-19089-01) Emergency Plan, June 7, 1996.

71. Letter to Mr. Geoffrey C. Wright, Acting Deputy Director, Division of Nuclear Materials Safety, Region III, U.S. Nuclear Regulatory Commission from Robert Meschter, RSO, Advanced Medical Systems, Inc., re: USNRC Inspection Report No. 030-16055/95006 (DNMS), June 7, 1996.

72. Letter to Mr. Geoffrey C. Wright, Region III, U.S. Nuclear Regulatory Commission from David Cesar,David Cesar, Vice President and Treasurer, Advanced Medical Systems, Inc., re: Advanced Medical Systems, Inc. Application to Amend USNRC License No. 34-19089-01, July 1, 1996.

73. Letter to Mr. Hubert Miller, Regional Administrator, Region III, United States Nuclear Regulatory Commission, from Robert Meschter, RSO, Advanced Medical Systems, Inc., re: Strategic Plan (USNRC License No. 34-19089-01), July 10, 1996.

74. Letter to David Cesar, Vice President and Treasurer, Advanced Medical Systems, Inc. from Kevin G. Null, Nuclear Materials Licensing Branch, Region III, U.S. Nuclear Regulatory Commission, re: Amendment No. 44, August 5, 1996, with enclosures, 1) Amendment No. 44; 2) Safety Evaluation Report.

Sincerely,

Marian L. Zobler
Counsel for NRC Staff

Enclosures: As stated

cc w/encl.: Service List

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

May 23, 1996

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

Dear Mr. Cesar:

During our May 7, 1996 meeting, you described a proposal to dispose of the majority of your bulk and sealed cobalt-60, and contaminated waste. We support your initiative to remove the majority of the bulk and sealed cobalt-60 material and contaminated waste from the Advanced Medical Systems, Inc. (AMS) London Road site. However, we have questions regarding how you intend to fund this initiative in that active licensees, such as AMS, that decommission portions of their facilities, typically do so using funds from sources other than those set aside in decommissioning financial assurance instruments. Nevertheless, we are open to any proposal that will improve the radiological conditions at the London Road facility and facilitate eventual decommissioning.

During the May 7, 1996 meeting, you indicated there are time constraints on signing a contract for disposal of the material. To facilitate NRC's timely review of your proposal, we need the following information:

1. Other Sources of Funding for Proposed Removal and Disposal of Radiological Material

   Confirm and demonstrate that AMS has exhausted all reasonable means to secure funding for the proposed radiological material removal and disposal aside from the current decommissioning financial assurance instrument.

2. Precise Source of Funding if Funds Set Aside for Decommissioning are Used

   Provide details on the amount and precise source of funding AMS is proposing to use to fund the radiological material removal and disposal. If the source of funding could affect the existing letter of credit (e.g., funds which presently serve as collateral for the letter of credit), describe how the instrument will be affected.

3. Effect of Material Removal on Decommissioning Plan

   Provide an estimate of the impact on the current decommissioning plan, including funding, that will result from the disposal of the material.

If AMS proceeds in accordance with its proposal, it will be required to take the following actions:

1. Revision to Decommissioning Plan and Cost Estimate

   If AMS is able to remove and dispose of the bulk and sealed sources and contaminated waste as proposed, it must submit a revised "Conceptual Decommissioning Plan" for NRC approval (the original plan dated October 20, 1996, is still being reviewed). This plan must include a revised radiological material inventory, as well as revised plans and costs for decommissioning the facility.

2. SAFSTOR and DECON

   The NRC has not made a decision as to whether AMS' use of the SAFSTOR approach to decommissioning originally proposed in its Conceptual Decommissioning Plan is acceptable. Accordingly, your revised Conceptual Decommissioning Plan and cost estimate(s) should address both prompt decommissioning (DECON) and delayed decommissioning (SAFSTOR).

3. Submittal of New Decommissioning Financial Assurance Instrument

   If funds for the proposed materials removal and disposal are used such that the net value of the current letter of credit is reduced, AMS must submit a new letter of credit for NRC approval.

If AMS proceeds in accordance with its proposal, the matter of AMS' final decommissioning cost estimates will remain unresolved. That matter will be addressed separately.

In accordance with 10 CFR 2.790, a copy of this letter and your response will be placed in the NRC Public Document Room (PDR). If AMS finds it necessary in its response to provide any information that it considers being proprietary under section 2.790(a)(4), AMS will file an application for withholding in accordance with section 2.790(b) and will also file a non-proprietary version that can be placed in the PDR.

Sincerely,

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

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

See Attached Distribution

Distribution

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
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Jane Harf, Chairperson
Ohio State Emergency Response
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Columbus, OH 43216-3669

Marian Zobler
U.S. Nuclear Regulatory Commission
Rockville, MD 20555

#0003

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

July 10, 1996

Mr. Hubert Miller
Regional Administrator, Region III
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: Strategic Plan (USNRC License No. 34-19089-01)

Dear Mr. Miller:

On August 29, 1995, a meeting was held at the request of Advanced Medical Systems, Inc. (AMS) to discuss an action plan for addressing outstanding issues that are of mutual interest to AMS and the USNRC in a timely fashion but within the resources currently available to AMS. In that meeting, AMS agreed to submit to the USNRC a written plan for meeting its short-term, intermediate-term and long-term objectives. That plan was, in fact, submitted on October 11, 1995.

Included in the plan was a commitment to provide quarterly updates on AMS's progress toward meeting its goals. Enclosed is Revision 3 of the "Strategic Plan for the London Road Facility", which is being submitted in response to our commitment. If you have any questions or if I can provide you with additional information, please call me at (216) 692-3270. You may expect to receive Revision 4 of the plan in October of 1996.

Sincerely,

Robert Meschter

Robert Meschter, R.S.O.

cc: D. Cesar
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM
Assistant General Counsel for Hearings and Enforcement, USNRC
D. A. Cool - Director, Division of Industrial and Medical Nuclear Safety, USNRC
C. D. Pederson - Director, Division of Radiation Safety and Safeguards, USNRC
J. Caldwell - Deputy Director, Division of Radiation Safety and Safeguards, USNRC
M. Weber - Region III, USNRC

STRATEGIC PLAN FOR THE LONDON ROAD FACILITY

Submitted by:

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio 44110
(216) 692-3270

Report No. 94009/G-3113, Revision 3
July 10, 1996

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INTRODUCTION

Advanced Medical Systems, Inc. (AMS) manufactured and fabricated sealed sources of ^{60}Co for teletherapy and radiography machines. Under the provisions of U. S. Nuclear Regulatory Commission (USNRC) license No. 34-19089-01, and as of the date of this report, AMS possesses approximately 54,000 curies of ^{60}Co, and 2,200 kilograms of depleted uranium (nickel plated) for use as shielding material.[1] Included are approximately 40 curies of radioactive material in a potentially dispersible form. This material, which consists primarily of dry solid waste, carbon granules and ion exchange resins, is stored in sealed 55-gallon drums or B-25 (steel) boxes. The types and quantities of licensed materials currently in the possession of AMS are shown in Table 1.

As part of its license compliance efforts, AMS is faced with completing a number of tasks ranging from license renewal to significant reductions in the existing radionuclide inventory. Timely completion of these activities is critical since they will ultimately result in streamlined routine operations, recovery of needed building/facility capabilities, and reduced regulatory demands on the operating staff.

However, due to limited personnel and financial resources, it is not possible for AMS to complete all of the outstanding activities in a single campaign. Therefore, to avoid unnecessary and negative financial impacts on the company, yet ensure steady and well-managed progress toward completion, the activities were prioritized based upon an activity's ability to improve the implementability of other activities, AMS's ability to fund the activity in the near-, intermediate- and long-term, and on the cost/benefit associated with the activity's timely completion. Table 2 shows the listing of the outstanding activities, along with their priorities (e.g., high priority, intermediate priority, and lower priority).[2]

A number of additional activities not shown in Table 2 will run concurrent with the prioritized activities. These include audit/assessment of the radiation protection program, upgrade of standard operating procedures, improvements in housekeeping, and attempts to increase community relations.

The remainder of this report contains additional discussion on each of the outstanding activities. Included is a brief discussion of the AMS strategy for each activity, the plan of action for completing the activity, a description of the current status (as of the date of this report) and an implementation schedule, where appropriate.

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[1] There is negligible radiological hazard associated with the depleted uranium inventory. Therefore, it is not addressed further in this report.

[2] In general, high priority items are scheduled for completion within the next year, intermediate priority items within the next one to three years, and lower priority items within the next three to five years.

Over the intermediate and long term, as actions are completed and as the scope/approach of specific activities (subitems) become solidified, the individual action plans will be expanded and specific dates will be entered in the implementation schedules. Therefore, this report will be revised on a quarterly basis and numbered revisions will be issued.

HIGH PRIORITY ACTIONS

Complete the Remediation Report

In late 1994, the Northeast Ohio Regional Sewer District (NEORSD) intentionally isolated AMS access to regional sewage treatment system. This action rendered the facility drainage system non-functional, increased the hydrostatic pressure on the foundation structure, and caused groundwater to enter the basement of the AMS facility. After AMS made timely notification to the USNRC about the deteriorating conditions at the building, AMS initiated action to drain the basement, remove the ^{60}Co from the water in the basement, remediate the foundation drainage system, isolate the residual radioactivity in the manhole and sewer line exiting the facility to the London Road Interceptor, and remediate the residual radioactivity in the London Road interceptor.[3]

One commitment made to the USNRC as part of the remediation project was to provide a final report that contains a description of the events that led to the site conditions, a review of the remedial actions implemented and their results, and a summary of all data acquired during the process. However, since all remedial activities are not yet complete, the final remediation report is still being compiled. Outstanding items are disposition of water in the collapsible storage tanks, disposition of contaminated solids (e.g., soils and water treatment media), implementation of the long-range surveillance plan for residual radioactivity that exists outside of the AMS building (e.g., in the abandoned footer drains and lateral connection from the building to the London Road Interceptor), disposition of water in the WHUT Room, and remediation of the London Road Interceptor.

In regard to the residual water in the WHUT Room, AMS investigated the use of a stabilizing agent known as STERGO™, solid granular, cross-linked polymer that rapidly absorbs and retains large quantities of aqueous-based liquids. It was considered because it is non-toxic, will hold from 12 to 40 times its weight in aqueous solutions, and testing indicates that its capacity to retain liquids at high dose rates and large integrated doses is good. However, on June 10, 1996 AMS forwarded to the USNRC a proposal for the Building Recovery Project. Task 3 of the proposal is to stabilize the radiological conditions in the basement and WHUT Room in order to reduce the impact of water incursion. Actions to address residual water are thus delayed pending USNRC acceptance of the proposal.

In regard to the contaminated solids from the excavation (rock, soil) that exist outside the AMS facility, a lined wooden structure was built on the south west quadrant of the property, approximately 200 feet from the building. These solids were transferred to the structure shortly thereafter. The structure and its environs have been posted pursuant to RSP-011, "Posting and Labeling", and have been included in the quarterly radiological surveillance program pursuant to RSP-008, "Instrumentation and Surveillance".

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[3] As of the date of this report, the NEORSD has not permitted AMS access to the London Road Interceptor. AMS's ability to complete the remediation is beyond its control.

In regard to the long-range surveillance plan for residual radioactivity, AMS submitted the plan to the USNRC on September 5, 1995. After a December 14, 1995 submission of additional information, the plan was approved as modified by the USNRC on January 18, 1996. On May 16, 1996, AMS implemented the provisions of the January 24, 1996 version of the plan with one exception. On May 23 1996, AMS submitted an application to amend the Plan in order to delay until Spring of 1997 the installation of the two wells referenced in the Plan. The purpose of the delay was to permit AMS to finalize other operational decisions pertaining to water handling and to better-coordinate well installation activities. As of the date of this report, there has been no USNRC action on the May 23, 1996 license amendment request.

Once all of the actions associated with the water treatment and sewer remediation project are complete, the remediation report will be finalized and submitted to the USNRC. However, for reasons that are beyond AMS's control, remediation of the London Road Interceptor may be delayed significantly. Therefore, AMS may elect to submit the Remediation Report in advance and exclusive of this item. Table 3 shows the action plan for this task.

License Renewal Application

In early 1995, AMS submitted an application to renew its USNRC license under the provisions of timely renewal. After initial USNRC review of the application, a letter of deficiency was issued and additional information was requested. Subsequently, an in-house review of the application, in light of the short- and long-range plan of AMS, was completed. This review confirmed that the application was indeed cumbersome and permitted AMS little flexibility in achieving its intermediate- and long-term goals. Therefore, a significantly revised application was submitted on October 30, 1995.

On December 5, 1995, the USNRC asked AMS to provide copies of the Radiation Safety Procedures that were referenced in the revised application. These were transmitted to the USNRC in three (3) separate submittals dated January 3, 1996, February 13, 1996 and March 8, 1996. To date, AMS has received no additional response from the USNRC and continues to operate under the provisions of the existing license. Table 3 shows the action plan for this task.

Emergency Plan

As part of license renewal efforts, an emergency plan was submitted to the USNRC for review and comment. On June 7, 1995, after initial USNRC review of the Plan, a letter of deficiency was issued and additional information was requested. Because the magnitude of deficiencies was significant, a revised Plan was submitted on September 22, 1995. This revision was consistent with the guidance contained in USNRC Regulatory Guide 3.67 (1992), "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities".

On February 28, 1996, the USNRC mailed comments on Revision 0 of the Emergency Plan. The AMS response to those comments was forwarded on March 22, 1996, along with the AMS response to comments received from the Ohio Environmental Protection Agency, the Ohio Emergency Management Agency, the Cuyahoga Emergency Management Assistance Center, the

Ohio Department of Health, and the City of Cleveland Division of Fire were forwarded to these agencies and to the USNRC.

On March 12, 1996, AMS received the results of a special inspection directed toward the structural integrity of the London Road facility. A number of the issues raised in the inspection report are pertinent to the Emergency Plan. The AMS response to those comments was submitted to Geoffrey Wright (USNRC) on June 7, 1996. The structural issues that pertained specifically to Emergency Plan comments were addressed in a June 7, 1996 letter to John Madera (USNRC). Table 3 contains the action plan for this task.

Decommissioning Funding Plan

As part of the recent license renewal efforts, a decommissioning funding plan was submitted to the USNRC for review and comment. On August 17, 1995, after initial USNRC review of the Plan, a letter of deficiency was issued and additional information was requested. Specifically, the USNRC indicated that the January 1995 cost estimate and site characterization submitted by AMS "are no longer valid". However, the January 1995 estimate was based upon a "decontaminate and release" decommissioning option, which is not suitable for a facility like AMS where the primary radionuclide of concern has a radiological half life of only five years. Therefore, AMS prepared a Conceptual Decommissioning Plan for the facility pursuant to 10 CFR 40.46(d) that is based upon a "safe storage" decommissioning option.[4]

The Plan, which was submitted to the USNRC on October 20, 1995, describes the decommissioning objective for the facility and its basis, a description of the items to be decommissioned, the proposed decommissioning methodology, an ALARA analysis to support the proposed methodology, a cost estimate (1995 costs) for implementing the methodology, and a review schedule for ensuring the Plan's continued applicability for the duration of License No. 34-19089-01. Once approved by the USNRC, AMS intended that the Plan will be funded by the corporation and reviewed for continued applicability on a planned and periodic basis.

On March 20, 1996, the USNRC mailed comments on the Plan, along with a request for additional information. The AMS response to these comments was forwarded to John Madera (USNRC) on April 12, 1996.

On June 10, 1996 AMS forwarded to the USNRC a proposal to complete a Building Recovery Project, the result of which would be a significantly reduced inventory of radioactive materials at the London Road facility. In that proposal, AMS requested that the USNRC to release a portion of the funds AMS has committed for decommissioning in order to support commercial disposal costs. One justification for this request is that the cost of decommissioning will be less than that reflected in the October 20, 1995 Conceptual Decommissioning Plan due to the reduction in inventory and restricted areas. At the request of the USNRC, AMS submitted an application to amend its radioactive materials license reflect a reduction from the current financial assurance

[4] Pending its concurrence with the Conceptual Decommissioning Plan, the USNRC did, in a January 8, 1996 letter to AMS, accept AMS's decommissioning financial assurance submittal based upon the January, 1995 cost estimate.

amount of $1,800,000 to $940,000 on June 26, 1996. As of the date of this report, there has been no USNRC action on this amendment request. Table 3 contains the action plan for this task.

Train First Responders in Emergency Plan Provisions

As part of its emergency response requirements, AMS must provide annual radiation safety training for first responders. Pursuant to the revised Emergency Plan, this training must include a review of items of mutual interest, instruction in emergency procedures, radiation protection guidelines, and the responder's anticipated role in an emergency. During the training session, the emergency response team activation scheme, notification procedures, and overall response coordination process will be reviewed.

Within 60 days after USNRC approval of the revised Emergency Plan, a training session for first responders will be scheduled. After training is complete, agency attendance will be documented and letters of agreement will be updated, as necessary. The training sessions will be scheduled annually thereafter. Table 3 contains the action plan for this task.

Stage Emergency Exercise and Perform Critique

As part of its emergency response requirements, and in order to maintain emergency preparedness, AMS must conduct an emergency exercise on a planned and periodic basis. Within 60 days after all first responders have received initial training in the provisions of the AMS Emergency Plan, the emergency exercise will be scheduled and staged.

Pursuant to the revised Emergency Plan, the exercise will include one or more of the accident scenarios postulated for the facility, and will involve off-site agencies that have provided letter agreements for support services (e.g., first responders). The scenario will not be known in advance by exercise participants, and a non-participating observer will provide an evaluation of the effort, along with recommendations for improvement.

The critique of the exercise will be used as a basis for modifying the Emergency Plan or for supplementing the training of off-site agencies. Deficiencies identified during critiques will be corrected and closure will be documented. As necessary, changes to the Emergency Plan, based upon the findings of the critique, will be implemented. Table 3 contains the action plan for this task.

INTERMEDIATE PRIORITY ACTIONS

Recover Hot Cell Capabilities

In order to decontaminate, leak test, package and ship sealed sources of ^{60}Co from the AMS facility, a functional hot cell is needed. Currently, the Hot Cell contains significant residual removable radioactivity. Consequently, cross-contamination of items that enter the Hot Cell is a concern. Therefore, AMS intended to recover sufficient Hot Cell capabilities to support inventory reduction efforts.

Shortly after issue of the initial version of this Strategic Plan, the Hot Cell capabilities that were needed to facilitate inventory reduction were evaluated. From this evaluation, it was determined that improved lighting and construction of a source transfer mechanism were the only items necessary to support initial inventory reduction. These items were implemented, a successful "trial run" of the system occurred on December 19, 1995, and the system became fully operational on December 27, 1995.

Return NPI Sources

There are currently 34 sealed sources in the AMS inventory that belong to Neutron Products Inc. (NPI). As part of on-going operations, AMS purchases sources from NPI for delivery to a customer. When the shipping cask is sent to NPI, one of the sources in the AMS permanent inventory is enclosed, thereby reducing the inventory.

AMS has attempted, without success, to escalate the return of all of the remaining sources now that Hot Cell capability has been recovered. Since NPI will accept only one returned source for each source shipped, the rate of reduction in the NPI inventory will significantly slower than expected. Nonetheless, AMS is proceeding with this task at the highest possible rate. As sources leave the London Road facility, the inventory log is debited. Table 3 contains the action plan for this task.

Identify a Market for Remaining Sources and Bulk Material

There are approximately 54,000 curies of sealed ^{60}Co sources and bulk ^{60}Co metal in the AMS inventory. AMS has attempted to identify a domestic or foreign market for this material. On March 20, 1996, AMS prepared and distributed a description of the type, form and curie content of the sources to a variety of agencies, including source distribution firms, government agencies, and non-domestic agencies. Included with the description was a form soliciting the level of interest of each recipient. Although a number of potential users were identified, their needs are for sources with significantly greater activity than is present in the AMS inventory. Therefore, AMS has not met with success in transferring the inventory to other users

After many conversations and levels of negotiation, it was determined that the relatively small volume but high activity of the sealed source inventory could provide a cost-mitigating factor for conventional disposal. This fact placed conventional disposal of the sources into the realm of financial possibility if AMS is permitted to "tap" funds that are currently held by the USNRC for

decommissioning funding. Therefore, on June 10, 1996 AMS forwarded to the USNRC a proposal for the Building Recovery Project, which included a brief description of the AMS facility and its planned operations, the reason why AMS wishes to implement the Building Recovery Project, a description of the Project's 12-point scope of work, a proposed project schedule, and the proposed mechanism whereby the project will be funded. Task 1 in the proposal is to dispose of all accessible sealed ^{60}Co sources and all canisters of bulk ^{60}Co at a commercial low level waste burial ground.

On July 8, 1996, AMS submitted an application to amend its USNRC license to permit commercial disposal of the sources and canisters. As of the date of this report, there has been no USNRC action on this amendment request. Table 3 contains the action plan for this task.

LOWER PRIORITY ACTIONS

Remove Plug in the Hot Cell

An estimated 4,000 curies of ^{60}Co in the form of sealed sources are located in a storage well in the Hot Cell. Because the well plug has become lodged in the well, these sources cannot be removed and included in the inventory reduction efforts. Therefore, AMS intends to dislodge the plug.

A methodology for dislodging the plug has been determined, and a contract for services has been let. Once the decision is made to proceed and the work plan and Radiation Work Permit have been completed, equipment and personnel will be staged, "dry runs" will be completed, and the plug will be removed. Table 3 contains the action plan for this task.

Decontaminate the Hot Cell

After the plug removal project is complete, significant residual radioactivity will likely exist within the Hot Cell. In order to ensure its continued usefulness, AMS intends to decontaminate the Hot Cell to levels necessary to support planned future operations.

The first step in the process will be determination of the methodology for Hot Cell decontamination. Once complete, the work plan will be prepared, outside services, if necessary, will be contracted, and the project will begin. Table 3 shows the action plan for this task.

Complete/Confirm the Physical Inventory and Transfer/Ship Remaining Sources

After removal of the plug, AMS will be able to confirm the physical inventory of licensable radioactive material present at the London Road facility. (AMS is obliged, by License Condition 14, to complete a physical inventory of all sources in its custody. In light of the low priority associated with this task and the activities that are scheduled to be performed for the Building Recovery Project, AMS intends to submit an application to amend Provision 14(c) of License No. 34-19089-01 requesting an exemption from performing a physical inventory of the sources in the stuck plug until the plug is removed. Included in the application will be an accounting of the sealed source status for the year prior to the application, a summary of surveillance information confirming that "unaccounted for" sources do not exist at the facility, and a commitment to complete the physical inventory once the stuck plug is removed. Table 3 contains the action plan for this task.

Disposition of Solid Waste at the Facility

As shown in Table 1, there are about 3,000 cubic feet of solid waste at the AMS facility. These materials are stored either within the AMS facility, or in a secured storage location within the fenced portion of the property.

On June 10, 1996 AMS forwarded to the USNRC a proposal for the Building Recovery Project. Task 2 of the proposal is to dispose of all dry solid waste currently stored in the facility basement and in the high-level waste storage through a commercial low-level waste broker. On July 8, 1996, AMS submitted an application to amend its USNRC license to permit this operation to

proceed pursuant to modified operating procedures. As of the date of this report, there has been no USNRC action on this amendment request. Table 3 contains the action plan for this task.

Disposition of Treated Water in Collapsible Storage Tanks

As part of the 1995 sewer remediation project, approximately 100,000 gallons of water was treated by the methodology of sub-micron filtration and reverse osmosis in order to reduce its radionuclide content to below drinking water standards. There are approximately 40 microcuries of ^{60}Co in the water, which is currently stored in collapsible storage tanks at the London Road facility. The solubility of the residual radioactivity was confirmed using American Public Health Association's Method 7110 "Gross Alpha and Gross Beta Radioactivity (Total, Suspended, and Dissolved)" from Standard Methods for Examination of Water and Wastewater.

AMS requested and received permission from the U. S. Environmental Protection Agency (USEPA) and the USNRC to evaporate this water. However, due to delays and difficulties in implementing the treatment process that were beyond AMS's control, more than four times the original amount of water had to be treated to reduce its concentration of radioactive cobalt at a cost that went well-beyond the original projection. In light of the magnitude of these unbudgeted expenses, the evaporation option became significantly more costly. Therefore, AMS is pursuing other options for disposing of the water.

Since the treated water meets the USEPA's criteria for man-made radionuclides in drinking water pursuant to 40 CFR 141, and since it contains no other hazardous substances, its presence at the AMS facility poses no radiological risk. Therefore, there is no urgency to ensure its final disposition. Nonetheless, AMS will pursue a direct discharge option until such time as it becomes patently unattainable. At that time, the evaporation option will be re-visited in light of available financial resources. Table 3 contains the action plan for this task.

ON-GOING ACTIONS

Audit/Assessment of Radiation Protection Program

In light of changing operational issues, pending licensing activity, and the desire to "streamline" compliance efforts, AMS intends to perform a series of audits of its radiation protection program in order to compare AMS's performance to that required and/or recommended by existing license/permit provisions, U. S. Nuclear Regulatory Commission regulations, and standard industry practices (e.g., USNRC Regulatory Guides, ANSI, ASME and ASTM Standards, ICRP Publications, NCRP Publications). The audits will be performed by AMS personnel and consultants to AMS. They will involve initial review of applicable operating procedures, quality assurance procedures, and other pertinent documentation related to a particular performance issue.[5] The initial document review is performed in order to identify possible areas of failure or liability, and to derive an efficient schedule for on-site assessments. While on site, AMS compliance with existing procedures will be determined and areas of inefficiency or poor function, as compared to industry standards and practices, will be identified.

