



OFFICE OF THE  
GENERAL COUNSEL

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

December 20, 1995

DOCKETED  
15178

95 DEC 22 AM 35

OFFICE OF THE  
DOCKET

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:

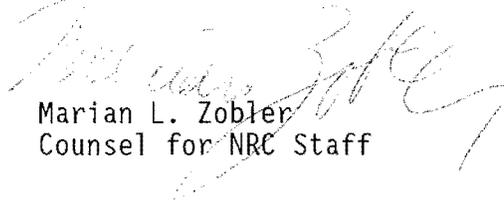
Pursuant to 10 C.F.R. § 2.1231(c), attached please find the following documents to be included in the hearing file for this proceeding.

43. Letter to Kevin G. Null, Nuclear Materials Licensing Branch, U.S. Nuclear Regulatory Commission from Robert Meschter, R.S.O., Advanced Medical Systems, Inc., Re: Response to Comments on USNRC License No. 34-19089 Renewal Application (Control No. 97891), dated November 29, 1995, with attachment.
44. Letter to David Cesar, Treasurer, Advanced Medical Systems, Inc., From Richard N. Connelly, Manager, Water Quality and Industrial Surveillance, Northeast Ohio Regional Sewer District, re: Comments on Proposed Emergency Plan, dated November 30, 1995, with attachments.
45. Letter to Advanced Medical Systems, Inc., Attn: David Cesar, Vice President from Kevin G. Null, Senior Materials Licensing Reviewer, U.S. Nuclear Regulatory Commission, re: Letter Dated October 30, 1995, dated December 5, 1995.
46. Letter to Advanced Medical Systems, Inc., Attn: David Cesar, Vice President from Kevin G. Null, Senior Materials Licensing Reviewer, U.S. Nuclear Regulatory Commission, re: Review of Trust Agreement, dated December 5, 1995.

17381

47. Letter to Advanced Medical Systems, Inc., Attn: David Cesar, Vice President from Hubert J. Miller, Regional Administrator, U.S. Nuclear Regulatory Commission, re: Response to Demand for Information (DFI), dated December 6, 1995. (Note: a copy of the Demand for Information and AMS' response was previously placed in the Hearing File by letter dated November 7, 1995, Document 39.)

Sincerely,



Marian L. Zabler  
Counsel for NRC Staff

Enclosures: As stated

cc w/encl.: Service List



# Advanced Medical Systems, Inc.

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

November 29, 1995

Kevin G. Null  
Nuclear Materials Licensing Branch  
U. S. Nuclear Regulatory Commission  
801 Warrenville Road  
Lisle, Illinois 60532-4351

**Re: Response to Comments on USNRC License No. 34-19089 Renewal Application (Control No. 97891)**

Dear Mr. Null:

The purpose of this letter is to transmit the Advanced Medical Systems, Inc. (AMS) response to your letter of October 31, 1995 regarding our license renewal application. During an August 29, 1995 meeting between representatives of AMS and the U. S. Nuclear Regulatory Commission (USNRC), AMS relayed its intent to prepare a revised renewal application in order to address the comments raised in the USNRC's April 17, 1995 deficiency letter. Pursuant to this commitment, and as confirmed in the "Strategic Plan for the London Road Facility" (forwarded to you on October 11, 1995), a significantly revised application was, in fact, submitted on October 30, 1995.

As a result of the October 30th submission, many of the comments contained in your October 31, 1995 letter have been addressed. If this was the case, it was so noted in the attached responses. For those comments that remain applicable, a notation as to where in the revised application the comment is addressed has been given.

Because our renewal application was originally submitted more than thirty (30) days prior to the expiration date of License No. 34-19089-01, AMS assumes the license will remain in effect, under its existing provisions, until final action is taken on this revised application. However, as you will note during your review of our revised renewal application, AMS wishes to institute significant changes in our radiation protection program in order to improve its applicability and auditability. Therefore, your prompt consideration of this revised application would be greatly appreciated. If you have any questions, please contact me at (216) 692-3270.

Sincerely

Robert Meschter, R.S.O.

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

RECEIVED

DEC 04 1995

REGION III

DEC 04 1995

11/2 - For Keenan



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

OCT 31 1995

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

Dear Mr. Cesar:

We have completed our review of your June 16, 1995 letter of response to our April 17, 1995 letter, and find that we need additional information and/or clarification on several issues. Each item below is headed by the section from which it appears in our April 17 letter.

The difficulty we experienced in the initial review of your application stems from the fact that inconsistencies occur throughout your application. For example, many statements made in opening chapters contradicted, or were inconsistent with, specific ISP procedures. Also, as a general comment, you made many references to "what nuclear power plants do" in order to justify certain procedures and practices. The NRC materials program operates independently of the reactor program, and is therefore under different policy and guidelines. Please avoid making comparisons between the two programs. What may be acceptable and considered standard practice in reactor programs may not be acceptable in a materials program. Such comparisons were made in both your initial application for renewal and your June 16 letter.

As a result of discussions between AMS and NRC management, it is our understanding that you recognize the inconsistencies and problems that exist in your current application in that it does not reflect the type of program that currently exists at AMS. Therefore, you requested the opportunity to resubmit your application in its entirety. We also understand that you will incorporate the comments below into a new application. Responses to the items in this letter should be highlighted in your resubmittal to assist us in our review. If your new application is submitted before you have the opportunity to incorporate the items addressed below, please then respond to this letter through either a separate document or modifications to the new application as appropriate.

