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

July 10, 1996

MEMORANDUM TO: Josephine M. Piccone, Acting Chief
Operations Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

FROM: David Brooks, Acting Chief
Engineering and Geosciences Branch
Division of Waste Management, NMSS

SUBJECT: REVIEW OF ADVANCED MEDICAL SYSTEMS, INC. RESPONSE TO
INSPECTION REPORT NO. 030-16055/95006(DNMS)

The review and evaluation of the June 7, 1996, submittal from Advanced Medical Systems, Inc. (AMS) has been completed, and the results of that effort are provided in the enclosure. An overall assessment of the AMS building integrity issue is provided below.

To our knowledge, there has not been a definitive statement provided by AMS regarding the additional period of time over which the 1958 building structure must perform its confinement function. Consequently, the actions or inactions proposed by AMS cannot be evaluated with respect to the time function. AMS has proposed no repairs, no maintenance program, and no periodic structural integrity inspections or evaluations, but has proposed a movement monitoring program for select areas of the building on a generally 2-year frequency after the initial program startup. AMS has accepted the fact that there may be localized failures of certain building elements under this philosophy of operation but along with its structural consultant has concluded there will be no loss of confinement of stored radioactive material in the concrete core structure. We agree with this assessment for normal conditions, but we do not agree that, based on the current facts, this conclusion is valid for the indefinite future. Therefore, the Nuclear Regulatory Commission will re-evaluate the conditions and facts at 10-year intervals, unless new information becomes available to cause a change in these intervals.

With regard to events impacting the AMS site relative to the emergency plan, such as seismic events and tornados, the AMS structural consultant has provided an assessment of the vulnerabilities of the building based on some very simplified analyses. The conclusion is that a 0.1g ground motion at the site would not cause the loss of confinement of the radioactive materials stored in the concrete core. A severe tornado would likely cause heavy damage to all but the concrete core structure, and the test cell and the radiography room would be vented to the atmosphere. NRC believes these are reasonable conclusions.

If there are any questions on this review and evaluation, please contact Robert E. Shewmaker at 415-6713.

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Enclosure: As stated

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Enclosure

REVIEW OF ADVANCED MEDICAL SYSTEMS, INC., RESPONSE TO INSPECTION REPORT NO. 030-16055/95006

Dated June 7, 1996

1. The Advanced Medical Systems, Inc. (AMS) and its structural consultant have identified additional cracking in the southeast corner of the second floor slab and have an opinion as to the cause of the distress in this area. In addition, they are willing to accept a local collapse in the southeast area of the structure and conclude that if such a local collapse were to occur, it would not compromise the concrete core structure where the radioactive materials are stored. The AMS consultant made no comment regarding the need for repairs. Based on these facts, the licensee has proposed that no repairs be made.

   The Nuclear Regulatory Commission believes that radioactive materials stored in the concrete core structure will be adequately confined to the concrete core structure that will remain intact after any local adjacent failures in the bearing walls. NRC believes there is a high degree of confidence that the core will remain intact for at least a period of 10 years.

2. AMS and its structural consultant have investigated the cracking of the north bay of the east wall and concluded that any associated failure with this distressed area would not result in compromising the concrete core structure that contains the radioactive materials. The consultant made no recommendation for repairs to the existing levels of observed distress unless the subject wall at the second floor level were to fail, leaving the building envelope open to the elements.

   NRC believes that radioactive materials stored in the concrete core structure will be adequately confined to that intact core. NRC believes there is a high degree of confidence that the core will remain intact for at least a period of 10 years.

3. The AMS consultant found no evidence of structural degradation in the roof decking where there was evidence of corrosion on the underside. AMS has proposed no additional activity relative to the roof decking.

   NRC believes the reroofing completed in 1994 should halt or severely retard the corrosion process related to the roof deck panels, and they are acceptable for use during the next 10 years.

4. During the investigation, the AMS consultant was able to determine the source of the fluids above the concrete slab of the second floor and also identified the pathway of the fluid as passing through pipe chases, not the structural concrete floor slab. It was concluded that no degradation had taken place as a result of the fluids.

   NRC accepts this additional information and conclusion.

5. AMS states that its structural consultant concluded "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." AMS concluded that a routine inspection program is not required but has elected to provide for a position or location survey to monitor the building movement at several critical locations in the structure. After the initial survey, a recheck will be made in 6 months and then every 2 years thereafter. The AMS radiation protection staff will perform routine inspections in order to identify unusual conditions that may warrant further study if conditions were to change between the intervals of surveys.

NRC notes that the AMS consultant stated that the need to periodically inspect and evaluate the building's ability to perform its intended functions over the utilization period was out of the scope of his review. The AMS consultant indicated that a sound maintenance program can result in the lifetimes of similar type facilities being extended 25 to 30 years; however, the elements of such a maintenance program were not provided in the report, and AMS has stated that no maintenance is necessary in order to assure protective confinement of the licensed radioactive materials inventory for many years into the future.

NRC expects that the AMS movement monitoring program will, as a minimum, address the possible additional vertical and horizontal movements associated with the southeast corner distress of the 1958 building, as well as the wall of the 1958 building above the original lobby area. NRC will observe the periodic results of the monitoring program and will re-evaluate the condition of the building structure, including the capability of the concrete core structure to continue to function at the end of a 10-year period.

Extra copy for NMSS

7/30/96

George Pangburn: NMSS has effectively responded to essentially all earlier OGC comments. We are providing some modification and supplementation of the explanation for the categorical exclusion. Please review the wording to verify its accuracy since I did not have all relevant documents. You have a "No Legal Objection" to this Safety Evaluation subject to these changes. Send Marian & me a copy of what you e-mail to R III for inclusion in the amendment.

7/26/96

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:

o 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.

o 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