On June 27, 1996, AMS prepared Radiation Safety Procedure No. RSP-020, "Quality Assurance Audits". Once this procedure is approved by the Radiation Safety Committee and after License No. 34-19089-01 has been renewed, the audit schedule will be set and incorporated into the computerized tracking program. While the results of the audits are intended to be used for demonstrating compliance and/or to guide future program modifications or improvements, any findings of significant regulatory non-compliance or conditions of imminent hazard will be immediately reported to and addressed by the RSO. Immediately after renewal of License No. 34-19089-01, the Radiation Safety Committee will set the audit schedule.

Upgrade of Standard Operating Procedures

In response to audit findings, and in light of changing operational demands and licensing activities, the current collection of standard operating procedures (ISPs) were reviewed for continued applicability. Wherever possible, multiple procedures that address a single topic were combined, and out-dated procedures were revised. Consistency between procedures was confirmed and compliance with the requirements of the AMS Radiation Protection Program Plan was assured. Since October 10, 1995, the following new/revised procedures have been developed and approved by the Radiation Safety Committee, and submitted to the USNRC for review:

- RSP-001, Radiation Protection Program Plan

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[5] The following programmatic issues will be audited on a planned and periodic basis: Organization and Administration; Facilities and Equipment; Training in Radiation Protection; Radiation Exposure Control; ALARA Program; Contamination Control; Instrumentation and Surveillance; Posting and Labeling; Receipt and Control of Radioactive Material; Packaging and Transportation of Radioactive Materials; Control of Radioactive Waste; Radiation Protection Records; Documentation; Emergency Response and Notifications; and Quality Assurance in Radiological Protection.

- 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
- RSP-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

Immediately after renewal of License No. 34-19089-01, these procedures will be implemented in their entirety.

Housekeeping Improvements

Currently, there are only three permanent employees at the London Road facility. Therefore, only a small fraction of the available space is used for routine operations, office areas and storage. However, AMS has instituted improvements in housekeeping in the useable areas of the facility.

On May 15, 1996, AMS instituted an aggressive program of waste consolidation, equipment decontamination, and facility surveys as part of the Building Recovery Project. In fact, Task 6 of the Project is to free-release (for unrestricted use) the London Road building, with the exception of the WHUT Room, the Hot Cell, the ventilation system, and an ancillary work area. This work is proceeding on an escalated schedule so that all waste generated can be disposed of under Task 2 of the Project.

Community Relations

In the past, issues or activities at AMS that required state, federal and local approvals were hampered due to lack of knowledge of AMS operations and/or an understanding of the fundamental principles of radiation and radioactivity on the part of decision-makers. In an effort to streamline future decision-making, AMS has mounted a community relations program to acquaint various officials and members of the print and broadcast media with the AMS function, its capabilities, and its short-, intermediate-, and long-range plans. This has been accomplished, on an as-needed basis, through briefings, tours, and development/publication of hand-out materials and brochures.

Reconnection of Sewer System to London Road Interceptor

Currently, the London Road facility does not have a direct connection to the regional sewer system. There are no sanitary discharges from the building, the roof drains discharge onto the ground surface, and all groundwater is pumped from a manhole on the property into storage tanks. Once a tank is full, the water is sampled and discharged. Since December 22, 1995, over 140,000 61,000 gallons of water have been collected, analyzed, and found to be free of insoluble ^{60}Co.[6] However, a series of extenuating circumstances have increased the urgency in reconnecting all drainage paths to the London Road Interceptor.

AMS is barred, by court order, from freely releasing the ground/surface water that collects in the remediated foundation drainage system. Therefore, on July 1, 1996, AMS renewed its March 1, 1995 and March 20, 1995 applications to amend its USNRC license to permit free-release of foundation drainage since USNRC authorization to free-release the water is a necessary part of a permanent legal solution. As of the date of this report, there has been no USNRC action on the July 1, 1996 license amendment request. However, once USNRC and legal authority to freely discharge the storm/ground water that collects in the foundation drainage system of the London Road building has been received, AMS will operate a temporary automatic pumping system to remove water that accumulates in the new manhole. This water will be discharged to a storm sewer catch basin on the west side of the building's west parking lot. AMS will then pursue the legal authority to re-institute a permanent (gravity-fed) discharge system.

---

[6] Cobalt-60 was identified in two 3,000-gallon batch tanks and one 25,000 gallon frac tank. However, the source of this contamination was the tanks themselves, which were used as process tanks for the water treatment project. The residual ^{60}Co that remained in the batch tanks when they were first filled with water from the remediated underdrain system was removed by filtration. Sampling of subsequent batches of water held in these tanks has been negative for the presence of ^{60}Co. Remedial action for the frac tank is delayed pending resolution of a non-radiological issue.

TABLES

Table 1 - Cobalt-60 Inventory as of July 3, 1996

Item	Form	Material Description	Estimated Activity (Ci)
Licensed Material	Solid	Bulk Metal and Sealed Sources	53337
Packaged waste	Solid	Materials contained in high-level waste storage, LSA boxes and drums in the basement of the facility.	28
Packaged waste	Solid	Solid waste generated during the water treatment project.	0.4
Unpackaged waste	Solid/sludge	Materials contained in WHUT Room	51
Surface radioactivity	Solid	Uncharacterized surface activity in the restricted areas of the facility	1
TOTALS			53417

Table 2 - Action Plan Summary[7]

High Priority Activity	Intermediate Priority Activity	Lower Priority Activity
Submit the Remediation Report for the water treatment and sewer remediation project	Recover the capabilities of the Hot Cell.	Remove the plug in the Hot Cell and extract the remaining sources
Finalize site emergency plan.	Reduce the inventory of sealed sources and bulk cobalt.	Decontaminate the Hot Cell.
Submit conceptual decommissioning plan		Complete the physical inventory of sources.
Finalize decommissioning funding plan.		Ship out remaining sources
Finalize license renewal activities.		Dispose of solid waste
Implement training requirements of the approved site emergency plan (e.g., train first responders and perform emergency exercise and critique)		Pursue disposition of treated water that currently exists in the collapsible storage tanks.

[7] Shaded areas denote closure.

Table 3 - Action Plan for Each Task[8]

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
Complete Remediation Report	Determine remedial alternative for the WHUT Room	8/29/95	10/3/95	Closed. Solidification has been identified as the preferred alternative.
	Determine storage methodology for contaminated solids	8/29/95	10/3/95	Closed. Construction of an above-ground storage container has been identified as the preferred alternative.
	Stabilize liquids that currently exist in the WHUT Room	10/3/95	3/1/96	To be addressed as part of the Building Recovery Project.
	Implement storage option for contaminated solids	10/3/95	4/30/96	Closed.
	Finalize and submit remediation report	8/1/95	TBD	Pending resolution of AMS/NEORSD litigation
	Begin direct discharge of ground and surface water from the AMS foundation drainage system.	1/15/96	TBD	Pending resolution of AMS/NEORSD litigation and reconnection of sewer system
License Renewal Application	Submit revised application	9/11/95	10/31/95	Closed. Application mailed to USNRC on 10/31/95
	Begin operations under provisions of renewed license.	1/1/96	TBD	Pending USNRC action on renewal application
Emergency Plan	Submit revised Emergency Plan to the USNRC	8/15/95	9/30/95	Closed. Plan mailed to USNRC and first responders on 9/26/95.
	Submit response to USNRC and agency comments on Revision 0 of Emergency Plan.	2/28/96	3/28/96	Closed. Comments mailed to USNRC and first responders on 3/22/96.
	Submit response to USNRC inspection report on structural integrity of the building	3/12/96	4/12/96	Closed. Response mailed to USNRC on 6/7/96.
	Begin operations under provisions of approved plan.	1/1/96	TBD	Pending USNRC approval of Emergency Plan.

[8] As actions are completed and as the scope/approach of specific activities (subitems) become solidified, the individual action plans will be expanded and specific dates will be entered in the implementation schedules. Changes will be noted in future revisions of this Plan. Shaded entries denote closure.

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
Decommissioning Funding Plan	Submit Conceptual Decommissioning Plan	9/8/95	10/23/95	Closed. Plan mailed to USNRC on 10/20/95.
	Submit response to USNRC comments on Conceptual Decommissioning Plan.	3/20/96	4/20/96	Closed. Response mailed to USNRC on 4/12/96
	Submit Revision 1 of Conceptual Decommissioning Plan	7/1/96	8/30/96	Open
	Submit Decommissioning Funding Plan	9/1/96	9/15/96	Open
	Scheduled review of Conceptual Decommissioning Plan and Decommissioning Funding Plan for continued applicability	TBD	One (1) year after USNRC approval	Pending USNRC approval of Decommissioning Funding Plan
Recover Hot Cell Capabilities	Determine Hot Cell requirements for inventory reduction.	8/29/95	10/27/95	Closed.
	Specify Hot Cell recovery actions	11/1/95	12/1/95	Closed
	Implement recovery actions	12/1/95	1/1/95	Closed
Return NPI Sources	Evaluate residual radioactivity on NPI Sources	9/11/95	9/15/95	Closed.
	Determine decontamination methodology	9/25/95	11/24/95	Closed.
	Perform "trial run" of decontamination methodology.	11/1/95	12/20/95	Closed
	Decontaminate and leak test sources	12/20/95	1/1/97	Ongoing
	Package and ship sources	12/20/95	1/1/97	Ongoing
Identify a Market for Remaining Bulk Cobalt	Identify domestic market possibilities	8/1/95	12/31/96	Closed.
	Identify foreign market possibilities	11/1/95	12/31/96	Closed.
	Prepare and mail solicitation letters to market possibilities.	2/15/96	4/1/96	Closed Letters mailed on 3/22/96
	Determine and implement permitting requirements	12/31/96	6/1/97	Closed. No longer applicable
	Complete contracts with purchasers	TBD	TBD	Closed. No longer applicable
	Package and ship sources	TBD	TBD	Closed. No longer applicable

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
Transfer Sealed Sources and Bulk Cobalt to Authorized Recipient	Submit license amendment to release decommissioning funds to fund transfer cost	6/1/96	7/5/96	Complete. Amendment application mailed to USNRC on 6/26/96
	Submit license amendment to permit source shipment pursuant to applicable Radiation Safety Procedures and vendor instructions.	6/1/96	7/5/96	Complete. Amendment application mailed to USNRC on 7/5/96
	Execute contract with waste broker	6/1/96	7/15/96	Open
	Package and stage the sources.	TBD	TBD	Unscheduled
	Prepare necessary permits and licenses	TBD	TBD	Unscheduled
	Ship Waste	TBD	TBD	Unscheduled
Train First Responders in Emergency Plan Provisions	Receive USNRC approval of the Emergency Plan	10/20/95	TBD	Pending response from USNRC
	Schedule initial first responder training session	10 days after USNRC approval	TBD	Unscheduled pending USNRC approval of the Emergency Plan
	Complete training and documentation	60 days after USNRC approval	TBD	Unscheduled
	Obtain updated letters of agreement, as necessary	TBD	TBD	Unscheduled
	Schedule refresher training	TBD	TBD	Unscheduled
Implement an Emergency Exercise and Critique	Schedule emergency exercise	60 days after completion of training	TBD	Unscheduled pending completion of first-responder training
	Prepare scenario	TBD	TBD	Partially complete
	Contract outside observer	TBD	TBD	List of qualified personnel prepared.
	Initiate emergency exercise	TBD	TBD	Unscheduled
	Generate critique report	TBD	TBD	Unscheduled
	Modify Emergency Plan in light of critique findings	TBD	TBD	Unscheduled

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
Remove Plug in Hot Cell	Determine methodology for plug removal	7/1/95	8/1/95	Closed
	Generate specifications plan for plug removal	7/1/95	8/1/95	Closed
	Issue Request for Quotation for plug removal	7/1/95	8/1/95	Closed
	Review bids and issue contract for services	7/1/95	8/1/95	Closed
	Prepare work plan and Radiation Work Permit	TBD	TBD	Unscheduled
	Mobilize personnel and equipment	TBD	TBD	Unscheduled
	Train personnel in provisions of work plan	TBD	TBD	Unscheduled
	Perform dress rehearsals	TBD	TBD	Unscheduled
	Remove plug	TBD	TBD	Unscheduled
Decontaminate the Hot Cell	Specify Hot Cell decontamination methodology and clean-up criteria	TBD	TBD	Unscheduled pending plug removal
	Generate work plan for decontamination activities	TBD	TBD	Unscheduled
	Contract decontamination services, as necessary	TBD	TBD	Unscheduled
	Mobilize equipment and personnel	TBD	TBD	Unscheduled
	Complete decontamination	TBD	TBD	Unscheduled
	Request amendment to License Condition 14 to postpone the physical inventory requirement pending plug removal.	5/1/98	6/30/98	Open pending action by USNRC on October, 1995 license renewal application
Complete/Confirm Inventory and Transfer/Ship Remaining Sources	Confirm physical inventory of remaining sealed sources	TBD	TBD	Unscheduled pending final decontamination of Hot Cell
	Evaluate residual radioactivity on remaining sources	TBD	TBD	Unscheduled
	Decontaminate and leak test sources	TBD	TBD	Unscheduled
	Obtain shipping cask	TBD	TBD	Unscheduled
	Package and ship sources	TBD	TBD	Unscheduled

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
Stabilize WHUT Room and Free-Release Basement	Secure engineering design for WHUT Room stabilization.	6/15/96	7/15/96	Open
	Contract stabilization services.	6/15/96	8/15/96	Open
	Contract decontamination services	6/15/96	7/15/96	Complete
	Decontaminate basement using HEPA-filtered scabbling	1/1/97	3/1/97	Open
	Stabilize WHUT Room using engineer-specified stabilizing agents and hydrological seals	1/1/97	3/1/97	Open
	Perform final status survey on basement	3/1/97	4/1/97	Open
Disposition of Solid Waste at the Facility	Evaluate disposition options in light of Conceptual Decommissioning Plan.	10/1/95	TBD	Complete
	Select the preferred option based upon an ALARA analysis.	TBD	TBD	Complete
	Submit license amendment to release decommissioning funds to fund disposal cost.	6/1/96	7/5/96	Complete. Amendment application mailed to USNRC on 6/26/96.
	Submit license amendment to permit waste shipment pursuant to applicable Radiation Safety Procedures.	6/1/96	7/5/96	Complete. Amendment application mailed to USNRC on 7/5/96
	Execute contract with waste broker	6/1/96	12/1/96	Open
	Characterize the materials.	6/1/96	12/5/96	Open
	Prepare necessary permits and licenses	11/1/96	12/5/96	Open
	Ship Waste	12/5/96	2/1/97	Open
Disposition of Treated Water in Collapsible Storage Tanks	Identify disposition options.	8/1/95	TBD	Open
	Prepare necessary permits and licenses	TBD	TBD	Unscheduled
	Implement preferred disposition option.	TBD	TBD	Unscheduled

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

June 7, 1996

Mr. Hubert Miller
Regional Administrator, Region III
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: Strategic Plan (USNRC License No. 34-19089-01)

Dear Mr. Miller:

Advanced Medical Systems, Inc. (AMS) is in receipt of your December 6, 1995 letter wherein additional information relating to the September 17, 1995 Demand for Information (DFI) was solicited. We responded to the issues raised in that letter in Revision 1 of the "Strategic Plan for the London Road Facility", and again in my letter to you dated April 24, 1996. However, we deferred our response to one of the comments as follows:

> **USNRC Comment:** 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 Plan). Therefore, in your response to this letter, please address the issues discussed in the structural integrity inspection report.
>
> > **AMS Response:** In an April 9, 1996 letter from R. Meschter (AMS) to G. C. Wright (USNRC), the USNRC was informed that AMS scheduled an independent evaluation of the findings of the Shewmaker inspection report. Once the evaluation is complete, a discussion of the issues contained in the Shewmaker report would be submitted to the USNRC by June 12, 1996. In an April 11, 1996 letter from G. C. Wright to R. Meschter, the USNRC approved this schedule.
> >
> > **Action Taken:** This comment will be resolved in the AMS response to the Shewmaker inspection report, which will be submitted to the USNRC by June 12, 1996.

AMS addressed the structural integrity issues raised by Mr. Shewmaker (Inspection Report No. 030-16055/95006) in a June 7, 1996 letter to Mr. G. Wright (USNRC). By this submission, AMS responded to the only outstanding USNRC comment from the December 6, 1995 request for information.

Please call me at (216) 692-3270 if I can answer any questions or provide you with additional information.

Sincerely,

Robert Meschter, R.S.O.

cc: D. Cesar
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM
Assistant General Counsel for Hearings and Enforcement, USNRC
D. A. Cool - Director, Division of Industrial and Medical Nuclear Safety, USNRC
C. D. Pederson - Director, Division of Radiation Safety and Safeguards, USNRC
G. Wright - Acting Deputy Director, Division of Radiation Safety and Safeguards, USNRC
M. Weber - Region III, USNRC

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

June 7, 1996

Mr. J. R. Madera, Chief
Nuclear Materials Licensing Section
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: Advanced Medical Systems Inc. (License No. 34-19089-01) Emergency Plan

Dear Mr. Madera:

Advanced Medical Systems, Inc. (AMS) is in receipt of your letter dated February 28, 1996 wherein comments on Revision 0 of the AMS Emergency Plan were provided. On March 21, 1996, we provided you with our responses and a description of our proposed follow-up actions. However, in that transmittal, we deferred our response to your Comment 2, "Engineers Opinion Report", pending receipt/review of USNRC Inspection Report No. 030-16055/95006. Since that review is now complete and all of the outstanding issues raised in the report have been addressed, attached is our response to Comment 2.

Once you have approved the responses and follow-up actions contained herein and in our March 21, 1996 letter, the Emergency Plan will be revised in accordance with our commitments. Revision 1 of the Plan will then be distributed to the USNRC and to those individuals on our "first responders" list. Shortly thereafter the first responders will be trained in the provisions of the Plan, and the first emergency drill will be scheduled.

If I can answer any questions or provide you with additional information, please call me at (216) 692-3270. We are looking forward to timely approval of our Emergency Plan.

Sincerely,

Robert Meschter

Robert Meschter, RSO

cc: D. Cesar
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM
M. Weber - USNRC, Region III

RESPONSE TO COMMENTS FROM
U. S. NUCLEAR REGULATORY COMMISSION

Agency Comment (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.

AMS Response: In a June 7, 1996 letter from R. Meschter (AMS) to G. Wright (USNRC), AMS addressed the structural integrity issues raised in Inspection Report No. 030-16055/95006. This response, which included a report generated by Dr. James Beavers, P.E., demonstrates that, baring unforseen circumstances, the AMS building on London Road is capable of providing protective confinement of the licensed radioactive materials in the restricted areas for many years into the future.

Action Taken: None required.

Agency Comment (2): Engineers Opinion Report - 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.

AMS Response: Concur. In a June 7, 1996 letter from R. Meschter (AMS) to G. Wright (USNRC), AMS provided a seismic analysis of the London Road facility (Attachments I and II of Dr. Beavers report). In that submission, we confirmed that if an earthquake were to occur, the horizontal loads would be transmitted into the hardened areas of the building (e.g., the WHUT Room, the Hot Cell and the High-level Waste Storage Room). As a result, the first floor unreinforced masonry load-beraing wall would see little, if any seismic load, there would be no displacement of the first floor, and there would be negligible, if any, displacement of the second floor. Although pre-existing cracking in the southeast corner of the building could initiate a partial building collapse in the event of an earthquake, the ability of the building to confine the licensed radioactive materials contained therein would not be compromised. Thus the impact of an earthquake-related emergency at the AMS facility is consistent with that reflected in Revision 0 of the Emergency Plan.

Action Taken: Page 2-3, lines 2 through 5, and Page 2-4, lines 1 through 3 of the "Emergency Plan for the London Road Facility" will be modified to reflect the findings in Dr. Beavers' report. References to the Engineers Opinion Report will be removed.

Advanced Medical Systems, Inc.
1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

June 7, 1996

Mr. Geoffrey C. Wright
Acting Deputy Director,
Division of Nuclear Materials Safety
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC Inspection Report No. 030-16055/95006 (DNMS)

Dear Mr. Wright:

Advanced Medical Systems, Inc. (AMS) is in receipt of your March 12, 1996 letter in regard to the referenced inspection report. In that report, the USNRC concluded that the 1994-1995 basement flooding had no observable impact on the structural integrity of the London Road facility. However, the USNRC asked AMS to provide an evaluation of the facility's ability to provide protective confinement of the radioactive materials stored therein over the facility's intended use period; plans for structural remediation, if warranted; and plans to periodically inspect and evaluate the building's ability to perform its defined functions over the intended use period.

Enclosed is the AMS response to the inspection report and to the USNRC's March 12, 1996 request. These responses are based upon the findings of an independent evaluation of the building's status that was performed by Dr. James Beavers, P.E. (MS Technologies, Inc., Oak Ridge, Tennessee). If you have any questions, please call me at (216) 692-3270.

Sincerely,

Robert Meschter

Robert Meschter, R.S.O.

enc.
cc: D. Cesar
D. Miller - Stavole & Miller
C. Berger - IEM
M. Weber - USNRC Region III

JUN 14 1996

RESPONSE TO COMMENTS FROM
U. S. NUCLEAR REGULATORY COMMISSION

Agency Comment 1: The depth and extent of cracking, structural impact, and any measures identified as necessary to repair the cracking identified in the load-bearing masonry wall in the 1958 building's southeast corner [should be addressed]. Associated distress that could limit the facility's ability to continue to provide protective confinement of the radioactive materials should also be assessed and corrective actions identified as necessary.

AMS Response: AMS contracted a registered Professional Engineer to perform an independent evaluation of this comment. The engineer's report of findings, included herein as Appendix A, states that the cracking noted by the inspector is likely from differential settlement, but that the vertical load-carrying capacity of the wall has not been significantly reduced as a result. He also confirms that a failure of the building at this location would not result in a breach of the concrete core structure wherein licensed radioactive materials are stored.

Action Taken: None required.

Agency Comment 2: The depth and extent of cracking, structural impact, and any measures identified as necessary to repair the cracking identified in the 1958 building's north bay of the east masonry filler/curtain wall [should be addressed]. Associated distress, caused by the introduction of moisture and other waterborne contaminants, that could limit the facility's ability to continue to provide protective confinement should also be assessed and corrective actions identified as necessary.

AMS Response: In the engineer's report of findings (Appendix A), it states that the cracking noted by the inspector is the result of the second floor in-filled wall moving outward over the lobby area. However, he confirms that the cracking and associated distress does not limit the facility's ability to provide protective confinement, and that a failure of the building at this location would not result in a breach of the concrete core structure wherein licensed radioactive materials are stored.

Action Taken: None required.

Agency Comment 3: The precast concrete roof panels that in several areas exhibit corrosion products on the visible surface [should be addressed].

AMS Response: The engineer's report of findings states that no evidence of roof decking structural degradation was noted upon inspection.

Action Taken: None required.

Agency Comment 4: The second floor concrete slab in the area where it forms the ceiling of the hallway in front of the hot cell and the radiography room, which exhibits the effects of previous fluid penetration through the slab from above [should be addressed].

AMS Response: The engineer's report states that equipment failure in the equipment room has caused leakage on the second floor. However, he concludes that the floor slab's structural strength has not been compromised as a result of the leak.

Action Taken: None required.

Agency Comment 5: The need to periodically inspect and evaluate the building's ability to perform its defined functions over the utilization period [should be addressed]. If a program is deemed appropriate, it should include inspection frequencies and evaluation activities.

AMS Response: The engineer's report concludes that even with no repair or maintenance the AMS building on London Road is capable of providing protective confinement for its licensed radioactive materials inventory for many years into the future. Therefore, a routine inspection program is not required.

Action Taken: None required. However, to ensure the long-term useability of the remainder of the building in light of the instances of cracking, settling, and distress that were noted by both the USNRC inspector and the AMS structural engineer, a survey program to monitor the movement of the walls for the purpose of predicting future corrective actions will be instituted. For this program, a survey crew will be contracted to set up a base of measurement for the north wall (first bay) of the 1963 building, the east wall of the 1963 building, the wall above the lobby of the 1958 building, and the southeast corner of the building. The crew will then return approximately six (6) months later to determine if any movement occurred. If none is noted, the survey will be repeated every two (2) years thereafter. However, if the six-month survey does reveal movement, a registered Professional Engineer will be asked to specify the frequency of future surveys in light of the magnitude of movement.

In addition to the survey program, the AMS radiation protection staff, as part of the routine surveillance program described in RSP-008, "Instrumentation and Surveillance", will inspect the building at the locations of interest in order to identify unusual conditions. Any follow-up action that might be warranted (e.g., repeat surveillance, repair, re-construction) will be specified by a registered Professional Engineer.

APPENDIX A
SEISMIC AND STRUCTURAL REVIEW OF ADVANCED MEDICAL SYSTEMS LABORATORY FACILITIES

INTEGRATED ENVIRONMENTAL MANAGEMENT

SEISMIC AND STRUCTURAL REVIEW OF ADVANCED MEDICAL SYSTEMS LABORATORY FACILITIES

by
James E. Beavers, Ph.D., P.E.
Vice President

June 6, 1996

MS Technology, Inc.
118 Ridgeway Center
Oak Ridge, Tennessee 37830

SEISMIC AND STRUCTURAL REVIEW OF ADVANCED MEDICAL SYSTEMS LABORATORY FACILITIES

AN ASSESSMENT

There were five areas addressed in the March 12, 1996, Nuclear Regulatory Commission letter (Wright 1996) concerning structurally distressed areas of the Advanced Medical Systems Laboratory Facility (AMSLF) shown in Figure 1. In the letter's attachment, a list of detailed concerns was provided for each of the five areas. Attachment I provides a response to those concerns. The five major areas of concern and this reviewer's response to them are provided below. Attachment II addresses seismic and tornado issues.