1. Item II.B.

Your response to item II.B. of our letter states that you "will take under advisement" our request that you develop an audit program per 20.1101(c). Please be advised that your radiation safety program will be inspected against Part 20, and we expect that you will audit the content and implementation of that program as required. Please also take note that with your intent to build into your program a greater amount of flexibility to make changes without amending your license, we

will be more persistent in requiring an audit program that reviews the activities of the RSO and staff. Please take this into consideration when rewriting your application for resubmittal.

2. Item III.A.

In light of the reopening of the waste disposal site at Barnwell, we recommend that you take advantage of this opportunity and ship your waste to this site. Please keep in mind that the NRC does not consider storage as a substitute for disposal. Other than storage for decay (currently NRC only authorizes decay-in-storage for radionuclides with up to 120 day half-life), low level waste should be stored only when disposal capacity is unavailable and for no longer than is necessary. Reference IN 90-09 (enclosed).

3. Item IV.

This question is for our information only. We are interested in the development of your staff and hence, their progression to more advanced positions. Continual training of staff is often an indicator to the NRC that a licensee is committed to improving their program. Please describe your staff development program.

4. Item V.

A. Please describe the criteria that will be used to determine if ancillary personnel will be examined to determine their comprehension of training material they receive.

B. Item 4.2 is not clear. As we requested, identify the instructors who will provide training for Isotope Technicians. The statement that "a trained health physicist and other qualified instructors shall provide classroom training" is not clear. A "trained health physicist," regardless at what level, may not have the knowledge of the uniqueness of your facility or the duties of an isotope technician to provide effective training. It appears that an individual who has been an isotope technician would be a good candidate as an instructor. Provide names of trainers and their qualifications.

Item 9 of attachment B (Isotope Technician Exam) implies that the RSO or designee can authorize a RWP. Define minimum criteria for naming a designee.

5. Item VI.

- A. Concerning your description of how the hot cell will be used since AMS will not be manufacturing sources, provide examples of "any activity related to source handling that can be accomplished by using the hot cell" as stated in your response to our question.
- B. and C. You did not respond to these items. Rather, you referenced an inspection report in which the ventilation and exhaust systems and associated sampling systems were reviewed in detail. Inspection reports are not part of your license. Therefore, you must provide this information so that it can be reviewed from a licensing standpoint and incorporated into your license.

6. Item VII.

You must provide additional information before we can grant your request for authorization to modify and revise procedures without an amendment. You must describe the types of things you wish to modify, as well as the criteria you will follow in determining if a modification/revision can be made in-house, or if an amendment will be necessary. For example, changes to certain aspects of a survey program, bioassay procedures, core training program, etc., would require an amendment. In addition, if you wish to pursue this flexibility, we request that changes made without an amendment be reviewed and approved by the isotope committee. Please confirm our understanding that Ms. Carol Berger will be a member of that committee and provide an updated list of committee members.

- A.1. Please address the second paragraph to this question concerning the hot cell manipulators.
- A.2.e. Modify attachment F such that 2E4 ml/hr is changed to read 2E4 ml/min.
- A.2.f. Describe what you mean by exceptional occurrence. There must be some limits set. For example, an exceptional occurrence may be when the RSO is sick, on vacation, or otherwise not physically present at the facility.
- A.4. Please respond to this question. We realize that Slawinski and Weber are familiar with security of the building, but that has nothing to do with the license. Please simply describe areas where material (including waste) is stored, and security and postings that are in place.

- A.6. Our interpretation of statements made on page 42 of your application was that 100 cpm above background referred to the upper limit, therefore you would be allowing a certain level of personnel contamination. Your explanation that you were referring to the lower limit of detection, and that the specified limit of 100 cpm above background equates to saying that the contamination limit is "none detected above background," is acceptable.
- B. Use of the word "should" instead of "shall" makes it difficult for the NRC to conduct a meaningful and effective inspection. It severely reduces the enforceability of a license. Procedures that "should" be done, as stated in a licensee's application, are more often than not indirectly related to regulatory compliance. For those procedures which are not directly related to regulatory compliance, and you feel the word "should" is appropriate, please identify them and demonstrate why you feel each is appropriate as written. If such procedures are irrelevant to your program and have no bearing on regulatory compliance, perhaps you should consider removing them from your application.
- B.1. As we requested in paragraph 2 to this item of our 4/17 letter, please include in Item 3.3.4.c. (typo in letter) of ISP-2 a commitment that surveys will be conducted at the end of each day of use of material. This is common practice in the materials (non-reactor) industry.
- B.5. The word "or" as appears in your sentence is used to indicate an alternative, that is, as an alternative to performing monthly safety checks you will perform them any time there is an abnormal increase on the monitor. As noted in our April 17 letter, this alternative is not acceptable. A minimum frequency must be established. Monthly is acceptable. However, please change the grammar of your wording to remove the possibility of an alternative to the monthly check.
- B.7. Please answer paragraph 2 to this question regarding calibration of flow meters used with portable air samplers.
- B.8. As noted in Item VII.A.2.f. above, please address the exceptional circumstance whereby the RSO may not be present during all cell entries.

Please modify ISP-11 to make it clear that continuous air sampling be conducted when work is being done in the hot cell. The statement in 3.1.4 that an air sample "should" be taken contradicts your response to VII.B.4.

