

JUL 16 1996

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

Dear Mr. Meschter:

We have completed our review of your March 21, 1996 response to our February 28, 1996 letter which outlined deficiencies in your Emergency Plan (EP). Overall, the majority of your responses were considered adequate; however, some additional changes are still needed as noted below. Each item below corresponds to AMS' response to a particular item of our February 28 letter.

1. AMS Response to Item 1(d)

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.

2. AMS Response to Item 1(e)

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.

3. AMS Response to Item 2

Concerns about 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.

4. AMS Response to Item 3(f)

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.

5. AMS Response to Item 3(q)

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.

6. AMS Response to Item 4(b)

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. The actual inventory currently possessed is irrelevant if the license will authorize an increase in that inventory. If the material is stored or used in a manner that would prevent the entire inventory from being involved in an accident, that justification must be provided in the plan. With regard to bulk cobalt-60, we accept that containers stored inside portions of the facility with heavy concrete construction are unlikely to be subject to falling debris that could rupture them. However, the movement of the containers outside of those areas still needs to be addressed. If the containers of bulk cobalt-60 will be packaged in Type-B shipping casks or other containers likely to withstand accident conditions (such as those described in 10 CFR 71.73) before being moved into the warehouse or other areas subject to structural damage, the plan should include that information as justification for not including any of the bulk cobalt in the source term available for release. Otherwise, we would expect the worst-case scenario to assume that some containers of bulk cobalt (such as the number of containers typically involved in a shipment) are in an area subject to structural damage when an earthquake or other accident occurs, and that some of these containers (50% would be acceptable) are broken open by falling debris.

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.

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. Your response states that the CAP88-PC code over-estimates the dose from a fire and no additional analysis is required even though

this model has no resemblance to the conditions that would exist during a fire at the facility. This response is unacceptable. We have obtained more conservative dose estimates using the calculations in NUREG-1140. The calculations in NUREG-1140 are based on exposure times and other conditions that would be expected during a fire. These calculations form the technical basis for the emergency plan requirements in 10 CFR Part 30. Use of the same calculations would provide a basis for NRC to find that your accident analysis is adequate, and it would eliminate contentions that it is fortuitous that the CAP88-PC results are close to the NUREG-1140 results. The formula in Section 2.1.3 of NUREG-1140 is not difficult to complete and we would accept the use of the stability class D curves on Figure 1 of the NUREG. We recommend that you use this formula.

7. AMS Response to Item 4(d)

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 above.

8. AMS Response to Item 5(b)

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.

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. Part 30 defines an "Alert" as an event that is not expected to require a response by offsite response organizations to protect persons offsite. Part 20 limits the dose to members of the public in unrestricted areas to 2 millirem in any one hour (see 20.1301). Therefore, we would expect offsite organizations to take actions to restrict access to offsite areas exceeding 2 mR/hr. More appropriate action levels should be established.

9. AMS Response to Item 5(d)

The plan should contain more detailed recommendations for offsite protective actions based on the worst-case accident scenarios defined in the plan. The initial recommendations should define the offsite areas where the protective 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 protective action recommendations should be consistent with your accident analysis.

10. AMS Response to Item 5(e)

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

11. AMS Response to Item 6(b)

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

12. AMS Response to Item 6(c)

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.

13. AMS Response to Item 6(d)

The Ohio Department of Health needs to be added to Section 4.4 also.

14. AMS Response to Item 7(d)

If AMS will rely on offsite firefighters to conduct search and rescue operations, the plan should include a statement to that affect.

15. AMS Response to Item 7(e)

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 plan.

16. AMS Response to Item 8(c)

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.

17. AMS Response to Item 8(e)

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. If the main building is inaccessible, the survey meter in the pump house will be the only one available in the early stages of the response. You have already indicated that local fire and police departments have no survey meters. The fact that this meter will not be used routinely between quarterly checks indicates that a malfunction may not be detected for several months. 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).

18. AMS Response to Item 9(e)

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.

19. AMS Response to Item 10

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.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 98538.

D. Cesar

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

Sincerely,

Original Signed By
Kevin G. Null
Nuclear Materials Licensing Branch

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

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