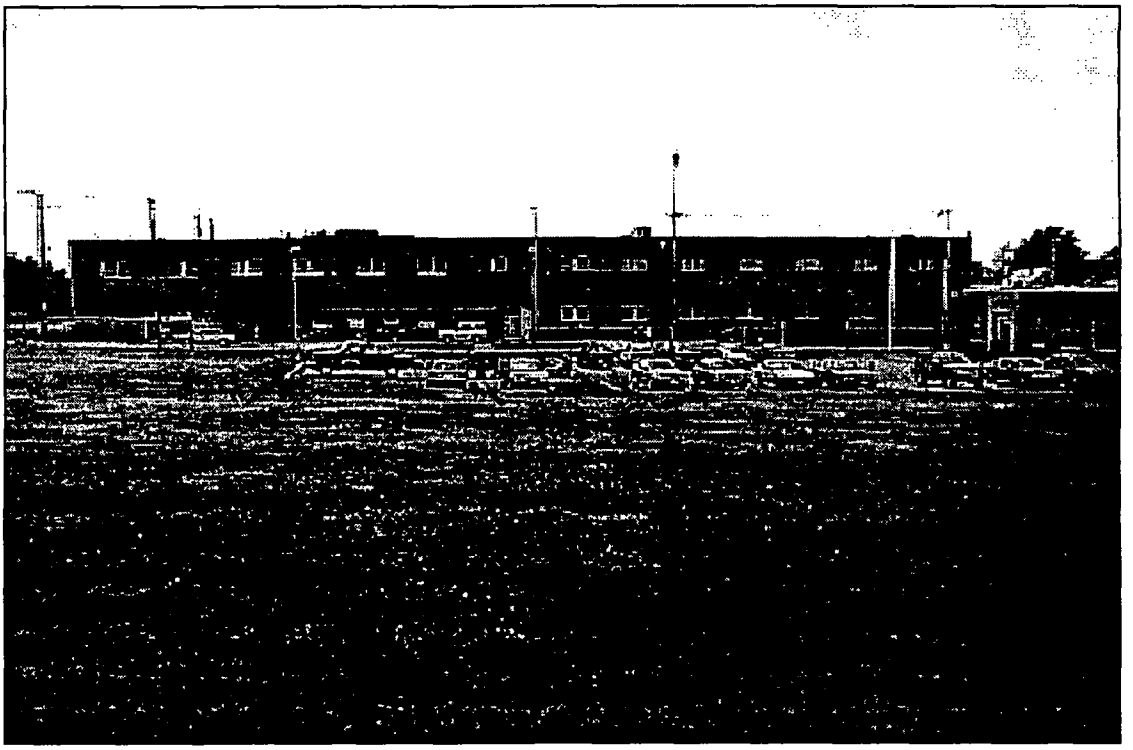

Figure 1. Advanced Medical Systems Laboratory Facility (looking west).

THE FIVE MAJOR NRC CONCERNS AND REVIEWER'S RESPONSE

1. *The depth and extent of cracking, structural impact, and any measures identified as necessary to repair the cracking identified in the load-bearing masonry wall in the 1958 building's southeast corner. Associated distress that could limit the facility's ability to continue to provide protective confinement of the radioactive materials should also be addressed and corrective actions identified as necessary.*

Response: As described in the NRC report, the cracking does exist. From the outside, the cracking appears to stop just short of the area where the second floor slab ties into the common wall brick. From inside the building below the second floor, it is evident that cracking does extend through the wall; however, it is not continuous, i.e., the cracking on the inside of the wall is almost an opposite pattern. From inside the building above the second floor, the east and south walls in the corner show no cracking; however, there are four cracks in the second floor slab that are visible to the human eye. One very large crack is nearest the corner, is at an approximate 45° angle to each wall, has a width of one-half inch, and has a length from wall to wall of about six inches. Based on the width of the crack nearest the corner, it appears that the southeast corner has moved southeast a distance of as much as one-half to three-quarters of an inch. These floor cracks seem to indicate excessive bending moment in the floor slab at this corner, which would be indicative of significant settlement at the corner. Underneath the second floor slab, matching crack patterns were found.

Unfortunately, it is difficult to tell what actually caused cracking at the southeast corner of the building. As noted in the NRC report, the structural support of the 1958 building is a mix of load and non-load bearing masonry and concrete block, reinforced concrete, and steel framing. These materials are not compatible from an aging and expansion point of view. In addition, the stiffness properties of the structure vary from extremely stiff (the test cell and radiography room) to very flexible (the lobby area). If a significant lateral or vertical load were to be applied to this location of the building, a localized corner failure of the building would occur between the first and second floors, while due to the purlin bearing on the east wall at the corner, a much broader area of the roof in the west direction would collapse. However, due to the construction of the building, this reviewer does not believe that such a loading would lead to overall collapse of the building. Such a failure would not cause loss of containment in the radioactive storage area of the garden room, WHUT room, or radiography room. In fact, based on the massive concrete walls, general building collapse would not cause loss of containment. See Attachment I for more detailed discussion.

2. *The depth and extent of cracking, structural impact, and any measures identified as necessary to repair the cracking identified in the 1958 building's north bay of the east masonry filler/ curtain wall. Associated distress, caused by the introduction of moisture and other waterborne contaminants, that could limit the facility's ability to continue to provide protective confinement should also be assessed and corrective actions identified as necessary.*

Response: Upon inspection of this wall's cracking and movement, it appears evident what is occurring. Basically, it is a problem of the second floor in-filled wall moving outward over the lobby area between the steel columns at Column Lines D and F. This movement can clearly be seen from the roof and is causing rotational stresses to be placed on the original corner of the 1958 building as the east-west wall tries to keep the east wall form moving outward. The fact that the 1958 building in-filled wall was placed tightly against the inner side of the outside column flange, and the fact that ties attached the two wythes of facing brick to the 1958 building concrete block, the 1958 building in-filled wall is being pulled outward next to Column F-1, failing the in-filled wall in shear at the edge of the flange. This is not a structural issue, but it is a life-safety issue. See Attachment I for more information on this issue.

The introduction of moisture and other waterborne contaminants has been minimized by the new roofs that were placed over the 1934 and 1958 buildings within the last five years. Minor migration of moisture may occur through small cracks through the building, but such moisture would not have an impact on the containment ability of the facility. A conceivable way for moisture and water contaminants to limit the facility's ability to provide protective containment or confinement could not be postulated. Obviously, if the in-filled wall of the second floor fell out into the street and was left open, serious penetration of moisture and waterborne contaminants could occur. Leaving the area of the failed wall open is an extremely unlikely event, unless the building were to be abandoned.

3. *The precast concrete roof panels that in several areas exhibit corrosion products on the visible surface.*

Response: While evidence of corrosion exists in some areas of visible roof decking, no structural degradation was noted. Thus, while past leakage has caused appearance problems, there appears to have been no structural degradation of the roof decking. See Attachment I for more details.

4. *The second floor concrete slab in the area where it forms the ceiling of the hallway in front of the hot cell and the radiography room, and exhibits the effects of previous fluid penetration through the slab from above.*

Response: Two chases, one for electrical service conduit and one for ventilation, penetrate the second floor from the first floor into the equipment room on the second floor. The equipment room has a 10-inch riser around its perimeter, including the two entrance doors; however, at both the conduit and ventilation chases, the risers are only two inches. In addition, at the ventilation chase, the riser has a 1½-inch deep notch in it. Thus, the maximum fluid that can be contained within the equipment room is about 40 gallons. Therefore, the fluid runs over the ½-inch riser, down the chase onto the false ceiling. The first time a leak of significance occurred, the fluid collected at the false ceiling and held there until the plaster of the false ceiling gave way. This leakage caused no deterioration of the second floor slab's structural strength, and the fluids did not penetrate the concrete floor slab. There is no visible degradation of the floor slab, and it is highly unlikely there has been any degradation. In addition, the main part of the equipment room is over the radiography room where the floor slab is 2-feet thick.

5. *The need to periodically inspect and evaluate the building's ability to perform its defined functions over the utilization period. If a program is deemed appropriate, it should include inspection frequencies and evaluation activities.*

Response: This concern is a management issue and is out of this reviewer's scope of responsibility.

REFERENCES

Wright, G.C. 1996. Letter Report to Mr. Robert Meschter, Advanced Medical Systems, Inc., Cleveland, Ohio, March 12.

ATTACHMENT I

NUCLEAR REGULATORY FACILITY INSPECTION REPORT ON THE ADVANCED MEDICAL SYSTEMS LABORATORY FACILITY

—

A RESPONSE

by
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The following provides responses to an itemized list of concerns, as identified by this reviewer, developed from the DETAILS of NRC Report No. 030-16055/95006 (DNMS) for the Advanced Medical Systems Laboratory Facility (AMSLF) (Wright 1996). Each concern is numbered first by section of the report and then by concern. To identify the location of each concern in the NRC Report, the concern is identified by page number, paragraph, and sentence. Thus, the identifier *2.1 CONCERN-3/1/2* is identifying a concern in Section 2, on Page 3 of the report, in Paragraph one of Page 3, and starting with the second sentence of the paragraph. This attachment addresses those concerns having to due with the basic structural integrity of the AMSLF. Seismic and tornado integrity of the AMSLF are discussed in Attachment II of the main report.

1. Persons Contacted

N/A

2. Purpose and Scope of Inspection

2.1 CONCERN-3/1/2: *The structural integrity of the building facility with areas of contamination, waste storage or source material storage needs to be assured for the expected future time period over which the radioactivity should be controlled...this time period may extend as much as an additional 25 to 30 years or more beyond the current time.*

2.1 RESPONSE: A sound maintenance program can result in such facilities' lifetimes being easily extended an additional 25 to 30 years.

2.2 CONCERN-3/2/1: *On-site inspections ...information related to the facility, the life of which to date has spanned nearly a forty-year period, with portions spanning over 60 years.*

2.2 RESPONSE: Based on two site inspections, the portion of the building built in 1934 as a stand- alone building appears to be in sound structural condition. Although no thorough inspection of the 1935 building was conducted, one inspection also included the attic and no noticeable cracking was found.

3. Background on the Development of the Facility

3.1 CONCERN-4/2/1: *The 1958 design, development and construction...encompassed the integration of a then existing warehouse/industrial building, with masonry load bearing walls and steel trusses as the roof framing steel...* This item was not a concern but a response is needed for clarification.

3.1 RESPONSE: The warehouse/industrial building referred to is not a complete load bearing masonry wall building with steel trusses, although at first glance it may appear to be. The building was constructed in 1934 as rectangular in shape. The east-west walls, the walls in the longer dimension (~100 ft), are non-load bearing masonry in-filled walls between steel-riveted columns that support the steel trusses. Some small amount of roof load between the trusses was originally carried by the east-west masonry wall, but this load was one-half of a purlin load, thus the wall typically would not be considered a load bearing wall. The tops of the east-west walls are basically unsupported in the out-of-plane direction except at the columns. At the columns, the masonry is placed flush with the column webs and a pilaster is built around the column flanges facing the original exterior of the building, with about six inches of brick covering the flanges. The sketch in Figure A-1 demonstrates the construction. Based on research done in the last 10 years (Henderson, et al., 1995), unreinforced masonry in-filled buildings provide excellent seismic resistance in low to moderate seismic zones. Although the 1935 building is not a true in-fill since the upper masonry walls are not confined by beams, the fact that they are in-filled within the floor and columns should provide lateral capacity of the building superior to a typical unreinforced load bearing wall. This is especially true where the old windows were filled in with masonry.

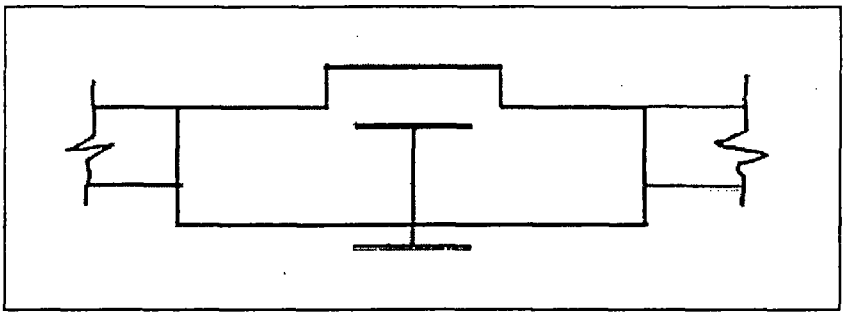


Figure A-1. Masonry pilasters and steel columns.

The north-south walls, the short dimension (~60 ft) of the building, are also constructed in the same fashion as the east-west walls. The only difference is the vertical columns at pilasters do not support any vertical load and the wall itself, between columns, supports one-half of the roof load that the trusses and columns support.

4. Design Basis of Building Facilities

4.1 CONCERN-6/1/1: *All of the loadings identified on the drawings, as noted above, include only vertical gravity loadings...*

4.1 RESPONSE: It would be extremely unlikely that seismic loads would have been included in the design. The BOCA Code of the Building Officials Code Administrators International introduced seismic design as an option in the late 1960s and made it mandatory in the late 1970s. However, in the 1950s and 1960s, the BOCA Code had requirements for wind design, although the city of Cleveland may have not adopted such code provisions. There is no evidence in any of the three buildings that special design features were made for lateral loads. However, the combined steel column and unreinforced masonry load and non-load bearing walls of the 1934 building, the unreinforced load bearing and in-filled steel column and beam walls of the 1958 building, and the 1963 building with Type II AISC column-to-beam connections all have inherent lateral strength for the typical wind and seismic loads of the region. For example, studies and tests on Type II connections used extensively in the 1940s and 1950s (Frye and Morris 1975) have shown they can provide lateral resistance through inherent moment capacity. Moment capacities for Type II connections using six-row fasteners, as used in the 1963 building, can generate moments up to 40,000 ft-lbs.

4.2 CONCERN-6/2/1: *The specifications for materials used in the structural system were, in general, not available...*

4.2 RESPONSE: There is a good chance that the concrete has a compressive strength in excess of 3000 psi since the compressive strength increases with age. If it was poured at 3000 psi, the compressive strength would now be in the neighborhood of 3700 to 4000 psi. Typical tests of such concrete shows the average strength to be 3800 psi. To determine the in situ concrete strength, core samples would have to be taken and then tested in the laboratory. However, based on the structural appearance of the concrete, i.e., there is no evidence of degradation, and the fact that long-term loads, even the seismic load, are not critical to the structural stability of the concrete structure, taking core samples and testing them does not seem warranted at this time.

4.3 CONCERN-6/2/2: *Dwg. F-1 indicated that the concrete for the foundation was to be 3000 psi concrete at 28-days, but no other information was provided on the properties of the reinforcing steel.*

4.3 RESPONSE: Based on the fact that intermediate grade reinforcing steel was commonly used at the time, the reinforcing steel is most likely intermediate grade having a specified yield strength of 40,000 psi. The extensive use of intermediate grade reinforcing steel began in the 1940s. For example, intermediate grade steel was used extensively in the 1940s, 1950s, and 1960s for the construction of high-level radioactive waste storage tanks at the Department of Energy's Hanford site in nearby Richland, Washington. Like concrete, the strength of the steel is typically higher than specified. Intermediate grade steel's mean yield strength is 49,000 psi. Its specified ultimate strength is 70,000 psi while its mean ultimate strength is 78,000 psi. Sample bars could be obtained for testing; however, as with the concrete strength, determining the in situ rebar yield and ultimate strengths does not seem warranted at this time.

5. Field Observations and Structural Evaluation

5.1 CONCERN-6/4/2: *In this area there is evidence of considerable amounts of water or other fluid apparently having penetrated on the second floor of the facility...*

5.1 RESPONSE: Two chases, one for electrical service conduit and one for ventilation, penetrate the second floor from the first floor into the equipment room on the second floor. The equipment room has a 10-inch riser around its perimeter, including the two doors, giving the impression that approximately 850 gallons of fluid would have to be spilled for a leak

outside the area to occur. This may have been the original intent; however, at both the conduit and ventilation chases, the risers are only two inches. In addition, at the ventilation chase, the riser has a 1½-inch notch in it. Thus, the maximum fluid that can be contained within the equipment is about 40 gallons. Therefore, the fluid runs over the ½-inch riser, down the chase onto the false ceiling. The first time a leak of significance occurred, the fluid collected in the false ceiling and was held there until the plaster of the false ceiling gave way as shown in Figure A-2.

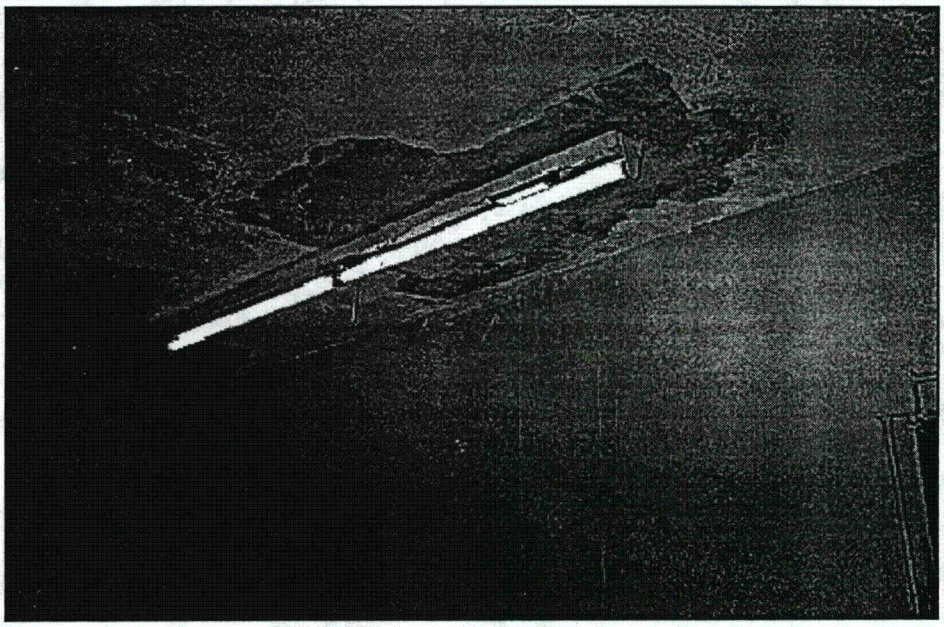


Figure A-2. Ceiling water damage.

This leakage caused no deterioration of the second floor slab's structural strength, and the fluids did not penetrate the concrete floor slab. There is no visible degradation of the floor slab, and it is highly unlikely there has been any degradation. In addition, the main part of the equipment room is over the radiography room where the floor slab is 2-feet thick.

5.2 CONCERN-6/4/4: *Evidence of the fluid that penetrated exists on the ceiling adjacent to the hot cell and in front of the radiography room and around the corner of the radiography room into a hallway at the north side of the radiography room.* (This was not a concern but a response is needed for clarification.)

5.2 RESPONSE: The first inspection of this AMSLF was conducted by this reviewer on April 30 through May 1, 1996. At that time, no ceiling water damage was noticed around the corner of the radiography room into a hallway at the north side of the radiography room.

A second inspection was conducted on June 3 to determine the discrepancy. While no water damage was noted in the false ceiling, it was quite apparent that fluid had run down the wall as shown in Figure A-3.

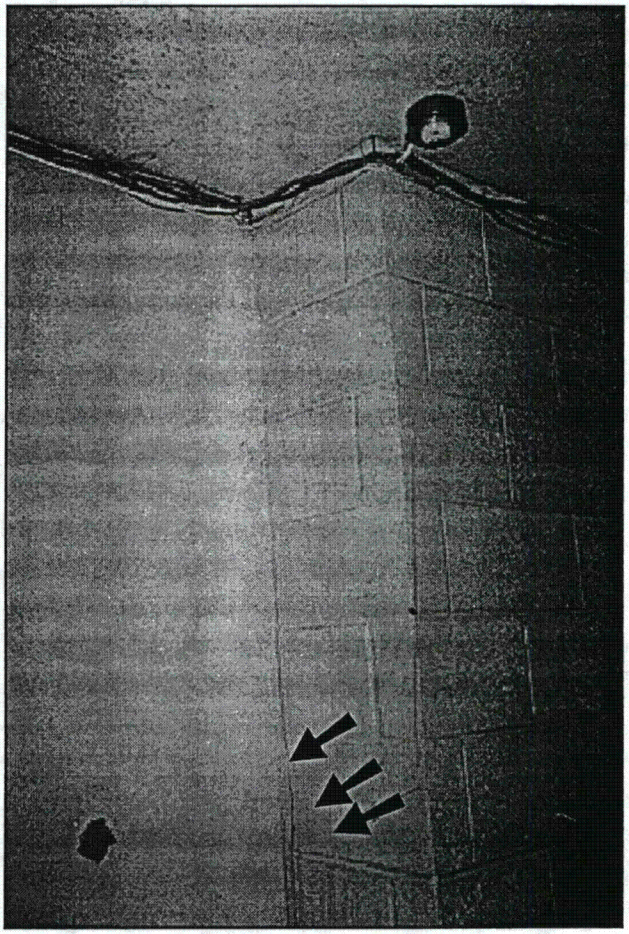


Figure A-3. No ceiling tile water damage but evidence of fluid on the wall

5.3 CONCERN-6/4/5: *It is not known what the source of this fluid was, but it could have been a source such as a ruptured pipe from freezing conditions or from the failure and leakage of exterior roof surfaces...*

5.3 RESPONSE: After discussing the potential source of the fluid with the operations manager and other staff, it became clear that most of the leaks had occurred as a result of equipment failures. For example, in the fall of 1995, a massive heat exchanger failed resulting in approximately 50 gallons of water being spilled into the equipment room which leaked

through to the first floor, as had previous leaks. In January 1995, a boiler leak occurred that caused leakage at the same location. Previous leaks caused the ~2 ft-by-2 ft ceiling plaster to fall from the false ceiling in this area. No one at the AMSLF knows the origin of the original leaks; however, most likely the leaks were caused by similar mechanical failures in the equipment room and possible roof leakage, especially since two major ventilation penetrations through the roof exist. However, it would take a serious roof leak to accumulate over 40 gallons of water.

5.4 CONCERN-6/4/7: *Evidence of significant roof leakage can be seen on the suspended ceiling of the second floor in several areas of the building...several areas such as in the southeast corner of the building and along the east front wall, there is evidence of water penetration of the roof deck structure.*

5.4 RESPONSE: Occasionally during the life of the building, leaks of the roof deck structure have occurred. In most all cases, the leaks have occurred where the roofing plies are tied into the older 1934 building or the parapet of the 1958 building. In October 1994, a new roof was placed over all of the 1958 building and the east half of the 1963 building. Thus, all of the current operating areas are protected by the new roof. In 1991, the roof over the 1934 building was replaced. It was not determined when the west portion of the 1963 building was last roofed. Minor leakage has occurred once or twice during a recent winter. No leakage has been observed since. While past leakage has caused appearance problems, there has been no apparent structural degradation of the building as a result (see also Response 5.5).

5.5 CONCERN-6/4/9: *This structure is made up of haydite (lightweight) precast concrete roof panels, that exhibit corrosion products from the embedded reinforcing steel.*

5.5 RESPONSE: While evidence of corrosion exists in some areas of visible roof decking, no structural degradation was noted. For structural degradation of the roof deck to occur, the reinforcing must corrode enough to significantly reduce its tensile strength. This much corrosion would result in significant expansion of the steel, thus causing spalling of the concrete away from the steel. Typically, failure of a concrete structure by corrosion occurs over a long period of time and shows ample evidence of distress long before failure occurs. Thus, while past leakage has caused appearance problems, there appears to have been no structural degradation of the roof decking.

5.6 CONCERN-7/1/2: *No information was available ... so it is unknown whether or not under freezing conditions there would be expansive forces created that would rupture the waterproof roof envelope again.*

5.6 RESPONSE: Over time it is inevitable that the waterproof roofing will fail causing penetration of the envelope. This could be caused by expansion due to freezing, expansion caused by high temperatures, damage by hail, or aging. Again, as with the precast concrete roof decking, early signs of distress, typically small leaks in the roofing, will be evident. Generally, the useful life of commercial roofing is 20 years before distress occurs. Since the replacement roof over the 1934 building is now five years old and the roof over the 1958 building and the east half of the 1963 building is two years old, one would not expect evidence of distress to appear prior to the year 2005. For the older roofing, distress could begin to show at any time. As such leakage occurs, operations management should have areas of leakage repaired until it is deemed necessary, from an operational or building degradation position, to replace that section of roof.

5.7 CONCERN-7/2/1: *The distress at the southeast corner of the building associated with the east 3-wythe load-bearing brick masonry wall...extending over approximately 4 feet vertically. The open crack, representing ... in the once continuous load bearing masonry wall that is 12 and ½-inches thick (Dwgs A-10 and P-2).*

5.7 RESPONSE: As described in the NRC report, cracking does exist and is shown in Figure A-4. From the outside, the cracking appears to stop just short of the area where the second floor slab ties into the common wall brick. From inside the building below the second floor, it is evident that cracking does extend through the wall; however, it is not continuous, i.e., the cracking on the inside of the wall is almost an opposite pattern, as shown in Figure A-5.