- B.11. Item 3.2.3(1) was not clarified as stated in your letter. To say that "the RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts when appropriate" does not provide clarification. Please re-address this question from our April 17 letter.
- B.12. You did not answer paragraph no. 1 of Item VII.B.12. of our letter. Please review this item and submit your response.
- B.13. Item 3.2.7(a) of ISP-21 discusses the shipment of LSA material. The shipment of LSA material requires shipping papers that must include an emergency response telephone number and an emergency response sheet. It appears that item 3.2.7(a) is not relevant to this ISP. If you do not ship LSA material, this section should be removed.
- B.16. Item 2.3 of ISP-25 still references compaction of solid radioactive waste. Please delete the reference to compaction.
- B.17. Please add a description of emergency procedures that will be included on a Bill of Lading for shipment of waste as we requested in question no. VII.B.17.
- B.18. Please submit criteria that will be used to determine the need for radiation safety job coverage prior to a worker entering an area that requires a RWP. Your statement that determining the need for radiation safety job coverage will be based upon "sound judgement" of a RWP preparer is of concern to us.
7. Item VIII.
- B.1. From your response, it is not clear that you actually contacted local authorities to determine if permits are required to store radioactive waste on-site for an extended period of time. Please contact the appropriate authorities and inform us as to their response, or confirm that this has in fact been done.
8. Item IX.C.
- Describe your basis for choosing 2000 cpm as a threshold for evidence that a source may or may not be leaking. Could not a source be leaking if there were 1500 cpm? By simply accepting anything < 2000 cpm as "not leaking" you may be allowing a source to remain in use that has exceeded 0.005 microcurie.

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 97891.

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

Sincerely,



Kevin G. Null  
Nuclear Materials Licensing Branch

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

Enclosure: IN 90-09

**RESPONSE TO USNRC COMMENTS OF OCTOBER 31, 1995  
ON THE ADVANCED MEDICAL SYSTEMS, INC.  
JANUARY 26, 1995 LICENSE RENEWAL APPLICATION**

**USNRC Comment 1:** Item II.B (see attached).

**AMS Response:** Concur

**Action Taken:** Section 5.16.2 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) addresses AMS's commitment to performing programmatic audits.

**USNRC Comment 2:** Item III.A.

**AMS Response:** Currently, only 0.05 percent of the total AMS inventory of <sup>60</sup>Co (less than 30 curies) is in the form of solid waste. This material is packaged and secured within the restricted area. With only one exception, AMS has not generated any production waste of significance since 1989.<sup>1</sup> Barring circumstances that are beyond AMS's control, AMS cannot envision a need to increase its radioactive material possession limits to accommodate additional generation of radioactive waste.

On August 29, 1995, representatives of AMS met with Dr. Donald Cool, Ms. Cynthia Pederson and Mr. Michael Weber of the U. S. Nuclear Regulatory Commission (USNRC) to discuss an action plan for addressing a number of issues that pertain to ongoing operations at the London Road facility.<sup>2</sup> One of the outstanding issues was disposition of the 30 curies of solid waste. In light of other more pressing demands for resources, AMS stated in that meeting, and later confirmed in the "Strategic Plan for the London Road Facility" (Revision 0, October 11, 1995), that the waste disposal issue was considered to be a low priority item because it was neither in the best interest of AMS, the USNRC or the general public for this material to be disposed of at a licensed radioactive waste burial ground at this time. The following are just a few of the justifications for this position:

- The relatively short half-life of the materials in question demands consideration for decay in storage as a disposal option.
- The AMS waste storage facility is physically stable, presents negligible (if any) radiological impact on the environment and surrounding population, and meets all of the recommended storage criteria contained in NRC Information Notice No. 90-09, "Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees" (IN 90-09).<sup>3,4</sup> Furthermore, personnel

---

<sup>1</sup>That exception was the solid waste generated during the water treatment and sewer remediation project that was on-going during 1995. The project was the result of the regional sewer district's intentional blockage of the stormwater discharge path for the London Road facility. (Title 10, Code of Federal Regulations, Section 8.4 states that a state or local authority has no legal authority to "tamper with" the safe operation of a USNRC licensee.)

<sup>2</sup>Due to limited personnel and financial resources, AMS informed the USNRC during this meeting that 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.

<sup>3</sup>For example, pursuant to IN 90-09, the waste is shielded from the elements and extremes in temperature,  
(continued...)

do not access the area, with the exception of routine surveillance and inventory activities, incur no waste-related dose.

- In 10 CFR 20, the USNRC requires that no practice shall be adopted unless its introduction produces a positive net benefit; that all exposures to ionizing radiation shall be kept as low as reasonably achievable, economic and societal factors being taken into account; and that the dose equivalent to individuals shall not exceed applicable regulatory dose limits. To ensure compliance with these requirements, an ALARA analysis was performed to support on-site storage of radioactive materials as the preferred facility decommissioning option.<sup>5</sup> The results of this analysis, which addressed the radioactive materials in the waste containers as well as other residual radioactivity, clearly demonstrated that there is no cost or dose benefit from immediate off-site shipment of the waste, and that such action would violate the ALARA requirement.

**Action Taken:** In order to ensure compliance with the ALARA requirement, to remain consistent with the recommendations contained in IN 90-09, and to maximize the use of the company's resources in the short-, intermediate- and long-term, AMS is requesting permission to store up to 35 curies of packaged radioactive waste as part of the SAFSTOR option for the decommissioning of the facility. This request, which appears in the revised renewal application, is being made with the understanding that within 50 years the majority of the activity contained in the solid waste will have decayed to levels that pose negligible hazards. At that time the materials can be safely disposed of as minimally-contaminated waste. However, waste disposition options will be reevaluated at each license renewal period in light of the operational conditions and constraints that may be relevant at the time.

