



Advanced Medical Systems, Inc.

1020 London Road
Cleveland, OH 44110
(216) 692-3270

August 10, 1996

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

Re: Amendment 44, License No. 34-19089-01

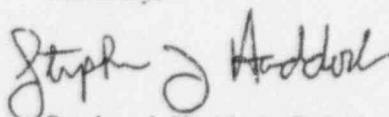
Dear Mr. Madera:

Advanced Medical Systems, Inc. (AMS) is in receipt of the referenced amendment and, as was relayed to you and to Mr. Mike Weber by AMS's technical consultant (Ms. Carol Berger) in a telephone conversation, we were confused about the intent of the last sentence in Provision 23.A. That sentence stated that "Implementation of Tasks 3 through 12 of the BRP is not authorized".

Subsequent to your interpretation of the intent of this statement, AMS now assumes that Tasks 3 through 12 of the BRP are simply not addressed in Provision 23, and that there is nothing in Amendment 44 that disallows these tasks. We are also assuming that Provision 23 authorizes payment of the performance of Tasks 1 and 2 only out of the released funds. Finally, we are also assuming that the parenthetical statement following reference to the June 10, 1996 letter in Provision I does not disallow performance of Tasks 3 through 12 of the Building Recovery Project; it only indicates that these Tasks have not yet been addressed.

If your understanding of these issues differs from ours, please call me at (216) 692-3270 at your earliest convenience. Thank you very much for your assistance.

Sincerely,


Stephen J. Haddock, R.S.O.

cc: D. Cesar
D. Miller - Stavole & Miller
C. Berger - IEM

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REGION III



Advanced Medical Systems, Inc.

1020 London Road
Cleveland, OH 44110
(216) 692-3270

August 14, 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:

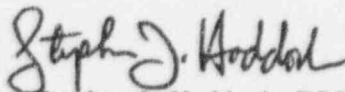
Advanced Medical Systems, Inc. (AMS) is in receipt of your letter dated July 16, 1996 wherein comments on Revision 0 of the AMS Emergency Plan and our March 21, 1996 responses to your first set of comments were provided. Enclosed are our responses to your second set of comments, along with a description 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 the USNRC's timely approval of our Emergency Plan.

Sincerely,


Stephen J. Haddock, RSO

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

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**RESPONSE TO COMMENTS FROM
U. S. NUCLEAR REGULATORY COMMISSION**

Agency Comment 1: The proposed actions appear to be adequate but it is still unclear how ADT will detect a power failure at the facility, or a disruption in telephone services. If ADT monitors the line such that it can promptly detect a loss of contact, a statement to that effect should be added to the plan.

AMS Response: Concur.

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. Part of their responsibility is to monitor the phone line so that power failure or disruption in telephone services are readily identified. When such a condition is detected, 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 2: In addition to the proposed actions, the plan should contain a commitment to maintain a map showing the restricted areas, or some other warning sign, at each entrance that a first responder may use to enter the facility.

AMS Response: Concur.

Action Taken: The following footnote to line 17 on page 7-1, as modified, will be inserted: "A map showing the location of radiologically-restricted areas is located in the immediate proximity of the two enunciator panels (front door and the old lobby door) and at all other entrances to the building, including the loading dock entrance."

Agency Comment 3: Concerns about the technical basis for worst-case earthquake scenario remain unresolved at this time. We are in receipt of your response to NRC Inspection Report No. 030-16055/95006, and have forwarded it to our Headquarters office for review. Once we have received comments from NRC Headquarters staff, we will contact you via separate correspondence.

AMS Response: None Required.

Action Taken: None.

Agency Comment 4: The proposed actions are adequate for NRC approval; however, we believe it would be helpful if the sand shield in the basement and the access manholes on the first floor (as described in Section 1.2.3) were shown in the drawings. Please submit revised drawings.

AMS Response: The manholes on the first floor have been sealed and are no longer accessible. To include them in future versions of the drawing would serve no purpose.

Action Taken: When the maps are re-drawn, notation of the sand shield in the basement will be made.

Agency Comment 5: If offsite features significant to emergency response (as described in Section 1.2 of Regulatory Guide 3.67) are clearly labeled on the topographical map or an additional map of the site area, the proposed action will be adequate. Please make the necessary modifications and submit them for our review.

AMS Response: None required.

Action Taken: A copy of the revised topographic map is included herein as Attachment 1.