Figure A-4. Cracked southeast corner wall.

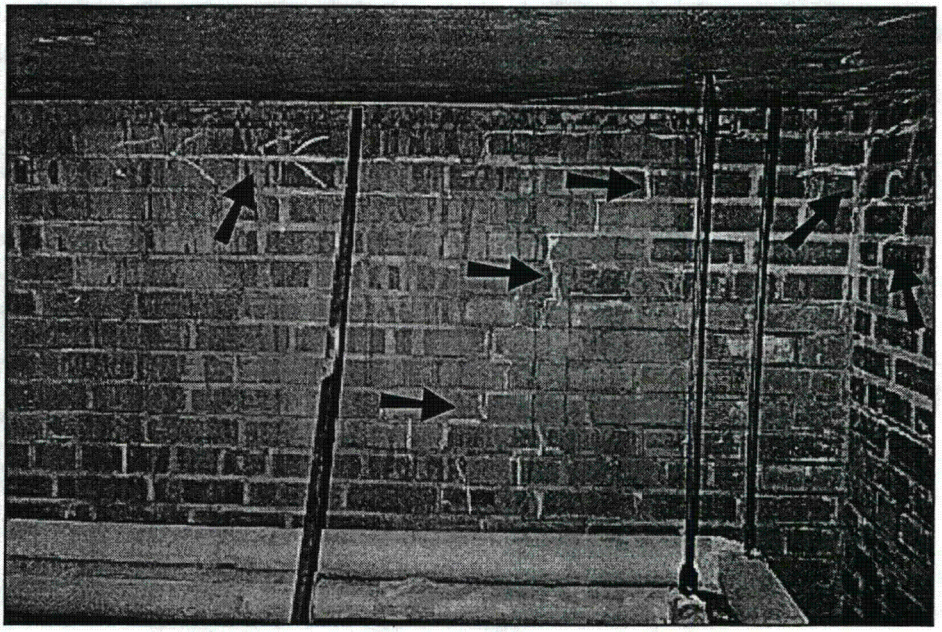


Figure A-5. Cracking on the inside wall.

From inside the building above the second floor, the east and south walls in the corner show no cracking; however, as shown in Figure A-6, there are four cracks in the second floor slab that are visible to the human eye. One very large crack is nearest the corner, is at an approximate 45° angle to each wall, has a width of one-half inch, and has a length from wall to wall of about six inches. Based on the width of this crack, it must be assumed that the crack continues through to the slab edges underneath both the east and south walls. No reinforcing steel was found in this crack. A second crack runs almost parallel to the south wall, appears to cross the third crack, and then merges into the fourth crack. The third and fourth cracks are also at about a 45° angle to each wall. Based on the width of the crack nearest the corner, it appears that the southeast corner has moved southeast a distance of as much as ½ to ¾-inch. These floor cracks seem to indicate excessive bending moment in the floor slab at this corner, which would be indicative of significant settlement at the corner. Underneath the second floor slab, matching crack patterns were found. It was determined that the as-built dimension of the floor slab was six inches.

Unfortunately, it is difficult to tell what actually caused cracking at the southeast corner of the building. As noted in the NRC report, the structural support of the 1958 building is a mix of load and non-load bearing masonry and concrete block, reinforced concrete, and steel framing. These materials are not compatible from an aging and expansion standpoint. In addition, the stiffness properties of the structure vary from extremely stiff (the test cell and radiography room) to very flexible (the lobby area). Thus, in a building over 30 years old with these types of similarities, one should expect to see cracking of this type; however, this cracking appears to have a unique cause. As noted in the NRC report,

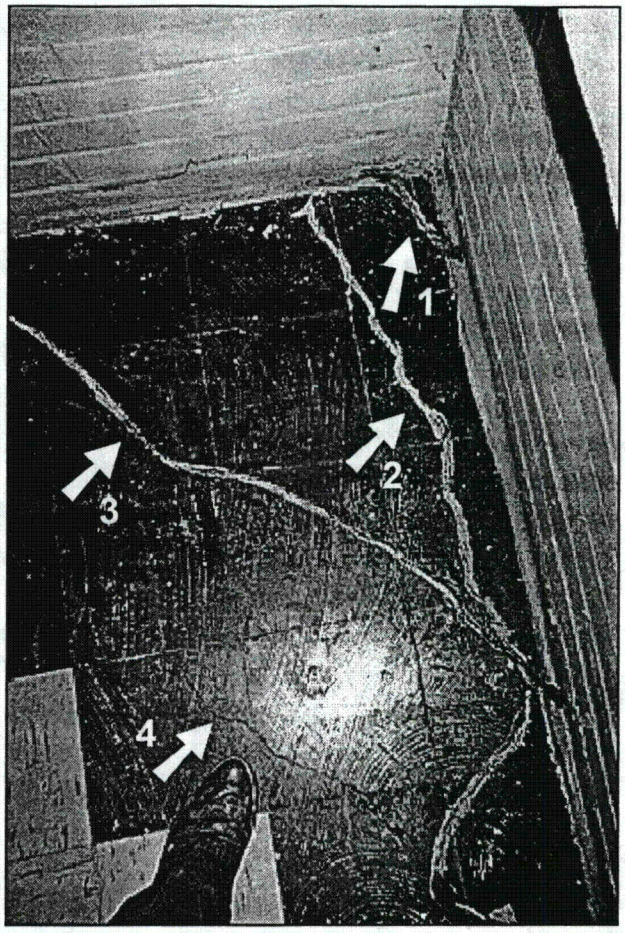


Figure A-6. Cracked second floor slab at southeast corner wall.

the cracking may have been caused by the 1986 earthquake; however, the highest Modified Mercalli Intensity rating for the East Cleveland area was an MMI V (Nicholson, et al., 1988), and the facility was located 25 miles southwest of the epicenter. An MMI is described as:

> Felt indoors by practically all, outdoors by many or most; outdoors direction estimated. Awakened many or most. Frightened few, slight excitement, a few ran outdoors. Buildings trembled throughout. Broke dishes, glassware, to some extent. Cracked windows, in some cases, but not generally. Overturned vases, small or unstable objects, in many instances, with occasional falls. Hanging objects, doors, swing generally or considerably. Knocked pictures against walls or swung them out of place. Opened or closed doors, shutters, abruptly. Pendulum clocks stopped, started, or ran fast or slow. Moved small objects, furnishings, the latter to slight extent. Spilled liquids in small amounts from well-filled open containers. Trees, bushes, shaken slightly.

It is not until an MMI VI has been reached that descriptions of building damage are included, as follows:

> Damage slight in poorly built buildings. Fall of plaster, in some amounts. Cracked plaster somewhat, especially fine cracks chimneys in some instances.

MMI VI was only recorded in a radius of 10 miles of the epicenter. In addition, the directional motion of the seismic wave should have been in a southwest direction. The southeast corner of the building has moved perpendicular to that motion. Thus, this reviewer believes this damage is the result of a different loading mechanism.

If a significant lateral or vertical load were to be applied to this location of the building, a localized corner failure of the building would occur between the first and second floors, while, due to the purlin bearing on the east wall at the corner, a much broader area of the roof in the west direction would collapse. However, due to the construction of this building, this reviewer does not believe that such a loading would lead to overall collapse of the building. The cracking has reduced the total vertical load carrying capacity of the wall. However, this corner and its associated purlin is carrying only half the load of the next northern purlin. See Response 5.12 for more discussion of the roof loads. In the long run, this is a life-safety issue, since failure of the building would not result in breach of the concrete core structure where the cobalt and other radioactive waste are located.

5.8 CONCERN-7/4/3: *The depth of the cracking into the 3-wythe wall is not known...*

5.8 RESPONSE: See Response 5.7.

5.9 CONCERN-7/4/5: *Whether or not the wall was constructed with a mortared collar joint is unknown, but it is assumed the wall was constructed as a solid masonry bearing wall.* This is not a concern, but a response is supportive.

5.9 RESPONSE: This is a good assumption.

5.10 CONCERN-7/4/6: *The crack then appears to trace downward at the vertical joint between the corner stone return on the southeast corner and the east wall.*

5.10 RESPONSE: As stated in the NRC report the fracture does traverse down the wall as noted. Also see Response 5.7.

5.11 CONCERN-7/4/7: *The crack then shows as a fracture in the stone ledge of the east wall at the corner.*

5.11 RESPONSE: The crack does show as a fracture in the stone ledge of the east wall at the corner. Based on the extensive movement that has occurred at this corner, this cracking is most likely a direct result.

5.12 CONCERN-7/4/8: *Originally, the sections of stone were pinned together with brass dowels and the joints were mortared. At some of the joints there has been rotation and translation with the rupture...Above the distressed region...wall supports the southern most roof structural steel purlin...*

5.12 .RESPONSE: As noted above, each stone is independently hung off of the common brick wall, thus, unless significant gross wall movement occurs, no further distress should occur to the stone. The cracking in the masonry wall is a stepping crack, typically following mortar joints as shown in Figure A-4, since the mortar is much weaker in shear than the masonry. The load being applied to that section of wall by purlin (P2) is half of the load being placed on the wall by the other purlin (P2) loads. Per Dwg. S-1, the roof dead load is 30 psf and the live load is 30 psf for a total roof load of 60 psf. Thus, the load applied to the wall by the purlin is approximately 3000 lbs, which, based on the base plate area, equals a compression load on the wall of 50 psi. The allowable compressive stress on a non-cracked masonry wall is 1500 psi. At the second floor slab area of the southeast corner of the building, the load applied to the load bearing masonry wall from the floor slab is approximately 1500 lbs/ft based on floor live and dead loads plus the 2100 lbs/ft dead load of the wall. This places an additional compression load of approximately 40 psi on the common wall below the second floor slab. A compression force on the wall of 40 psi is a trivial load compared to the allowable load of 1500 psi. Again, it appears that this cracking must be from localized settlement at the corner.

5.13 CONCERN-7/4/12: *On the inside of the 1958 building at this purlin bearing there is evidence of movement between the bearing wall and the purlin in the longitudinal direction...is not known...which structural element remains with the permanent movement...*

5.13 RESPONSE: This movement appears to be approximately ¼-inch as shown in Figure A-7. Although such movement may occur for a building having a mix of materials involving steel, concrete, and masonry as main structural elements, this movement must be attributed to the corner moving to the southeast at the second floor. According to Dwg. S-1, all beams bearing on the masonry wall have wall anchors. These anchors are two angles, 6 inches by 4 inches by 3/8 inch. Thus, the wall anchor should be holding the common masonry wall from moving further eastward at the top. No sign of distress in the veneer

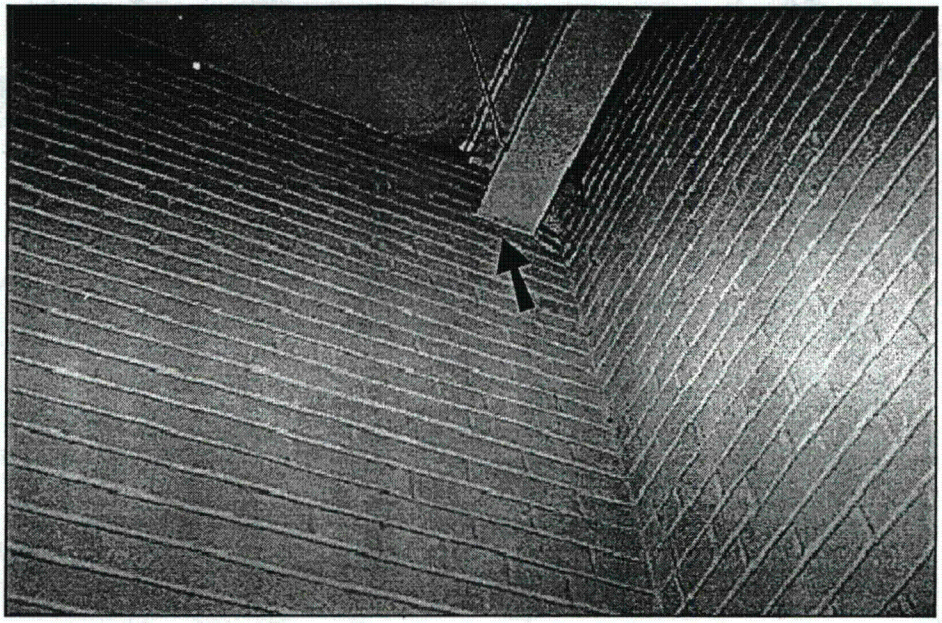


Figure A-7. Wall movement at purlin in corner.

wall was noted from the outside, however, some cracking was noted in the load bearing wall beneath the purlin.

5.14 CONCERN-7/4/14: *In addition to the cracking of the east wall, evidence of lateral loading was found at a point about 17-feet...Rupture of the joints of this wall where the masonry was fit around the purlin as occurred...*

5.14 RESPONSE: It is the opinion of the reviewer that this movement has nothing to do with what has happened at the southeast corner of the building. The biggest problem with the construction of this building is that none of the interior non-load bearing walls were interlocked or tied in with any of the structural members, and most of the non-load bearing walls have separated leaving visible cracks from adjoining walls. The location of the cracking in question is shown in Figure A-8 and, as indicated in the NRC report, the crack opening is approximately one inch. This wall is the west side of a right angle interior wall forming a small room in the southeast corner. If the north side of the interior wall is compared to the paint lines on the roof decking, it is evident that the entire top of the non-load bearing wall has moved northward about one inch. There is no evidence that the purlin has moved southward at this location.

5.15 CONCERN-8/2/1: *The distress of the east wall near the northeast corner of the 1958 building is associated with a rupture type failure...rupture line is most pronounced in a verti-*

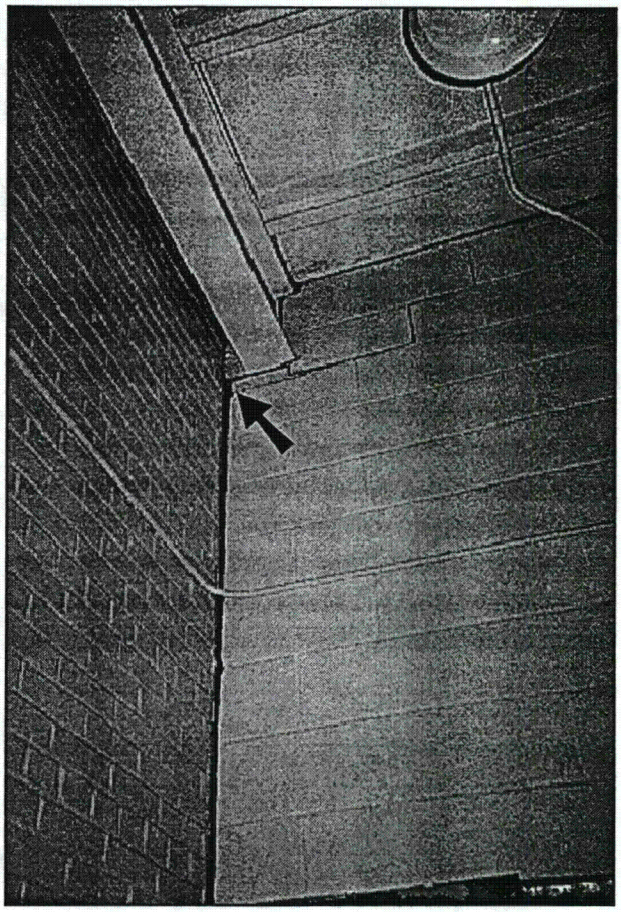


Figure A-8. Purlin and Wall Movement.

cal direction just adjacent to the northeast steel column... rupture surface is generally through every other course of concrete block and does not follow a saw tooth pattern...

5.15 RESPONSE: Paragraph two on Page 8 of the NRC report is mostly about the cracking of the in-filled wall. Upon inspection of this wall's cracking and movement, it seems quite evident what is occurring. Basically, it is a problem of the second floor in-filled wall moving outward over the lobby area between the steel columns at Column Lines D and F. This movement can clearly be seen from the roof and is causing rotational stresses to be placed on the original corner of the 1958 building as the east-west wall tries to keep the east wall from moving outward. The fact that the 1958 building in-filled wall was placed tightly against the inner side of the outside column flange, and the fact that ties attached the two wythes of facing brick to the 1958 building concrete block, the 1958 building in-filled wall is being pulled outward next to Column F-1, failing the in-filled wall in shear at the edge of the flange. Without further inspection, and possibly some destructive inspection, it is difficult to determine the specific cause. Fricke, et al. 1978 have addressed such problems and found that temperature and moisture effects combined with constrained

expansion can result in this type of behavior in such construction. This is not a structural issue, but it is a life-safety issue.

5.16 CONCERN-8/2/17: *In addition, the stone corner and stone return at the northeast corner of the 1958 building show displacement and rotation at the corner with failed joints.*

5.16 RESPONSE: It is believed that the failure of the stone corner at the bottom of the wall has resulted from a totally different cause, but may have something to do with the in-filled wall movement at the second floor. This stone corner is located next to the lobby entrance of the 1958 building. Upon inspection of the site, it is very apparent that the joint failure of the mortar has been caused by salting the lobby entrance to remove snow and ice. The stone facing is discolored where the salt was thrown as shown in Figure A-9, and where discoloration has occurred, mortar in the joint was attacked. At a distance of approximately one foot north of the south corner of the stone, there is no stone discoloration and the joint is intact. As a result of joint failure, the stone has fractured. Again this is a life-safety issue and has no bearing on the structural stability of the 1958 building.

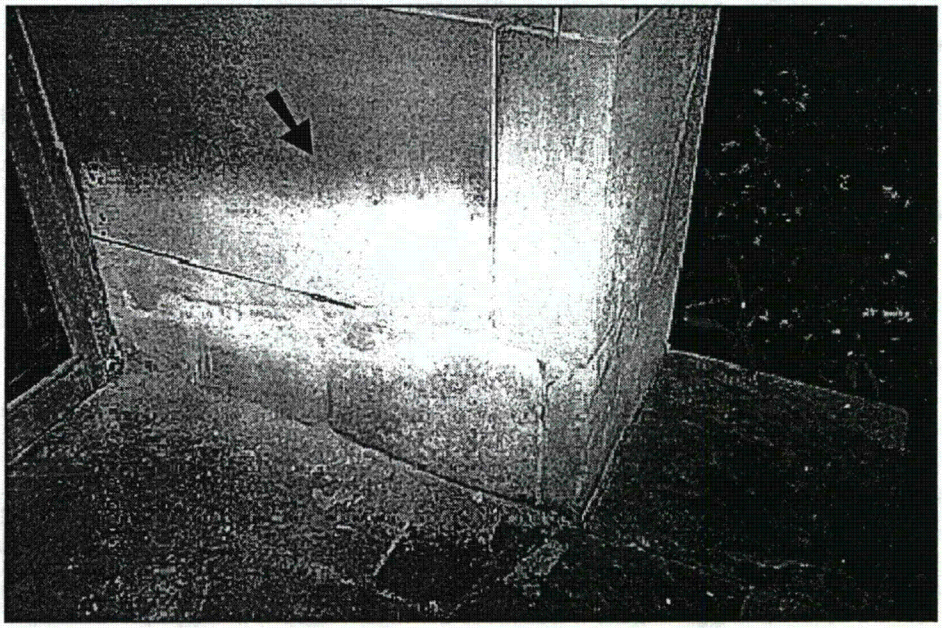


Figure A-9. Lobby stone showing salting.

5.17 CONCERN-8/2/18: *The distress was also reflected in the displacement of the stone coping at the top of the walls as they intersect at the northeast corner of the building...*

5.17 RESPONSE: While there is significant distortion of the stone coping on the parapet of the 1963 building as shown in Figure A-10, with the 1958 building parapet being in the background, this distortion is not believed to be associated with Concerns 5.15 or 5.16 discussed above. Rather, it is believed to have been caused possibly by a crane or crane-like piece of equipment placing workers or equipment on the roof. The movements of the stone coping of the 1963 building do not relate to the movements that have occurred at the northeast corner of the 1958 building.

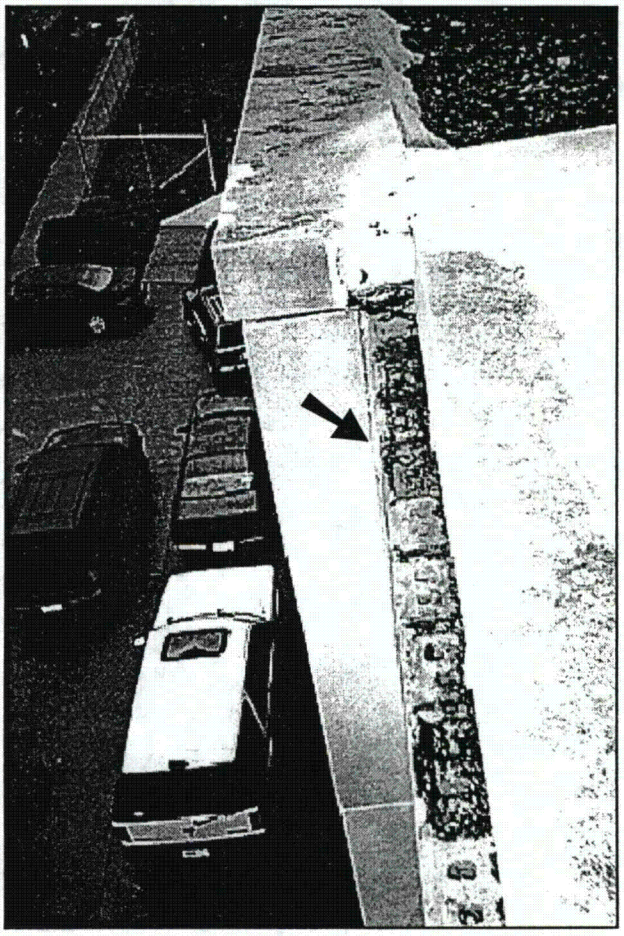


Figure A-10. 1963 building parapet.

5.18 CONCERN-9/2/1: *Based on the observations of the areas of distress of the two ends of the east front wall of the 1958 building, the interface..*

5.18 RESPONSE: The remaining structural integrity concerns of the NRC report have to do with the 1958 building's resistance to seismic load and the impact of the 1963 building's response on the 1958 building. See Attachment II of the main report for a simplified seismic assessment of the 1958 building response.

REFERENCES

Fricke, K.E., W.D. Jones, and J.E. Beavers 1978. *Problems in Masonry Walls - A Case History, Proceedings North American Masonry Conference*, University of Colorado, August 14-16.

Frye, M.J., and G.A. Morris 1975. *Analysis of Flexibly Connected Steel Frames*, Canadian Journal of Civil Engineering, 2, 280.

Henderson, R.C., J.E. Beavers, and W.D. Jones 1995. *Hollow Clay Tile Wall Program Summary Report*, Report No. Y/EN-5347, Center for Natural Phenomena Engineering, Martin Marietta Energy Systems, Inc., July 30.

Nicholson, C., E. Roeloffs, and R.L. Wesson 1988. *The Northeastern Ohio Earthquake of 31 January 1986: Was It Induced?*, Bulletin of the Seismological Society of America, Vol. 78, No. 1, pp. 188-217, February 1988.

Wright, G.C. 1996. Letter Report to Mr. Robert Meschter, Advanced Medical Systems, Inc., Cleveland, Ohio, March 12.

ATTACHMENT II

SEISMIC AND TORNADO STRUCTURAL INTEGRITY OF THE ADVANCED MEDICAL SYSTEMS LABORATORY FACILITY

by
James E. Beavers, Ph.D., P.E.
Vice President
MS Technology, Inc.
118 Ridgeway Center
Oak Ridge, Tennessee 37830

SEISMIC ISSUES

Some seismic issues were addressed in Attachment I of the full report concerning the likely cause of damage to the south-east corner of the Advanced Medical Systems Laboratory Facility (AMSLF). This attachment looks at the vulnerability of the AMSLF to an earthquake.

The location of the AMSLF places it between the 0.05 and 0.10 g contours of peak velocity-related acceleration coefficient, A_v based on the NEHRP Provisions. Based on the shape of the map's contours, a new facility at this location would be designed for an A_v of about 0.07 g. Typically, well designed unreinforced masonry structures can perform as expected up to an A_v ranging between 0.10 and 0.15 g. The AMSLF is in Seismic Hazard Exposure III because it contains some level of radioactive material. Since it is located between A_v contours 0.05 and 0.10 g it is in a Seismic Performance Category C.

Some simplified calculations were done to determine the response of the AMSLF in an earthquake and are attached. The AMSLF foundation rests on shale, thus, there would be no amplification of the ground motions from that specified on the map. From the seismic map, the design input for such a facility would be about 0.07 g (the calculations in the attachment use 0.05 g as the basic input load).

The structure representing the test cell basement, test cell, and radiography room is a massive reinforced concrete structure with wall thickness varying form three to five and half feet. This is an extremely rigid structure, probably having a fundamental frequency in the 25 to 35 hz range. In

addition, over the radiography room a two foot thick second floor slab is tied into the 3 foot walls. The remaining six inch second floor slab is tied into the test cell and the two foot thick slab over the radiography room. In addition, the first floor is also tied into the test cell structure and foundation of the radiography room. Both the first and second floors can be considered as rigid diaphragms. An east west elevation of the test cell is shown on page one of the calculations and the second floor test cell and radiography room rigid body in the horizontal plane at the second floor level is shown on page five of the calculations.