**USNRC Comment 3:** Item IV.

**AMS Response:** AMS finds there to be a considerable difference between the issue of staff qualifications and staff "progression to more advanced positions". AMS understands and concurs with regulatory requirements regarding the qualifications and continuing education of radiation protection personnel. However, AMS does not consider corporate promotion policy/practices to have any application to license compliance. Perhaps the reviewer would be willing to provide additional clarification on this issue.

**Action Taken:** Section 5.1 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) references procedure No. RSP-006, "Training and Qualifications of Radiation Protection Personnel", wherein the training, re-training and qualification of all members of the radiation safety organization are specified.

**USNRC Comment 4:** Item V.A.

**AMS Response:** All radiation protection personnel must meet a minimum level of training and qualification prior to performing work unsupervised. Certain of their training programs include the requirement for written examinations, performance verification, exams and performance verification, or none of the above.

---

<sup>3</sup>(...continued)

the waste is packaged in shipping containers, the containers are maintained in a restricted area, the area permits ready visual inspection, and the physical contents are not conducive to decomposition.

<sup>4</sup>The waste currently stored at the facility remained contained in spite of the recent basement flooding event. Therefore, no credible water leakage scenario for the stored waste exists.

<sup>5</sup>Advanced Medical Systems, Inc., "Conceptual Decommissioning Plan for the London Road Facility", October 20, 1995.

**Action Taken:** Section 5.1 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) references procedure No. RSP-006, "Training and Qualifications of Radiation Protection Personnel", wherein the training and qualification requirements for all members of the radiation safety organization are specified.

**USNRC Comment 4:** Item V.B.

**AMS Response:** AMS has instituted a procedural requirement for maintaining, as part of its programmatic records, the names and qualifications of trainers for all training programs that will be attended by AMS personnel.

The comment in regard to Item 9 of attachment B is no longer applicable.

**Action Taken:** Section 5.13 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) references procedure No. RSP-004, "Radiation Protection Records", wherein the record requirements in regard to training activities (i.e., instructor qualifications, lesson plans, certificates of completion, etc.) are specified.

**USNRC Comment 5:** Item VI.A

**AMS Response:** This issue is no longer applicable. However, for informational purposes only, AMS continues to use the Hot Cell facility for packaging, leak testing and shipping of sealed sources as part of the inventory reduction program described in the "Strategic Plan for the London Road Facility".

**Action Taken:** None required.

**USNRC Comment 5:** Item IV.B. and C.

**AMS Response:** This issue is no longer applicable.

**Action Taken:** A revised description of the ventilation system is contained in Attachment 4 of the revised renewal application.

**USNRC Comment 6:** Item VII

**AMS Response:** Partially concur. All Radiation Safety Procedure amendments must be reviewed and approved by every member of the Radiation Safety Committee (formerly known as the Isotope Committee) prior to implementation. Also, if a recipient name/address is provided, the USNRC will receive a controlled copy of the current version of all RSPs. The AMS protocol for procedure amendment, control and distribution is clearly specified in RSP-003, "Control of Radiation Safety Procedures", which was submitted as an attachment to the revised renewal application, and will require a license amendment if modifications are deemed necessary.

**Action Taken:** RSP-003, "Control of Radiation Safety Procedures", is contained in Attachment 5 of the revised renewal application. A listing of the current members of the Radiation Safety Committee, along with their qualifications, is contained in Attachment 2 of the revised renewal application. Section 5.1.4 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) requires that a Certified Health Physicist serve as a permanent member of the Radiation Safety Committee. During the October 31, 1995 meeting of the Radiation Safety Committee, Carol D. Berger, C.H.P. was appointed to that position.

**USNRC Comment 6:** Item VII.A.1.

**AMS Response:** This issue is no longer applicable.

**Action Taken:** None required.

**USNRC Comment 6:** Item VII.A.2.e.

**AMS Response:** This issue is no longer applicable.

**Action Taken:** None required.

**USNRC Comment 6:** Item VII.A.2.f.

**AMS Response:** In the revised renewal application, AMS provides for an Alternate RSO (ARSO) in the radiation protection organization. Either the RSO or the ARSO will be present during normal business hours at AMS.

**Action Taken:** The name and the qualifications of the ARSO is contained in Attachment 2 of the revised renewal application. Section 5.1.3 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) describes the authority of the ARSO. RSP-006, "Training and Qualifications of Radiation Protection Personnel", contains the training and qualification requirements for all members of the radiation safety organization, including the ARSO.

**USNRC Comment 6:** Item VII.A.4.

**AMS Response:** This issue is no longer applicable.

**Action Taken:** The fire protection, security and alarm systems at AMS are described in Attachment 4 of the revised renewal application. A detailed description of where radioactive materials are stored at the AMS facility, including maps, is also included in Attachment 4. Section 5.9 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) references procedure No. RSP-011, "Radiological Areas and Posting", wherein posting and labeling requirements for the facility are specified.

**USNRC Comment 6:** Item VII.A.6

**AMS Response:** This issue is no longer applicable.

**Action Taken:** None required.

**USNRC Comment 6:** Item VII.B

**AMS Response:** The Radiation Safety Procedures referenced in the Radiation Protection Program Plan are written to ensure proper interpretation of whether an action is a requirement (shall), a recommendation (should) and an option (may).

**Action Taken:** Section 4 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) references procedure No. RSP-002, "Definitions", wherein definitions for the terms "shall", "should" and "may" are included. The majority of the actions specified in the RSPs are designated as "requirements".

