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

OFFICE OF THE
GENERAL COUNSEL

May 22, 1996

Marshall E. Miller
Presiding Officer
512 Magnolia
Frederick, MD 21701

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.

59. Letter to David Cesar, Vice President, Advanced Medical Systems, Inc., from John R. Madera, Chief, Nuclear Materials Licensing Branch, U.S. Nuclear Regulatory Commission, re: Conceptual Decommissioning Plan, March 20, 1996.

60. Letter to Mr. J. R. Madera, Chief, Nuclear Materials Licensing Branch, 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, March 21, 1996, with attachment.

61. 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), April 8, 1996, with attachment.

62. Letter to Mr. Geoffrey C. Wright, Acting Deputy Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission from Robert Meschter, RSO, Advanced Medical Systems, Inc., re: USNRC Inspection Report No. 030-16055/95006(DNMS), April 9,1996.

63. Letter to Mr. Robert Meschter, Radiation Safety Officer, Advanced Medical Systems, Inc. from Geoffrey C. Wright, Nuclear Materials Safety Branch, U.S. Nuclear Regulatory Commission, re: 60-day extension, April 11, 1996.

64. Letter to Mr. John R. Madera, Chief, Nuclear Materials Licensing Section, U.S. Nuclear Regulatory Commission, re: Conceptual

Decommissioning Plan for Advanced Medical Systems Inc. (License No. 34-19089-01, Control No. 98507, April 12, 1996, plus attachment.

65. Letter to Mr. Robert Meschter, Radiation Safety Officer, Advanced Medical Systems, Inc. from Kevin G. Null, Nuclear Materials Licensing Branch, U.S. Nuclear Regulatory Commission, re: Amendment No. 41 to Material License No. 34-1908089-01, April 16, 1996, plus attachment.

66. 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), April 24, 1996, with attachment.

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

MAR 20 1996

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

Dear Mr. Cesar:

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

John R. Madera, Chief
Nuclear Materials Licensing Branch

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

Enclosures: As stated

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

March 21, 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. Enclosed are our responses to your comments, along with a description of our proposed follow-up actions.

Once you have approved these responses and follow-up actions, 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.

AMS is operating under the conditions of its existing license until final action is taken on our revised renewal application. Consequently, these responses, and ultimately Revision 1 of the Emergency Plan reflect some discontinuity between procedures that do not exist under the provisions of the current license, and those that are proposed for the renewed license. We are hopeful that timely USNRC action on our revised renewal application will permit us to convert all procedural references in the Emergency Plan to the new Radiation Safety Procedures before Revision 1 of the Plan is ready for distribution.

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

RESPONSE TO COMMENTS FROM
U. S. NUCLEAR REGULATORY COMMISSION

Agency Comment 1(a): It appears that the onsite emergency organization is comprised of three individuals during working hours, and the absence of one or more individuals could severely impact the licensee's capability to promptly notify offsite response organizations and coordinate the response to an emergency. The licensee is required by 10 CFR 30.32(i)(3)(vii) to plan the notification and coordination so that unavailability of some personnel will not prevent notification and coordination. The plan should describe how the licensee will compensate for the functions assigned to an absent member of the emergency organization.

AMS Response: Concur. AMS recognizes its potential staffing limitations in the event of an Alert or Site Area Emergency. However, due to the low probability of occurrence of these events, and the limited activities that are currently on-going at the London Road facility, a staffing increase is not warranted. Furthermore, Section 2 of the Emergency Plan shows that the radiological impact of accidents such as building fires, earthquakes, tornados, vandalism, floods and events at neighboring industrial facilities is relatively small and in no case requires countermeasures or recovery actions. As a result, personnel demands are likely to be small.

Action Taken: Page 4-2, lines 19 will be modified to read: ". . . dose consequences of the incident. If only one AMS staff member is available to assist the Emergency Manager, that staff member will assume both site access and site surveys responsibilities until additional staff members arrive. If no AMS staff members are available to assist the Emergency Manager, the Emergency Manager will delegate both site access and site surveys responsibilities, to the best of his abilities, to other responders until additional staff members arrive."

Page 4-2, lines 20 through 23 will be modified to read: "The Emergency Manager is responsible for contacting off-site emergency response agencies for assistance if the Plan is activated. If less than three (3) AMS staff members are available to assist, the Emergency Manager will assign the responsibility for notifications to the Vice President. In addition, an environmental . .".

Agency Comment 1(b): Section 4.2 of the plan should clearly state the order in which AMS staff members assume the role of Emergency Manager if the Radiation Safety Officer (RSO) is not available.

AMS Response: Concur.

Action Taken: After line 15 on page 4-1, the following sentence will be added: "In the absence or unavailability of the RSO, the authority for implementing the radiation protection program is delegated to the Alternate Radiation Safety Officer (ARSO)."

The sentences beginning on line 11 of page 4-2, will be changed to read: "In the absence of the RSO, the ARSO can serve as the acting Emergency Manager until the arrival of the RSO. In the absence of the RSO and the ARSO, the remaining AMS staff member can serve as the acting Emergency Manager until the arrival of the RSO or the ARSO. All AMS staff members at the facility during an . . ."

Agency Comment 1(c): It is still difficult to determine which personnel are assigned to each of the functional areas specified in Section 4.2.2 of Regulatory Guide 3.67. It would be helpful if these functional responsibilities were all specified in one place such as Figure 7.

AMS Response: Concur.

Action Taken: The position entitled "Emergency Manager" on Figure 7 will be modified to read: "Emergency Manager (Personnel evacuation and accountability; search and rescue operation, communications, personnel decontamination; record keeping). The position entitled "Vice President" will be modified to read: "Vice President (Media Contact). The position entitled "Environmental consultant" will be modified to read "Environmental Consultant (Certified Health Physicist, post event assessment, mobilization of intermediate resources). The position entitled "AMS Staff Member (Site Access and Security)" will be modified to read: "AMS Staff Member (Facility system operation, assist fire control, assist first aid, facility security and access control; facility repair and damage control). The position entitled "AMS Staff Member (Radiation Surveys and Assessments)" will be modified to read: "AMS Staff Member (Radiological survey and assessment, facility decontamination).

Agency Comment 1(d): During nonworking hours, it is unclear whether a fire or other emergency situation will be detected promptly if power lines or phone lines are down. The plan should describe how the alarm system signal is transmitted to ADT Security Systems and how ADT would detect a loss of contact with the alarm system. Any difference in the response to a loss of contact versus an alarm signal should also be described also.

AMS Response: Concur. However, because this letter and the AMS Emergency Plan are public documents, a detailed description of the alarm system has the potential to compromise its integrity.

Action Taken: Footnote 22 on page 2-6 will be modified to read: "ADT Security Systems, Inc. provides the monitored alarm system for the facility. In the event of a power failure or disruption in telephone services, ADT contacts the individuals on the AMS call-back list. In the event of a fire or intruder alarm, ADT first places a call to the fire or police department, as applicable, and then contacts the individuals on the AMS call-back list."

Agency Comment 1(e): During nonworking hours, it appears that local fire or police units could arrive before AMS staff and it is unclear whether there are adequate provisions to alert offsite response personnel to radiological hazards if no AMS personnel are there to meet them. The plan should describe arrangements with fire, police and rescue personnel regarding how they will fight fires and respond to alarms if AMS personnel are not present when they arrive at the site. The plan should also describe signs and other provisions to prevent offsite response personnel from unknowingly entering areas with elevated radiation levels.

AMS Response: In Section 7.2 of the Plan (page 7-1), AMS has committed to providing annual radiation safety training for first responders. Included in the training is instruction in emergency procedures and the agency's anticipated role in an emergency. During that training, the first responders will be instructed in how to access the facility in the absence of an AMS representative, the maps that are posted immediately inside both entrances on the east side of the building showing the restricted areas, and how to recognize the postings at the entrance to the restricted areas.

Action Taken: Page 7-1, line 17 will be modified to read: ". . . procedures, radiation protection guidelines, location of restricted areas, posting/labeling, and the agency's anticipated . . ."

Agency Comment (2): Engineers Opinion Report

AMS Response: AMS did not receive the USNRC's Inspection Report No. 030-16055/95006, dated March 12, 1996, in sufficient time to evaluate the information and prepare a response. Thus we wish to defer response to Agency Comment (2) until the report has been reviewed.

Action Taken: None at this time. However, a specific response to Agency Comment (2) will be included in the AMS response to Inspection Report No. 030-16055/95006.

Agency Comment 3(a): Section 1.1 contains a brief description of activities formerly conducted at the site, but there is no description of activities currently authorized or conducted. The plan should describe the current activities.

AMS Response: Concur.

Action Taken: Page 1-1, line 6, will be modified to include the following sentence: "These materials are possessed for the purpose of sale or transfer to an authorized third party; for storage incident to disposal, discharge and/or decommissioning; or for use as shielding for AMS and Picker teletherapy and radiography units. Source manufacturing at the London Road facility ceased in 1987."

Agency Comment 3(b): Section 1.1 and Table 1 describe the amount of licensed material possessed on September 21,1995. This inventory is subject to change and could increase up to the possession limits stated in the license. The plan should state the total quantity of radioactive material authorized by the license. Typical quantities possessed at one time may be noted also.

AMS Response: Concur.

Action Taken: Page 1-1, line 5 will be modified to read: ". . . license No. 34-19089-01, AMS is currently licensed to possess 340,000 curies of ^{60}Co in the form of solid metal or sealed sources, and up to 4,040 kilograms of depleted uranium. As of the date of this report, AMS . . ."

Agency Comment 3(c): Section 1.1 states that there are over 60,000 curies of cobalt-60 and 2200 kilograms of depleted uranium in the facility, but it is unclear where this material is typically located. Sections 1.2 through 1.2.12 only identify the location of approximately 34,000 curies of cobalt-60. The typical storage locations for the remaining material authorized by the license should be identified.

AMS Response: There are two storage containers holding a total of 20,000 curies of ^{60}Co in the form of sealed sources. The contents of these containers, which may be re-located within the restricted area from time to time, were omitted from Revision 0 of the Plan.

Action Taken: Page 1-4, line 11 will be modified to read: "that contains approximately 20,000 curies of ^{60}Co in a non-dispersible form (e.g., in sealed sources housed in shipping containers).

approximately 2,100 kilograms of depleted uranium in non-dispersible form, and approximately two (2) millicuries . . ."

Agency Comment 3(d): The plan still lacks a detailed site drawing showing the exterior features of the building and property described in Section 1.2 of Regulatory Guide 3.67. A detailed drawing of the exterior features of the site must be provided in addition to the interior floor plans. In addition to detailed information about the license's property, the drawing should show the pump house on Mandalay Avenue, the rail line that runs past the facility, and the nearest residents in each direction.

AMS Response: Concur.

Action Taken: An exterior drawing that shows the pertinent features of the site, including the pump house on Mandalay Avenue, the rail line that runs past the facility, and the nearest residents in each direction will be included as Figure 8.