Based on the construction as described above, if an earthquake were to occur all of the horizontal loads would be transmitted into the massive concrete structure. Therefore, the first floor unreinforced masonry load bearing wall would see very little, if any, seismic load because there would no displacement of the first floor and virtually no, if any, displacement of the second floor. The second floor wall would experience some load. A simplified calculation of the shear load for and input load of 0.10 g, page 7 of the calculations, shows that the demand on the unreinforced load bearing masonry wall on the second floor is 0.82 psi verses a code allowable of 10 psi. It is well known that unreinforced masonry ultimate shear load is typically higher than 40 psi. Thus, in the critical operational areas of the AMSLF seismic loads do not place significant stress on the unreinforced masonry load bearing wall. However, as a result of the pre-existing cracking in the south east corner of the building an earthquake could initiate partial collapse. As noted in other sections of the main report, collapse of the building would not result in loss of containment or confinement of the facility.

Because of the stiffness differences between the 1958 and 1963 buildings, they will respond differently. For the low earthquake hazard, the short duration of earthquakes in low hazard zones, and the one-half inch spacing between the 1963 building and the 1958 building walls, if pounding did occur it should not be severe and only minor damage would be expected. However, damage of the roof waterproofing could occur because it will be flexed.

TORNADO ISSUES

Tornadoes can do significant damage to an engineered structure when their wind speeds exceed 120 mph. If a severe tornado having wind speeds in excess of 270 mph, where many engineered buildings can be severely damaged, were to strike the AMSLF everything except for the test cell and radiography room on the first and second floors would experience damage. The ventilation system filters related to the test cell and radiography room would be vented to the atmosphere and the doors to the radiography room would be blown outward. Because of the massive reinforced concrete structures of the test cell and radiography room, they would remain in place with very little, if any, structural damage. The walls of both room would prevent the penetration of the most severe missiles. The basement level that includes the garden room and the test cell basement would not be impacted. While the confinement of the radiography room and test cell would be breached in a

severe tornado, high concentrations of exposure of site of the facility would not occur because of the dispersing power of a tornado.

ATTACHMENT

SIMPLIFIED CALCULATIONS

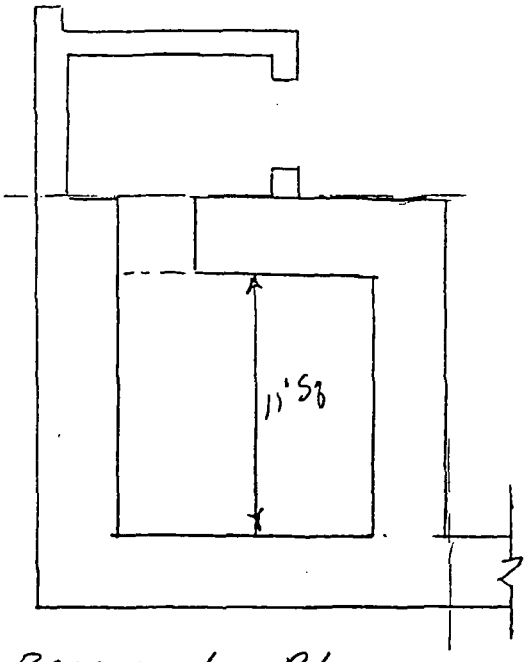
ATTACHMENT II-A

SIMPLIFIED CALCULATIONS

5/26/96

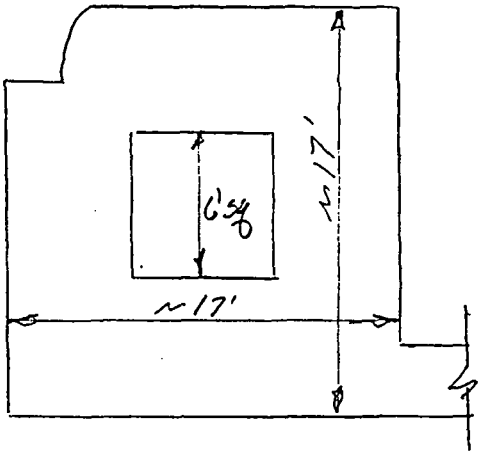
MODEL 1

Mass of Test Cell Structure



Basement Plan

Assume Rectangular Structure and Ignore Reinforced Concrete East West Shear Wall



First Floor Plan

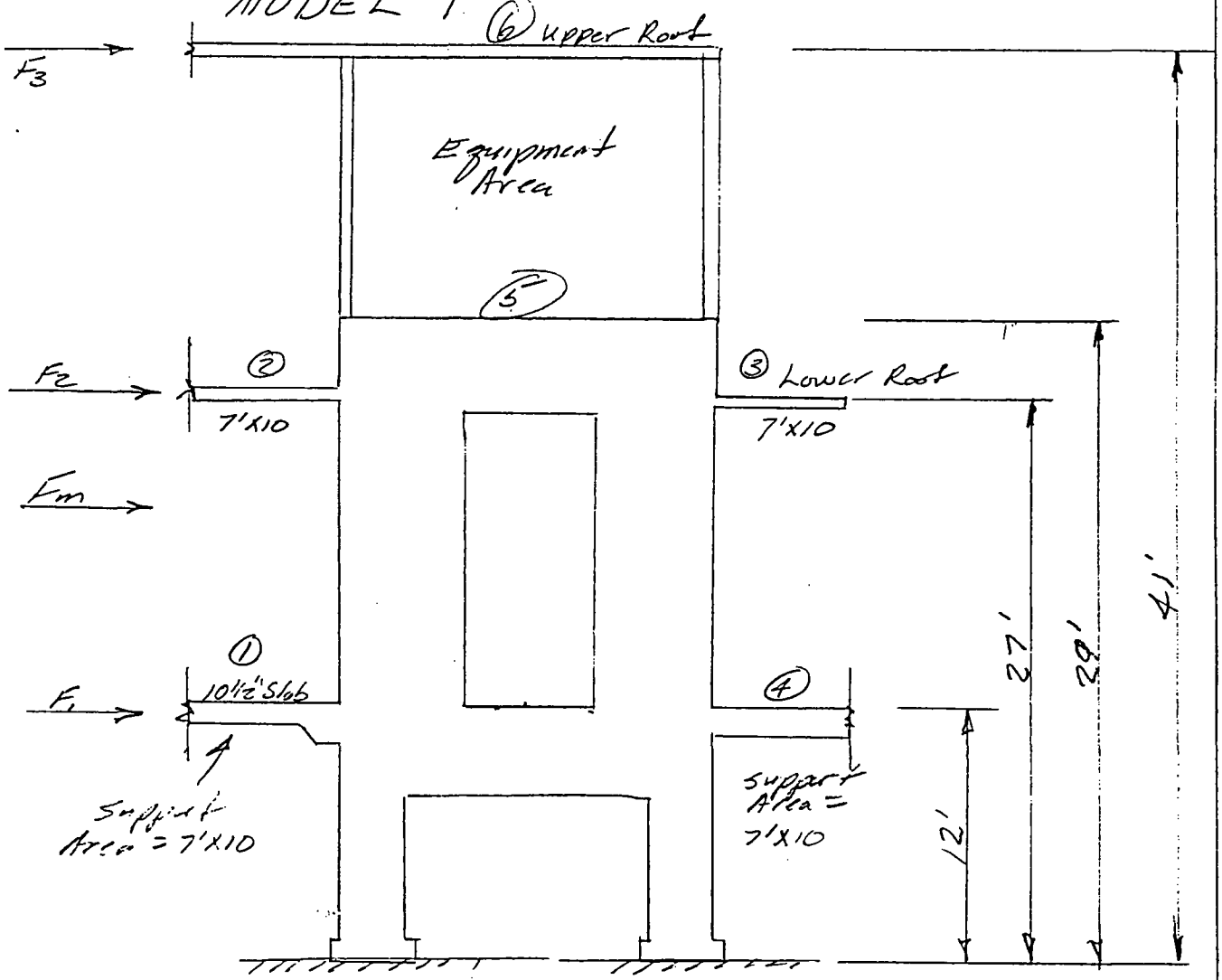
Ingnore Port Areas This Add Mass

5/26/96

ATTACHMENT
SIMPLIFIED SEISMIC ANALYSIS
ADVANCED MEDICAL SYSTEM FACILITY

1. TEST CELL MODEL AND CALCULATIONS

MODEL 1



From Section A-A Dwg A-5

East West Section

Test Cell Mass = [17x17x29 - 11x11x6.5 - 6x6x13.5] x 150

Concrete Wt = 150 #/ft³

= [8381 - 786 - 486] 150 = 1.1x10⁶ lbs

= 1066 kips

Contributing Floor Loads

D.L. = 175 #/ft³ L.L. = 500 #/ft³

Floors 1 & 4 2 x 7x10 x [175+500] = 94 kips

Floor 2 = 7x10 x [90+150] = 17 kips

Floor 5 = 17x17 x [90+150] = 61 kips

Roof 3 = 7x10 [50] = 3.5 kips

Roof 6 = [17x17 + 7x10] 50 = 18 kips

Total Mass ≈ 1066 k + 194 k = 1,260 kips

Assume 1 dim model of test cell in east-west direction as a simple cantilever beam with total mass applied at top of test cell (a large shear wall) having a 1 foot width. This equals a 1g earthq

Max moment = $\left(\frac{1260}{17'}\right)$ 29' = 2,149 kft

$$f = \frac{Mc}{I} = \frac{2149\left[17/2\,(12)\right]}{\frac{12\,(17/2 \times 12)^3}{12}} = \frac{2149\,(102)}{1.1\times10^6}$$

= 0.207 kips/in² or 207 psi <<< 3000 psi

Check for overturning

Downward Load = $\frac{1,260 \text{ kips}}{12(17)(12)} = \frac{1260 \text{ kips}}{2448 \text{ in}^2}$ = 0.515 kips

= 515 psi

Downward Load of 515 psi >>> 207 psi

The BOCA code uses the NEHRP Seismic Map. Cleveland is in the low seismic zone where Aa = 0.05 g

Actual Earthquake stress in the above model = 207 psi (.05) = 10 psi

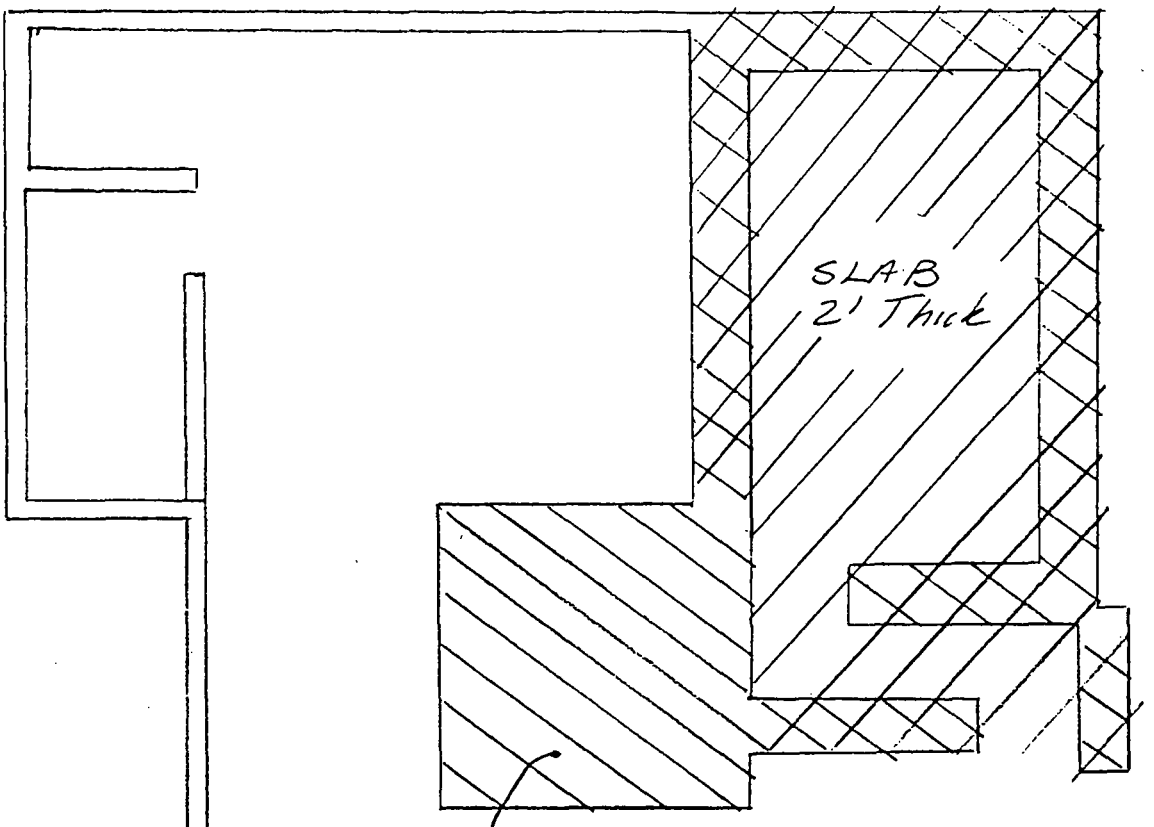
Thus the test cell is a very rigid structure. And an area earthquake would apply almost no load on it.

2. Effect of Test Cell Rigidity on the rest of the facility

The first and second floors represent rigid diaphragms that will take all of the load along the exterior walls of the building directly into the test cell because of its rigidity. In addition, the shear wall ignored in the test cell model also adds rigidity to the system. In addition on the north west side of the test cell the concrete floor slab is two feet thick over the radiography room of the first floor. The shear wall is around the radiography room

Due to fact the second floor acts as a rigid diagraphm and is tied into the test cell and radiography room walls, all of the load will be carried by the test cell and radiography room walls, and ~~is~~ very little, if any, shear load will be applied to the first floor exterior unreinforced masonry walls.

5/26/96



All lateral load transferred to second floor will go into test cell and radiography rigid bodies

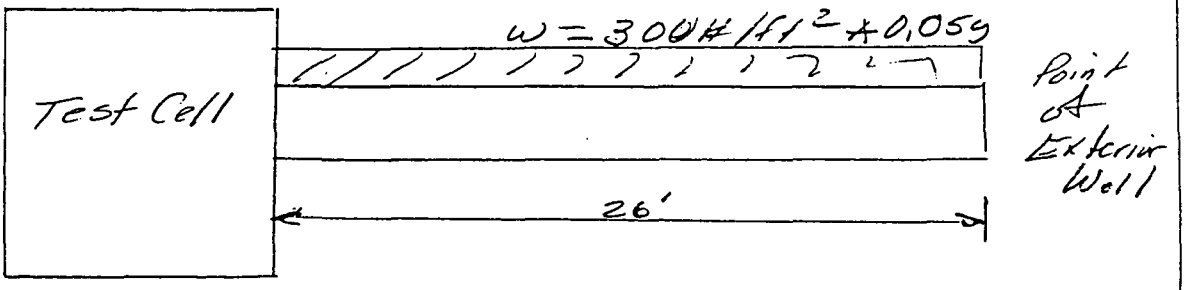
Plan To Scale

Check Assume only test cell is rigid

Assume both roof and second floor load are on second floor

$90 + 150 + 60 = 300\ \#/ft^2$ of floor mass

Assume 3 ft section of floor is cantilevered out from test cell in vertical direction



$$M_{max} = \frac{w l^2}{8} = \frac{300(.05)(26*12)^2}{8} = 183 k\,in$$

$$\sigma = \frac{Mc}{I} = \frac{183 k\,in\,(18)}{\frac{12(36)^3}{12}} = \frac{3294 k\,in^2}{46656 in^4} = 0.071 k\,in^2$$

$\sigma = 71$ psi <<< Concrete tensile stress

$$\text{Displacement} = \frac{wl^4}{8EI} = \frac{.15'[260^2]^4}{8 \times 3\times10^6 [46656]}$$

$$= \frac{.15(9.5\times10^9)}{24\times10^6 \times 4.6\times10^4} = \frac{137.32\times10^9}{110.4\times10^{10}}$$

$= 0.12\ in^2$ Very Small Displacement

Actual Displacement would be much smaller

Thus there would be no amplification of the earthquake motion at the second floore

Above the second floor you have a rigid roof diaphragm

1' Unreinforced Masonry Wall is 13' to base plate of purlins

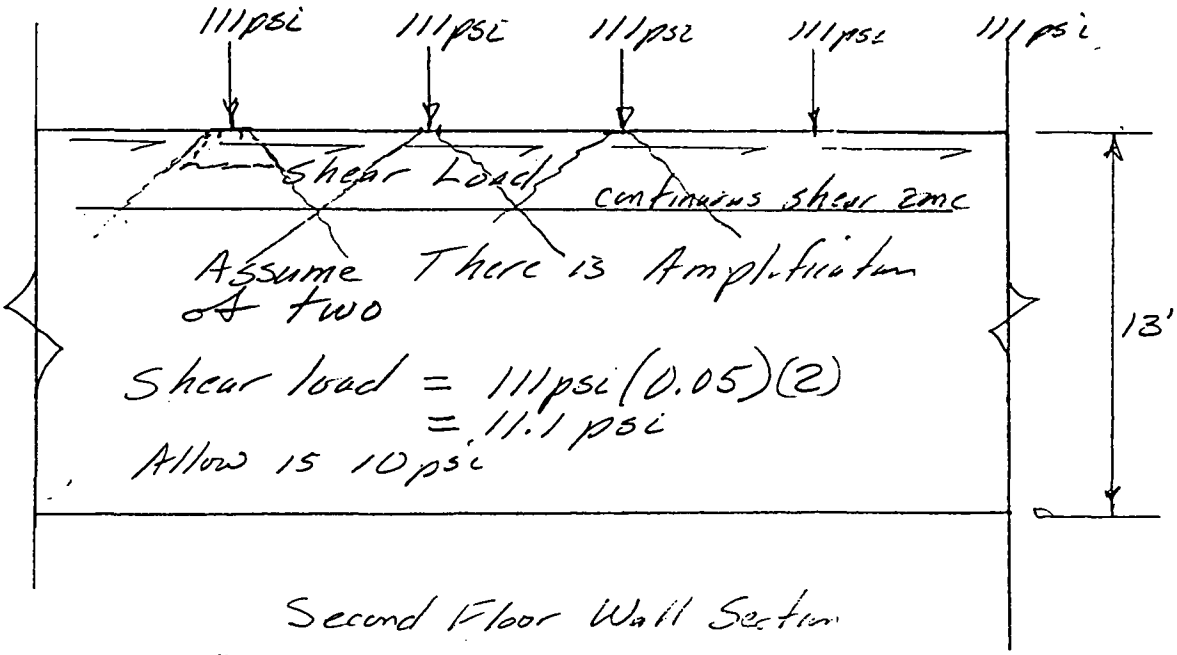
purlin load on east wall is

$26' \times 8' \times (60 psf)/2 = 6,240$ lbs

Bearing Plate Area = $7" \times 3/8" \times 8"$

Purlins P2 = 14 W=30 Flange width = $6\ 3/4"$

Wall stress = $\frac{6240}{7 \times 8} = 111$ psi



Second Floor Wall Section

Allowable Shear Load In Unreinforced Masonry is 10psi

Gross Area Supporting Purlin Load is approximately $8 \times 8' \times 12" = 768$ in^2

Shear = $\frac{6240}{768}(.05)(2) = 0.82$ psi << 10psi

10psi is allowable most masonry ultimate shear is 40psi and above

Include mass of wall

$150\ \#/ft^3 (1ft)(1ft)(13ft) = 1950\ lbs$

$\frac{1950}{8"(12)"} = \frac{1950}{96} = 20\ psi$

$20psi(.05)(2) = 2\ psi$ shear load

See pg 9 for same calculations using NEHRP Provisions

NEHRP Provisions fairly conservative for unreinforced masonry.

At a 45° purlin load distribution there would be overlapping of the purlin loads at a depth of 3.6 ft in the wall. At this location there would be a continuous vertical load of P_r

$P_r = \frac{6240}{8"(8')(12')} = 8,125\ psi$ not 111 psi

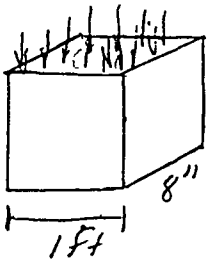
not counting wt of 3.6ft wall which is $540\ \#/ft^2 = 3.75\ psi$

Shear Load at this location would be

$11.875\ psi(.05) = 0.594\ psi$ << 10 psi

Another way of looking at it

6240# load over 8ft = uniform load of 780#/ft



Vertical load 780 #

$A_n = 12(8) = 96$

(See next page also)

$S_{NL} = 1.5\sqrt{f'_c A_n} = 804\#$

Shear Load = 780(.05) = 39# << 804#

For unreinforced masonry the allowable shear per the NEHRP Guidelines is

$S_{ALL} = 1.5\sqrt{f'_c}\,A_n$ $\quad A_n = 7 \times 8 = 56\ in^2$ plate

Assume $f'_c = 3000$ psi $\quad$ Actual A_n of wall is (12)(8) = 96

$S_{ALL} = 1.5\sqrt{3000(96)} = 805$ lbs

Purlin Load is 6240 lbs

Purlin Shear Load = 6240(.05)(2) = 624 lbs

or $S_{ALL} \leq 120\,A_n$ lbs = 120(96) = 11,520 lb (NO) >> 805

$60A_n + 0.3N_v = 60(96) + 0.3(6240) =$ No Good! >> 805

With an amplification of 2 which is not likely since the unreinforced masonry is relative rigid until it cracks.

Thus the actual seismic load is more like 0.05 g resulting in a shear stress value of around

$\frac{6240}{8'}(.05) =$ 39 lbs vs an allowable of 805 lbs

or 8.38 psi vs an allowable of 10 psi

if seismic load is 0.07 g shear stress is 55 lbs.

Advanced Medical Systems, Inc.
121 North Eagle Street • Geneva, Ohio 44041
(216)466-8005 FAX (216)466-8629

A
030-16055

July 1, 1996

Mr. Geoffrey Wright
U. S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: Advanced Medical Systems, Inc. Application to Amend
USNRC License No. 34-19089-01

Dear Mr. Wright:

The purpose of this letter is to request an amendment to the Advanced Medical Systems, Inc. (AMS) radioactive materials license in regard to decommissioning financial assurance. Specifically, AMS wishes to modify its standby letter of credit dated January 27, 1995, to reflect a reduction from its current amount of $1,800,000 to $940,000.[1] The released funds will be used to finance a portion of the Building Recovery Project that was described in our June 10, 1996, proposal. The following are the specific provisions associated with this amendment request:

(1) Upon receipt of the license amendment, AMS will request Bank One to reduce the collateral used to secure the letter of credit line of credit by $860,000 and issue a new letter of credit for $940,000.

(2) The $860,000 released from the collateral will be used by AMS for the sole purpose of funding transfer/disposal of the sealed sources of ^{60}Co, the canisters of bulk ^{60}Co, and the low-level radioactive waste. Task 1 and Task 2 of the June 10, 1996, proposal for the Building Recovery Project contain a description of these materials and the general approach AMS intends to follow to effect their final disposition.

(3) Any funds remaining after the fees associated with Tasks 1 and 2 of the Building Recovery Project have been paid will be returned to Bank One for the sole purpose of increasing the value of the letter of credit. At that time, AMS will request Bank One to issue a new letter of credit to reflect the increased collateral amount.

---

[1] Irrevocable Standby Letter of Credit No. SB300980 in the amount of $1,800,000, issued by Bank One, Cleveland on January 27, 1995, currently serves as the AMS decommissioning funding instrument. This Letter of Credit is secured with the following: A one-year CD with Bank One (Certificate No. 088-006-0292518, matures 07/22/96, principle amount at inception was $250,000); a 180-day CD with Bank One (Certificate No. 086-006-0292517, matures 07/16/96, balance at last maturity, $256,595.89); a 30-day CD with Bank One (Certificate No. 086-006-292516, matures 05/17/96, balance at last maturity, $285,171.88); and pledged assets of approximately $1,000,000 in the form of negotiable securities and government bonds.

30555

(4) By August 30, 1996, AMS will submit Revision 1 of the "Conceptual Decommissioning Plan for the London Road Facility" to reflect the abbreviated quantity of items to be decommissioned after the Building Recovery Project is complete.[2] Because the USNRC has not yet made a decision as to the appropriate decommissioning methodology for the London Road Facility (e.g., DECON versus SAFSTOR), all applicable technologies will be evaluated in Revision 1. Revision 1 will also contain a clear description of the preferred methodology and a detailed cost estimate for implementing that methodology.[3]

(5) By September 15, 1996, and in anticipation of USNRC approval of Revision 1 of the "Conceptual Decommissioning Plan for the London Road Facility", AMS will submit a revised Decommissioning Funding Plan wherein new decommissioning financial assurance instruments will be described. Within 15 days after USNRC approval of the Plan, AMS will request Bank One to issue a new letter of credit for the amount shown in Revision 1 of the "Conceptual Decommissioning Plan for the London Road Facility".

A license amendment fee, in the amount of $680, is enclosed. If I can answer any questions or assist you in any way in expediting your review, please call me at 216/466-8005. We are asking for prompt USNRC action on this important issue.