**USNRC Comment 6:** Item VII.B.1.

**AMS Response:** This issue is no longer applicable.

**Action Taken:** None required.

**USNRC Comment 6:** Item VII.B.5.

**AMS Response:** This issue is no longer applicable.

**Action Taken:** None required.

**USNRC Comment 6: Item VII.B.7**

**AMS Response:** This issue is no longer applicable. However, for informational purposes only, AMS calibrates all instrumentation in the active inventory that are used for radiation protection purposes on a planned and periodic basis. This calibration schedule also applies to ancillary instrumentation such as pumps, metering devices, scales and timers.

**Action Taken:** Section 5.7 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) references procedure No. RSP-008, "Instrumentation and Surveillance", wherein the provisions for purchase, testing, calibration and use of radiation detection instrumentation and ancillary equipment are defined.

**USNRC Comment 6: Item VII.B.8**

**AMS Response:** See response to USNRC Comment 6:VII.A.2.f

**Action Taken:** See response to USNRC Comment 6:VII.A.2.f

**USNRC Comment 6: Item VII.B.11**

**AMS Response:** Concur. The AMS commitment to ALARA, and the manner in which AMS will ensure that all radiation exposures incurred at the facility are ALARA, are addressed in both the Radiation Protection Program Plan and in an implementing procedure.

**Action Taken:** Section 5.5 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) describes the management commitment to ALARA. RSP-005, "ALARA Program" contains the implementing procedures to ensure and demonstrate that AMS is meeting the management commitment.

**USNRC Comment 6: Item VII.B.12**

**AMS Response:** This issue is no longer applicable.

**Action Taken:** None required.

**USNRC Comment 6: Item VII.B.13**

**AMS Response:** This issue is no longer applicable.

**Action Taken:** Section 5.11 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) references procedure No. RSP-015, "Packaging and Transportation of Radioactive Materials", wherein the provisions for shipping radioactive materials from the London Road facility are defined.

**USNRC Comment 6: Item VII.B.16**

**AMS Response:** This issue is no longer applicable.

**Action Taken:** No action required.

**USNRC Comment 6: Item VII.B.17**

**AMS Response:** See response to USNRC Comment 6:VII.B.13

**Action Taken:** See response to USNRC Comment 6:VII.B.13

**USNRC Comment 6: Item VII.B.18**

**AMS Response:** This issue is no longer applicable.

**Action Taken:** Section 5.4 of the Radiation Protection Program Plan (Attachment 3 of the revised renewal application) references procedure No. RSP-010, "Exposure Control", wherein the provisions for exposure control are defined. In addition, RSP-012, "Control of Work", describes the means by which AMS intends to implement Section 5.4.2 of the Radiation Protection Program Plan.

**USNRC Comment 7: Item VIII.B.1**

**AMS Response:** This issue is no longer applicable.

**Action Taken:** None required.

**USNRC Comment 8: Item IX.C**

**AMS Response:** This issue appears to be no longer applicable. However, AMS is unable to determine whether the reviewer takes umbrage with the threshold level of 2,000 cpm or with the 0.005 microcurie leakage criterion. The threshold level of 2,000 cpm (removable activity) from accessible areas of a sealed source is used to demonstrate that there is not more than 0.005 microcurie of removable contamination on the source. If a nominal instrument efficiency of 30% is assumed:

$$2000 \frac{c}{m} \times \frac{1 \frac{d}{m}}{0.3 \frac{c}{m}} \times \frac{1 \text{ min}}{60 \text{ sec}} \times \frac{1 \text{ Ci}}{3.7 \times 10^{10} \frac{d}{s}} \times \frac{10^6 \mu \text{ Ci}}{1 \text{ Ci}} = 0.003 \mu \text{ Ci}$$

Pursuant to 10 CFR 34.25(c), if a sealed source exhibits less than 0.005 microcuries of residual surface activity, it may be used without regard for transferable activity.

**Action Taken:** RSP-008, "Control of Sealed Sources" describes the procedure for leak testing sealed sources.



# Northeast Ohio Regional Sewer District

4747 East 49th Street • Cuyahoga Heights, Ohio 44125-1011 216 • 641 • 6000 FAX: 216 • 641 • 8118

November 30, 1995

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

Re: Comments on Proposed Emergency Plan

Dear Mr. Cesar:

1. Your September 21, 1995 version of the proposed Advanced Medical Systems, Inc. Emergency Plan ("Plan") was received by the Northeast Ohio Regional Sewer District ("District") October 2, 1995. Accordingly, the following comments are timely provided pursuant to 10 CFR Part 30.32, which allows offsite response organizations 60 days in which to comment on a proposed emergency plan. The AMS *Response To Comments from Northeast Ohio Regional Sewer District* forwarded with the September 21, 1995 version of the proposed Plan was difficult to follow because of your comment numbering system. Each of these District comments on the September 21, 1995 revision is therefore numbered so that no confusion can be created as to what comment is being referred to in any response hereto.

(The comment numbering by AMS did not appear to directly correspond to the paragraphs contained in the District's Comments. Matches of District comments were made to the AMS enumeration by correlating, for example, AMS' concurrence with the District's comment on misuse of abbreviations in the plan (AMS' response number 27). This matching appeared to fit, based on the match of comment and response on the meaning of the word "dispersible" in AMS' response number 57. When the paragraphs are so enumerated, however, it appears that AMS began its numbering at number 8. That is, the first paragraph in the Page-Referenced Comments on Proposed Emergency Plan for Advanced Medical Systems, Inc. by Northeast Ohio Regional Sewer District would be numbered 8 to correspond to AMS' Response to Comments from Northeast Ohio Regional Sewer District.)

