

Advanced Medical Systems, Inc.

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August 4, 1995

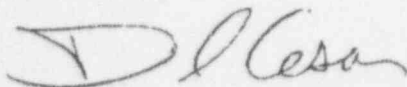
Mr. J. R. Madera, Chief
Nuclear Materials Licensing Section
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60525-4351

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

Dear Mr. Madera:

Advanced Medical Systems, Inc., (AMS) received your letter dated June 7, 1995, wherein you provided comments on the AMS Emergency Plan submitted as part of our license renewal application. Attached are our responses to your comments. Included also are the comments submitted by other agencies, along with the responses provided by AMS. The revised Emergency Plan, incorporating the commitments made on the attachment, is being submitted to you under separate cover. You may expect receipt by September 30, 1995. Once the revised Emergency Plan is approved, AMS will begin scheduling an exercise. In the meantime, if I can answer any questions or provide you with additional information, please call me at (216) 692-3270.

Sincerely,



DAVID CESAR
Treasurer

DC/cs

cc: R. Meschter - AMS-RSQ
D. Miller, Esq. - Stavole & Miller
H. Billingsley - Arter & Hadden

F/65

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RESPONSE TO COMMENTS FROM U. S. NUCLEAR REGULATORY COMMISSION

Agency Comment I.A.: Due to the limited number of staff at your facility responsible for emergency response actions, we are concerned that you may not be able to effectively implement your Emergency Plan.

AMS Response: The staff at the facility is adequate to handle emergency situations at the facility. The staff has authorization to marshal whatever resources are necessary to contain an emergency.

Action Taken: None. The company employees are very knowledgeable with the facility and are very well trained in radiation safety and protocol.

Agency Comment I.B.: Section 3 of the EP includes your consultant's offsite dose assessment for a vandalism induced fire and explosion involving 15 curies of radwaste in the basement of the facility. The consultant's assessment also discusses natural disasters, discounting the release of radioactivity from such events due to their infrequent occurrence and because the majority of the cobalt-60 inventory is in "primary containment that is resistant to ready release". However, the assessment did not provide sufficient justification to support your conclusion that the worst case scenario would involve only 15 curies of radwaste. Specifically, your assessment did not adequately evaluate the effect of natural disasters and fire/explosion on the radioactive material you currently possess in various areas of your facility in the form of bulk and sealed sources. You currently possess about 70,000 curies of cobalt-60 in bulk and sealed source form.

In order to support your conclusion, you must conduct an engineering analysis of the facility structure and primary containment systems housing your cobalt-60 inventory to demonstrate its integrity will be maintained during a natural disaster or fire/explosion. The structural assessment of the facility and containment systems should also include the WHUT room and the offsite dose consequences if it is determined that the room's cobalt-60 inventory could be released to the environment. For example, evaluate the scenario of falling structural debris from an earthquake/tornado striking several containers of bulk cobalt-60 and releasing its contents. The loose bulk material is then exposed to a fire caused by a ruptured natural gas line in the building. Also, please evaluate the potential for an earthquake to crack the foundation of the building near the isotope garden, allowing a beam of unshielded radiation to exit the facility. Guidance for such an engineering analysis for reinforced concrete structures, for example, is contained in three documents of the American Concrete Institute [documents listed]. As an example of a potential natural event, one should consider the ramifications of the January 31, 1986, NE Ohio seismic event on the facility and the magnitude of future seismic events.

In addition, the possibility of damage from an earthquake/tornado breaching the shield window to the hot cell, allowing an unshielded beam of radiation to exit the cell should also be evaluated.

The potential direct radiation levels in the building and in unrestricted areas outside the building resulting from this breach should be calculated.

AMS Response: Partially concur.

Action Taken: Attachment 1 will be revised to reflect current conditions and additional information on accident potential. Added to the Emergency Plan will be an engineering evaluation of certain restricted areas of the building.

Agency Comment II.A.: Section 1.1 of your EP does not include the 40 curies of cobalt-60 in the form of radwaste specified in Section 1.1 of the licensed application nor the cobalt-60 waste housed in the WHUT room. This section should match the possession limits specified in the license and as discussed in Item III.A of our deficiency letter dated April 17, 1995.

AMS Response: Concur.

Action Taken: The section on Licensed Activity Description is being modified to include the quantity of cobalt-60 that currently exists in the WHUT room, based upon an analysis of the data provided in the SEG "Waste Holdup Tank Room Survey", May, 1995:

Item	Form	Material Description	Estimated Activity (Ci)
Licensed Material	Solid	Bulk Metal	23,000
Licensed Material	Solid	Sealed Sources	75,000
Packaged waste	Solid	Materials contained in high-level waste storage, LSA boxes and drums in the basement of the facility.	29
Packaged waste	Solid	Solid waste generated during the water treatment project.	0.4
Unpackaged waste	Solid/sludge	Materials contained in WHUT Room	53
Surface contamination	Solid	Uncharacterized surface activity in the restricted areas of the facility	11
TOTAL			93.4

Agency Comment II.B.: The plan lacks a detailed site drawing as suggested in Section 1.2 of Regulatory Guide 3.67. Figure 1-11 provides a general area drawing and Figures 1-8, 1-9 and 1-10 provide floor plans for the interior of the building. The plan should contain a detailed drawing of the entire site showing or indicating the following information [list provided].