Sincerely,

DAVID CESAR
Vice President and Treasurer

DC/cs
Enclosure

c: R. Meschter
D. A. Miller, Esq. - Stavole & Miller
R. A. Duff - IEM
C. D. Berger - IEM

---

[2] *Since the only items remaining will be the Hot Cell, the stabilized WHUT Room, the Hot Cell ventilation system, a small section of abandoned drain tiles, and the abandoned lateral connection from the building to the regional sewer system, the estimated decommissioning cost will be significantly reduced from those contained in Revision 0 of the Plan, dated October 20, 1995.*

[3] *The cost estimated for the preferred alternative will be presented in the same format as Appendix F of USNRC Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72" (June, 1990).*

Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216)466-8005 FAX (216)466-8629

June 10, 1996

Ms. Cynthia D. Pederson, Director
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: Building Recovery Project
Advanced Medical Systems, Inc. (License No. 34-19089-01)

Dear Ms. Pederson:

The purpose of this letter is to solicit the USNRC's authorization to proceed on a comprehensive Building Recovery Project at the Advanced Medical Systems, Inc. (AMS) facility on London Road. This project is subsequent to and consistent with the AMS "Strategic Plan for the London Road Facility" (Revision 2, March 26, 1996), and demonstrates our desire to honor our previous regulatory commitments in a proactive and well-managed fashion.

Enclosed are one (1) bound and one (1) unbound copy of Report No. 94009/G-6125, "Building Recovery Project Proposal". We believe the project described therein presents a viable and timely means of resolving the issues raised in the Strategic Plan in regard to the sealed sources, the bulk cobalt, the solid waste, the radiological stability of the WHUT Room, the hydrological stability of the basement, and decommissioning funding issues for the recovered building that concern both AMS and the USNRC. In addition, the physical inventory question, emergency plan issues, on-going and pending licensing issues, and long-range strategic planning (e.g., after the Building Recovery Project is complete) are also addressed.

Included in our proposal is a brief description of the AMS facility and its planned operations, the reason why AMS wishes to implement the Building Recovery Project, a description of the Project's twelve-point scope of work, a proposed project schedule, and the proposed mechanism whereby the project will be funded. As you will see during your review of our proposal, we are asking the USNRC to release a portion of the funds AMS has committed for decommissioning the London Road facility to support the commercial disposal costs. Once the project is complete, there will be significantly reduced radiological risk at the facility, license commitment will more accurately reflect AMS's on-going operational activities, compliance costs will be lower, routine personnel exposures will be lower, and AMS will be subject to reduced regulatory scrutiny.

Your prompt attention to this matter is crucial since the Building Recovery Project Proposal is possible only because AMS was presented with a "window of opportunity" from a waste broker (e.g., the broker's contract will be valid for a specified time period only).[1] If USNRC authorization to proceed is delayed beyond that time limit, AMS may no longer be in a position to initiate the project.

It is also important that all twelve of the tasks described in the proposal be permitted to go forward, since our final goals will only be achieved when the entire project is complete.[2] If USNRC concurrence on only a portion of our proposal is forthcoming, it is not likely that AMS will be able to initiate the project.

USNRC License No. 34-19089-01 is currently under timely renewal. Therefore, we are assuming that the Building Recovery Project, once authorized, is to be performed under the provisions of that license and its associated radiation safety program. However, since AMS wishes to institute significant changes in the radiation protection program in order to improve its applicability and auditability, timely USNRC action on our November 9, 1995, revised license renewal application would simplify the process. In any event, immediately upon your acceptance of our proposal and our execution of a contract with the waste broker, AMS will submit a request to amend our existing license to permit disposal of the sources and solid waste, and a time line for completing the rest of the twelve-point program.

If you have any questions or if I can provide you with additional information, please call me at 216/466-8005. I am looking forward to your timely response and acceptance of our proposal.

Sincerely,

D. L. Cesar

DAVID CESAR
Vice President and Treasurer

DC/cs

Attachments

cc: Robert Meschter, RSO
Dwight Miller, Esq., Stavole & Miller
Carol Berger, C.H.P., IEM
Mike Weber, USNRC Region III

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[1] We will transmit this date to the USNRC as soon as AMS and the broker have completed contract negotiations.

[2] For example, if AMS were authorized to dispose of its sealed sources but not all of its solid waste, it would not be possible to decontaminate the basement. If the basement cannot be decontaminated, any incursion of water into the area will require another financially-devastating clean-up effort. If such an event occurred, AMS could not possibly fund it.

BUILDING RECOVERY PROJECT

A Proposal to:

U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

from:

Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio 44110
(216) 692-3270

Report No. 94009/G-6125
June 10, 1996

TABLE OF CONTENTS

INTRODUCTION

Advanced Medical Systems, Inc. (AMS) is currently facing a number of extenuating regulatory, legal and financial circumstances that are hindering its efforts to remain a viable business entity. To obtain relief from these circumstances, AMS proposes to perform a Building Recovery Project.

The proposal described herein presents a viable and timely means of resolving outstanding issues raised in the "Strategic Plan for the London Road Facility",[1] with particular emphasis on the sealed sources, the bulk cobalt, the solid waste, the radiological stability of the WHUT Room, the hydrological stability of the basement, and decommissioning funding issues for the recovered building. In addition, the physical inventory question, emergency planning issues, on-going and pending licensing issues, and long-range strategic planning (e.g., after the Building Recovery Project is complete) are also addressed.

This proposal contains a brief description of the AMS facility and its planned operations, the reason why AMS wishes to implement the Building Recovery Project, a description of the Project's 12-point scope of work, a proposed project schedule, and a proposed mechanism for funding the project. AMS is prepared to implement the project described herein immediately upon U. S. Nuclear Regulatory Commission (USNRC) authorization to proceed, and upon execution of a waste disposal contract.

[1] "Strategic Plan for the London Road Facility", Report No. 94009/G-3113, Revision 2, March 26, 1996.

FACILITY STATUS

At one time, AMS manufactured and fabricated sealed sources of ^{60}Co for use in teletherapy and radiography machines manufactured by AMS. However, since 1989, the only operations being performed by AMS involve machine assembly, including source exchanges and sales. The sealed sources used in these machines are purchased from another firm.

At this time, and under the provisions of U. S. Nuclear Regulatory Commission (USNRC) license No. 34-19089-01, AMS possesses approximately 55,000 curies of ^{60}Co.[2] The majority of this is in the form of doubly-encapsulated sealed sources or screw-top bulk containers. The remainder consists of approximately 40 curies of radioactive material in a potentially dispersible form. This material, which consists primarily of dry solid waste, carbon granules and ion exchange resins, is stored in sealed 55-gallon drums or B-25 (steel) boxes in the basement of the building, in the isotope shop warehouse, or in the high level waste storage area (first floor).

[2] AMS is also licensed to possess depleted uranium (nickel plated) for use as shielding material. The current inventory of depleted uranium is approximately 2,200 kilograms.

PROPOSAL

Statement of the Problem

As part of its license compliance efforts, AMS is committed to completing a number of tasks ranging from license renewal to effecting significant reductions in the existing radionuclide inventory. These tasks are described in greater detail in the "Strategic Plan for the London Road Facility" (Strategic Plan).[3] Timely completion of these activities is critical since they will ultimately result in streamlined routine operations, recovery of needed building/facility capabilities, and reduced regulatory demands on the operating staff because of a smaller and more controllable inventory. However, AMS's ability to proceed quickly toward closure has been hampered by a lack of financial means, personnel limitations and other issues.

In addition to its severe regulatory burden, AMS is also faced with a complicated legal issue, the impact of which is that the London Road facility does not have direct access to the regional sewer system. Even though a comprehensive sewer remediation effort was completed in 1995, and even though no detectable radioactivity has been identified in storm and ground water pumped from the remediated foundation drainage system since that time, AMS must nonetheless pump storm water that collects around the foundation of the building into hold-up tanks, sample the tanked water for the presence of radioactivity, and hold the water for an additional four days until the regional sewer district has had an opportunity to confirm the results of the sampling.[4,5]

Water management activities at the London Road facility have become a financial and strategic nightmare. AMS is at the mercy of local weather conditions, and must bear the on-going and exorbitant costs of having samples analyzed at a commercial analytical laboratory prior to discharging any water. Furthermore, if the pumping system should fail, for any reason, or if a significant rainfall event exceeds available tank space or pumping capacity, water incursion into the basement of the building is likely. Although AMS recovered once from such an event (e.g., the 1995 basement flood), the financial impact was devastating and the company is unable to bear the cost of a repeat occurrence.

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[3] "Strategic Plan for the London Road Facility", Revision 3, April 24, 1996.

[4] As of the date of this letter, over 180,000 gallons of radiologically benign water has been pumped out of the remediated foundation drainage system.

[5] Cobalt-60 was identified in two 3,000-gallon batch tanks when they were first put into service. However, the source of this material was the tanks themselves, which were used as process tanks during the water treatment project. The residual ^{60}Co found in the tanks after the foundation drain water was transferred to it was removed by filtration. All subsequent batches of foundation drain water held in these tanks have been negative for the presence of ^{60}Co.

Since 1994, AMS has had steady sales with a positive gross profit. This indicates that the manufacturing of its C-9 units and the selling of sealed sources is a profitable line of business given this sales volume. But when the cost of regulatory compliance, water management, and ancillary issues are factored in, AMS regularly posts net losses.

After recovering from the 1995 basement flood, AMS's cash reserves were exhausted, rendering it unable to aggressively pursue the higher priority items listed in the Strategic Plan.[6] Consequently, the viability of AMS as a business entity is being threatened.

Proposed Solution

In order to survive as a going business concern, AMS must reduce the cost of regulatory compliance, streamline its regulatory obligations, reduce its current level of storm water management activities, and eliminate the likelihood of another financially-devastating basement flood. To accomplish this, AMS proposes to implement a comprehensive Building Recovery Project, to be partially-funded by the release of a portion of its existing financial assurance instruments.

Because the result of the project will be a much smaller radioactive materials inventory and significantly reduced building surface contamination at the London Road facility, the cost of regulatory compliance will match the current scope of operations and will be in line with projected cash flow. Also, AMS employees will cease to incur unnecessary radiation exposures by simply performing routine tasks and surveillance activities. In addition, emergency response obligations will be minimized because the facility will be reduced to possessing only non-dispersible sources of radioactivity. Finally, while awaiting a legal solution to the sewer discharge issue, a more streamlined water management program will be possible, and the radiological and financial impact of an inadvertent water incursion into the basement of the building will be minimized.

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[6] Unfortunately, alternative sources of funding are not available. Corporations related to AMS are not in a position to render the financial assistance that AMS needs to meet its commitments. Third-party funding from commercial banks or other lending institutions is simply not an option in light of the company's net losses and the contingent liability posed by the pending lawsuit with the regional sewer district

PROJECT SCOPE

The proposed Building Recovery Project consists of 12 specific tasks. The following is the listing of these activities:[7]

1. Dispose of all accessible sealed ^{60}Co sources and all canisters of bulk ^{60}Co at a commercial low level waste burial ground.

2. Dispose of dry solid waste currently stored in the facility basement and in the high-level waste storage through a commercial low-level waste broker.

3. Stabilize the radiological conditions in the basement and WHUT Room in order to reduce the impact of water incursion.

4. Remedy the hydrological condition of the facility in regard to ground/surface water in order to reduce the probability of water incursion.

5. Revise the AMS Conceptual Decommissioning Plan to reflect actual site circumstances after points (1) through (4) are complete, to include a comprehensive estimate of the cost of decommissioning (today's value), followed by submission of a new Decommissioning Funding Plan.

6. Free-release (for unrestricted use) the remainder of the London Road building, with the exception of the WHUT Room, the Hot Cell, the ventilation system, and an ancillary work area.

7. Submit a request for exemption from the physical inventory requirement for the sealed sources that remain in the "stuck plug" of the Hot Cell.

8. Submit a request for exemption from the Emergency Plan requirements of 10 CFR 30.32(i) based upon the lack of dispersible activity at the London road facility.

9. Submit a request to extend the safe storage period for decontamination of the WHUT Room based upon considerations of personnel exposure and waste volume.

10. Submit a request to reduce the ^{60}Co license limit from the October 30, 1995 request of 93,110 curies to 10,000 curies.

11. Submit long-range strategic plan to address the issues that will remain outstanding when the Building Recovery Project is complete (e.g., removal of the "stuck plug" in the

[7] The order of this listing is not necessarily the order of performance or the order of importance.

Hot Cell; completion of the physical inventory; eventual decontamination of the Hot Cell, WHUT Room, and ventilation system prior to decommissioning; and submission of a Decommissioning Funding Plan that accurately reflects the radiological condition of the London Road facility.)

12. Throughout the term of the Building Recovery Project, continue to perform routine operations and meet all commitments made to the USNRC pursuant to license requirements and ancillary communications (e.g., revised Strategic Plan due July 12, 1996; response to Shewmaker inspection report due June 12, 1996; response to Question-2 of the USNRC's comments on the Emergency Plan due June 12, 1996; response to structural issues in December 6, 1996 request for additional information in regard to the Demand for Information due June 12, 1996).

Appendix A contains a description of why each task must be performed, the approach AMS proposes to use to complete each task, a listing of task responsibilities, and a description of deliverables, if any, associated with each task.

PROJECT SCHEDULE

The scheduled completion date for the 12 points in the Building Recovery Project will depend upon the date that USNRC authorization to proceed is given, and the date the contract with the waste broker is executed A date-specific time line will be submitted, along with an application to amend License No. 34-19089-01 to permit disposal of the sources and solid waste pursuant to Appendix A, immediately upon USNRC approval of this proposal and AMS execution of the broker's contract. However, for the purposes of USNRC review of this proposal, and baring unforseen interferences or circumstances that are beyond AMS control, AMS intends to adhere to the date-independent schedule for completion of each of the 12 points in the scope of work that is shown in Table 1.

FUNDING PROPOSAL

The sales of the AMS C-9 teletherapy units and sealed sources that are manufactured by others have been promising, although the future sales picture is unpredictable. Nonetheless, once the cost of regulatory compliance becomes consistent with the scope of these operations (e.g., once the Building Recovery Project is complete), AMS will be in a better financial position to address the longer-term provisions of the Strategic Plan.

In the meantime, one of the highest priority items in the AMS Strategic Plan is reduction in the inventory of radioactive materials at the London Road site. However, AMS does not have sufficient cash at this time to enter into a contract arrangement with the disposal site and waste broker.[8] (Appendix B contains a profit/loss statement and a balance sheet for AMS.) In addition, because of the lawsuit between AMS and the regional sewer district, the lack of net company profitability, and a financially-overwhelming corporate regulatory obligation, third-party funding of Task 1 and Task 2 of the Building Recovery Project is impossible. Therefore, to ensure timely completion of all 12 of the project tasks, AMS proposes that a portion of our existing financial assurance for decommissioning be released for the sole purpose of funding the commercial disposal costs and broker fees.

Description of Existing Decommissioning Funds

An Irrevocable Standby Letter of Credit No. SB300980, dated January 27, 1995, issued by Bank One, Cleveland, in the amount of $1,800,000 currently serves as the AMS decommissioning funding instrument. This Letter of Credit is secured with the following:

- One-year CD with Bank One, Certificate No. 088-006-0292518, matures 07/22/96, principle amount at inception was $250,000
- 180-day CD with Bank One, Certificate No. 086-006-0292517, matures 07/16/96, balance at last maturity, $256,595.89
- 30-day CD with Bank One, Certificate No. 086-006-292516, matures 05/17/96, balance at last maturity, $285,171.88
- Pledged assets of approximately $1,000,000 in the form of negotiable securities and government bonds.

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[8] Prior to shipment of the sources, AMS must pay all disposal charges. The remainder of the fees (e.g., broker fees, South Carolina disposal taxes, transportation) are payable upon service. However, the broker may withhold the performance of its services in the event it becomes insecure of payment.

Legal Argument for Release of Existing Decommissioning Funds

The USNRC has the duty to require certain of its licensees to promulgate and fund a decommissioning funding plan (DFP). This duty is contained at 10 CFR 30.35, et seq. Without question, AMS is one of those licensees required by 10 CFR 30.35(a) to promulgate such a plan.

Title 10 CFR 30.35(a) states as follows:

> (a) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (3) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule) where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30.

The USNRC is also vested with considerable latitude in approving or disapproving particular provisions in a proposed plan. For instance, in 10 CFR 30.36(f)(2):

> (f)(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section if the commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

Also, in section 30.36(h)(5), it states:

> (h)(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, which as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensees.

The code of Federal Regulations does not specifically refer to the USNRC's ability to release previously segregated funds for use in decommissioning in order to remove certain radioactive material from the building and place such material in storage. However, the Code does provide that the USNRC is to be the judge of the efficacy of the proposed DFP and to adjust the amount of segregated funds needed accordingly.

AMS has presently in excess of $1,700,000 in cash deposits and negotiable securities committed for decommissioning funding. Removal of all accessible sealed radiation sources and all packaged radioactive waste in the London Road building, together with the other measures proposed herein, would drastically reduce the amount of funds necessary to insure that funds will be available to decommission the building at the termination of the AMS operating license.

In Task 11 of the Building Recovery Project, AMS has pledged to provide a new DFP. If adopted, the AMS Building Recovery Project would present no undue risk of radiation exposure of the public and is in the public interest since it would remove, from the AMS building, all sealed sources and all potentially dispersible radiation. Therefore, under the conditions set forth herein, the USNRC has the implied authority to reset the level of funds required by the DFP and to release those funds necessary to effect the disposal of the sealed sources and radioactive waste in accordance with this proposal.

Proposed Project Funding Plan

Appendix C contains a description of the contract that AMS proposes to enter into with Chem Nuclear Systems, Inc. (CNSI). That contract shows that CNSI will dispose of the AMS solid waste and sealed sources for a total cost of $852,725. Although AMS is optimistic that the actual costs will be significantly less than this estimate, AMS requests the USNRC to release this amount from existing decommissioning funding in order to honor the CNSI contract at the rate/amount shown on individual CNSI invoices (to be forwarded to the USNRC and AMS by CNSI).[9] The cost of the remainder of the Building Recovery Project will be borne by AMS through the use of operating funds. Table 2 shows the proposed allocation of project costs.

The remainder of the committed funds (e.g., those remaining after the CNSI invoices have been paid) will be sufficient to fund decommissioning of the "recovered" facility.[10] Therefore, AMS does not intend to request the release of decommissioning funds for any purpose other than payment of CNSI invoices.

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[9] The CNSI proposal assumes that the unpackaged sealed sources at AMS will require two shipments. However, AMS is confident, due to the curie content and waste volume of these sources, that a single shipment will suffice. Therefore, a $159,000 reduction in the total cost is likely. Also, since alternative DAW disposition methodologies (e.g., incineration, supercompaction) were not considered by CNSI in its estimate, AMS is optimistic that additional cost reductions are forthcoming when these alternatives are considered in the final contract.

[10] Detailed cost estimates for two decommissioning options (e.g., DECON and SAFSTOR) and a revised Decommissioning Funding Plan are listed as deliverables for Task 5.

TABLES

Table 1 - Work Duration

Task No.	Scheduled Completion/Submission Period After Receipt of USNRC Authorization to Proceed (years)			
	0.5	1	2	5 (Within Term of License)
1 - Dispose of sources	x			
2 - Dispose of waste	x	x		
3 - Stabilize basement and WHUT Room			x	
4 - Remedy hydrological conditions			x	
5 - Revise Conceptual Decommissioning Plan and Decommissioning Funding Plan	x			
6 - Free-release building				x
7 - Exemption from physical inventory requirement		x		
8 - Exemption from Emergency Plan		x		
9 - Extension of safe storage period for WHUT Room		x		
10 - Reduce license limit		x		
11 - Long-range strategic plan			x	
12 - License compliance and regulatory commitments	On-going			

Table 2 -Allocation of Costs

Task No.	Proposed Funding Mechanism	
	To be Paid out of Existing Decommissioning Funding Instruments	**To be Paid out of AMS Operating funds**
1 - Dispose of sources	x	
2 - Dispose of waste	x	
3 - Stabilize basement and WHUT Room		x
4 - Remedy hydrological conditions		x
5 - Revise Conceptual Decommissioning Plan and Decommissioning Funding Plan		x
6 - Free-release building		x
7 - Exemption from physical inventory requirement		x
8 - Exemption from Emergency Plan		x
9 - Extension of safe storage period for WHUT Room		x
10 - Reduce license limit		x
11 - Long-range strategic plan		x
12 - License compliance and regulatory commitments		x

APPENDICES

Appendix A - Task Descriptions for the Building Recovery Project

Task 1: Disposal of Sealed Sources and Bulk Cobalt

Purpose

There are approximately 55,000 curies of sealed sources and bulk ^{60}Co metal in the AMS inventory. Since October of 1995, AMS has attempted to identify a domestic or foreign market for these sources. Although a number of potential users have been identified, their needs are for sources with significantly greater activity than is present in the AMS inventory. Therefore, AMS has not met with success in transferring the inventory to other users.

Other than those that currently exist in device heads, the sealed sources at AMS are of no operational value in that they are not a necessary part of current operations. To reduce the liabilities associated with their possession (e.g., increased emergency plan, decommissioning funding, surveillance, security and licensing requirements), in light of the fact that a third-party transfer is unlikely, AMS pursued other solutions to the inventory reduction problem.

After many conversations and levels of negotiation, it was determined that the relatively small volume but high activity of the sealed source inventory could provide a cost-mitigating factor for conventional disposal. This fact placed conventional disposal of the sources into the realm of financial possibility, but only if AMS is permitted to "tap" funds that are currently held by the USNRC for decommissioning funding.

Approach

For Task 1, the current inventory of unpackaged sealed sources and bulk cobalt, with the exception of those sources in the hot cell stuck plug (see Task 7), will be stabilized with a disposal site stabilization agent that has been approved by the State of South Carolina.[11] This stabilization will be performed in the AMS hot cell by AMS and Chem Nuclear Systems, Inc. (CNSI) personnel inside of the shipping cask liners. Remote handling capabilities will be used to the greatest possible extent in order to minimize personnel exposures from handling and stabilization of the materials. Once the stabilization agent has cured adequately, the cask liner will be loaded by AMS and CNSI personnel into a lead shielded, Type B shipping cask(s) for shipment to the low-level radioactive material burial site in Barnwell, South Carolina.

AMS anticipates that the transfer will be accomplished in one or two shipments, based upon the type of Type B cask that is utilized. AMS also anticipates that the shipments will be highway route controlled, which will require notification of states through which they are transported.

Responsibilities

All permitting and licensing actions for this task will be handled by AMS or technical consultants to AMS, with the assistance of CNSI. CNSI will be responsible for "receiving" the stabilized materials, disposition of the sources in the transfer liner, overpacking the transfer liner, stabilization of sources in the liner, transport of sources to Barnwell, and off-loading the disposal liner into a Class "C" trench for disposal. AMS has assigned a project manager (R. Alan Duff, IEM) to coordinate the source loading/packaging. The movement of sources from storage areas into shipping containers will be performed by qualified AMS employees (S. Haddock and C. Reed). Project health physics and dose tracking will be preformed by the AMS Radiation Safety Officer (R. Meschter). All CNSI shipments will be inspected and released by the

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[11] Materials that are already packaged in AMS shipping casks (e.g., the GE-500 and the "Blue" casks) will be transported and disposed of "as is".

project manager prior to departure from the London Road facility. The radioactive materials inventory will be debited by the RSO. All documentation associated with this task will be maintained by the RSO.

CNSI will periodically forward invoices for services to AMS, who will forward a copy to the USNRC. AMS will then request that the USNRC release sufficient decommissioning funds to honor the invoice.

Deliverable

Once the sources are accepted at the Barnwell site, a Certificate of Disposal will be returned to AMS. The certificate will be maintained in the AMS record keeping system pursuant to RSP-004, "Radiation Protection Records".

Task 2: Disposal of Dry Solid Waste

Purpose

In addition to the sealed sources and the bulk cobalt, there are approximately 2,500 cubic feet of dry solid radioactive waste (containing approximately 25 curies of ^{60}Co at the London Road facility). Some of these materials are located in the facility basement, and others are contained within the high level waste storage area and the isotope shop warehouse. Like the sources and bulk cobalt, this material serves no purpose at AMS and, in fact, presents a number of operational disadvantages such as increased demands for surveillance and accountability actions, increased potential for facility contamination, and increased personnel exposures. Therefore, as part of the contract with CNSI, AMS has negotiated for disposal of the dry solid waste at the Barnwell facility. However, successful execution of this contract is dependent upon whether AMS is permitted to "tap" its resources currently held by the USNRC for decommissioning funding.

Approach

A final inventory of the materials to be disposed of (e.g., type, form, packaging, activity) will be prepared and forwarded to CNSI. Shortly before CNSI arrives at the London Road facility to effect the solid waste shipment, the packaged materials will be staged. All materials will be packaged in the appropriate shipping containers (Type A, Type B, or industrial packaging). Depending upon exposure rates, overpacks may be used. AMS intends to dispose of the low-level radioactive waste at the Barnwell facility.

It remains a possibility that not all of the low-level waste materials at the London Road facility can be properly characterized and/or packaged prior to CNSI's arrival on site. Therefore, some waste materials may be left on site for storage until other wastes can be consolidated with them. These wastes will be shipped for disposal at some future date.

Responsibilities

AMS has assigned a project manager to coordinate waste characterization, packaging and loading activities (A. Duff, IEM). An inventory of the materials to be disposed of will be prepared by AMS, and the waste will be packaged. Handling of the packaged waste between the AMS staging areas, the transport vehicle, and the Barnwell facility will be performed by CNSI. Project health physics and dose tracking will be preformed by the AMS Radiation Safety Officer (R. Meschter). All CNSI shipments will be inspected and released by the project manager prior to departure from the London Road facility. The radioactive materials inventory debited by the RSO shortly thereafter. All documentation associated with this task will be maintained by the RSO.

CNSI will periodically forward invoices for services to AMS, who will forward a copy to the USNRC. AMS will then request that the USNRC release sufficient decommissioning funds to honor the invoice.

Deliverable

Once the materials are accepted at the Barnwell site, the Certificate of Disposal will be returned to AMS. There it will be maintained in the AMS record keeping system pursuant to RSP-004, "Radiation Protection Records".

Task 3: Radiological Stabilization of Basement

Purpose

As a result of technically-indefensible legal action taken by the Northeast Ohio Regional Sewer District (NEORSD), the AMS facility on London Road does not have a direct connection between the building and the regional sewer system for the discharge of sanitary waste, rain water from the building's roof drains or storm water that surrounds the building. Even after completion of an extensive sewer remediation project that involved installation of a new foundation drainage system and a new manhole, the free-flow of water away from the building is still not possible for a variety of legal and regulatory reasons. As of the date of this proposal, AMS is bound by court order and USNRC license requirements to pump water from the foundation drains into hold-up tanks, sample the tanks for the presence of radioactivity, notify the NEORSD of pending discharge of each tank, and await the results of a NEORSD confirmatory sampling effort prior to discharge. As a result, a major portion of the daily activities performed by the AMS staff at the London Road facility involves water management.

As of the date of this letter, over 180,000 gallons of water have been pumped, sampled and discharged from the remediated foundation drainage system. To date, no detectable ^{60}Co has been identified. Furthermore, in an April 12, 1996 letter from Robert Meschter (AMS) to John Madera (USNRC Region III), AMS demonstrated that the soils upon which the London Road building was constructed have the same radiological character now as they did before the 1995 flood. Therefore, baring a failure in the function of the remediated foundation drainage system, the probability of contaminated water inadvertently entering the regional sewer system is remote, at best.

Because of the delay associated with discharge of each tank (e.g., typically five days), coupled with the increased precipitation AMS has experienced during the spring and early summer months, temporary limitations in tank storage capacity can occur. If a spring or summer storm should occur such that the tank or pumping capacity is exceeded, AMS has one of two options: (1) it must discharge the pumped water directly into the street without sampling and in violation of the court order, or (2) it must cease pumping the water out of the manhole. If pumping ceases, (e.g., if the foundation drainage system is rendered non-functional), the storm water that accumulates around the building will enter the building basement, come in contact with the contents of the WHUT Room and the stored waste, and become contaminated. This water cannot be discharged until the radioactivity is removed.

The financial and radiological impacts associated with foundation drain failure or impaired tank capacity would be similar to those suffered during the financially-devastating flood event of 1995. This occurrence forced AMS to implement an expensive water treatment and sewer remediation program, costing in excess of $1M, only to be forced to store the treated water on site.[12] It also drained the corporation of almost all of its cash reserves, rendering it unable to bear the cost of another water clean-up project if such an event should be required. Thus it is imperative that the basement of the London Road facility be converted into a radiologically benign environment such that potential water incursion will result in negligible regulatory or financial harm.

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[12] As of the date of this report, the treated water from the 1995 project continues to be stored in the AMS warehouse in collapsible storage tanks.

Approach

The basement of the AMS facility currently contains two primary sources of transferrable radioactivity. These are the basement itself, which exhibits removable activity of approximately 10,000 dpm per 100 cm^2, and the WHUT Room,[13] which is hydraulically-connected to the remainder of the basement and contains approximately 40 curies of ^{60}Co in the form of residual surface contamination, residual Hot Cell waste in the tanks, and contaminated water.[14] In order to ensure that a future water incursions into the basement does not produce a large volume of contaminated water, this step of Building Recovery Project is to decontaminate the basement to levels that are below the AMS release criteria, and to stabilize the WHUT Room such that no water may enter or exit.

A proposal from Pentek, Inc. (Coraopolis, Pennsylvania) has been received wherein a dustless decontamination methodology for the concrete floors and walls of the AMS basement will be used. Pentek will provide a decontamination crew of trained operators, and all equipment and accessories for decontamination of approximately 3,500 square feet of concrete surface. (The scabbling depth is anticipated to be less than 1/8-inch, however arrangements for additional effort at "hot spots" and slab anomalies has been included in the contract.) The release criteria for the basement will be: 1,000 dpm/100 cm^2 removable activity and 5,000 dpm/100 cm^2 total (fixed plus removable) activity.[15] The waste generated as part of this effort (e.g., approximately 10 drums of loose powder) will be incorporated into the WHUT Room stabilization effort, described as follows.

A proposal has been received from MS Technology, Inc. (Oak Ridge, Tennessee) to provide an engineering design for stabilization of the radioactive materials in the WHUT Room. The purpose of the project is to ensure that liquids do not enter or exit the WHUT Room for the duration of its safe storage period. The design must address any standing water or void spaces that currently exists in the WHUT Room and incorporation of the waste generated from the Pentek work. However, all stabilizing materials used for this task must be readily removable during eventual building decommissioning. The work for this sub-task will be performed under the supervision of a registered Professional Engineer (PE). Once the design has been received and reviewed by AMS, a copy will be forwarded to the USNRC for final approval.

Immediately after the basement has been decontaminated and the WHUT Room has been stabilized, a final status survey, pursuant to the methodologies described in NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination" will be performed and documented. A copy of the survey report will be provided to the USNRC.

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[13] The WHUT room, located directly beneath the Hot Cell, collected waste from the hot cell via a floor drain. It was designed to hold liquid wastes generated in the hot cell and in the isotope area. It contains a 100-gallon tank for waste water from a cell sink and floor drain; a 500-gallon tank for overflow from the smaller tank and liquid waste from the showers, sinks and drains in the laboratory, and a two-column ion exchange system. The surfaces of the WHUT Room are unpainted poured concrete. A small dike is located at its entrance to prevent the migration of liquids to other areas of the basement in the event of a spill. The various pipes and conduit that originally penetrated the walls have been removed and sealed with lead rope, lead wool, concrete and silicone. No light or power exists in the room, and there is no floor drain.

[14] Integrated Environmental Management Report No. 94009/G-3104, "Evaluation of the WHUT Room Source Term", June 16, 1995.

[15] U. S. Nuclear Regulatory Commission, Regulatory Guide 1.86.

Responsibilities

AMS will obtain the engineering design for the WHUT Room stabilization from a registered Professional Engineer and forward it to the USNRC for final approval. AMS will assign a project manager for the basement decontamination and the WHUT Room stabilization (R. Alan Duff, IEM). The WHUT Room stabilization and decontamination effort will be performed by AMS personnel and Pentek, with the assistance of a registered Professional Engineer. The final status survey of the basement will be performed by the project manager and AMS. Project health physics and dose tracking will be preformed by the AMS Radiation Safety Officer (R. Meschter). All documentation associated with this task will be maintained by the RSO.

Deliverable

At the completion of this task, the final status survey report will be generated. A copy of the survey will be forwarded to the USNRC, along with a request for performance of a confirmatory survey and release of the basement for unrestricted use.

Task 4: Hydrological Stabilization of Basement

Purpose

After the 1995 basement flood, questions were raised in regard to the structural integrity of the building. In subsequent inspections by the USNRC and a registered Professional Engineer under contract to AMS, it was determined that there was no apparent damage to the building or its ability to contain its inventory of licensed radioactive materials. However, there is no guarantee that a future flood event will have a similar outcome.

Task 3 (above) of the Building Recovery Project is to stabilize the radiological conditions in the basement of the AMS facility such that the radiological impact of water into the basement is minimized or eliminated. Task 4 then will ensure that the probability for water incursion is minimized.

Approach

For this task, AMS will submit to the USNRC a formal request to free-release ground/surface water from the foundation drains. This request will be based upon the volume of clean water that has been pumped to date from the new foundation drainage system, a statement of the radiological stability of the basement, the WHUT Room, the abandoned lateral connection from the building to the sewer interceptor, and the abandoned drain tile located in the vicinity of the source garden, and a proposal for periodic confirmatory measurements during an interim period of mutually-agreeable duration.

Since the regional sewer system is a combined sanitary/storm system, it is possible, even after the new connection has been made, that a major storm could cause basement flooding. Should this unlikely event occur, the radiological impacts will be minimal because the basement of the building will have been released for unrestricted use (see Task 3).

Responsibilities

The request to free-release foundation drainage water will be prepared by AMS. Once the amended license has been received, AMS and its legal counsel will pursue the legal authority to free release this water.

Deliverable

A request to permit free-release of foundation drainage water, along with all supporting documentation, will be submitted to the USNRC. A copy of the court order to permitting free-release of the water will be submitted to the USNRC. Confirmatory sampling results from the discharge system will be made available at the AMS facility for review by the USNRC during future inspections.

Task 5: Modify Conceptual Decommissioning Plan and Decommissioning Funding Plan

Purpose

As part of the license renewal process, and pursuant to 10 CFR 30.36, AMS must provide the USNRC with a decommissioning funding plan. The current basis for the funding plan is the Conceptual Decommissioning Plan for the London Road Facility (Revision 0) which was submitted to the USNRC on October 20, 1995. On March 20, 1996, AMS received comments on the Plan from the USNRC, responses to which were returned on April 12, 1996. To date, the USNRC has taken no additional action on this Plan.

The approach and cost estimate contained within Revision 0 of the Plan were designed to accommodate on-going possession of up to 93,100 curies of ^{60}Co in a building with a variety of radiologically-restricted areas and potentially-significant dispersible activity. Once the Building Recovery Project is complete, the abbreviated quantity of items to be decommissioned will demand lesser funds for eventual decommissioning. Therefore, a revision to the Plan will be required.

Because the USNRC has not yet made a decision as to the appropriate decommissioning methodology for the London Road Facility (e.g., DECON vs SAFSTOR), all applicable technologies will be evaluated in Revision 1 of the Plan. The goal will be to optimize cost, waste generated for eventual disposal, and the magnitude of personnel exposures. However, Revision 1 will also contain a clear description of the preferred methodology and a detailed cost estimate for implementing that methodology.

Once the USNRC has approved the Conceptual Decommissioning Plan, AMS will submit a revised Decommissioning Funding Plan wherein new decommissioning financial assurance instruments will be included. If, as anticipated, the net value of the current letter of credit is reduced, a new letter of credit will be submitted.

Approach

The key components of Revision 0 of the Conceptual Decommissioning Plan are the description of items to be decommissioned, the methodology by which decommissioning will be implemented at the time of license termination, and the decommissioning cost estimate. For the revised Plan, the only items remaining to be decommissioned after the Building Recovery Project is complete will be the Hot Cell, the stabilized WHUT Room, the Hot Cell ventilation system, a small section of abandoned drain tiles, and the abandoned lateral connection from the building to the regional sewer system. Thus, the "items to be decommissioned" section of the Plan will be modified accordingly in Revision 1.

Although an ALARA analysis will be presented for both the DECON and SAFSTOR decommissioning alternatives, AMS anticipates that the preferred decommissioning alternative in Revision 1 will remain SAFSTOR, since this alternative clearly satisfies the requirements for protecting the public while minimizing initial commitments of time, labor, money, occupational radiation exposure, and waste disposal.[16] Modifications to the facility would be limited to those which ensure the security of the building against intruders, and ensure containment of the licensed inventory. Finally, a revised cost estimate for the preferred alternative, presented in the same format as Appendix F of USNRC Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70 and 72" (June, 1990), will be prepared.

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[16] As a result of radioactive decay of this material, reductions in personnel exposure and simplifications in the complexity of operations will be achieved by deferring major decontamination efforts for 50 years. Also, because much of the residual radioactivity present in the facility will have decayed to background levels after the storage period, the volume of material that must be packaged for disposal, if any, will be significantly reduced.

Responsibilities
Revision 1 of the Conceptual Decommissioning Plan for the London Road Facility will be prepared by AMS and forwarded to the USNRC for review/comment. Once approved, the Plan will be funded by the corporation to the level of the decommissioning cost estimate shown therein.

Deliverable
AMS will submit to the USNRC Revision 1 of the Conceptual Decommissioning Plan for the London Road Facility, and a Decommissioning Funding Plan that contains a new letter of credit. The scheduled delivery date of these items is subject to timely USNRC approvals, but is anticipated within six (6) months after authorization to proceed on the Building Recovery Project is given.

Task 6: Free-release Remainder of Building

Purpose
Because only sealed sources will be handled at the AMS facility after the Building Recovery Project is complete, it is in the best interest of AMS to release the remainder of the building, with the exception of the Hot Cell and the WHUT Room, for unrestricted use. This action will reduce the cost of on-going surveillance and will ensure that personnel are not unnecessarily exposed to radioactive materials. Furthermore, full-facility decontamination will reduce/eliminate the potential for re-contamination of the basement and will permit the corporation to pursue other (non-radiological) uses for the building.

Approach
Prior to the start of work, a plan of action will be developed. This will begin with performing an initial "scoping" survey, using wide area detectors, for the purpose prioritizing activities and securing the necessary supplies and resources. It is likely that work will proceed from "least contaminated" to "most contaminated" areas of the facility. However, throughout the project, close attention will be paid to waste minimization since all waste generated during this task must be packaged for eventual off-site shipment.

Immediately after the remainder of the building has been decontaminated, a final status survey, pursuant to the methodologies described in NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination" will be performed and documented. A copy of the survey report will be provided to the USNRC, along with a request to release the building for unrestricted use.

Responsibilities
Project management, surveys, decontamination, and waste packaging will be performed by AMS personnel. The final status survey of the building will also be performed by AMS personnel. Project health physics and dose tracking will be preformed by the AMS Radiation Safety Officer (R. Meschter). All documentation associated with this task will be maintained by the RSO.

Deliverable
At the completion of this task, the final status survey report will be forwarded to the USNRC, along with a request for performance of a confirmatory survey and release of the building, with the exception of the WHUT Room, Hot Cell and ventilation system, for unrestricted use.

Task 7: Request Exemption from Physical Inventory Requirements

Purpose
Approximately 3,000 curies of ^{60}Co in the form of doubly-encapsulated sealed sources are currently located in a storage well in the Hot Cell. Because the well plug has become lodged in the well, these sources cannot be removed and included in the inventory reduction efforts (Task 1) without incurring significant damage to the Hot Cell's capabilities. Since the integrity of the Hot Cell is necessary to support on-going

licensed operations, the Building Recovery Project does not include removal of the "stuck plug" and extraction of the sources contained therein.[17]

Provision 14(c) of USNRC license No. 34-19089-01 states that "A physical inventory of all radioactive material possessed under this license will be conducted on or before June 1, 1993. Thereafter, a physical inventory of all radioactive material possessed under this license will be completed within 60 months of the previous physical inventory". Since the physical inventory of the remaining sealed cannot be performed until the stuck plug is removed, AMS will submit an amendment application requesting deferral of the physical inventory requirement for these sources until after plug removal. Supporting information for this amendment will be a copy of the inventory log showing the disposition of all sealed sources between June 10, 1996 and the end of the Building Recovery Project, that were at the London Road facility, the number and location of sealed sources that remain at the London Road facility after the Building Recovery Project is complete, and documentation to show that additional sources *do not exist* in any other location of the building. This information will show that all sealed source (e.g., those that can be physically inventoried and those that are sealed within the stuck plug of the Hot Cell) are "accounted for" and under the control of the AMS Radiation Safety Officer.

Approach

Immediately after Tasks 1 through 4 of the Building Recovery Project are complete, AMS will submit an application to amend Provision 14(c) of License No. 34-19089-01 requesting an exemption from performing a physical inventory of the sources in the stuck plug until the plug is removed. Included in the application will be an accounting of the sealed source status for the year prior to the application, a summary of surveillance information confirming that "unaccounted for" sources do not exist at the facility, and a commitment to complete the physical inventory once the stuck plug is removed.

Responsibilities

The amendment application will be submitted by the AMS Radiation Safety Officer.

Deliverable

An application to amend License No. 34-19089-01, along with supporting documentation, will be forwarded to the USNRC.

Task 8: Request Exemption from Emergency Plan Requirements

Purpose

Title 10, Code of Federal Regulations, Section 30.32(i) requires submittal of an "Emergency Plan for Responding to a Release" if the possession limit at the licensee's facility exceeds 5,000 curies of ^{60}Co. As part of its license renewal efforts, an emergency plan was in fact, submitted by AMS to the USNRC for review and comment. On June 7, 1995, after initial USNRC review of the plan, a letter of deficiency was issued and additional information was requested. Because the magnitude of deficiencies was significant, a revised Plan was submitted on September 22, 1995. This revision was consistent with the guidance contained in USNRC Regulatory Guide 3.67 (1992), "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities". On February 28, 1996, the USNRC mailed comments on Revision 0 of the Emergency Plan. The AMS response to those comments was forwarded on March 22, 1996. To date, the USNRC has taken no additional action on this issue.

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[17] This task will eventually be completed. Therefore, it will be included in the long range strategic plan for the facility, submittal of which is addressed in Task 11 of the Project.

Included in the March 22, 1996 submittal were the AMS responses to comments received from the Ohio Environmental Protection Agency, the Ohio Emergency Management Agency, the Cuyahoga Emergency Management Assistance Center, the Ohio Department of Health, and the City of Cleveland Division of Fire. These agencies were listed in the AMS emergency plan as "first responders". However, many of these agencies were "less than cooperative" in providing a written commitment to respond and a listing of services they would/could provide to AMS in the event of an emergency.

Task 10 of the building Recovery Project is for AMS to submit an amendment application to reduce the maximum inventory to 10,000 curies. This limit will be sufficient for the sources contained within the stuck plug of the Hot Cell, and the sources that will be brought to the facility for calibration, loading and shipping to purchasers of teletherapy units. Without exception, the 10,000 curies will be comprised of only non-dispersible materials. Therefore, an exemption from the emergency planning requirement of 10 CFR 30.32 will be solicited after Task 10 is complete.

Approach

Even after completion of the Building Recovery Project, the AMS license limit will exceed the 5,000 curie exemption for submission of an emergency plan. However, as permitted in 10 CFR 30.32(i), AMS will submit an evaluation showing that the maximum dose to a person offsite in the event of an emergency will not exceed one (1) rem effective dose equivalent based upon the fact that the radioactive material inventory is not subject to release during an accident because of its physical form and the way in which it is packaged. The evaluation will contain sufficient hypothetical dose estimates to support the AMS position.

Responsibilities

The application for exemption from emergency plan requirements will be prepared by the AMS Radiation Safety Officer.

Deliverable

An application for exemption from emergency plan requirements, including an evaluation of the maximum dose to a person offsite in the event of an emergency, will be submitted to the USNRC.

Task 9: Request Extension of Safe Storage Period for WHUT Room

Purpose

In an October 20, 1988 letter from A. B. Davis (USNRC) to Dr. Seymour S. Stein (AMS), the USNRC concurred with AMS's February 8, 1988 and July 6, 1988 request to delay decontamination of the WHUT Room until personnel exposure rates are reduced significantly, stating that "isolation can be carried out safely with some benefit in the reduction in occupational exposure and waste requiring disposal" (see page 1 of the October 20, 1988 letter). AMS continues to maintain that effective decontamination of the WHUT Room will result in significant but unnecessary personnel exposures. Therefore, an extension of the safe storage period for the WHUT Room for an additional license term (e.g., five years) will be requested.

Approach

AMS will perform an ALARA analysis comparing two WHUT Room decontamination options. Option (1) will be immediate decontamination and option (2) will be delayed decontamination. The analysis will emphasize short- and long-term personnel exposures, waste volume considerations, and cost.

Responsibilities

The ALARA analysis will be performed by AMS. The report of findings, attached to a request to extend the safe storage period for the term of the license, will be submitted to the USNRC by the AMS Radiation Safety Officer.

Deliverable

The request to extend the WHUT Room safe storage period for an additional license term will be submitted to the USNRC. Included will be a detailed description of radiological conditions in the WHUT Room and the findings from the ALARA analysis, and a commitment to re-visit this issue during subsequent license renewals.

Task 10: Request Reduction in License Limit

Purpose

At the completion of the Building Recovery Project, approximately 3,000 curies of residual radioactivity will remain.[18] In addition, and as part of its routine operations, AMS may also bring up to 6,000 curies in the form of sealed sources to the facility for calibration, loading and shipping to purchasers of teletherapy units. So that the scope of License No. 34-19089 reflects actual site activities and conditions for the purpose of reducing regulatory liabilities, AMS will seek an amendment to License No. 34-19089-01 to reduce the maximum possession limit.

Approach

Pursuant to 10 CFR 30.32, AMS will submit an application to amend License No. 34-19089-01 to permit a maximum possession limit of 10,000 curies of ^{60}Co in the form of sealed sources and residual contamination in the Hot Cell, ventilation system and WHUT Room. Included will be a description of the intended use of the materials, and a copy of the AMS Radiation Protection Program Plan.

Responsibilities

The amendment application will be submitted by the AMS Radiation Safety Officer.

Deliverable

An application to amend the maximum license inventory to 10,000 curies of ^{60}Co, along with all supporting documentation and amendment fees, will be submitted to the USNRC.

Task 11: Submit Long-Range Strategic Plan

Purpose

After completion of the Building Recovery Project, limited personnel and financial resources will still render it impossible for AMS to complete the remaining activities in the "Strategic Plan for the London Road Facility" in a single campaign. Therefore, to avoid unnecessary and negative financial impacts on the company, yet ensure steady and well-managed progress toward completion, the remaining activities will be prioritized based upon an activity's ability to improve the implementability of other activities, AMS's ability to fund the activity in the near-, intermediate- and long-term, and on the cost/benefit associated with the activity's timely completion. In general, high priority items will be scheduled for completion within one year after the Building Recovery Project, intermediate priority items within one to three years, and lower priority items within three to five years.

Approach

To ensure steady progress toward completing the outstanding activities, a revision to the "Strategic Plan for the London Road Facility" will be prepared. As with the previous revisions, this document will contain AMS's commitment to and schedule for completing such remaining items as the physical inventory of sealed sources, WHUT Room decontamination, disposition of treated water in the collapsible storage tanks, audit/assessment of the Radiation Protection Program, upgrade of Standard Operating Procedures,

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[18] With the exception of the contents of the WHUT Room and surface contamination in the Hot Cell and its ventilation system, the physical form of these materials will be doubly-encapsulated sealed sources.

housekeeping improvements, community relations, reconnection of sewer system to London Road Interceptor, and any other items that may be identified by AMS or the USNRC.

Revision 0 of the Strategic Plan for the London Road Facility" was submitted to the USNRC on October 11, 1995. Included in Revision 0 was a commitment to provide quarterly updates on AMS's progress toward meeting its goals. The last quarterly report, Revision 3 of the Plan, was submitted to the USNRC on April 8, 1996. Therefore, Revision 4 of the Plan, due for submittal on July 15, 1996, will address, primarily, activities performed during the Building Recovery Project. Revision 5 of the Plan, due for submittal on October 15, 1996, will show the status of the Building Recovery Project, but will also address the long-range plans for the facility.

Responsibilities

Revisions 4 and 5 of the Strategic Plan for the London Road Facility will be prepared by the AMS Radiation Safety Officer.

Deliverable

Revisions 4 and 5 of the Strategic Plan for the London Road Facility will be submitted to the USNRC pursuant to the Revision 0 schedule (e.g., July 15, 1996 and October 15, 1996, respectively).

Task 12: Perform Routine Operations and Meet Regulatory Commitments

Purpose

As part of its continuing license obligations, AMS has committed to performing certain duties and implementing certain specific actions in response to USNRC requests. To ensure that the Building Resource Project does not inadvertently divert attention from timely response to previous regulatory demands, and to avoid the need to solicit extensions in meeting those commitments. AMS intends to track all outstanding regulatory and compliance issues along with the 11 tasks in the Building Recovery Project.

Approach

A task list for the Building Recovery Project, which includes the task description, responsible party(ies), due date, and current status, was developed on May 10, 1996. Included in the task list are specific regulatory commitments such as Radiation Safety Committee meetings, routine surveillance activities, and responses to USNRC requests for information (e.g., the Shewmaker inspection report, the December 6, 1995 Demand for Information Letter). The task list is updated on a daily basis.

Responsibilities

Commitment tracking throughout the Building Recovery Project will be performed by the AMS Radiation Safety Officer. Activities will be performed by specified individuals as shown on the task list for the Building Recovery Project.

Deliverable

None. However, the USNRC may wish to review the task list as part of its routine inspections of the AMS facility.

APPENDICES B AND C WITHHELD PURSUANT TO 10 C.F.R. § 2.790

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

AUG 05 1996

David Cesar
Vice President and Treasurer
Advanced Medical Systems, Inc.
1020 London Road
Cleveland, OH 44110

Dear Mr. Cesar:

Enclosed is Amendment No. 44 to your NRC Material License No. 34-19089-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (708) 829-9887 so that we can provide appropriate corrections and answers.

Based upon the attached Safety Evaluation Report (SER), this amendment authorizes Advanced Medical Systems to proceed with the actions described in its July 1, 1996 letter for the purpose of financing Tasks 1 and 2 of the Building Recovery Project (BRP), described in letter dated June 10, 1996.