2. We have attached as Exhibit "A" a June 8, 1995 letter to the District from James L. Caldwell, Deputy Director of Radiation Safety and Safeguards, indicating that the District was to submit comments on AMS' proposed Plan pursuant to 10 CFR Part 30.32(i)(4). The NRC has confirmed to the District that it has confirmed to you that it has discussed your error in failing to consider the District's status as a first emergency responder with your Radiation Safety Officer ("RSO") Robert Meschter, your attorney Dwight Miller, and your radiological consultant Carol Berger. The NRC

reported that you are henceforth required to recognize the reality that the District is indeed a first responder as contemplated under applicable federal regulations, and that these comments will be taken into account as required under 10 CFR Part 30.32. Accordingly, it is an error for your RSO to state in his September 22, 1995 transmittal letter that the revised Plan is being forwarded merely as a courtesy; instead, it is a federal requirement.

---

3. The AMS *Response To Comments from Northeast Ohio Regional Sewer District* forwarded with the September 21, 1995 version of the proposed Plan set forth a number of areas in which AMS declared itself ignorant and on which it plans to take no action. These are areas of very serious concern, and we believe that your failure to seek any explanation thereon from the District shows an absence of good faith on your part to comply with relevant federal regulations and the requirements of NRC Regulatory Guide 3.67, *Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities*. In particular, it appears to be in violation of Sections 3.3 (Information To Be Communicated) and 4.4 (Coordination with Participating Government Agencies). Several specific areas you identified as being unable to understand are listed below, with explanations of how they relate to emergency preparedness.

---

4. Comment 52: *Is the origin of equipment on which AMS operates relevant to emergency response? If not, references thereto should be deleted.*

**AMS Response: AMS does not understand the intent of this comment. Therefore, no action has been taken.**

An emergency plan is intended to provide emergency responders information relevant to emergency response. Any other information distracts from this purpose and should therefore be eliminated.

---

5. Comment 60: *In what way are the access controls provided during (a) an electrical blackout, (b) a telephone service interruption, or ((c) a combination of (a) and (b)?*

**AMS Response: AMS does not understand the intent of this comment. Therefore, no action has been taken.**

It is stated in the proposed plan that a number of doors are electrically interlocked. If they are tied in to the alarm systems, which are known to be tied in to telephone service, there could well be alarm system failures in the event of telephone system failure. This potential failure raises several questions that obviously bear on emergency response: (A.) Would such a failure lead to an electrical locking of any doors? (B.) In the event of a loss of power, would individuals in contaminated areas controlled by electrical locks be trapped? (C.) In the event of a power failure, is there a means to

enable access to the Hot Cell if a human were inside it, or a means to close the Hot Cell door if power is lost when the door is open?

---

6. *Comment 64: Reference is also made to "remote security links" between ADT and, presumably, the facility. What backup systems exist in the event of a power outage combined with a telephone service discontinuity?*

**AMS Response: AMS does not understand the intent of this comment. Therefore, no action has been taken.**

It appears that fire and security monitoring for the facility is provided by ordinary telephone lines, and that the fire and security sensors themselves are powered by ordinary public power lines. Accordingly, in the event of a thunderstorm, tornado, or other problem, the facility would not only be without emergency monitoring, but also without means of emergency communication.

---

7. *Comment 65: What is the nature of the site security system that windows on both the first and second floor can remain broken for months at a time and a pick-up truck can breach the parking lot fence and be set on fire in the parking lot without raising alarms or prompting rapid response?*

**AMS Response: AMS does not understand the intent of this comment nor its relevancy to radiological emergencies. Therefore, no action has been taken.**

In large measure, AMS attributes the absence of realistic release modelling in emergency planning for the AMS facility to the physical security of the facility. It is clear that the physical security of the facility has been breached many times without rapid response by AMS, if in fact AMS became aware of the breaches as they occurred at all. Surface contamination is stated by AMS to be distributed about the building, hence any broken window should be a matter of concern. However, windows at the facility remain broken or covered with duct tape and cardboard for months at a time. Large scale breaches of the perimeter fencing on weekends go unnoticed by AMS until the work week begins on Monday.

---

8. *Comment 91: The Hot Cell is described as having "Numerous small access ports ... located on the front and side faces of the cell, and a 20-inch square port opens from each side." What is meant by numerous? What is the size of each such "small" access port? In what manner are these ports sealed, if they are indeed sealed at all? What is the exact location of each of these access ports? Are*

*photographs or diagrams of these numerous small access ports available? What is meant by "20-inch square port"? Does that mean it is 20 inches on each side of a square opening, or does it mean that the total area of the port is 20 square inches? Considering the Hot Cell contains a very large amount of radioactive material, this information could be very important to emergency responders.*

**AMS Response: AMS does not understand the applicability of this comment to emergency response efforts. Therefore, no action has been taken.**

As stated by John Grobe of NRC Region III before the Ohio State Emergency Response Commission, at least 30 Curies of Cobalt-60 are in unsealed form in the AMS Hot Cell. Several thousand more are contained in sealed form in the Hot Cell. Accordingly, the nature of openings into the Hot Cell are critical to an assessment of whether loose Cobalt-60 could be distributed about the building by high pressure water hoses or whether beams of gamma radiation can be expected to issue from these ports.