Agency Comment 3(e): The terminology used to describe areas in the facility is still inconsistent. [Examples given.] consistent terminology should be used and all areas discussed in the text should be indicated on the drawings.

AMS Response: Concur.

Action Taken: Page 1-1, line 16 will be modified to read:" a Hot Cell, a High Level Waste Storage Room, and miscellaneous . . ." Page 1-1, line 18 will be modified to read: "a Clean Equipment Room, and the HEPA Equipment Room. The basement . . ." Page 1-1, line 19 will be modified to read: "contains a Source Garden, waste storage . . ."

Agency Comment 3(f): Section 1.2.3 states that there is an L-shaped shield of sand-filled vaults on two sides of the source garden in the basement, but the floor plan in Figure 2/Appendix B does not show the shield. Significant safety features such as the sand shield, the emergency generator, fire pull stations, and storage locations of emergency response kits should be shown on the floor plans. The floor plans should also identify where electrical and natural gas services enter the building.

AMS Response: The sand-filled shield located on two sides of the Source Garden is an integral part of the structure. The shield itself is no more of a special safety feature that the walls on the remaining two sides of the Source Garden. Therefore, additional detail to show the location of this shield in Figure 2 and Appendix B is not necessary. The fire pull station and the electrical control panel are clearly identified on Appendix B.

Action Taken: Page 1-3, line 17 will be modified to read: "Additional shielding for accessible areas of the basement is provided by an L-shaped sand-filled shield at the basement level."

The location of the emergency generator, the emergency response kit and the location where natural gas services enter the building will be identified on Appendix B.

Agency Comment 3(g): Section 1.3 states that Figure 5 identifies the facility and its proximity to near-by structures. It states that figure 5 shows the location of schools, hospitals and fire stations also. Figure 5 appears to be a poor quality copy of a street map and neither the licensee's building nor any structures

within 1 mile of the site are clearly identified. Figure 1 does not provide an adequate picture of the area near the site either. The plan should contain a reasonably detailed drawing of the site area as described in Section 1.3 of Regulatory Guide 3.67. The plan should also contain a U. S. Geological Survey topographic map (7.5 minute series).

AMS Response: Concur.

Action Taken: Figure 5 will be replaced with a USGS topographical map showing structures and buildings within one (1) mile of the AMS site.

Agency Comment 4(a): The discussion on page 2-2 refers to guidance issued by the ICRP. This guidance is not directly applicable to facilities in the United States. The guidance applicable to protecting the public in this country is contained in the "Manual of Protective Action Guides and Protection Actions for Nuclear Incidents" issued by the U. S. Environmental Protection Agency. The plan should refer to this guidance regarding offsite protective action recommendations.

AMS Response: Concur.

Action Taken: The paragraph that begins on line 14 of page 2-2 will be revised to read: "The U. S. Environmental Protection Agency provides guidance on when and how to institute countermeasures and recovery actions in the event of a major radiation accident (USEPA, Office of Radiation Programs, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents", October, 1991). However, countermeasures and recovery actions themselves involve some risk to the public. Consequently, to ensure that the risk avoided is much greater than the risk of the action, they have set a dose limit below which they recommend that no follow-up action whatsoever be taken. The USEPA protective action guides for early-phase countermeasures (evacuation and sheltering) ranges from 1,000 to 5,000 millirem. Therefore, for the major fire scenario at the AMS site, wherein an off-site individual might receive up to 0.3 millirem, countermeasures or recovery actions for purposes of protecting that individual are not indicated."

Agency Comment 4(b): We have a number of concerns regarding the analysis in Section 2.1.1 and Appendix C of potential doses from a fire. Appendix C states that the source term for the worst case fire was assumed to be 40.4 curies, but the basis for that number is not provided. This does not appear to be a conservative assumption because the revised AMS license application dated October 30, 1995 requests a possession limit of 50 curies for packaged waste and surface contamination, and there is no explanation why the source term should not include bulk quantities of cobalt-60 from containers ruptured by one of the accidents postulated in Chapter 2 such as a gas line explosion, train derailment, or earthquake.

AMS Response: It is clearly stated in Sections 1.2 1 through 1.2.12 of the Plan, and again on Table 1 (page 11-2) that approximately 40 curies of the current radioactive materials inventory at AMS are considered to be potentially dispersible. Therefore, this is the value that was used as input to the dose assessments.

In the October 30, 1995 license amendment application, radioactive materials possession limits in excess of the actual inventory were requested for all material forms (e.g., sealed sources, bulk metal, residual contamination, and packaged waste). Since the purpose of the dose estimates in the Emergency Plan are to arrive at a realistic evaluation of the impact of a major building fire,

AMS maintains that 40 curies of potentially-dispersible material is the appropriate source term for the calculations.

Because the bulk ^{60}Co and the sealed sources are contained in either hardened storage areas (e.g., the Hot Cell, the Source Garden, source heads or shipping containers), it is not likely that these materials would be released in the event of an explosion, train derailment, or earthquake. This explanation was given on page 2-1, lines 25 through 28, and on page 2-1, lines 1 through 5. It is highly improbable that release quantities of these materials that even approaches those contained in 10 CFR 30.72 would occur. Furthermore, the smallest physical size of these materials (1 mm x 1 mm pellets with a density of over 8 grams per milliliter) are not respirable, and the deposition velocity is not conducive to dispersion. AMS sees no justification for including the bulk quantities and sealed sources in a realistic evaluation of the radiological impacts from a major building fire.

Action Taken: None required.

Agency Comment 4(b): In addition, we disagree with the statement in footnote 40 that a 10-meter release height is a conservative assumption. A ground level release with no plume rise would maximize the off-site dose estimate.

AMS Response: AMS agrees that a ground-level release with no plume rise would definitely maximize the offsite dose estimate. However, footnote 40 on page 13-8 refers to the means by which the emission source is modeled in the event of a major building fire. In this scenario, airborne radioactive materials would exit the building through doors, windows or the existing ventilation system, which has a 10 meter above-grade stack height. In all cases, the release height is above ground level. Furthermore, thermal rise would ensure an even greater release height before the materials could disperse or diffuse through the atmosphere.

The purpose of the dose estimates in the Emergency Plan are to arrive at a realistic evaluation of the impact of a major building fire. Therefore, AMS maintains that a ground-level release is not realistic under the circumstances and that a release height of 10 meters above the ground is indeed a conservative assumption.

Action Taken: None required.

Agency Comment 4(b): We note that the CAP88-PC computer code is not intended to estimate short term doses resulting from an unplanned release during an emergency. [An alternative evaluation is provided.] A more detailed and conservative analysis using more appropriate calculational methods should be provided.

AMS Response: AMS acknowledged, in footnote 37 on page 13-7, that the CAP88-PC computer code was designed for assessing annual average exposure rates from routine releases of radioactive materials, as opposed to short-term doses from a "puff" release. However, using the assumptions shown in that footnote, the CAP88-PC code will, indeed, over-estimate the dose.

Like the CAP88-PC code, the NUREG-1140 calculation referenced in Agency Comment 4(b) is based upon a gaussian plume model. However, if the Agency representative who used the NUREG-1140 calculation for Comment 4(b) assumed a ground-level release with no plume rise

and a highly-conservative dispersion category, it is not unreasonable to see a dose estimate that exceeds the CAP88-PC estimate shown on page 13-9.

It is important to note that, in both cases, mathematical models are being used to estimate the potential impact on people. When one considers the limitations of these models in regard to such influences as terrain effects, building wake effects, stability categories, and person-specific exposure factors, the difference between 7.7 millirem from the NUREG-1140 calculation and 0.2 millirem from the CAP88-PC calculation is insignificant. Furthermore, all calculated doses are less than the 10 millirem per year dose limit promulgated by the U. S. Environmental Protection Agency in Title 40, Code of Federal Regulations, Part 61, Subpart I (National Emission Standards for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H). Therefore, additional refinements to the computer model or selection of an alternative model, in light of these negligible calculational differences, is not warranted.

Action Taken: None required.

Agency Comment 4(c): Section 2.1.2 and Appendix C state that an earthquake could create a 100 millirem/hour dose rate 20 feet beyond the outside wall of the source garden. The plan should state the distance at which the dose rate would drop below 2 millirem/hour and whether that location is in an area accessible to the public. In addition, we attempted to run the Microshield code using the assumptions stated in Appendix C but we could not duplicate the results stated in the plan. The input parameters and assumptions should be described in enough detail to permit us to duplicate and evaluate the calculation.

AMS Response: Concur.

Action Taken: Page 2-3, line 11, will be modified to read: "the building, 0.1 R per hour at a distance of 20 feet from the wall of the building, and two (2) mR per hour at a distance of 140 feet away from the building at the elevation of the Source Garden. There are no off-site residents at any of these locations. However, they are accessible by members of the general public."

Appendix B . . ." Page 13-9, footnote 46 will be modified to read: "The Microshield code is distributed by Grove Engineering, Inc.. Version 4.10 was used for this assessment. The following were used as input to the code: x-coordinate = distance from receptor to outside wall of the Source Garden (e.g., x = 20 feet); y-coordinate = the mid-point of the height of the Source Garden's active area (e.g, y = 21.9 cm); z-coordinate = the mid-point of the width of the Source Garden's active area (e.g., z = 21.9 cm); the outer concrete wall of the Source Garden is 45.7 centimeters thick with a density of 3.6 grams per ml; and the density of the sources in the Source Garden is 8.8 grams per milliliter."

Agency Comment 4(d): Section 2.1.3 states that a tornado would not compromise the structural integrity of restricted areas and references the Engineers Opinion Report issued by Neff & Associates. Although this report states that portion of the building contained within the bunker-type construction would not sustain any appreciable distress, it also states "that it is scientifically certain that a tornado passing over this facility would impose significant structural damage" to other parts of the building. Restricted areas on the second floor and in the warehouse areas of the first floor could be completely demolished by a tornado releasing radioactive materials in those areas. Section 2.1.3 should provide a more accurate description

of the potential damage from a tornado, and postulate the maximum amount of radioactive material that could be in these areas as a result of routine storage, preparation for shipments, or other operations.

AMS Response: Partially concur. It is likely that a tornado passing over the facility would impose structural damage to a variety of restricted areas that are not of "hardened" construction. However, of these areas, only the HEPA Room on the second floor contains any dispersible activity of consequence (e.g., two curies). If one disregards the grossly increased dispersion of this material in a tornado, the maximum dose to the nearest off-site resident would be only a fraction of that associated with the fire scenario, wherein 40 curies could potentially be dispersed. Therefore, AMS maintains that the radiological impact of a tornado would be minimal.

Action Taken: None.

Agency Comment 5(a): Section 3.2 is still inconsistent with the notification requirements in the regulations. Pursuant to 10 CFR 30.32(i)(3)(viii), the plan must contain a clear commitment to notify appropriate offsite response organizations promptly after declaring an Alert or Site Area Emergency (SAE). The plan should not differentiate between these classifications or give the impression that the licensee can needlessly wait a full hour before notifying offsite officials of an Alert declaration. In addition, the plan must clearly state that the licensee shall notify NRC immediately after notification of local and State authorities. Simply stating that NRC will be notified within one hour is not sufficient.

AMS Response: Partially concur. Title 10, Code of Federal Regulations, Section 30.32(I)(3)(viii) states that the licensee shall "also commit to notify the NRC operations center immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency".

Action Taken: Page 3-3, line 17 will be modified to read: "First responders will be notified promptly (within 15 minutes) after an alert or a site area emergency has been declared. The USNRC Operations Center is notified immediately (within one hour) after notification of the first responders after an. . ."

The following bullet will be added after line 17 on page 3-2 and after line 10 on page 3-3: "Notify USNRC Operations Center".

Agency Comment 5(b): Several of the emergency action levels in Attachment 1 of Appendix D are defined in terms of potential exposure rates or actual exposures. It is unclear how the Emergency Manager will be able to identify these conditions in a timely manner. It is unacceptable to wait for survey results if it will take more than 15 minutes to get them. EALs must be defined in terms of conditions that are apparent within the first few minutes of an emergency. This is especially important during nonworking hours. If an alarm goes off and the condition cannot be verified within 15 minutes, the Emergency Manger should act conservatively by declaring an emergency and initiating notification of offsite response organizations. The EALs should be redefined.

AMS Response: Concur.

Action Taken: Attachment 1 of Appendix D will be revised in its entirety. An attachment to this letter shows the revision.

Agency Comment 5(c): The offsite response organizations listed in Attachment 1 of Appendix D to receive a notification vary depending on the event. Each of the organizations identified as a "first responder" should be notified every time an Alert or Site Area Emergency is declared. In addition, all NRC notifications should be made to the NRC Operations Center. The Operations Center coordinates event reports with regional staff.

AMS Response: Concur.

Action Taken: Attachment 1 will be revised to indicate that an Alert and an Site Area Emergency will require notification of all first responder list as well as the USNRC Operations Center. An attachment to this letter shows the revision.

Agency Comment 5(d): The plan does not establish the initial recommendations for offsite protective actions that will be included in the initial SAE notification to offsite organizations. If an accident has the potential to require road blocks or other protective actions offsite, the licensee should act conservatively and make initial recommendations to offsite officials until the scope of the accident can be verified. This would include recommendations to stop traffic on the rail line or rope off potentially contaminated areas. Protective action recommendations should be addressed in Sections 3.1.4 and 3.3., and Appendix D.

AMS Response: Concur.

Action Taken: Attachment 1 to Appendix D will be revised to include protective action recommendations to off-site responders in the event of a Site Area Emergency. An attachment to this letter shows the revision.

The following will be added after line 10 on page 3-3: "The RSO transmits recommendations for offsite protective actions and the recommended radius of protective action implementation to first responders. If the emergency is due to elevated off-site exposure rates, initial recommendations may include roadblocks, traffic/train access control, or evacuation. If the emergency is due to elevated effluent concentrations, initial recommendations may include respirator usage, roadblocks, sheltering, or evacuation. If the emergency is due to elevated exposure rates and effluent concentrations, initial recommendations may include roadblocks, traffic/train access control, respirator usage, sheltering or evacuation."

Agency Comment 5(e): Section 3.3 should specify the minimum frequency of updates to offsite response organizations after the initial notification. The response to our previous comment states that Section 8.3 was being modified to include the information, but the revision does not include this information.

AMS Response: Concur.

Action Taken: After line 10 on Page 3-4, the following sentence will be added: "To ensure the information has been received by the offsite response organization, and to continuous understanding of the status of the emergency, an update call to each first responder for an Alert or a Site Area Emergency will be placed within 90 minutes of the initial notification. Subsequent updates will be as agreed upon between AMS and the responder during the first update call."

Agency Comment 6(a): Section 4.2 states that an environmental consulting firm and a certified health physicist have been retained to assist in all matters relating to radiation safety and environmental issues. Figure 7 shown the environmental consultant as part of the AMS emergency organization and it is unclear what function either of these parties would perform during an emergency. The roles of the environmental consultant and the certified health physicist should be clarified.

AMS Response: See response to Agency Comment 1(c), above. As stated in page 4-2, line, 22, the environmental consulting firm, and the Certified Health Physicist who is a member of that firm, provides consultation to AMS, on an as-needed basis, "in all matters relating to radiation safety and environmental issues". The environmental consulting firm can, at the direction of AMS, mobilize additional resources in the form of equipment, personnel and services to support the intermediate and long-term emergency response efforts. However, neither the environmental consulting firm nor the Certified Health Physicist are listed as first responders in the event of an emergency at AMS.

Action Taken: Page 4-2, line 22 will be modified to read: "Health Physicist have been retained by AMS to assist, on an as-needed basis, in all matters relating to radiation safety and environmental issues. The firm can, at the direction of AMS, mobilize additional resources in the form of equipment, personnel and services to support the emergency response effort."

Figure 7 will be modified as described in the response to Agency Comment 1(c), above.

Agency Comment 6(b): The response to our previous comment states that letters from the hospital, fire department and police department will be included in the plan. Section 4.3 states that Appendix E contains letters of agreement from "applicable first responders" listed in Table 2 along with information on the agreed upon means of communication and notification with these agencies. Contrary to these statements, Appendix E only contains letters from the fire department and two State agencies and there is almost no information about methods of communication. Complete documentation that offsite response agencies are aware of, and have agreed to their roles as specified int the plan should be provided.

AMS Response: In order to give first responders sufficient time to comply with the AMS request for a letter of agreement to respond, and in order to meet our comment to submit Revision 0 of the Emergency Plan to the USNRC within the agreed-upon date, Appendix E of the Plan (page 13-13) contained a listing of those agencies to whom a solicitation was sent, and the notation that "Letters received to date [emphasis added] are included in this section". A copy of the solicitation letter is attached. Since that time, we have received additional letters of agreement, but their contents were not "as expected".

Action Taken: A second solicitation letter is being sent to each first responder. Included will be a form to assist them in providing the required information. A copy of the form is attached to this letter.

Agency Comment 6(c): The response to our previous comment concerning the capabilities of offsite organizations and rumor control arrangements stated that the plan would be modified to address these items. The plan does not include this information. In addition to other capabilities, Section 4.4 should specially address whether local fire or police personnel have the capability to conduct radiation surveys.

AMS Response: The local fire and police personnel do not have the capability for conducting radiation surveys. It is our position that including a list of capabilities that the agency does not have in Section 4.4 is counterproductive.

Action Taken: See response to Agency Comment 6(b).

Agency Comment 6(d): Section 4.4 fails to describe some of the organizations listed in Table 2. A description of the responsibilities and capabilities of each of these organizations should be provided.

AMS Response: Concur.

Action Taken: Section 4.4 of the Plan (page 4-3) will be modified to include the responsibilities of the USNRC Operations Center and the Ohio Emergency Management Agency.

Agency Comment 6(e): In Table 2, the organizations do not appear to be listed it the order they would be called. The NRC Operations Center should be notified immediately after appropriate local and State organizations. Table 2 and Attachments 2 and 3 of Appendix D should be revised to prevent confusion.

AMS Response: Concur.

Action Taken: Table 2 of the Plan and Attachment 3 of Appendix D will be re-ordered to match the order shown in Attachment 2 of Appendix D. Attachment 2 will be ordered as follows: City of Cleveland Fire/Police (911 call), Cleveland Emergency Medical Services, Ohio Environmental Protection Agency; Ohio Emergency Management Agency; USNRC Operations Center, and University Hospital of Cleveland.

Agency Comment 7(a): The terms used for accidents are still inconsistent. The plan should establish the terms for accidents in Chapter 2 and these terms should be used consistently throughout the rest of the plan. [Examples given.]

AMS Response: Concur.

Action Taken: Page 5-1, line 13 will be modified to read: ". . . with personnel. The incident will be characterized as a fire, natural phenomenon (e.g., earthquake, tornado or flood), vandalism, explosion (industrial facility impact or underground gas line explosion), or transportation accident. The Emergency Manager . . ."

Attachment 1 of Appendix D will be modified to include the following event types only for Alerts or Site Area Emergencies: fire, natural phenomenon, vandalism, explosion and transportation accident.

Agency Comment 7(b): We disagree with the statement in Section 5.3 that no actions can be taken to mitigate the consequences of a tornado or flood. When there is advance warning of sever weather conditions, we would expect the licensee to take reasonable steps to secure the facility and minimize releases. If a tornado warning is issued for the site area, we would expect the licensee to declare an alert and take immediate steps to secure licensed materials especially in the warehouse portions of the facility. Section 5.3 and Appendix D should address the mitigating actions that will be taken if a severe weather warning issued.

AMS Response: Partially concur. Because the majority of the AMS inventory is not readily dispersible (see page 2-1, lines 25 through 28, and on page 2-1, lines 1 through 5), there are no additional actions that can be taken to better secure the materials if advance notice of severe weather conditions is received. Procedure step 5.2.3 in Appendix D describes the actions that shall be taken in the event of a "potential compromise" to health and safety.

Action Taken: The following sentence will be added after Page 5-1, line 25: "In the event of advance warning of severe weather conditions or other natural phenomenon, all on-going operations involving the handling of radioactive materials will be terminated and the materials will be stored/secured."

Agency Comment 7(c): Section 5.4.1 states that evacuated personnel will assemble at the designated muster area, however the location of the muster area is not specified and it is not shown on any of the drawings. The location of the muster area should be identified.

AMS Response: Concur.

Action Taken: Page 5-2, line 6 will be modified to read: ". . . and assemble in the AMS parking lot (west) or the Super Cast Inc. parking lot (east), depending upon the direction of prevailing winds. The . . ."

Agency Comment 7(d): Section 5.4.1 does not describe provisions for search and rescue operations if the RSO cannot account for all personnel. This issue should be addressed.

AMS Response: Concur.

Action Taken: The following sentence will be added after line 7 on page 5-2: "The RSO will initiate search and rescue operations for individuals that are unaccounted for."

Agency Comment 7(e): Section 5.3 states that licensee staff will assist the fire department by conducting surveys during fire fighting efforts. Footnote 25 on page 5-2 states that in the event of a fire, only self-contained breathing apparatus (SCBA) should be worn, and full- or half-face respirators are not permitted. Section 6.4 states that respirators are maintained in the building and Table 3 indicates that a respirator is maintained at the pump house. Please indicate what types of respirators are maintained in the building and the pump house. SCBAs should be available in the building and the pump house to respond to a fire.

AMS Response: Footnote 25 on page 5-2 was added for information purposes only. This footnote was not intended to imply that AMS maintains SCBA's in its inventory. The Cleveland City Fire Department provides its own SCBAs.

Action Taken: Footnote 25 on page 5-2 will be deleted.

Page 6-2, line 3 will be modified to read: "clothing and a minimum of four (4) particulate respirators (full face, negative pressure).

On Table 3, page 11-4, the item listed as "Respirator" will be modified to read "Respirator (full face, negative pressure).

Agency Comment 7(f): Section 5.5 still does not address informed consent. The plan should describe how the Emergency Manager will verify that a volunteer is aware of the health risks before authorizing emergency exposures exceeding 25 rem.

AMS Response: Concur.

Action Taken: Page 5-2, line 2 will be modified to read: "dose, and only after informed consent has been given."

Page 7-1, line 17 will be modified to read: ". . . procedures, radiation protection guidelines, location of restricted areas, posting/labeling, radiation risks, informed consent for lifesaving operations, and the agency's anticipated . . ."

Agency Comment 7(g): Issuing dosimeters to firemen is not addressed in section 5.11 of Appendix D. This issue should be addressed in the implementing procedure.

AMS Response: Concur.

Action Taken: The following procedural step will be added after step 5.2.2 in Appendix D: "The RSO shall, as necessary, deploy personnel monitoring devices (pocket ionization chambers and/or thermoluminescent dosimeter badges) to emergency personnel."

Procedural step 5.11.6 will be modified to read: "Upon arrival, firemen shall be cautioned as to where radioactive materials are stored and may be issued personnel monitoring devices."

Procedural step 5.11.8 will be modified to read: "A thorough survey of firemen and their equipment shall be performed and personnel dosimeters, if issued, shall be collected prior to their departure from the controlled area."

Agency Comment 7(h): Section 5.5 states that personnel will be monitored for contamination, but there is no description of the procedure for decontaminating personnel if contamination is found. This issue should be addressed.

AMS Response: Concur.

Action Taken: Page 5-3, line 7 will be modified to read: ". . .an AMS staff member, and decontaminated, as necessary, pursuant to Radiation Safety Procedure No. RSP-009, "Contamination Control".

Agency Comment 7(I): Section 5.6 states that the Cleveland Emergency Medical Service personnel receive annual training, but it is unclear who conducts this training. In addition, there is no letter of agreement confirming that his organization has agreed to transport contaminated individuals. The training issue should be clarified and a letter of agreement should be provided.

AMS Response: Section 7.2 (page 7-1, line 15) states that annual training is provided by AMS.

Action Taken: See response to Agency Comment 6(b).

Agency Comment 7(j): Sections 5.6 and 5.7 state that the University Hospital of Cleveland is capable of diagnosing and treating radiation injuries, and has a Radiation Safety Officer who will perform surveys and control contamination. There is no letter of agreement from the hospital verifying its capabilities and confirming its agreement with these statements. A letter of agreement should be provided.

AMS Response: Concur.

Action Taken: See response to Agency Comment 6(b).

Agency Comment 8(a): Section 6.2 does not describe any communications capability at the alternative command center (the pump house). Both the primary and alternative command center should have a telephone or other means of communicating with offsite organizations.

AMS Response: Both command centers have telephone communications.

Action Taken: Page 6-1, line 8 will be modified to read: "system at the London Road facility and at the alternate Command Center (Pump House) are used for . . ."

Agency Comment 8(b): Section 6.4 states that dosimeters and survey meters are stored in the "instrument calibration room" shown in Figure 3, and that protective clothing and respirators are stored "in the locker room or storage room". There is no instrument calibration room indicated on Figure 3 and the storage location for the protective clothing is too vague. It is unclear whether these locations would be accessible during postulated accidents. Section 6.4 should use terminology that is consistent wit the labels on the drawings. It would be helpful if the command center, equipment storage locations, first aid kits, emergency generator and other features related to emergency response were specifically indicated on the drawings.

AMS Response: Concur.

Action Taken: See response to Agency Comment 3(f).

The location of the instrument calibration room and the storage location will be noted on Appendix B.

Agency Comment 8(c): Section 6.4 and Table 3 only list pocket dosimeters. While pocket dosimeters are useful for real-time dose assessments, they are not very accurate. The licensee should provide more accurate dosimeters (e.g., film badges or TLDs) that can be used to verify personnel exposures after an emergency is brought under control.

AMS Response: AMS takes exception to this comment. Pocket dosimeters, if calibrated, serviced and used as described in USNRC Regulatory Guide 8.4, "Direct and Indirect-reading Pocket Dosimeters" and ANSI N322, "Inspection and Test specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters", are sufficiently accurate indicators of the deep-dose equivalent incurred by the wearer. Film badges and TLD badges are not necessarily more accurate, although they can, in addition to the deep dose equivalent, provide an indication of the shallow dose equivalent and the eye dose equivalent to the wearer. The fact that they have additional capability does not render them more "accurate".

Action Taken: None required.

Agency Comment 8(d): Table 3 indicates that only one respirator and two pocket dosimeters are maintained at the pump house. This does not appear to be sufficient to equip the licensee's staff and offsite rescue personnel that may need to enter the building. The pump house should contain enough respirators and dosimeters to equip the licensee's emergency staff, and enough additional dosimeters to monitor hose crews, search and rescue teams, or other offsite rescue personnel.

AMS Response: Partially concur. Respirators worn for the purposes of limiting internal doses, must be issued and worn pursuant to the requirements contained in 10 CFR 20.1703(3). Since AMS can only ensure compliance with these requirements for AMS personnel, a single respirator at the Pump House is deemed sufficient for use by AMS personnel. Fire fighting personnel are generally equipped with their own respiratory protection (SCBA) and must meet NIOSH/MSHA specifications for their own program..

Action Taken: On Table 3, page 11-4, the Minimum Number of the item listed as "Pocket Dosimeters (0 to 1 R)" will be modified to read "6".

Agency Comment 8(e): Table 3 indicates that only one frisker and one survey meter are maintained at the pump house. We believe that at least one additional survey meter should be provided at this location for backup. The range of the survey meters should be specified also.

AMS Response: Partially concur. The operational status of the frisker and survey meter are checked quarterly as described on page 6-2, line 6. Since the devices are not used routinely between quarterly checks, the probability of failure in the event that the Command Center must be evacuated to the alternate location is considered to be small. It is not practical to equip the alternate Command Center similar to the main facility.

Action Taken: On Table 3, page 11-4, the item listed as "Survey Meter" will be modified to read "Survey Meter (0 to 1 R/hr range)". The item listed as "Frisker" will be modified to read "Frisker (0 to 500,000 cpm range)".

Agency Comment 9(a): Section 7.2 should specifically state that the risks of emergency doses will be covered in the training offsite rescue personnel so they can decide in advance what risks they would be willing to accept during lifesaving operations. Numerical estimates of health risks are provided in the EPA Manual of Protective Action Guides.

AMS Response: Concur.

Action Taken: Page 7-1, line 17 will be modified to read: ". . . procedures, radiation protection guidelines, location of restricted areas, posting/labeling, radiation risks, informed consent for lifesaving operations, and the agency's anticipated . . ."

Agency comment 9(b): Section 7.3 should state that the exercise objectives and scenario shall be provided to NRC in advance (typically 60 days) to allow NRC to review and comment on the exercise.

AMS Response: Concur.

Action Taken: The following footnote will be added to the end of the sentence on line : "The objectives of the exercise and a summary of the scenario will have been reviewed by the USNRC prior to implementation."

Agency Comment 9(c): Sections 7.4 and 7.5 should specify who is responsible for tracking findings from critiques and audits, and verifying that the findings are closed out.

AMS Response: Concur.

Action Taken: The following sentence will be added after page 7-2, line 9: "The IC will track and ensure closure of critique items." Page 7-2, line 14 will be modified to read: "The audit findings are presented at the next scheduled meeting of the IC, who are responsible for tracking and ensuring closure."

Agency Comment 9(d): Section 7.5 states that there will be periodic audits. The plan should state that there will be annual audits.

AMS Response: Concur.

Action Taken: Page 7-2, line 11 will be modified to read: "AMS participates in annual audits of all aspects of its . . ."

Agency Comment 9(e): Section 7.6 should state that the self-life of protective clothing and other degradable materials shall be tracked and changed out on a regular basis. In addition, provisions for calibration of the stack monitor and testing of the emergency generator should be described.

AMS Response: Partially concur.

Action Taken: Page 7-2, line 20 will be modified to read: "Inoperable, expired or missing equipment are repaired/replaced . . ."

The following sentence will be added after line 21 on page 7-2: "The emergency generator and other facility devices are confirmed to be operational during routine surveillance activities described in Radiation Safety Procedure No. RSP-008, "Instrumentation and Surveillance".

Agency comment 10: Section 8.1 should specify that records of incidents shall be permanently retained with the licensee's decommissioning records.

AMS Response: Partially concur. ISP-37, procedure item 7, describes the provisions for maintaining records generated during an incident. AMS does not distinguish between radiation protection records and "decommissioning records". All are maintained pursuant to RSP-004, "Radiation Protection Records".

Action Taken: Page 8-1, line 7 will be modified to read: ". . . is included in ISP-37 (See Appendix D) and in Radiation Safety Procedure No. RSP-004, "Radiation Protection Records".

Agency Comment 11(a): The plan still does not have a list of effective pages that a reader can use to verify his copy is complete an up-to-date. A list of effective pages should be provided.

AMS Response: Page 7-1, lines 3 through 5 state that page changes to the Plan will not be made. If changes of significance are necessary, the Plan will be re-issued in its entirety.

Action Taken: The total number of pages in the Plan will be included in the Table of Contents.

Agency Comment 11(b): Although Figures 2,3,4 and 5, and Appendix B have cover pages that are numbered, the actual drawings are not numbered or identified as part of the emergency plan. The drawings can be removed from the plan without creating any gaps in the page numbers. Every page of the plan, including the drawings, must be identified with a page number and a revision number/date.

AMS Response: Concur.

Action Taken: Every page of the plan, including the drawings, will be identified with a page number and a revision number. In addition, the total number of pages in the Plan will be included in the Table of Contents.

ATTACHMENT
Proposed Revision to Attachment 1 of Appendix D

F = Fire; X = Explosion; IJ = Injury; P - Personnel Exposure; SP = Spill; L = Loss/Theft; T = Transportation; NP = Natural Phenomenon; O = Other

Event Type	Mechanism	Action Levels	Class	Notifications	Actions	I/E Report	Critique
Building security compromised	L, IJ, P	Indication of unauthorized entry	Unusual Event	USNRC Region III	RSO secures condition.	No	no
	L, IJ, P	Confirmation of unauthorized entry with potential for intruder exposures in excess of 100 mR	Incident	USNRC Region III City of Cleveland Police Department	Operating staff to a state of readiness; provide off-site authorities with sequence of events	yes	no
	L, IJ, P	Confirmation of theft of less than 0.5 Ci of licensed material	Incident	USNRC Region III City of Cleveland Police Department	Operating staff to a state of readiness; provide off-site authorities with sequence of events; assist in return of materials.	yes	yes
	L, IJ, P	Confirmation of theft of greater than 0.5 Ci of licensed material	Alert	First Responders USNRC Command Center	Operating staff to a state of readiness; provide off-site authorities with sequence of events	yes	yes
Loss of Electrical Power	P	Hot cell door in open position with personnel exposures of less than 250 mrad	Unusual Event	Cleveland Public Power	RSO secures condition	no	no
	P	Hot cell door in open position with personnel exposures in excess of 250 mrad	Incident	Cleveland Public Power USNRC Region III	RSO secures condition	yes	no
Minor spill	SP, IJ, T	Unexpected Airborne activity in the building <10 DAC over 24 hours	Incident	None	RSO secures condition	yes	no
	SP, P, T	Unexpected exposure rates in the building <20 mR/hr	Incident	None	RSO secures condition	yes	no
Major Spill	SP, IJ, P, T, F	Unexpected Airborne activity in the building >10 DAC over 24 hours or exposure rates in the building > 20 mR/hr	Incident	USNRC Region III	Operating staff to state of readiness	yes	no

Event Type	Mechanism	Action Levels	Class	Notifications	Actions	I/E Report	Critique
Minor Release	F,X,L, IJ, P	Projected effluents >10x expected	Incident	USNRC Region III	Operating staff to a state of readiness	yes	no
	F,X,L, IJ, P	Actual or projected site boundary exposure rates >20 mR/hr	Incident	USNRC Region III	Operating staff to a state of readiness; off-site emergency response agencies to a state of readiness; provide off-site authorities with status reports	yes	no
Major Release	F,X,L, NP, IJ, P	Potential for effluents >100x expected	Alert	First Responders USNRC Operations Center	Man response center; dispatch monitoring personnel; mobilize offsite emergency response personnel; provide public information; provide off-site authorities with status reports	yes	yes
	F,X,L, NP, IJ, P	Actual or projected effluents >100x expected	Site Area Emergency	First Responders USNRC Operations Center	Man response center; dispatch monitoring personnel; mobilize offsite emergency response personnel; recommend protective actions; provide public information; provide off-site authorities with status reports	yes	yes
	F,X,L, NP, IJ, P	Potential for boundary exposure rates >100 mrad/hr	Alert	First Responders USNRC Operations Center	Man response center; dispatch monitoring personnel; mobilize offsite emergency response personnel; provide public information; provide off-site authorities with status reports	yes	yes
	F,X,L, NP, IJ, P	Actual or projected boundary exposure rates >100 mrad/hr	Site Area Emergency	First Responders USNRC Operations Center	Man response center; dispatch monitoring personnel; mobilize offsite emergency response personnel; recommend protective actions; provide public information; provide off-site authorities with status reports	yes	yes

ATTACHMENT
Solicitation Letter Sent to First Responders

September 12, 1995

FIELD(Name)
FIELD(Address)

Dear FIELD(Salutation):

In the Emergency Plan for Advanced Medical Systems, Inc. (AMS), your organization is listed as a first responder to certain types of emergencies at the London Road facility. Shortly you will be receiving the revised version of the Emergency Plan for this facility. The Plan will describe the type and radiological impact of potential emergencies at the facility, along with information that will be of assistance to you in the event of an emergency.

Pursuant to regulatory guidance, the plan must also contain letters of agreement with all first responders. Therefore, AMS is soliciting a letter of agreement from your agency. The letter should contain your commitment to support AMS in the event of an emergency, your instructions on how to notify and communicate with you during an emergency, and any other information or instructions that should be considered.

Please forward your letter of agreement to me at the address shown above before September 22, 1995. In the meantime, if you have any questions or if I can provide you with additional information, please call me at (216) 692-3270. Thank you in advance for your assistance.

Sincerely,

Robert Meschter, RSO

ATTACHMENT
Solicitation Form for First Responders

Agency Name	Agency Telephone
Agency Address	Agency Contact (name):
AMS should call this telephone number **during normal business hours** in the event of an emergency:	AMS should call this telephone number **after normal business hours** in the event of an emergency:
AMS should relay the following information to our agency in the event of an emergency:	

Our agency will provide the following services in the event of an emergency (check all that apply):

☐ Personnel	☐ Radiation Survey Equipment	☐ Emergency Medical Services
☐ Respiratory Protection (agency use)	☐ Respiratory Protection (use by others)	☐ Earthmoving Equipment
☐ Site Security	☐ Fire Fighting	☐ Crowd Control
☐ Protective Clothing (agency use)	☐ Protective Clothing (use by others)	☐ Analytical Services

☐ Evacuation Services (describe)_____
☐ Other (describe)_____
☐ Other (describe)_____
☐ Other (describe)_____
☐ Other (describe)_____
☐ Other (describe)_____

Describe the authority and responsibility of your agency in the event of an emergency at AMS:

Describe your interface with other agencies in the event of an emergency at AMS.

Describe your location with respect to the AMS facility at 1020 London Road, Cleveland, Ohio

If an emergency occurs at AMS, to whom should the public and the media be referred in order to obtain information about the emergency? (Provide name and telephone number).

Agency Commitment: This agency agrees to respond to an emergency at AMS.

Agency Representative (Signature)	Agency Representative (Print)
Position:	Today's Date:

AMS Commitment **Advanced Medical Systems, Inc. agrees to abide by these instructions when requesting the emergency assistance of this agency.**

AMS Representative (Signature)	AMS Representative (Print):
Position: Radiation Safety Officer	Today's Date:

Please return your completed form to: Robert Meschter, R. S. O., Advanced Medical Systems, Inc., 1020 London Road, Cleveland, Ohio 44110. A fully-executed copy will be returned to you, at the address shown above, shortly thereafter.

Advanced Medical Systems, Inc.

1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

April 8, 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 2 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 3 of the plan in July of 1996.

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
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 2
April 8, 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 55,000 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™. This product is a 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. AMS's intent is to inject STERGO™ directly into the WHUT Room through the existing access holes where it will absorb residual liquids. The ventilation in the area then will be increased to facilitate slow evaporation.[4] AMS is awaiting the vendor's final testing of the holding capacity of STERGO™ under conditions of very high integrated exposures before proceeding further. In the meantime, to ensure no outward migration of the water in the WHUT room, water from the building foundation drainage system is tanked and sampled prior to discharge.

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,

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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.

[4] Even after full de-hydration, STERGO™ does not lose its capacity to re-absorb moisture. Therefore, should there be future incursions of water into the WHUT Room, its outward migration will be prevented.

approximately 200 feet from the building. Shortly, the solids will be transferred to the structure. The structure and its environs will then be posted pursuant to RSP-011, "Posting and Labeling", and will be included in the quarterly radiological surveillance program pursuant to RSP-008, "Instrumentation and Surveillance".

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. AMS intends to implement the provisions of the January 24, 1996 version of the plan as scheduled.

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 is currently being prepared.

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.[5]

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, 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 is being prepared. 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.

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[5] 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.

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 Bulk Material

There are approximately 11,750 curies of bulk ^{60}Co metal in the AMS inventory. AMS is attempting to identify a domestic or foreign market for this material, prepare and submit whatever permit or license applications are necessary, package the material, and ship it to a buyer.

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. Once one or more markets are identified from this mailing, permitting requirements will be determined, applications will be filed, and materials will be packaged/shipped.

In light of the relatively small volume (but high activity) of the AMS source inventory, an attempt is being made to negotiate reduced disposal costs at a licensed low-level waste disposal facility.

To date, a project manager from the facility has been assigned and a cost estimate is being prepared. 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, an amendment to License No. 34-19089-01 to postpone the inventory requirement may be necessary, depending upon the timeliness of action on AMS's recent license renewal application.) AMS then intends to identify a market for the remaining sources, evaluate their levels of residual radioactivity, decontaminate and leak test the sources as necessary, package the sources, and ship them to the purchaser. As sources leave the London Road facility, the inventory log will be debited appropriately. Table 3 contains the action plan for this task.

Disposition of Solid Waste at the Facility

As shown in Table 1, there is about 1,500 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. The disposition of this solid waste is dependent upon the decommissioning methodology selected for the facility, and upon the availability/cost of off-site disposal at the time of project initiation.

AMS intends to continually evaluate disposition options and select/implement the one that results in the lowest personnel exposures and disposal costs. 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.[6] 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.

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. The general provisions have been incorporated into RSP-008, "Instrumentation and Surveillance".

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
- RSP-002, Definitions

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[6] 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-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. Additional improvements will be implemented on an on-going basis. Since October 10, 1995, the following has taken place:

- The stairwell to the basement has been fully decontaminated and released for unrestricted use.

- The temporary restricted area in the warehouse that housed the water treatment equipment has been cleared and released for unrestricted use.

- Three (3) process batch tanks used for the water treatment project have been decontaminated.

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 intends to mount 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 will be accomplished through briefings, tours, and development/publication of hand-out materials and brochures. Since October 10, 1995, the following has taken place:

- A briefing with local print media representatives was held on October 31, 1995, which resulted in publication of an article that was favorable to AMS in the local press.

- Two briefings with City of Cleveland officials were arranged and invitations were issued. The briefing dates were August 29, 1995 and October 31, 1995. Although AMS received acceptances from the office of the Mayor and other individuals, no officials appeared for either briefing.

- A Cleveland City Council member (R. Coates) visited the London Road facility on November 22, 1995.

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, approximately 61,000 gallons of water have been collected, analyzed, and found to be free of insoluble ^{60}Co. For operational reasons, and because current discharge paths do not comply with local building codes, AMS continues to pursue re-connection of all drainage paths to the London Road Interceptor through legal channels.

TABLES

Table 1 - Current Cobalt-60 Inventory

Item	Form	Material Description	Estimated Activity (Ci)
Licensed Material	Solid	Bulk Metal and Sealed Sources	54375
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			54455

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.		Address solid waste issues.
		Pursue disposition of treated water that currently exists in the collapsible storage tanks.
Implement training requirements of the approved site emergency plan (e.g., train first responders and perform emergency exercise and critique)		

[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	Delayed pending receipt of technical information from vendor.
	Implement storage option for contaminated solids	10/3/95	4/30/96	Open
	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	Open
	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	Open
	Submit Decommissioning Funding Plan	10/21/95	TBD	Pending USNRC approval of Conceptual Decommissioning Plan
	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	Unscheduled
	Complete contracts with purchasers	TBD	TBD	Unscheduled
	Package and ship sources	TBD	TBD	Unscheduled

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
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
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

Primary Action Item	Sub-Item	Scheduled Start Date	Scheduled End Date	Current Status
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
Disposition of Solid Waste at the Facility	Evaluate disposition options in light of Conceptual Decommissioning Plan	10/1/95	TBD	Pending USNRC approval of Conceptual Decommissioning Plan
	Select the preferred option based upon an ALARA analysis.	TBD	TBD	Unscheduled
	Characterize the materials.	TBD	TBD	Unscheduled
	Prepare necessary permits and licenses	TBD	TBD	Unscheduled
	Implement the preferred option	TBD	TBD	Unscheduled
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
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April 9, 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 facilty's intended use period; plans for structural remediation, if warranted; and plans to periodially inspect and evaluate the building's ability to perform its defined functions over the intended use period.

In order to comply with this request, and to address an outstanding (but related) comment on the AMS Emergency Plan (see letter from AMS to Mr. John Madera dated March 21, 1996) AMS is scheduling an independent evaluation of the structural integrity of the building. To permit us sufficient time to complete the evaluation, select appropriate actions and prepare our response to the USNRC, we are requesting a 60-day extension to the deadline contained in the March 12th letter. Baring any unanticipated delays in our schedule, you may expect to receive our response before June 12, 1996. In the meantime, please call me at (216) 692-3270 if you have any questions or if I can provide you with additional information.

Sincerely,

Robert Meschter, R.S.O.

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

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

April 12, 1996

Mr. John R. Madera, Chief
Nuclear Materials Licensing Section
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Conceptual Decommissioning Plan for Advanced Medical Systems Inc. (License No. 34-19089-01, Control No. 98507

Dear Mr. Madera:

Advanced Medical Systems, Inc. (AMS) is in receipt of your March 20, 1996 letter to David Cesar wherein comments on our Conceptual Decommissioning Plan were provided. Enclosed are our responses to your comments, along with a description of our proposed follow-up actions.

Once you have approved these comments, the Plan will be funded by the corporation and reviewed for continued applicability at the agreed-upon schedule. In the meantime, if you have any questions or if I can provide you with additional information, please call me at (216) 692-3270.

Sincerely,

Robert Meschter

Robert Meschter, R. S. O.

cc: D. Cesar
D. A. Miller, Esq. - Stavole & Miller
C. D. Berger, C.H.P. - IEM

RESPONSE TO USNRC COMMENTS ON THE AMS CONCEPTUAL DECOMMISSIONING PLAN

Agency Comment: The cost estimate and financial assurance instrument must cover the decommissioning costs if decommissioning began today, as opposed to a projected decommissioning date in the future.

AMS Response: The Conceptual Decommissioning Plan forwarded to you on October 3, 1995 was based upon the SAFSTOR decommissioning methodology. The intent of the Conceptual Decommissioning Plan, in concert with the decommissioning funding requirement of 10 CFR 40.36, is that the USNRC would implement a similar decommissioning methodology should it be forced to draw on the financial assurance. Included in the cost estimate (Table 3) is $362,000 dollars dedicated to weekly facility surveillance and maintenance for the duration of the safe storage period. The eventual goal of SAFSTOR is release of the site for unrestricted use. Therefore, the cost of on-going surveillance/maintenance, eventual decontamination and waste disposal is included in the cost estimate shown in Table 3 of the conceptual Decommissioning Plan. Because these funds are already dedicated, there would be no additional financial burden to the taxpayers of the state in the unlikely event of an AMS default during the term of its license.

Action Taken: No additional action required.

Agency Comment: The amount of financial assurance required should be based upon the quantity of material authorized on a license.

AMS Response: Concur. However, on November 9, 1995, AMS submitted a revised license renewal application wherein a materials limit for ^{60}Co of 93,110 Ci was requested[1]. To date, the USNRC has taken no action on this application. The current license limit is 300,000 Ci, but it has been at least three (3) years since AMS has had in excess of 100,000 Ci of material in site. Therefore, it is inappropriate to require AMS to provide financial assurance for an inventory that is significantly above the likely inventory at any point in time simply because action has not yet been taken on AMS's application to modify the limit.

Action Taken: No additional action required. However, timely USNRC action on our November 9, 1995 renewal application would be greatly appreciated.

Agency Comment: Please submit an evaluation of the radiological conditions of the soil under the basement and WHUT room floors or justify why the three core samples should be considered representative of the current radiological condition.

AMS Response: AMS maintains that the soils upon which the London Road building was constructed have the same radiological character now as they did before the 1995 flood. The following are our reasons for this position:

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[1] The requested limit was set to accommodate possession and sale of sealed sources as well as the radioactivity that exists in solid waste and residual radioactivity on building surfaces.

(1) Throughout the period of time that the basement of the London Road flooded due to the NEORSD's intentional blocking of all discharge paths, AMS maintained a minimal pressure differential between the inside and outside water levels in order to minimize uplift on the floor slab and eliminate the possibility of "back flow" of contaminated water to areas outside of the building. AMS's pumping efforts clearly provided the necessary level of pressure control. In fact, USNRC Inspection Report No. 030-16055/95006(DNMS) stated that, with the exception of one location on the second floor of the building, "the reinforced concrete core structure of the 1958 building that forms the hot cell, the WHUT room, the original radiography room, the source garden and the front and back basements was found to be in good condition". Furthermore, the inspector found "no additional signs of distress" on the basement slab, and concluded that "there was no observable significant impact on the structural integrity of the 1958 building as a result of the basement flooding event". Therefore, the structural evidence supports our that the radiological conditions of the soil under the basement and the WHUT room have not changed since the three core samples were taken in 1994 (e.g., before the flooding).

(2) During the 1995 sewer remediation project, AMS determined that the shale layer upon which the building is built and which formed the base of the existing footer drains, did not contain detectable radioactivity. In fact, no detectable activity was identified during the remediation other than that in the existing drain tile and fill material upon which they rested. Therefore, the radiological evidence from the remediation project supports our that the radiological conditions of the soil under the basement and the WHUT room are equivalent to the pre-flood conditions.

(3) Between the 1995 completion date of the sewer remediation project and the date of this letter, over 80,000 gallons of water have been pumped from the foundation drainage system, confirmed to be "clean" through laboratory analyses, and discharged[2]. This indicates that no mobile contamination is under the basement or in the new drainage system.

(4) Included herein as Attachment 1 is a Registered Hydrogeologist's report wherein he concludes that the new foundation drain is hydraulically connected to the soils under the basement floor, and that it is unlikely that contamination migrated from the basement to these soils.

In summary, the findings of the USNRC Inspection Report, the fact that the water being pumped from the foundation drains is radiologically benign, and the hydraulic connection between the soils under the building and the foundation drain all serve to support our position that the soils were not contaminated from the basement flood. Until the basement has been fully decontaminated, attempts to breach the integrity of the floor for the sole purpose of securing additional confirmation runs the risk of injecting contamination into the sub-basement environment where none currently appears to exist.

Action Taken: Page 8, line 14 of the Conceptual Decommissioning Plan will be modified to read: ". . . did not occur. However, if information is obtained at some time in the future to invalidate this assumption (e.g., if contamination is detected in the remediated foundation drainage system),

---

[2] Cobalt-60 was identified in one 3,000-gallon batch (e.g., hold-up tank No. 880), as I reported in my letter of February 26, 1996 to Cynthia Pederson, USNRC Region III. However, the source of this material was the tank itself, which was used as a process tank during the water treatment project. The residual cobalt-60 that was in the tank when the foundation drain water was transferred to it was later removed by filtration.

this Plan will be revised to include the cost of addressing the additional contamination during decommissioning."

Agency Comment: The deferment of decommissioning through implementation of SAFSTOR is only applicable to power reactors. The GEIS (NUREG-0586) indicates that deferred dismantlement could be a preferred option only for radionuclides that decay within a few weeks or months. By providing decommissioning financial assurance below a level that would fund complete remediation of the facility at any time during the SAFSTOR period, the public taxpayer would be forced to accept a decommissioning obligation that substantially exceeds the proposed level of funding.

AMS Response: AMS takes exception to this comment for the following reasons:

(1) The GEIS shows that SAFSTOR is an acceptable decommissioning alternative for "short lived radionuclides" at power reactors *as well as* for materials licensees (see page 0-4, section 0.2.4 and page 14-9, section 14.3.2.2).[3] Furthermore, on page G-8 of the GEIS, the definition of short-lived radionuclides is given as "those radioactive isotopes with half-lives less than about 10 years". Since the ^{60}Co at AMS, a materials licensee, has a radiological half life of approximately five (5) years, the GEIS is supportive of decommissioning by the methodology of SAFSTOR for materials licensees.

(2) The GEIS does state that use of a "safe storage period of a few days to a few months may allow the radioactivity to decay to low enough levels that no further decontamination required" (see page 14-9, section 14.3.2.2) for a reference sealed source and radiochemical manufacturer. But the GEIS also states that while generic criteria were used for development of the report, "each facility can present problems that are unique to its decommissioning" (see page 14-4, section 14.2). The reference facility used to derive the findings for sealed source production was a generic manufacturer of sealed sources that carried "out their operations in small batches in glove boxes, hoods or remote operation cells, and contamination outside these structures is limited almost entirely to the ventilation ducts and filters" (see pages 14-4 and 14-5, section 14.2). The radiological conditions at AMS are distinctly different since there is extensive area contamination, significant solid waste recovered from remediation of the old sewer system, and there is a facility that was closed to all access under the authorization of the USNRC (e.g., the WHUT Room). Therefore, strict application of the GEIS' recommendations for the reference sealed source manufacturer to all sealed source manufacturers is inappropriate.

(3) In evaluating decommissioning alternatives, there are considerations that go beyond immediate license termination and release of the site for unrestricted use. Both DECON and SAFSTOR will result in unrestricted release of the site. However, the GEIS clearly states that the overwhelming advantage of SAFSTOR at a facility like AMS is the reduction in occupational exposure and the quantities of radioactive waste from radioactive decay. The ALARA analysis shown on page 16 of the Conceptual Decommissioning Plan further demonstrates this advantages.

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[3] U. S. Nuclear Regulatory Commission, "Draft Generic Environmental Impact Statement on Decommissioning of Nuclear Facilities", NUREG-0586, January, 1981.

(4) The mission of the USNRC is to ensure adequate protection of the public health and safety, the common defense and security, and the environment from the use of nuclear materials in the United States. The USNRC and its licensees share a common responsibility to protect the public health and safety. Once a facility like AMS has reached the end of its useful life, there is no question that it must be decommissioned. However, decommissioning means that the facility must be placed in a condition such that there is no unreasonable risk to public health and safety. It would be contrary to the mission of the USNRC to categorically reject the SAFSTOR option as a decommissioning alternative for AMS. Furthermore, since the eventual goal of SAFSTOR is release of the site for unrestricted use, and since the cost of on-going surveillance maintenance, as well as eventual decontamination and waste disposal is included in the cost estimate for the Conceptual Decommissioning Plan, there would be no additional financial burden to the taxpayers of the state.

(5) The USNRC, in its October 20, 1988 letter to Dr. Seymour S. Stein (AMS), 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. (In the July 6th letter, AMS stated that: "To move this material from its present safe concealment through the general public environment merely to deposit it at another safe concealment presents unreasonable and unnecessary man-rem exposure and risk to the public health and safety at an unjustifiable exposure".) Since the Conceptual Decommissioning Plan that is the subject of this letter was developed with similar concerns in mind, AMS respectfully requests that the USNRC reconsider its current position on SAFSTOR in light of its previous position 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 from A. Bert Davis to Dr. Stein).

Action Taken: None required.

Agency Comment: Table 3 to your Conceptual Decommissioning Plan entitled "Manpower and Cost Estimates" lacks the specificity the NRC needs to verify your cost estimate. Resubmit your cost estimating table using the format provided [citation given].

AMS Response: Concur.

Action Taken: Included herein as Attachment 2 is additional cost information for the SAFSTOR option. This information is 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).

ATTACHMENT 1

Quality
Environmental
Solutions, Inc.

April 11, 1996

Ms. Carol D. Berger
Integrated Environmental Management, Inc.
1680 East Guide Drive
Suite 305
Rockville, Maryland 20850

Dear Carol:

I have reviewed the letter dated March 20, 1996 from the U. S. Nuclear Regulatory Commission (NRC) to your customer, AMS, regarding the Conceptual Decommissioning Plan of the AMS Facility. It is my opinion that, based upon the effect of the hydraulic gradient in the vicinity of the basement when the basement contained water, the additional sampling of soils below the basement and the WHUT room floors should not be required. According to the evidence, it is unlikely that contamination migrated from the building to these soils, and, therefore, conditions in the soils would not have changed due to the flooding of the basement referenced in the NRC's letter.

Following is a brief recap of the evidence and the historical events:

1. Prior to the flooding, three core samples were obtained from native soils under the basement in the vicinity of the WHUT room. Contamination was not discovered in any of the samples;

2. Based upon a suspected discharge of radioactive contamination, the outfall of the AMS Building basement drainage system was plugged by the local sewer authority. As a result, ground water that normally was carried off site by the drainage system began to accumulate and enter the basement;

3. Prior to the removal of the water from the basement, monitoring records show the water elevation in the drainage system to be higher than the water level in the basement. Additionally, during the removal of water from the basement, the surface elevation of the basement water was intentionally maintained below the water elevation in the drain system;

4. Since the flooding, the basement drainage system was closed in place and has been replaced with a new subsurface perimeter-drain system; and,

5. The new drain system is utilized to remove ground water from the soils around the basement by pumping collected water into aboveground storage. Contamination has not been discovered in the removed water, and the water has been discharged to the local sewer. Since the initiation of the pumping, the basement has been dry.

My conclusion that soil conditions did not change during the period when the basement was flooded is based upon the following:

1. The original drainage system created a local sink, collecting ground water from the basement vicinity and maintaining the ground water level below the basement floor. The water level observed in the drain is representative of conditions in the surrounding soils. In addition to intercepting ground water flowing toward the basement, the new drainage system is also hydraulically connected to the soils surrounding the basement floor;

2. The differential water levels between the drainage system and the basement during the period in which the basement contained water indicate a positive hydraulic gradient from the surrounding soils toward the basement. Water would not leak out of the basement under these conditions; and,

3. If water was leaking from the basement, contamination could be expected to show up in the water that is collected by the new drain system. Therefore, the lack of contamination in the removed water also indicates that the ground-water flow was toward the basement during its flooded period.

Thank you for the opportunity to be of service on this project. Please call me at 410-841-5552 if you have any questions regarding this letter.

Sincerely,

Donald E. Jones, P.G.
Registered Hydrogeologist

ATTACHMENT 2

Cost Estimating Table - SAFSTOR Alternative
(USNRC Regulatory Guide 3.66, Appendix F)

Table 1

Planning and Preparation						
Task	Work Days					Total Cost ($)
	Supervisor	Foreman	HP	Clerical	Total	
Preparation of Documentation for Regulatory Agencies	4	4	2	0.5	10.5	4560
Submittal of Decommissioning Plan to NRC when required by 10 CFR 30.36	10	10	10	1	31	14560
Development of work plans	10	10	10	1	31	14560
Procurement of Special equipment	2	2	0	0.5	4.5	1680
Staff training	1	1	1	0.5	3.5	1620
Characterization of radiological condition of the facility (including soil and tailings analysis or groundwater analysis, if applicable)	20	20	5	2	47	19520
Other	0	0	0	0	0	0
Total	47	47	28	5.5	127.5	56400

Table 2

Position	Unit Cost for Workers		Worker Cost/year ($)
	Basic Salaries ($/yr)	Overhead Rate (%)	
Supervisor	60000	100	120000
Foreman	40000	100	80000
Craftsman	30000	100	60000
Technician	30000	100	60000
Health Physicist	80000	100	160000
Laborer	30000	100	60000
Clerical	20000	100	40000

Decontamination and/or dismantling of Radioactive Facility components					
	No.	Dimensions		No.	Dimensions
Glove Boxes	0	n/a	Amount of Floor Space	--	200 m^2
Fume Hood	0	n/a	Ventilation ductwork	--	50 m
Hot Cells	1	27 m^3	Amount of Wall Space	--	3100 m^2
Lab Benches	0	n/a	Other	--	--
Sink and Drain	2	25 m		--	--

Table 3

Task	Work Days							Total Cost ($)
	Supervisor	Foreman	Technicians	HP	Craftsmen	Laborer	Total	
Decon/dismantle major components and/or processing storage tanks (Hot cell SAFSTOR and decon after SAFSTOR)	10	10	20	2	0	15	57	17680
Decon/dismantle laboratories, fume hoods, glove boxes, benches, etc.	--	--	--	--	--	--	--	--
Decon/dismantle waste areas (radwaste area, scrap recovery, other) WHUT room	3	12	15	3	0	15	48	14400
Decon/dismantle service facilities (maintenance shop, decontamination areas, ventilation systems, other) includes HEPA system and misc. Areas	14	55	65	8	22	65	229	65920
Decon/dismantle waste treatment facilities and storage areas on site (including exhume and package contaminated soil and tailings, if any)	--	--	--	--	--	--	--	--
Monitor for compliance, reclean and monitor, if necessary	2	8	10	2	0	10	32	9600
Other (e.g., contractor fees)	80	0	0	0	0	0	80	38400

Table 4

Equipment/supply	Quantity	Cost
Personnel protective equipment	1 lot	18000
Misc. Decon supplies	1 lot	20000
Security system upgrade SAFSTOR	1ea	2000
Office supplies, misc. other	1 lot	2000
Survey equipment	1 lot	4000
Decon equipment rental	4 mo.	20000
Misc. items for 50 yr. SAFSTOR	1 lot	50000
Total		116000

Table 5

Waste type	Volume (m^3)	No. Of containers	Type of Container	Unit Cost of Container	Cost of Container
LLW	2.83	1	B-25	500	500
Asbestos	0.59	4	Drum	35	140
Total	3.42	5	--	--	640

Table 6

Distance shipped	2525 (miles)
Unit Cost for shipment	2.65 ($/mile/truckload)
Additional Charges - Overweight	0 ($/mile)
Additional Charges - Surcharge	0 ($/mile)

Waste Type	No. Of shipments	Unit Cost for shipping ($)	Distance Shipped (miles)	Surcharge ($)	Transportation Cost ($)
LLW	1	2.654	700	0	1855
Asbestos	1	2.65	1825	0	4836
Total					6691

Table 7

Burial Charges	340 ($/ft^3)
Surcharges - Per container	0 ($)
Surcharges - Disposal	0 ($/ft^3)

Waste Type	Burial Volume (ft^3)	Unit Cost of Burial ($/ft^3)	Surcharge ($)	Burial Cost ($)
Class A - LLW	100	340	0	34000
Asbestos	21	150	0	3150
Total				37150

Table 8

Restoration of Contaminated Areas on Facility Ground						
Task	Work Days					Total Cost ($)
	Supervisor	Foreman	HP	Clerical	Total	
Backfill and restore site	0	0	0	0	0	0

Table 9

Final Radiation Survey						
Task	Work Days					Total Cost ($)
	Supervisor	Foreman	HP	Clerical	Total	
Outdoor release survey	36	40	20	1	87	43040
Building release survey	12	15	6	0.5	33.5	14480
Total	48	55	26	1.5	130.5	57520

Table 10

Site Stabilization, Long-Term Surveillance (if applicable)						
Task	Work Days					Total Cost ($)
	Supervisor	Foreman	HP	Clerical	Total	
On-going building maintenance and surveys (50 yr)	125	600	62.5	125	912.5	312000

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

April 11, 1996

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

Dear Mr. Meschter:

This is to confirm the telephone conversation between you and Messrs. John Madera and Michael Weber of my staff, on April 10, 1996, regarding your April 9, 1996 letter. In your letter, you requested a 60-day extension to the deadline contained in our March 12, 1996 letter, which transmitted NRC Inspection Report No. 030-16055/95006(DNMS). During the telephone conversation, we indicated that our March 12, 1996 letter requested that, within 30 days of the letter's date, AMS provide its plans and schedule for completing an assessment of the structural integrity of the AMS building. In your April 9, 1996 letter, you indicated that AMS is scheduling an independent evaluation of the building's structural integrity, and that we will receive a complete response to our March 12, 1996 letter by June 12, 1996. Your notification satisfies our request for AMS' plans and schedule for completing the structural integrity assessment. Therefore, a 60-day extension is unnecessary.

Sincerely,

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

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

See Attached Distribution

Distribution

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

Lisa Mehringer
City of Cleveland Law Department
601 Lakeside Avenue, Room 106
Cleveland, OH 44114

Erwin J. Odeal, Executive Director
Northeast Ohio Regional Sewer District
3826 Euclid Avenue
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County of Cuyahoga
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Marian Zobler
U.S. Nuclear Regulatory Commission
Rockville, MD 20555

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

APR 16 1996

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

Dear Mr. Meschter:

Enclosed is Amendment No. 41 to your NRC Material License No. 34-19089-01 in accordance with your letters dated October 17, 1995 and December 11, 1995. This action amends the following three license conditions by removing references to grouting-in the four-inch sewer discharge line and the abandoned footer drain in the vicinity of the Source Garden:

1) License Condition No. 19.E.i

"Completely grout-in the radioactively contaminated four-inch sewer discharge line ... as described in 'Issue 4' of the 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."

2) License Condition No. 22.H. (Supplement 1 to letter dated March 1, 1995)

"When the areas are dewatered, ... grout-in the four-inch line ... "

3) License Condition No. 22.I (letter dated July 19, 1995)

"AMS intends to grout-in the entire length of the four-inch line that protrudes from the back of the building to ensure no migration of contamination."

"The foundation drain that remains in the vicinity of the Source Garden will also be grouted-in ... as shown in Attachment 1 and Attachment 3."

Regarding the requirement to completely grout-in the four-inch sewer discharge line in order to immobilize the radioactive contamination, this requirement has been satisfied by the following actions taken by AMS in 1995: (1) in July, AMS contractors capped the line at both ends with brick and concrete, (2) in November, AMS provided NRC an old photograph which indicates that the discharge line is encased by concrete, (3) in August, AMS contractors drilled a hole in the basement (near the four-inch line) to a depth of 14 inches which showed concrete, whereas the normal slab thickness is six inches, and (4) in

December, AMS provided NRC a statement from AMS' engineer, who reviewed the the photograph and drilling data and concluded that the four-inch line is encased by concrete.