Agency Comment 6(a): The response is inadequate. With regard to packaged waste and surface contamination, the worst-case scenario must assume that the entire quantity authorized by the license is available for release unless some justification is provided to explain why it is unreasonable to make the assumption. [Other information provided]. The movement of the containers [of bulk cobalt-60] outside of [hardened areas of the facility] needs to be addressed. [Other information provided].

AMS Response: Concur.

Action Taken: Page 2-2, lines 1 through 3 will be modified to read: "in §71.71(c). The remainder of the sources are maintained in either the subterranean Source Garden, the vault-like Hot Cell, in lead/steel-encased source heads weighing approximately 4,000 pounds each, or in Type-B shipping containers weighing 8,100 pounds that were designed to withstand the accident conditions listed in §71.71. All of the canisters of bulk cobalt are contained in a Type B package. (The Type-B containers are, as of the date of this report, staged for shipment in the hardened area of the building. If shipment were not pending, the sources would be kept in the Source Garden or Hot Cell.) Consequently, the probability for major . . ."

Agency Comment 6(b): With regard to the assumption of a 10-meter release height, we consulted with inspection staff familiar with the site. It appears that most of the doors and windows through which a plume could be released are on the second floor, so we will accept the assumption of a 10-meter release height.

AMS Response: None required.

Action Taken: None.

Agency Comment 6(c): With regard to the calculations used to estimate potential offsite doses, your response acknowledges that the CAP88-PC code models a gradual release of radioactive material over 12 months and estimates doses using several environmental pathways including the food and water pathways. [Other information provided]. We recommend that you [use the formula in Section 2.1.3 of NUREG-1140, with a stability class of D].

AMS Response: Concur.

Action Taken: Section 2.1.1 and Appendix C will be modified to incorporate the result of the recommended calculation methodology as additional support for the conclusions drawn.

Agency Comment 7: The plan should reflect your response that it is likely a tornado would impose structural damage to restricted areas that are not of "hardened" construction. The plan should also mention the possibility that some containers may be in these damage prone areas (during shipments, etc.) when a tornado strikes, and discuss whether the containers would be expected to withstand accident conditions. See the discussion in Item 6(a) above.

AMS Response: Concur.

Action Taken: Page 2-4, lines 1 through 3 will be modified to read: "The AMS building may incur structural damage in the event of tornado impact. Certain restricted areas (e.g., those that are not of "hardened" construction) may be included in the damage area. However, only the HEPA Room on the second floor contains any dispersible activity of consequence (e.g., two curies). (The remainder of the materials materials are stored in shipping containers that are designed to withstand accident conditions.) Consequently, the maximum dose to the nearest off-site resident from the dispersible activity would be only a fraction of that associated with the fire scenario, wherein 40 curies could potentially be dispersed. Therefore, the radiological impact of a tornado is likely to be minimal."

Agency Comment 8(a): The revised emergency action levels (EALs) are defined in terms of projected effluents and site boundary exposure rates. It is still unclear how the Emergency Manager will be able to project these conditions in a timely manner. It would be better to define EALs in terms of the quantity of material that would be needed to produce those conditions. The Emergency Manager then would be able to declare an emergency based simply on the location of the emergency and the amount of radioactive material in those areas.

AMS Response: Concur.

Action Taken: Attachment 1 of Appendix D will be revised in its entirety. Attachment 3 to this letter shows the revision.

Agency Comment 8(b): We also note that the proposed revision to Attachment 1 of Appendix D classifies a 20 mR/hr dose rate at the site boundary as an incident and indicates that an emergency will only be declared if the dose rate at the site boundary could exceed 100 mR/hr. These action levels are too high. [Additional information provided.] More appropriate action levels should be established.

AMS Response: Concur.

Action Taken: Attachment 1 of Appendix D will be revised in its entirety. Attachment 3 to this letter shows the revision.

Agency Comment 9: The plan should contain more detailed recommendations for offsite protection actions based on the worst-case accident scenarios defined in the plan. The initial recommendations should define the offsite areas where protection actions should be implemented. We note that you have not postulated any accidents with projected doses approaching 1 rem so it is unclear why you indicate that evacuations may be recommended. Your emergency classifications and protection action recommendations should be consistent with your accident analysis.

AMS Response: Concur.

Action Taken: Attachment 1 of Appendix D will be revised to address these issues. Attachment 3 to this letter shows the revisions.

Agency Comment 10: We believe that 90 minutes is too long for the first update. Sixty (60) minutes would be better. Please modify accordingly.

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 60 minutes of the initial notification. Subsequent updates will be as agreed upon between AMS and the responder during the first update call."

Agency Comment 11: The proposed actions will be adequate if agreement letters are obtained and submitted with the emergency plan.

AMS Response: None required.

Action Taken: Agreement letters will be submitted with the revised plan.

Agency Comment 12: The proposed actions are adequate. However, the emergency plan must provide reasonable assurance that a sufficient number of survey meters will be available since the local fire and police departments do not have the capability to perform radiation surveys.

AMS Response: Page 6-1, Section 6.4 describes the type and minimum number of survey instruments that will be available during an emergency.

Action Taken: None.

Agency Comment 13: The Ohio Department of Health needs to be added to Section 4.4 also.

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, the Ohio Department of Health, and the Ohio Emergency Management Agency.

Agency Comment 14: If AMS will rely on offsite firefighters to conduct search and rescue apparitions, the plan should include a statement to that affect.

AMS Response: Concur.

Action Taken: The following sentence will be added after line 7 of page 5-2: "The RSO will initiate and, if necessary, assist firefighters in search and rescue operations for individuals that are unaccounted for."

Agency Comment 15: Even though the footnote will be deleted, the response doesn't address the question of whether AMS personnel will be able to accompany firefighters during the fire if self-contained breathing apparatus is required to enter the building. If the assistance during fire fighting efforts mentioned in the plan is limited to conducting surveys outside of the building, that should be stated in the plan.

AMS Response: Partially concur. Those AMS employees who are trained in the use of self-contained breathing apparatus pursuant to 29 CFR 1910 may render assistance.

Action Taken: Page 5-2, line 10 will be modified to read: "... during fires. However, if the use of self-contained breathing apparatus is required for entry, only those AMS personnel who are qualified in the use of such devices will assist in rescue operations. Those that are not qualified will assist firefighters by conducting surveys outside of the building only. Radiation monitoring instrumentation will be made ..."

Agency Comment 16: Pencil-type pocket dosimeters that use a thin filament are susceptible to false readings if they are bumped or dropped. Pocket dosimeters are susceptible to environmental conditions also. We believe that more reliable dosimeters should be provided for emergency response personnel. Please address this issue.

AMS Response: As stated in our March 21, 1996 response, AMS does not consider pocket dosimeters to be necessarily less reliable than other dosimeter types. If subject to insult beyond their performance specifications, they will, in fact, fail. However, other than a catastrophic insult that completely destroys the dosimeter, a dosimeter that is bumped or dropped will discharge and consequently "read high". A damaged TLD-based dosimeter almost always "reads low". Furthermore, a pocket dosimeter is no less able to withstand environmental impacts such as water and heat than is a conventional TLD-based dosimeter. Finally, the pocket meter provides the added advantage of "real time" monitoring that is not possible with TLD-based dosimeters.

Action Taken: Page 6-2, line 3 will be modified to read: "... respirators (full face). In addition, and at the discretion of the RSO, TLD-based dosimeters may be issued to emergency personnel."

Agency Comment 17: The response fails to provide a basis for NRC to find there is reasonable assurance that an operable survey meter will be available during an emergency. [Additional information provided.] The plan must provide reasonable assurance that an inoperable survey meter will not prevent response personnel from performing initial assessments. This assurance could be provided by a second survey meter, or more frequent operational checks (weekly would be acceptable).

AMS Response: Concur.

Action Taken: Page 6-2, line 6 will be modified to read: "... availability are checked weekly and confirmed to be present and functional."

Agency Comment 18: Although a statement describing typical calibration intervals and operational check frequencies is preferred, referencing Radiation Safety Procedure No. RSP-008 is acceptable. A copy of this procedure should be provided for information when the plan is resubmitted.

AMS Response: None required.

Action Taken: For information only, a copy of Radiation Safety Procedure No. RSP-008, "Instrumentation and Surveillance" is included herein as Attachment 2. Since RSP-008 is subject to revision, the August 14, 1996 version shown in Attachment 2 should not be considered a part of the Emergency Plan.

Agency Comment 19: The regulations in 10 CFR 30.35(g) require that records important to decommissioning be retained until the license is terminated. The plan should describe the provisions for ensuring that records of incidents are retained until the license is terminated.

AMS Response: Concur.

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". All records important to decommissioning shall be retained until license termination."

ATTACHMENT 1
REVISED TOPOGRAPHICAL MAP

ATTACHMENT 2
RSP-008, "INSTRUMENTATION AND SURVEILLANCE"