---

9. *Comment 93: No mention is made of the fact that the new Hot Cell window was replaced in 1984 because the old one cracked. In what ways does the new design and construction differ from the earlier model?*

**AMS Response: AMS does not understand the applicability of this comment to emergency response efforts. Therefore, no action has been taken.**

As indicated above, much of AMS' failure to model several radioactive material releases from its facility is based on an assumption of unimpaired physical integrity of containment means. In the case of the Hot Cell window, this is known to be a specious proposition. The prior window cracked because of static electricity; were it to crack again, the several dozen Curies of Cobalt-60 in unsealed form would be accessible, and no zinc bromide solution would be available for shielding radiation beams from the several thousand more sealed sources of Cobalt-60 contained in the Hot Cell. Because the Hot Cell is in line with the main entrance, either problem would profoundly impair access to the building.

Moreover, the designer/manufacturer of the window has indicated that should the window be hit by a fire hose water stream, it could well break. The hot cell window designer/manufacturer would not in any way suggest that it could tolerate such additional pressure, insofar as the window was already under pressure from the zinc bromide solution itself.

---

10. *Comments 96 - 98: The description of the Hot Cell door operation is unclear. A diagram of the device would be helpful. The statement is made that the forty-ton door is removable in*

*case of bearing failure. Is it removable on an emergency basis? If not, that fact should be made explicit.*

*Because of the large amount of radioactive material contained in the Hot Cell, the emergency plan would have to be updated substantially in the event the forty-ton door were in fact removed for any period of time.*

**AMS Response: AMS does not understand the applicability of this comment to emergency response efforts. Therefore, no action has been taken.**

The Hot Cell door appears to be a critical part of the means by which the dozens of Curies of unsealed Cobalt-60 are contained in the Hot Cell itself. It also appears to be an important shield against beams of gamma rays. However, it also appears to weigh several tons. Should the door be removed for any reason, the danger posed to emergency responders would be much higher than might otherwise be presented. Accordingly, some notice to emergency responders of such removal would be an important safety notice.

Also, should the door fail, the same heightened hazards would be presented. Hence, how the door works and whether there are emergency means by which it can be closed should be conveyed to emergency responders to ensure that avoidable exposures are not encountered, and that loose Cobalt-60 is not released.

---

11. *Comment 101 - 105: The Hot Cell door is said to operate electrically. Is the Hot Cell door provided with an emergency back-up?*

*Similarly, is there an emergency back-up to the electrical interlock for the electric door drive?*

*There is an indication that switches prevent the operation of the cell door without a second person present. Is there an emergency override to enable rescue in an emergency?*

*The statement regarding shielding for the Hot Cell, "The shielding thickness was chosen as sufficient to handle to largest sources currently available with complete safety, and to provide adequate shielding for the larger sources the future may require," appears inaccurate as it relates to any persons who may enter the Hot Cell, as it relates to occasions during which the Hot Cell door is open, and during all times at which the Hot Cell window may be compromised.*

*Moreover, inasmuch as it appears that there are a number of other opening into the Hot Cell of unknown shielding, the statement that "the Hot Cell is shielded by 5-1/2 feet of concrete, with 1/4-inch steel plate on the inside faces," is overbroad and should be modified.*

**AMS Response: AMS does not understand the**

**applicability of this comment to emergency response efforts.  
Therefore, no action has been taken.**

As discussed above, the Hot Cell door appears to play an important role in preventing the spread of unsealed Cobalt-60 source material, and in shielding beams of gamma rays. It would be of extreme importance to emergency responders to know whether the Hot Cell door can be halted in an open position in the event of a power failure.

Even if power is not lost, it would also be important to know how to operate the Hot Cell door in the absence of AMS employees in the event that such employees were unconscious or otherwise unable to assist in rescuing persons who may be in the Hot Cell or in securing the Hot Cell.

As to the District comment on the adequacy of shielding, it is clear that openings do not provide shielding. It is also obvious that an open Hot Cell door does not provide shielding to the same extent that a closed door does. Consequently, the assumption that shielding is adequate is inappropriate for the occasions when the door is open and may become stuck in that position.

As AMS does not provide information about emergency backup power to close the door in the event of a power failure, or for sealing the aperture remaining in the event of breakage of the Hot Cell window, such arrangements should be made or all Cobalt-60 should be removed from the Hot Cell.

---

12.                   Comment 106 - 108: *The statement that "the Hot Cell does not contain any flammable material" conflicts with statements by the NRC to the effect that one paint-can-full of flammable material may be present in the Hot Cell.*

*The first two paragraphs of section 1.2.4 does not assist emergency responders and should be deleted.*

*The first sentence of the third paragraph of section 1.2.4 appears misleading. There are residential areas right next door to the facility. The phrase "within a block of the facility" may mislead emergency responders into believing they have a greater margin of safety than is the case.*

**AMS Response: AMS does not understand the applicability of this comment to emergency response efforts. Therefore, no action has been taken.**

According to statements made by John Grobe of NRC Region III, up to one paint-can-full of flammable material may be present in the Hot Cell. As there is also abundant Cobalt-60 in unsealed form, a fire involving this one paint-can-full of flammable material could well generate smoke, which could in turn carry loose Cobalt-60 into other parts of the building or to the environment.

As indicated above, information in the proposed plan that does not actually bear on emergency preparedness or emergency response should be eliminated as a distraction.

Finally, the proximity of the facility to residents is an important factor in emergency response, since it is principally for those residents that the emergency responders have undertaken their duties.