Regarding the requirement to grout-in the abandoned foundation drain to ensure no migration of contamination into the new under drain system, this requirement has been satisfied by the following actions taken by AMS in July 1995: (1) AMS contractors installed an underground slurry wall between the abandoned and the new underdrain systems, and (2) AMS contractors installed a plastic tarp covering the ground over the abandoned footer drains. As discussed in your July 19, 1995 letter, the wall and tarp were designed to minimize migration of contamination out of the abandoned area, and minimize the potential for water infiltration into the abandoned area (e.g., from rain and melting snow), respectively.

We've added License Condition No. 22, which retracts the requirement to grout-in the four-inch sewer discharge line and the abandoned footer drain.

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 so that we can provide appropriate corrections and answers.

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, 10 CFR Part 2, Appendix C. 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,

Kevin G. Null

Kevin G. Null
Nuclear Materials Licensing Branch

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

NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 41

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.

30112

Licensee	
1. Advanced Medical Systems, Inc.	In accordance with letters dated October 17 and December 11, 1995 3. License Number 34-19089-01 is amended in its entirety to read as follows:
2. 1020 London Road Cleveland, OH 44110	4. Expiration Date December 31, 1994
	5. Docket or Reference No. 030-16055/040-08764/030-17154

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

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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.

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.

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

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

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

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

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

AMS/PICKER TELETHERAPY/RADIOGRAPHY UNITS MODELS

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

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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.

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. 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.

23. (Continued)

A. Application dated November 12, 1984;

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

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

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

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

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

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

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.

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23. (Continued)

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 and December 11, 1995 (with referenced photograph).

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

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 4/4/96

By _____
Nuclear Materials Licensing Branch, Region III

COPY

AMC medical group

Advanced Medical Systems, Inc.

1020 London Rd.
Cleveland, Ohio 44110
216-692-3270

April 24, 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, except for those pertaining to the Shewmaker structural integrity report, in Revision I of the "Strategic Plan for the London Road Facility". This document was forwarded to you on January 15,1996.

On April 22, 1996, Ms. Cynthia Pederson (USNRC) requested a more formal response than what was contained in our January 15th submittal. In compliance with her request, enclosed are our item-specific responses to your December 6th letter, along with a description of follow-up actions associated with each item. If you have any questions or if I can provide you with additional information, please call me at (216) 692-3270.

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
G. Wright - Acting Deputy Director, Division of Radiation Safety and Safeguards, USNRC
M. Weber - Region III, USNRC

MAY 0 3 1996

USNRC Comment: You designated the recovery of the capabilities of the hot cell, and the subsequent reduction of sealed source and bulk cobalt 60 inventory, as intermediate priority actions, to be completed within the next one to three years in accordance with your priority scheme. We consider that a higher priority should be given to these actions. Furthermore, given the importance of the inventory reduction we request estimated completion dates rather than the "TBD" stated in Table 3 of your response. You should describe the actions taken to date and planned, to identify a market for the sealed and bulk sources. We request specific justification if the actions discussed [in this paragraph] are not designated as high priority actions with specific schedules assigned.

AMS Response: In regard to recovery of the Hot Cell's capabilities, page 7, lines 12 through 17 of Revision 1 of the "Strategic Plan for the London Road Facility" (Strategic Plan), which was submitted to the USNRC on January 15, 1996, shows that the Hot Cell's capabilities were recovered and the system became fully operational with respect to its ability to decontaminate, leak test, package, and ship sealed sources, on December 27, 1995. AMS began returning sources to NPI shortly thereafter. Table 3 on page 16 and 17 of the Plan shows the scheduled end dates for the referenced activities.

In regard to inventory reduction efforts, page 7, lines 38 through 43 of Revision 1 of the Strategic Plan states that discussions with a variety of potential recipients of the sealed sources and bulk cobalt were underway. Table 3 on page 17 of the Plan shows the scheduled end date for these discussions. Because discussions were still underway as of the date of Revision 1 of the Plan, these items remained open. Since that time, and as shown on page 7 of Revision 2 of the Strategic Plan (submitted o the USNRC on April 8, 1996), the discussions were completed and on March 20, 1996 AMS prepared and distributed a description of the type, form and curie content of the sources to agencies and firms with potential interest. As of the date of this letter, AMS continues to receive responses to its March 20th letter.

Action Taken: No further action required. However, Revision 3 of the Strategic Plan, which will be forwarded to the USNRC by July 15, 1996, will show the inventory reduction efforts elevated to a "high" priority, and will report on the outcome of the March 20, 1996 mailing.

USNRC Comment: We also regard the training of the offsite emergency response personnel in AMS' Emergency Plan, and the subsequent emergency exercise, as high priority actions. We expect this training to take place expeditiously after NRC approves the Emergency Plan, as you stated in your response, and the exercise to follow within two months after the training is completed. Therefore, you should designate these actions as high priority actions. We request specific justification if the actions discussed [in this paragraph] are not designated as high priority actions with specific schedules assigned.

AMS Response: Table 2 in Revision 1 of the Strategic Plan shows training of offsite emergency response personnel and performance of the emergency exercise to be high priority actions. Page 5, line 29 of the Plan states that "within 60 days after USNRC approval of the revised Emergency Plan, a training session for first responders will be scheduled". Page 5, line 36 of the Plan states that "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".

Action Taken: No further action required.

USNRC Comment: Regarding Item A.2 of the DFI (offsite disposal of wastes), we consider this action to be a high priority action, given that (1) these wastes are the only radioactive material at AMS which are in a potentially dispersible form, and (2) offsite disposal of wastes is now possible due to the recent reopening of the licensed low-level waste disposal facility at Barnwell, South Carolina. We request specific justification if the actions discussed [in this paragraph] are not designated as high priority actions with specific schedules assigned.

AMS Response: With the exception of the excavated soils from the sewer remediation project, the majority of the solid waste remaining at the AMS facility is stored in Type-A 55-gallon drums or B-25 boxes. As such, they meet the DOT criteria for the water spray test (simulated exposure to rainfall), free drop test (from a height of four feet), compression test, and penetration test. Although the contents of the containers are listed as "potentially dispersible" in the Strategic Plan and the Conceptual Decommissioning Plan, they are not likely to be dispersed even in the event of a major natural disaster. Furthermore, as shown in Section 2 of the "Emergency Plan for the London Road Facility" (Revision 0, September 21, 1995), even if the potential for dispersal is assumed, the radiological impact on members of the general public would be negligible.

The 60,000 curies of sealed sources and bulk cobalt at the London Road facility no longer serve a useful purpose in light of on-going operations. Their mere presence places great physical and financial demands on AMS that would either not exist or would be reduced in magnitude if the inventory were no longer present.

AMS would like nothing better than to immediately dispose of the packaged waste and immediately complete all the rest of the items listed on Table 2 of Revision 1 of the Strategic Plan. However, due to limits on personnel availability and financial resources, it is simply not possible for AMS to act on all of these outstanding issues at once. Given a choice between dedicating its limited resources to inventory reduction, which has significant programmatic and financial benefits, or disposal of the packaged low-level radioactive waste, which has negligible programmatic or financial benefits, since both choices entail significant expenditure of funds, AMS has placed a higher priority on the inventory reduction and relegated the solid waste disposal to a lower priority.

Action Taken: None.

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

AMS Response: Page 8, lines 27 through 31 of Revision 1 of the Strategic Plan states that an amendment to License No 34-19089-01 to postpone the inventory requirement may be necessary because of the low priority assigned to removal of the stuck plug. However, the decision to submit an amendment application is dependent upon the timeliness of USNRC action on AMS's recent license renewal.

Action Taken: No further action required.

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

AMS Response: Page 5, lines 1 through 19 of Revision 1 of the Strategic Plan states that the methodology for decommissioning the AMS facility, including decommissioning/decontamination of the WHUT Room, is contained in the "Conceptual Decommissioning Plan for the London Road Facility". This document was submitted to the USNRC on October 20, 1995. Therein, AMS indicated that the preferred decommissioning methodology for the WHUT Room is SAFSTOR, followed by release for unrestricted use after a safe storage period of up to 50 years.

This methodology is preferred (e.g., over DECON) because of its overwhelming reduction in occupational exposures and quantities of radioactive waste due to radioactive decay. It is also compatible with a previous position in regard to the WHUT Room taken by the USNRC in an October 20, 1988 letter from A. B. Davis (USNRC) to Dr. Seymour S. Stein (AMS). In that letter, 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).

Action Taken: No further action required.

USNRC Comment: AMS is required, by License Condition 22, to decontaminate restricted areas if surface contamination levels exceed 40,000 disintegrations per minute per 100 square centimeters (dpm/100 cm^2). Consistent with ALARA principles your plan should address steps that will be taken to further reduce contamination levels and permit a greater degree of worker safety and accessibility throughout the facility. Therefore, you should re-address this issue and describe your plan of action for the decontamination of the AMS facility.

AMS Response: In this comment, we assume the USNRC is referring to License Condition 23.F, where the July 23, 1990 letter from S. J. Stein (AMS) to J. Madera (USNRC) is cited. The Stein letter served to transmit Isotope Shop Procedure No. ISP-1. Section 3.3.2(b)(1) of this procedure contains the following action level for surface contamination in restricted areas: "Contamination levels [except Hot Cell] exceeding 4.0 x 10^3 dpm/100 cm^2 shall be reduced ALARA." Excluding the Hot Cell, the only locations at the London Road facility with removable contamination in excess of 40,000 dpm/100 cm^2 are the Isotope Shop, the Source Garden, the Decontamination Room, and the WHUT Room. Of these, only the Isotope Shop and the Decontamination Room are accessed by personnel and then only rarely (e.g., during Hot Cell entries or for performance of routine surveillance activities).

When the exposure potential associated with a decontamination effort (e.g., direct and inhalation exposure potential) is assessed in light of the limited need to access the Isotope Shop and the Decontamination Room, the existing contamination levels in these areas (e.g., an average of 50,000 cpm/100 cm^2 in the Isotope Shop and 3,000,000 dpm/100 cm cm^2 in the Decontamination room) are considered to be as low as reasonably achievable. However, if these areas are accessed more frequently than the current, this position will be re-evaluated.

Action Taken: Revision 3 of the Strategic Plan, which will be submitted to the USNRC before July 15, 1996, will address decontamination of the Isotope Shop and the Decontamination Room to levels

that are ALARA in the Section entitled "On-Going Actions" (subsection entitled "Housekeeping Improvements").

USNRC Comment: Please provide us information regarding the expected long term (3-5 years) integrity of the collapsible storage tanks.

AMS Response: Pursuant to vendor specifications, the rubberized fabrics that form the tanks comply with MIL-T-52983, MIL-T-53029 and MIL-T-53066 military specifications for performance and durability. In a December 12, 1995 discussion between the manufacturer of the collapsible storage tanks (Mr. David H. Dack, Aero Tec Laboratories Inc., Spear Road Industrial Park, Ramsey, New Jersey) and R. Meschter (AMS), the manufacturer stated that tanks that have been deployed for at least eight (8) years have suffered no loss of integrity. Since the AMS tanks are located in a controlled (indoor) environment and are frequently inspected, their containment ability should endure for at least eight years.

Action Taken: None required.

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 prior to June 12, 1996.