AMS Response: Concur.

Action Taken: The building floor plans are being re-drawn to more accurately depict the location and type of hazards present throughout the building.

Agency Comment II.C.: The plan should describe any hazardous chemicals used at the site including typical quantities possessed and locations of storage and use.

AMS Response: Other than toner for Xerox machines and White-Out, there are no hazardous chemicals used or stored at the site.

Action Taken: None required.

Agency Comment II.D.: The terminology used to describe areas in the facility should be consistent with the labeling in Figures 1-8, 1-9 and 1-10 of your plan. [Other terminology and labeling inconsistencies provided].

AMS Response: Concur.

Action Taken: The Emergency Plan is being reviewed and revised to ensure consistency in terminology, labeling, numbering and references.

Agency Comment II.E.: The description of the air handling system on page 1-6 should include the stack height, flow rate, and efficiency of the emission control devices. Incorporate this information into your EP.

AMS Response: Concur.

Action Taken: The following information will be incorporated into the Emergency Plan: Stack height is 12.2 meters above the ground, the system flow rate is 971 SCFM, the filtration efficiency is 99.97% for particulates of physical diameter of 0.3 and larger.

Agency Comment II.F.: The quality of Figure 1-11 of your EP is poor and some of the symbols are hard to read. [Other labeling omissions are provided].

AMS Response: Concur.

Action Taken: The map is being replaced with one that clearly designates the position of AMS with respect to nearby schools, hospitals, police and fire stations and other major facilities.

Agency Comment III.A.: The second action item in Sections 3.2.1 and 3.2.2 of your EP should state that the NRC Operations Center shall be notified immediately after the State and local response organizations are notified, but no later than 1 hour after an Alert or Site Area Emergency is declared.

AMS Response: Concur.

Action Taken: Sections 3.2.1 and 3.2.2 are being modified to reflect the recommended changes.

Agency Comment III.B.: The first action item in Section 3.2.2 should include an initial offsite protective action recommendation for the offsite officials. By definition, a Site Area Emergency is an event that could require actions by offsite response organizations protect persons offsite (sheltering, evacuation, etc.). The plan should contain the initial protective action recommendations that have been established in advance for transmittal with the initial notification. If there are no postulated accidents which would require actions by offsite response organizations to protect persons offsite, then there would be no need to declare a Site Area Emergency or prepare protective action recommendations. Please make the necessary modifications to address this issue.

In addition, your plan should contain emergency action levels (EALs). EALs are site-specific equipment readings or readily available indicators that will be used to immediately declare an Alert or Site Area Emergency. EALs should be based on conditions that can be identified within the first few minutes of an accident. [Reference to a Regulatory Guide is given.]

AMS Response: Concur.

Action Taken: The Emergency Plan is being modified to include EALs.

Agency Comment III.C.: Modify Section 3.2 so that your definitions for "Alert" and "Site Area Emergency" match the definitions for these terms in 10 CFR 30.4 (enclosed).

AMS Response: Concur.

Action Taken: The definitions is being modified to match those contained in 10 CFR 30.4.

Agency Comment IV.A.: The consultant's report beginning on page 3-5 provides a detailed analysis of one scenario (fire involving radioactive waste). The quantity of cobalt-60 assumed to be involved in the fire is 15 curies, however, the renewal application request authorization to

possess 40 curies of cobalt-60 in the form of radioactive waste. It would appear that the worst case situation in this scenario would be a fire involving 40 curies of cobalt-60. The analysis should assume that a deliberately set fire would involve the entire inventory of radioactive waste. If there are specific license restrictions which would limit the amount of radioactive waste available for this scenario, those restrictions should be clearly stated. Also, you should include the inventory in the WHUT room with the scenario, or provide justification why it should not be included in the source term.

AMS Response: Partially concur.

Action Taken: Attachment 1 will be revised to reflect current conditions and additional information on accident potential.

Agency Comment IV.B.: Section 5.3 of your plan contains a statement that Chapter 3 described the postulated accidents as spills, fires, and natural phenomena. However, Section 3.3 lists the postulated accidents as fires, natural disasters, and vandalism. Please review these chapters and make the necessary changes so that they are consistent.

AMS Response: Concur.

Action Taken: The Emergency Plan is being reviewed and revised to ensure consistency in terminology, labeling, numbering and references.

Agency Comment V.A.: Section 3.0 in Appendix A states that the Director of Regulatory Affairs has certain responsibilities including the quarterly communications checks to verify telephone numbers. However, Section 7.3 of the plan states that the Radiation Safety Officer (RSO) is responsible for the quarterly checks. The conflicting responsibilities should be resolved and the role of the Director of Regulatory Affairs (and any other company officials) in the emergency response program should be clearly defined in Chapter 4 of the plan.

AMS Response: The Emergency Response Organization is shown in ISP-37, "Emergency Response and Notifications". There is no Director of Regulatory Affairs at AMS.

Action Taken: Appendix A will be replaced with a site-specific document that shows the Emergency Response Organization.

Agency Comment V.B.: Section 4.1 of the plan, entitled "Normal Plan Operations" states that the RSO has overall responsibility for all aspects of the facility. Section 4.1 should provide a brief description of the entire organization present at the facility under normal circumstances.

AMS Response: Concur.

Action Taken: The Emergency Plan is being modified to reflect the entire organization.

Agency Comment V.C.: Section 4.2.1 states that when the RSO is absent, "the emergency personnel on call will contact offsite authorities." It is unclear which individuals serve as the emergency personnel on call. The plan should identify who is responsible for declaring an emergency and assuming the role of Emergency Manager when the RSO is absent.

AMS Response: Concur.

Action Taken: The Emergency Plan is being modified to reflect these roles.

Agency Comment V.D.: The description of the emergency organization in Sections 4.2 through 4.2.2.3 is too vague. The plan should describe how many workers have been assigned to support the RSO in responding to an emergency, and how many workers are simply responsible for evacuating when an alarm sounds. Organizational charts comparing the normal facility organization to the emergency organization would be helpful. We have concerns that a single individual cannot reasonably be expected to fulfill all of the responsibilities assigned to the RSO in an emergency. The plan should describe the number of workers assigned to each applicable function listed in Section 4.2.2 of Regulatory Guide 3.67. It is unclear who is responsible for controlling site access and maintaining security during an emergency.

AMS Response: Concur.

Action Taken: The Emergency Plan is being modified to reflect the additional information.

Agency Comment V.E.: Section 4.3 states that arrangements have been made with local police, fire, and medical services to respond to emergencies at the site. No letters of agreements were found in the plan or the renewal application. Please establish and submit for our review formal letters of agreement with each offsite response organization and submit copies of the letters signed by each organization to NRC with the emergency plan.

AMS Response: Concur.

Action Taken: Letters from the University Hospital of Cleveland, the Cleveland City Fire Department and the Cleveland City Police Department will be included in the Emergency Plan.

Agency Comment V.F.: Section 4.3 states that letters indicating to whom the plan was sent are contained in Appendix B to the plan. Appendix B however contains maps and drawings. Please submit the letters for our review. Also, pursuant to 10 CFR 30.32 (I) (4), provide any comments received from those offsite response organizations.

AMS Response: Concur.

Action Taken: The Emergency Plan is being reviewed and revised to ensure consistency in terminology, labeling, numbering and references. Comments received from offsite response organizations, as well as the AMS response to each comment, are attached.

Agency Comment V.G.: Section 4.4 contains a single statement that the Ohio Emergency Management agency maintains the Governor's response team for radiation accidents. Based on correspondence from the City of Cleveland the Cuyahoga Emergency Management Assistance Center, it appears that there are city and county agencies that have responsibilities for emergencies at the facility also. For each of these agencies, the plan should describe [information provided].

AMS Response: Concur.

Action Taken: The Plan will be modified to describe the capabilities of each organization.

Agency Comment V.H.: The emergency plan should contain a commitment to meet at least annually with each offsite response organization to review items of mutual interest, including changes to the licensee's program, the emergency action level scheme, notification procedures, and response coordination.

AMS Response: Concur.

Action Taken: Section 4.0 is being modified to include this statement.

Agency Comment VI.A.: Section 5.5 of your EP states tat the U. S. Environmental Protection Agency (EPA) Guidelines for emergency exposures are 75 rem for lifesaving actions and 25 rem to protect the facility and control fires. [citation from EPA-400-R-92-001 provided]. Please make the necessary modifications to your plan as noted above, and submit them for our review.

AMS Response: Concur.

Action Taken: Section 5.0 has been modified to incorporate the necessary information and to reflect the appropriate dose limits.

Agency Comment VI.B.: Section 5.5.3 should describe how you will assure that all offsite response personnel entering the building during a fire or other emergency have been issued a dosimeter before they enter the building. The means of tracking the number of dosimeters issued, who wore each dosimeter, and the number of dosimeters returned should be described.

AMS Response: Concur.