---

13. *Comment 122 - 127: What is the schedule for testing the emergency generator?*

*The emergency generator apparently provides power only to "air handling equipment, the monitoring facilities and the liquid waste facilities" and the "emergency lighting system". What liquid waste facilities require emergency power? Are all aspects of air handling provided with emergency power? What monitoring facilities are provided with power?*

*Does the phrase "monitoring facilities" also include gamma alarm systems? If so, please make that clear. If not, they should be included.*

*Why are electrical door interlocks not included in list for emergency power back-up? What other systems are left without back-up by the gas burning emergency generator?*

*What is the inspection schedule for the natural gas emergency generator? In what way are the results of such inspection logged? At the time of inspection, is the Fire Department given the opportunity to observe and/or certify the results of such inspection?*

*In the final paragraph beginning on page 1-6, what devices are included in "all safety and monitor devices"?*

**AMS Response: AMS does not understand the applicability of this comment to emergency response efforts. Therefore, no action has been taken.**

The reliability of emergency backup devices at AMS is of great importance to actual first responders, as it is known that AMS has been cited in the past for failure to maintain its backup generator. Regular testing is an obvious demonstration of reliability.

Further, the equipment that emergency power actually reaches in the event that the backup generator does work is an important factor in emergency response. For example, it is not clear that electric door locks or gamma alarms are provided with backup power, hence it is not clear what access responders will have to given areas of the facility, or whether actual radiation hazards may be present.

Knowing what other systems -- whether for access or for hazard detection/communication -- are not powered by the backup generator will help responders plan what equipment they will need at a particular part of the building and how to get there.

---

14. *Comment 130 - 137: Is the "Storage Garden" the same as the*

*"Isotope Garden" shown on Figure 1-10? Only one designation should be used to reduce chance of confusion.*

*Description is made of the "Storage Garden" and how its shielding could be improved. Why has shielding not been maximized?*

*What is the nature of waterproofing for the Storage Garden and Irradiation Facility?*

*Why is there an Irradiation Facility contemplated in the plan when no provision therefor may be found in the present AMS NRC license and irradiation is not a use of radioactive materials for which AMS is licensed?*

*Reference is made to a "well drilling point" that extends to the basement floor level beneath each manhole cover so that temporary additional shielding may be obtained by flooding the voids of the sand with water. What is meant by "well drilling point"? Under what circumstances would such additional temporary shielding be necessary?*

*No manhole covers are depicted on any of the facility drawings; please supply. To what do these manholes connect?*

*The statement is made that, "If storage needs ever require it, the rooms can be emptied and filled with concrete, steel shot or other higher density material." What storage needs would create such a requirement?*

*Inasmuch as AMS contemplates the use of concrete for shielding and storage purposes in this context, AMS should consider covering the loose Cobalt-60 waste on the bottom of the Waste Hold-Up Tank ("WHUT") room with concrete to immobilize that loose Cobalt waste powder and/or sludge.*

**AMS Response: AMS does not understand the applicability of this comment to emergency response efforts.**

The use of inconsistent designations of building areas can lead to confusion and cause delays in response, thus aggravating dangers posed.

As the Storage Garden possess many thousand Curies of Cobalt-60, it presents a significant radiation exposure risk to emergency responders. If, as is implied, the shielding for this area can be improved, it should be done so. Anywhere that risks can be minimized or eliminated, it should be done so.

As a principle mode of distribution of radioactive materials about the AMS facility has been waterborne transport, the nature of waterproofing of areas known to harbor thousands of Curies of Cobalt-60 is important to emergency responders. If, for example, the waterproofing is shoddy, plans should be put in place to enable fire fighters to avoid allowing water runoff to enter such areas.

As to the District's comment on the existence of an Irradiation Facility, it is important to know if AMS is using its radioactive materials in ways not contemplated by its NRC license. The NRC license to AMS clearly does not contemplate irradiation, hence reference thereto appears to be

surplusage that should be eliminated from the proposed emergency plan.

References to the well drilling points and manholes are made, indicating that undisclosed pathways for fire control runoff exist. Further information on such pathways would enable emergency responders to assess the potential impact of fire control efforts on further distribution of Cobalt-60 contamination throughout the building or into the environment.

Finally, it appears that shielding can be enhanced by the use of concrete. It also appears that the loose Cobalt-60 that contaminates the WHUT Room and potentially other areas of the facility may be immobilized with the use of concrete. This very idea was contemplated by the NRC (*see* Region III Objectives/Strategy Concerning Advanced Medical Systems, Inc. (AMS) 34-19089-01, a copy of which is attached hereto, paragraph (B)(3) ("solidification in concrete")), but the NRC never followed up on the idea. While removing Cobalt-60 to a proper nuclear waste facility is an obvious and available option, immobilizing the Cobalt-60 contamination in concrete is an immediately implementable means of minimizing risks associated with this loose Cobalt-60.

---

15. Beginning with Comment 165 in the September 22, 1995 *Response to Comments*, AMS becomes evasive and no longer directly addresses whether or not they are ignorant of an area or merely refuse to take action thereon. As to the vast bulk of the remaining District comments, AMS states "No longer applicable, comment unrelated to emergency response issues, comment is unintelligible, comment indicates a lack of understanding of the issue, or no response required." Some, but certainly not all, of the comments appear to have been read, but very few appear to have been acted on.

This type of comment is unfortunate, as it does not allow the District to determine whether AMS is ignorant as to basic emergency response issues, or is merely unwilling to implement basic emergency response practices. The District is thus compelled to comment upon the September 21, 1995 version of the proposed Plan *in toto*, rather than merely commenting upon those areas adjusted by AMS. This is poor practice on the part of AMS, inasmuch as it wastes the resources of emergency responders.

---

16. