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

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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 [illegible]stion, emergency planning issues, on-going and pending licensing issues, and long-range [illegible]gic 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.

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1. "Strategic Plan for the London Road Facility", Report No. 04609/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).

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[2] AMS is also licensed to possess depleted uranium, nickel plated, for use as shielding material. The current inventory of depleted uranium is approximately 3,200 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 5,000-gallon batch tanks when they were first put into service. However, the source of this material was the tanks themselves, which had been 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 dilution. 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 and a positive gross profit. This indicates that the manufacturing of its C-3 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.[*] 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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[*] 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:

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

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* 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, WHTF Room, and ventilation system prior to decommissioning; and submission of a Decommissioning Funding Plan that accurately reflects the radiological condition of the Lemon 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.* (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.
- Pledged assets of approximately $1,400,000 in the form of negotiable securities and government bonds.

* 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 10^4 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 10^4 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 groundwater 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 ensure 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 Description for the Building Recovery Project

Appendix B - Profit/Loss Statement and Balance Sheet for AMS (Proprietary information requested)

Appendix C - Chem Nuclear Systems, Inc. Contract Description (Proprietary information requested)

File

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

October 8, 1996

MEMORANDUM TO: John R. Madera, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety, RIII

FROM: Josephine Piccone, Chief
Operations Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST - SHIPPING OF COBALT-60 BY ADVANCED MEDICAL SYSTEMS

I am responding to your technical assistance request (TAR) dated September 20, 1996 (Attached), regarding plans by Advanced Medical Systems (AMS) to dispose of ^{60}Co sources. As indicated in the telephone conversation between yourself, Kevin Null, Mike Weber, and Sami Sherbini on September 26, 1996, we have reviewed the AMS procedures provided with the TAR and have no concerns regarding the submitted procedures.

We were concerned, however, that the procedures submitted by AMS did not include any radiation protection procedures, but were largely procedures dealing with shipping cask movements, liner loading, and other waste shipping items. Sami Sherbini of my staff telephoned Stephen Haddock, Radiation Safety Officer for AMS, to discuss this matter. Mr Haddock informed us that radiation protection during this project will be addressed in two ways: (1) general radiation safety will be undertaken in accordance with the procedures in AMS' safety procedures manual (which contains their radiation safety procedures), and (2) job specific aspects of the project will be addressed by means of radiation work permits. In other words, radiation safety for this project is to be conducted in a manner that falls within normal radiation safety practices at the site. We find this approach acceptable, especially since the highest expected exposure rate during waste handling by personnel is about 5 R/hr, which is well within the scope of activity that may be safely conducted in the manner proposed by AMS.

The project is expected to be under the supervision of both a Chem Nuclear manager and the AMS radiation safety officer. Chem Nuclear, a waste management contractor, will be responsible for the packaging and shipping aspects, and AMS will be responsible for radiation safety. In addition, AMS will have on site a radiological protection consultant to assist in any problems that may arise. You have also indicated that the Chem Nuclear manager and AMS' radiation safety officer both have extensive experience in their respective areas, waste disposal, shipping, and source handling and radiation safety.

Contact: Sami Sherbini, NMSS
(301) 415-7902

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9610110135 XA

We have no further concerns, and as indicated in our telephone conversation, we recommend that AMS be permitted to start the project without any further delays, and will consider your TAR closed.

Attachment: As stated

IMCB

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: September 20, 1996

Mail to: Don Cool (DAC), Mail Stop: 8F5 TWFN

E-Mail to: IMNSMAIL
If E-mail, cc:CLE ,Division of Industrial and Medical Nuclear Safety, NMSS

From: John R. Madera (JRM4), Region III J R. Madera
Chief, Nuclear Materials Licensing Section

Licensee: AMS, Inc.
License No. 34-19089-01

☐ Control No.

☐ Letter dated:

☐ Suggested change in licensing procedure (enclosed):

☐ Problem/Issue: ENTER TEXT~

☐ Action Required:

In preparation of AMS' efforts to ship cobalt-60 sources and radioactive waste off-site, the licensee has submitted the contractors procedures (attached) for the project for NRC review. We request headquarters review and comments. In order that the project can be accomplished in a timely fashion, we ask that you provide your comments by September 30, 1996. We are also reviewing the procedures, and will incorporate any comments you have into a deficiency letter.

☐ Recommended Action (with revisions): ☐ Approve or ☐ Reject

Remarks:

Headquarters Reviewer: _____
Regional Reviewer: Kevin Null
Reviewer Code: R2
Reviewer Phone No.: (630)829-9854 FAX No.: (630) 515-1259
Request Needed by: 9/30/96 Form TAR-10 8/93

Cathy/Sami

cc: C. Pederson