Action Taken: Section 5 of the Emergency Plan is being modified to reflect that dosimeters will be logged upon issue and collected/logged upon their return.

Agency Comment VI.C.: Sections 5.6 and 5.7 should provide a better description of how contamination inside the ambulance and at the hospital will be controlled. Will licensee personnel always travel with the ambulance to the hospital to survey and release the ambulance and hospital treatment areas, or are there other qualified individuals at the hospital who can survey and release areas when licensee personnel are not available?

AMS Response: Depending upon the type/form of accident, licensee personnel will accompany the injured, if contaminated, to the hospital. However, the local hospital is equipped with a nuclear medicine department and a Radiation Safety Officer who will provide surveillance and radiological control services in the event of a contaminated patient being transferred to the facility.

Action Taken: Appendix A will be replaced with a site-specific document with an improved discussion of these activities.

Agency Comment VI.D.: Section 5.7 should describe the hospital's capability to evaluate and treat injuries from radiation exposure. Does the hospital have a nuclear medicine department with in-house expertise, or do they plan to use medial [sic] consultants such as the Department of Energy's Radiation Emergency Assistance Center/Training Site (REACTS [sic])? It is often useful to have the hospital describe its capabilities in its letter of agreement.

AMS Response: The hospital has the in-house expertise to evaluate and treat injuries from a radiation accident.

Action Taken: The hospital is forwarding a copy of their Emergency Plan to AMS.

Agency Comment VI.E.: Section 7.4.2.b in Appendix A [additional critique given].

AMS Response: Concur.

Action Taken: Appendix A will be replaced with a site-specific document.

Agency Comment VI.F.: Sections 13, 14, and 15 in Appendix A [additional critique given].

AMS Response: Concur.

Action Taken: Appendix A will be replaced with a site-specific document.

Agency Comment VII.: The list of emergency supplies in Section 6.4 should specify the minimum quantity of each item that will be stored. For each survey meter/frisker, the plan should describe the type of detector, the range of detection, and calibration of the instrument.

AMS Response: Concur.

Action Taken: Section 6.4 is being modified to include the additional information.

Agency Comment VIII.A.: Section 7.2 of your EP states that staff with limited emergency responsibilities receive limited emergency response training. This description of the training program is inadequate. [Additional critique provided].

AMS Response: Concur.

Action Taken: Section 7.0 is being modified to reflect site-specific information and to reference applicable ISPs.

Agency Comment VIII.B.: Section 7.2 should describe the instructions and orientation tours that the applicant will offer fire, police, medical, and other offsite response personnel. You may wish to coordinate this training with the annual meeting with offsite response organizations (see Item V.H).

AMS Response: Concur.

Action Taken: Section 7.0 is being modified to include this additional information.

Agency Comment VIII.C.: Section 7.3 should specify that one or more nonparticipating observers will be used during drills and exercises to evaluate the effectiveness of the response and recommend changes for improvement. The plan should describe how criteria for acceptable performance will be developed and provided to these observers. Also, the plan should specify that exercise scenarios will not be known to exercise participants.

AMS Response: Partially concur.

Action Taken: Section 7.0 is being modified to include additional information and to reference applicable ISPs.

Agency Comment VIII.D.: Sections 7.4 and 7.5 should specify who will be responsible for tracking findings from critiques and audits and verifying that corrective actions are completed. In addition, Section 7.5 should specify that audits will be performed by persons not having direct responsibility for implementing the emergency response program. Section 7.6 should specify that equipment calibration dates and material shelf lives will be tracked, and that operational checks or equipment will be performed.

AMS Response: Partially concur.

Action Taken: Section 7.0 is being modified to include additional information and to reference applicable ISPs.

Agency Comment IX.A.: Section 8.2 should state that training record will include lesson plans and test questions used in training sessions. Letters of agreement with offsite response organizations should also be maintained in the records.

AMS Response: Concur.

Action Taken: Section 8.2 is being modified to include additional information and to reference applicable ISPs.

Agency Comment IX.B.: Section 8.3 should specify a minimum frequency of updates after the initial notification. This frequency may be revised during an emergency by mutual agreement of the parties involved.

AMS Response: Concur.

Action Taken: Section 8.3 is being modified to include additional information and to reference applicable ISPs.

Agency Comment XI.: Your emergency plan does not contain a certification that AMS has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986. A certification or an explanation why this Act is not applicable to the applicant's activities must be provided.

AMS Response: Concur.

Action Taken: A toxic release inventory will be prepared and distributed to local emergency response organizations.

Agency Comment XII.: The table of contents of your Emergency Plan should include a list of effective pages. [Additional critique of table of contents and page numbering provided.]

AMS Response: Concur.

Action Taken: The entire Emergency Plan, including the table of contents, is being revised to ensure consistency in terminology, labeling, numbering and references.