License Condition Numbers 23 and 24 have been added to license the activities requested in your June 10 and July 1, 1996 letters. Condition Number 23 authorizes AMS to perform Tasks 1 and 2 of the BRP with the following stipulations:

- The funds released from the collateral supporting the letter of credit dated January 27, 1995 be used only for the purpose of completing Tasks 1 and 2 of the BRP described in the June 10 letter;

- The existing letter of credit be promptly amended to reflect the remaining balance of the supporting collateral, and then submitted to NRC for review; and

- Any funds remaining after completion of Tasks 1 and 2 be added to the collateral supporting the letter of credit. The letter of credit must be revised to reflect the addition of these funds.

Condition Number 24 was added to require that AMS submit the following documents to NRC for review:

- A revised Conceptual Decommissioning Plan (CDP) and cost estimate no later than August 30, 1996, and assuming NRC approval of the revised CDP, a revised Decommissioning Funding Plan that will contain a description of a new decommissioning financial instrument no later than September 15, 1996.

- The vendor's/contractor's radiological health and safety procedures and radioactive materials license for NRC review prior to initiation of Tasks 1 and 2 of the BRP.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

for

Kevin G. Null
Nuclear Materials Licensing Branch

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

Enclosures:
1. Amendment No. 44
2. Safety Evaluation Report

MATERIALS LICENSE

Amendment No. 44

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

Licensee	
1. Advanced Medical Systems, Inc.	In accordance with the letter dated July 1, 1996
2. 1020 London Road Cleveland, OH 44110	3. License Number 34-19089-01 is amended in its entirety to read as follows:
	4. Expiration Date December 31, 1994
	5. Docket or Reference No. 030-16055/040-08764/030-17154

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Cobalt-60	A. Solid Metal	A. 150,000 curies
B. Cobalt-60	B. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	B. 135,000 curies (no single source to exceed 13,700 curies)
C. Cesium-137	C. Sealed sources (teletherapy/ radiography sealed sources which have been evaluated and approved for commercial distribution by the NRC or an Agreement State)	C. 40,000 curies (no single source to exceed 2,200 curies)
D. Depleted Uranium	D. Nickel Plated	D. 4,040 kilograms
E. Cobalt-60	E. Sealed Sources	E. 15,000 curies

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-19089-01

Docket or Reference Number
030-16055/040-08764/030-17154

Amendment No. 44

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
F. Cobalt-60	F. Sealed Sources (any sealed source approved by the NRC or an Agreement State)	F. 15 millicuries

9. Authorized Use:

A. For storage only incident to waste disposal or transfer to an authorized recipient. This license does not authorize the manufacture of sealed sources.

B. For installation, maintenance of, dismantling and servicing of Picker Corporation and Advanced Medical Systems, Inc. teletherapy units and Picker Model 6145 radiography units possessed by licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State. For installation and removal of sealed sources into Picker Corporation, Advanced Medical Systems, Inc. and Keleket Barnes teletherapy units of licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State. For training Hospital or Clinic personnel for in-house service operations on teletherapy equipment, on unit model per course, in accordance with letter dated August 15, 1988 and September 29, 1988.

C. For installation, maintenance, dismantling and servicing of Picker Corporation and Advanced Medical Systems radiography and teletherapy units of licensees authorized to possess the radioactive material pursuant to a specific license issued by the Commission or an Agreement State.

D. Shielding material in Picker Corporation and Advanced Medical System, Inc., radiography and teletherapy devices.

E. For storage only, those non-NRC approved sources in the possession of the licensee prior to the issuance of this amendment.

F. For use in devices (including Tech OP Model 571 Calibrator described in application dated November 12, 1984) approved by the Nuclear Regulatory Commission or an Agreement State to calibrate radiation survey instruments.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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CONDITIONS

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

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

The Alternate Radiation Protection Officer for routine health physics activities only is Christopher Reed.

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

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

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

	CS 600	C 1000	C 2000	C 3000	C 5000	C 10,000	C4	C8	C9	C12	Cyclops
USER											
Stephen Haddock	5	5	5	5	5	5	5	5	5	5	5

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

	V 1000	V 2000	V 3000	V 10,000	C V4	C V9					
USER											
Stephen Haddock	5	5	5	5	5	5					

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-19089-01

Docket or Reference Number
030-16055/040-08764/030-17154

Amendment No. 44

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

12. A. (1) Each sealed source acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transfer or indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries of less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than hydrogen-3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designated for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in what the sealed source is permanently or semi-permanently mounted or stored on which one might expect contamination to accumulate. Records o leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch, describing the equipment involved, the test results, and the corrective action.

13. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. Inventory Requirements:

A. An inventory system will be established that accounts for the receipt, movement, transfer and disposal of all radioactive material possessed under this license. Records of inventories will be maintained for 10 years from the date of each inventory.

B. A complete examination of records will be completed every six months to confirm the location of all radioactive material and ensure that possession is within the limits specified in this license.

C. A physical inventory of all radioactive material possessed under this license will be conducted on or before June 1, 1993. Thereafter, a physical inventory of all radioactive material possessed under this license will be completed within 60 months of the previous physical inventory.

15. The licensee's field service audits (as described in the ATC Medical Group Management Plan, revised April 1, 1989, and submitted with letter dated April 17, 1989) shall be performed unannounced by the Radiation Protection Officer (i.e., Radiation Safety Officer).

16. The licensee shall follow the recommend survey frequencies outlined in Regulatory Guide 8.21, Revision 1, October 1979, in work areas where radioactive materials are handled or used.

17. The licensee shall maintain records of information important to safe and effective decommissioning at 1020 London Road, Cleveland, Ohio per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

18. The licensee shall maintain and execute the response measure of their Emergency Plan dated October 25, 1991 and revised January 1992, May 27, 1992 and April 26, 1993. The licensee shall make no change in the emergency plan submitted pursuant to 10 CFR [30.32(i), 40.31(j), 70.22(i)] that would decrease the effectiveness of the plan without prior Commission approval. The licensee may make changes to its Emergency Plan without prior Commission approval if the changes do not decrease the effectiveness of the plan. The licensee shall maintain records of changes that are made to the plan without prior approval for a period of three years from the date of the changes and shall furnish the Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and the appropriate NRC Regional Office specified in Appendix D of 10 CFR 20, a report, within six months after the change is made, containing a description of each change.

19. The licensee is authorized to begin the following activities no sooner than March 17, 1995, and must complete them by the date specified in each item in accordance with letters dated January 27, February 2, 10, and 14, and March 1, 3, 8, and 10, 1995, wherein the licensee proposed and clarified its plans for: (1) dealing with the accumulation of ground water in and around its facility basement; (2) immobilizing and/or remediating contamination that has collected in below ground sewer piping and manholes; and (3) processing future ground water that builds up around the facility. These plans address the following actions the licensee will take.

    A. Process water that is currently stored outside its facility in above-ground tanks.

        i. Tanked water will be processed in-situ using a submersible water treatment system that includes filtration and ion-exchange demineralization as described in letters dated March 1, 3, 8, and 10, 1995.

        ii. Water will be treated until it contains no detectable non-soluble cobalt-60 and less than 1000 pCi/l of soluble cobalt-60 as determined by a contract analytical laboratory. The licensee may continue to pump treated water to the collapsible storage containers prior to receiving results of solubility tests from the contract laboratory. The treated water will subsequently be pumped to 25,000 gallon storage containers located in the facility warehouse, as described in letters dated March 3, 8 and 10, 1995.

    B. Simultaneously pump and process water currently residing in the sewer manhole and lateral, building sump pit and basement. This project shall be completed by June 30, 1995.

        i. Pumping will be sequenced as described in letter dated March 1, 1995, to ensure a positive hydrostatic pressure is maintained from outside to inside the facility's basement.

ii. Water in the sewer manhole, lateral, building sump pit, and basement will be pumped to a radiologically controlled area of the facility and processed using a skid mounted, multi-stage filtration and ion-exchange system as described in letters dated March 1, 3, 8 and 10, 1995. Spill procedures and radiological controls will be implemented as described in letter dated February 14, 1995, and Attachment 2 to letter dated March 1, 1995.

iii. Water removed from the sewer manhole, lateral, building sump pit, and basement will be treated to contain no detectable non-soluble cobalt-60 and less than 1000 pCi/l soluble cobalt-60 as determined by a contract analytical laboratory. The licensee may continue to pump treated water to the collapsible storage containers prior to receiving results of solubility tests from the contract laboratory. The treated water will subsequently be pumped to 25,000 gallon storage containers located in the facility warehouse, as described in letters dated March 3, 8, and 10, 1995.

C. Water sampling and analytical protocols will be as described in letter dated February 2, 1995, as clarified in letters dated February 14, and March 3, 1995. Solubility of cobalt-60 in samples containing detectable activity will be demonstrated in accordance with the reference in Supplement 2 to letter dated March 3, 1995. All solid radwaste generated from the water processing activities, including filter and demineralizer resin wastes, will be collected and stored at the London Road facility pending its ultimate disposal as radioactive waste.

D. Excavate areas around the facility to allow: (i) access to the radioactively contaminated four-inch waste discharge line; and (ii) the radiological evaluation of the facility's underdrain system and surrounding soils.

i. Excavate the soil in the vicinity of the building's four-inch waste discharge line and underdrains and disconnect these drains as described in letter dated March 1, 1995. Evaluate the radiological contamination status of the underdrain system and remediate or replace the system. Reconnect the underdrain system to the building sump pit and pump, test and process the underdrain system waters as described in letter dated March 1, 1995. The testing and processing of water pumped from the underdrain system will continue until sampling of the water consistently reveals no detectable non-soluble cobalt-60 and less than 200 pCi/l soluble cobalt-60.

ii. Evaluate the radiological status of the soil in the vicinity of the underdrain system and building sump pit as described in the letter dated March 1, 1995.

E. Immobilize the radioactive contamination present in the sewer manhole and lateral.

i. Completely grout-in the radioactively contaminated manhole and lateral up to the sewer interceptor as described in "Issue 4" of letter dated January 27 and letter dated March 1, 1995. The grouting will render the existing sewer discharge piping system inoperable and immobilize (fix) the radioactive contamination that resides in the system.

F. Remediate the London Road interceptor in the vicinity of the abandoned lateral, as described in letter dated January 27, 1995. The remediation activities will be coordinated with the Northeast Ohio Regional Sewer District.

G. i. The licensee shall notify the NRC Region III office no later than July 14, 1995, regarding the status of the completion of License Condition Numbers 19.B., 19.D. and 19.E.

ii. The licensee shall notify the NRC Region III office no later than July 14, 1995, to confirm initiation of the remediation project described in License Condition Number 19.F., and provide an estimated completion date.

H. The licensee shall notify the NRC Region III office in writing of any change in projected milestone dates specified in letter dated July 19, 1995 for the projects described in License Condition Nos. 19.D., E. & F. Included in the notification must be the reason for the change, and the revised milestone date.

20. The licensee is authorized to install a new manhole and lateral and re-connect this to the existing under drain system. The purpose of the new manhole is strictly to act as a means of collecting water from the under drain system which will be pumped to storage containers and subsequent analysis for cobalt-60 concentration.

21. The licensee is authorized to install and operate the water evaporation equipment described in letters dated March 22, 1995, June 8, 1995 and June 29, 1995.

22. Notwithstanding previous requirements, and based upon additional information provided in letters dated October 17, 1995, and December 11, 1995, the licensee is not required to grout-in the 4-inch sewer discharge line and the abandoned footer drain.

23. The licensee is authorized to perform Tasks 1 and 2 of the Building Recovery Project (BRP) as described in the letter dated June 10, 1996. The following are conditions under which the BRP funds may be used:

A. The BRP funds released from the collateral supporting the letter of credit dated January 27, 1995 shall be used solely for the purpose of completing Tasks 1 and 2 of the BRP. Implementation of Tasks 3 through 12 of the BRP is not authorized.

B. Immediately after the release of funds, the licensee shall secure an amendment to the January 27, 1995 letter of credit to reflect the remaining balance of the supporting collateral. This shall be submitted to NRC for review immediately after the instrument is amended.

C. Any funds remaining after Tasks 1 and 2 are completed shall be added to the collateral supporting the letter of credit, and the letter of credit must be revised to reflect the addition of the collateral. This shall be submitted to the NRC for review.

24. The licensee shall submit the following items for NRC review regarding Tasks 1 and 2 of the Building Recovery Project described in the letter dated June 10, 1996:

A. A revised Conceptual Decommissioning Plan (CDP) and cost estimate no later than August 30, 1996, and assuming NRC approval of the revised CDP, a revised Decommissioning Funding Plan that will contain a description of a new decommissioning financial instrument no later than September 15, 1996.

B. The vendor's/contractor's radiological health and safety procedures, and radioactive materials license prior to initiation of Tasks 1 and 2 of the BRP.

25. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated November 12, 1984;

B. Letters dated November 12, 1984 (excluding Item 4), February 12, 1985, June 7, 1985 (excluding letter Item 4), September 6, 1985 (excluding change to Page 29 of ISP-1 manual);

C. Letters dated May 29, 1986 (Response to Enclosure A, Significant Licensing Deficiencies of NRC letter dated March 7, 1986);

D. Letter dated July 23, 1986 (Response to Enclosure B, Additional Licensing Issues for Renewal Applications of NRC letter dated March 7, 1986) excluding approval of the licensee's in-house training program;

E. Letters dated August 22, 1986, October 28, 1986, November 13, 1986, November 14, 1986 and December 4, 1986 (with Revised ISP-1 Manual, Appendices A and B attached), May 7, 1987, August 3, 1987, December 31, 1987, January 15, 1988 (Item V only), August 15, 1988 (with attached course manual), September 29, 1988 (with attachments) and November 21, 1988; and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-19089-01

Docket or Reference Number
030-16055/040-08764/030-17154

Amendment No. 44

F. Letters dated March 29, 1989 (except Section 3.4 "Hot Cell Entry and Action Levels"), April 7, 1989, August 25, 1989 (except Item B(4)), July 23, 1990 (except Sections 3.0 and 5.0 of ISP-14 procedure), March 1, 1991 (with attachments), March 27, 1991 (with attachments), May 9, 1991, May 14, 1991, February 27, 1992, February 28, 1992, March 2, 1992, and March 5, 1992.

G. Letters dated April 16, 1992 (with enclosures), June 15, 1992 (with attachments), August 10, 1992, September 18, 1992, December 29, 1992 (with enclosures), January 20, 1993, March 30, 1993, March 31, 1994 (with enclosure), April 11, 1994, and September 21, 1994.

H. Letters with attachments dated January 27, 1995, February 2, 10, and 14, 1995, and March 1, 1995 (excluding reference to grouting-in the four-inch sewer discharge line), and March 3, 8, and 10, 1995.

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

i. The discharge of treated water to the sanitary sewer system.

ii. Installation of a composite sampler and flow gage.

iii. Conventional disposal of excavated soils exhibiting cobalt-60 concentrations greater than 8 pCi/g.

I. Letters dated May 3, 1995, May 17, 1995, June 6, 1995, June 13, 1995 and June 14, 1995 (received June 21, 1995) March 22, 1995 (Item 1 related to water evaporation use and associated attachments), June 8, 1995, June 14, 1995 (received June 19, 1995), June 29, 1995, July 19, 1995 (excluding all references to grouting-in the four-inch sewer discharge line and the abandoned footer drain in the vicinity of the Source Garden), July 20, 1995, July 21, 1995, October 17, 1995, December 11, 1995 (with referenced photograph), June 10, 1996 (excluding Tasks 3 through 12 of the Building Recovery Project) July 1, 1996, July 15, 1996; and

J. Surveillance Plan for the London Road Facility submitted in letters dated September 5, 1995, December 18, 1995 and May 23, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 5/2/96

By John R. Mack
Nuclear Materials Licensing Branch, Region III

DOCKET NO: 030-16055

LICENSEE: Advanced Medical Systems, Inc.
Cleveland, Ohio

SUBJECT: SAFETY EVALUATION REPORT: ADVANCED MEDICAL SYSTEMS, INC., APPLICATION TO AMEND NRC LICENSE NO 34-19089-01 DATED JULY 1, 1996

The purpose of this memorandum is to document the staff's safety review of a license amendment application submitted by Advanced Medical Systems (AMS) in a letter of July 1, 1996. In that letter, AMS requested that NRC amend License No. 34-19089-01 to allow it to implement Tasks 1 and 2 of the Building Recovery Plan which AMS submitted in a letter of June 10, 1996. Task 1 encompasses disposal of all accessible sealed cobalt-60 sources and all canisters of bulk cobalt-60 currently possessed at the licensee's London Road facility at a commercial low-level radioactive waste disposal facility while Task 2 includes disposal of dry solid waste currently stored at the facility.

The effect of these tasks would be to reduce the inventory of cobalt-60 at the licensee's London Road facility by approximately 52,000 curies. In its July 1 letter, AMS also proposed to reduce its standby letter of credit from its current amount of $1,800,000 to $940,000 and thereby free up $860,000 to finance the cost of implementing Tasks 1 and 2. These funds would be used solely for the purpose of funding transfer/disposal of the bulk and sealed sources of cobalt-60 and low-level radioactive waste. AMS also agreed in this letter to submit by August 30, 1996 a revision to the "Conceptual Decommissioning Plan for the London Road Facility" that will reflect the reduced onsite source inventory, and by September 15, 1996, assuming approval of the revised conceptual Decommissioning Plan, a revised Decommissioning Funding Plan that will contain a description of a new decommissioning financial assurance instrument.

BACKGROUND

From 1979 to 1989, AMS manufactured cobalt-60 sealed sources for teletherapy and radiography machines at its London Road facility. Since May 1991, the licensee has not been authorized, nor does it now desire, to manufacture sealed sources. License No. 34-19089-01 currently authorizes possession of up to 300,000 curies of cobalt-60. At present, approximately 55,000 curies of cobalt-60 in the form of bulk metal, sealed sources and dry solid waste are onsite at AMS' facility. (Of this inventory, approximately 3,000 curies is located in a storage well behind the hot cell stuck plug and will not be removed as part of Tasks 1 and 2.) This large quantity of cobalt-60 is not needed for the limited operations currently authorized under the AMS license.

On November 29, 1994, AMS submitted an application for license renewal. As part of the license renewal process and in accordance with 10 CFR 30.35 (c)(2) and (e), AMS submitted on January 27, 1995, an executed standby letter of credit in the amount of $1,800,000, which was supposed to reflect its cost estimate for decommissioning. By letter dated March 30, 1995, NRC informed AMS that AMS had underestimated the cost of decommissioning the facility.

On October 11, 1995, in response to a Demand for Information issued by NRC on September 17, 1995, AMS submitted a Strategic Plan to NRC for review. This plan described a number of tasks needed to assure regulatory compliance as well as streamlined routine operations and assigned priorities of high, medium and low to those tasks, as appropriate. One of the highest priority items in the AMS Strategic Plan is a reduction in the inventory of radioactive materials at the London Road facility.

On October 20, 1995, AMS submitted a "Conceptual Decommissioning Plan for the London Road Facility" to NRC. In this document, AMS estimated decommissioning costs to range between $913,000 and $3,300,000 depending on decommissioning methodology. As noted above, AMS' January 27, 1995 standby letter of credit submitted in support of its license renewal application was executed in the amount of $1,800,000. By letter dated March 20, 1996, NRC requested additional information from AMS regarding its decommissioning plan. NRC has received AMS' response and it is currently under staff review.

On June 10, 1996, AMS requested NRC authorization to proceed on a comprehensive Building Recovery Project (BRP) at the AMS facility. The BRP contained a twelve point scope of work. AMS developed this plan because it is currently facing a number of extenuating regulatory, legal and financial circumstances that are hindering its efforts to remain a viable business entity. Included in that letter was a request that NRC release a portion of the funds that AMS has committed for decommissioning the London Road facility to support the commercial disposal costs. AMS believes that once the project is complete, there will be a significantly-reduced radiological risk at the facility, license commitments will more accurately reflect AMS's on-going operational activities, compliance costs will be lower, and routine personnel exposures will be lower.

As noted above, AMS submitted an amendment request on July 1, 1996 to, among other things, amend License No. 34-19089-01 to approve implementation of Tasks 1 and 2 of the BRP.

DISCUSSION

Task 1 of the BRP involves stabilization, transfer and disposal of approximately 52,000 curies of cobalt-60. Under Task 1, the licensee and the contractor will stabilize the sources and bulk cobalt-60 (excepting those sources inside the hot cell stuck plug) with a disposal site stabilization agent that has been approved by the State of South Carolina. This stabilization will be performed inside shipping cask liners by AMS and the contractor. AMS has committed to use remote handling capabilities to the greatest possible extent in order to minimize personnel exposures from handling and stabilization of the materials. Once the stabilization agent has cured sufficiently, the cask liner will be loaded by AMS and contractor personnel into a lead-shielded, Type B shipping cask for shipment to the Low-Level Waste (LLW) disposal facility at Barnwell, South Carolina. AMS anticipates that this task will be accomplished in one or two shipments, based upon the size of Type B cask that is used. Under Task 2, approximately 2500

cubic feet of dry solid radioactive waste (containing approximately 25 curies of cobalt-60) will be inventoried by AMS, packaged in appropriate shipping containers by the contractor and shipped for disposal at the Barnwell LLW disposal facility. All onsite operations, including those of the contractor, will be conducted under the AMS license.

NRC's Office of Nuclear Material Safety and Safeguards (NMSS) and Region III have been interested in reducing the radioactive source inventory at the AMS London Road Facility since AMS amended its license in 1991 to limit authorized use of licensed materials to non-manufacturing purposes. The highest priority concern listed in the staff's September 17, 1995 Demand for Information (DFI) was "...removal of large quantities of radioactive material and low-level radioactive waste from the facility...." While AMS' continued possession of 55,000 Curies of cobalt-60 in the form of bulk metal, sealed sources and dry solid waste poses no imminent public health and safety risk, the staff noted in the DFI that continued possession of this material "...serves no useful purpose to AMS and poses avoidable risks to the workers and potential risk to members of the public." Staff believes that reduction in this inventory is consistent with the ALARA philosophy and will allow the licensee to focus on the remaining concerns expressed in the staff's September 17, 1995 DFI and the resultant AMS Strategic Plan.

Interest in decreasing source inventory has been heightened by recent legal and financial circumstances facing AMS that have the potential to hinder AMS' efforts to remain a viable business entity that can continue to provide control over activities at the London Road facility so as to protect public health and safety from radiological hazards. Staff believes that AMS' plan to reduce source inventory is a positive step towards reducing any potential for significant repercussions that could impact public health and safety should AMS cease to be a viable entity.

AMS indicated in its June 10, 1996, letter that approximately 40 curies of radioactive material that is stored onsite at the London Road facility is in a potentially dispersible form. This material consists primarily of dry solid waste, carbon granules and ion exchange resins stored in sealed 55-gallon drums or B-25 (steel) boxes. Given that this material is potentially dispersible, staff is concerned that continued storage of material increases the long-term likelihood that radioactive material may be dispersed into areas outside AMS' control.

The request to reduce the amount of the present financial instrument, and use those funds to dispose of the bulk metal, sealed sources and dry radioactive waste is premised on:

- The importance of prompt action since the waste broker's proposal will be valid for a limited period of time. If NRC does not proceed expeditiously to approve the licensee's proposal, AMS may not be in a position to initiate the project.

- The Licensee's operating funds are limited and are not sufficient to pay the costs of preparation, transfer and disposal of the material by the waste broker.

ENVIRONMENTAL REVIEW

Issuance of this license amendment is covered by the categorical exclusion set forth in 10 CFR 51.22 (c)(14)(xvi) from the requirement to prepare an environmental assessment or environmental impact statement. AMS was previously licensed to manufacture and distribute to specific licensees teletherapy and radiography units containing Cobalt-60 sources. The authorization of that activity is covered under a categorical exclusion set forth in 10 CFR 51.22 (c)(14)(xiii). The activities authorized by this amendment involve quantities and forms of byproduct material similar to those previously authorized and hence are covered by 10 CFR 51.22 (c)(14)(xvi). Transportation of the materials from the AMS facility to the Barnwell LLW disposal facility will be accomplished under a general license pursuant to 10 CFR Part 71 and is not part of this licensing action.

CONCLUSION

Based on information provided in this safety evaluation and in the licensee's June 10, 1996, and July 1, 1996 letters, staff concludes that License No. 34-19089-01 should be amended to authorize the licensee to proceed with the actions described in its July 1, 1996 amendment request: i.e., implementation of Tasks 1 and 2 of the BRP. Although the onsite operations are to be conducted under the AMS license, this amendment will be conditioned to require that the contractor's radiological health and safety procedures be submitted for NRC review and approval before any work begins. This approval is with the further understanding that any funds remaining, after Tasks 1 and 2 of the BRP have been paid, will be returned to Bank One for the purpose of increasing the value of the letter of credit.

The NRC staff acknowledges that the decommissioning funding instrument that will be in place, if AMS reduces the amount of the letter of credit, will be significantly less than what the staff has estimated the decommissioning costs to be. The NRC staff also notes, however, that by allowing AMS to take action to implement Tasks 1 and 2, the onsite source inventory will be significantly reduced. The licensee is attempting to take advantage of a window of opportunity provided by a waste broker and disposal facility. Staff believes that public health and safety will be served by AMS' proceeding with Tasks 1 and 2, even though implementation of those tasks will entail reduction of the letter of credit, inasmuch as those tasks will result in removal of the great majority of the cobalt-60 inventory at the site. This is with the understanding that AMS has committed in its July 1, 1996, letter to submit a revised Conceptual Decommissioning Plan and cost estimate by August 30, 1996. This staff approval is without prejudice to the final NRC staff decision on the acceptability or adequacy of the current decommissioning cost estimate.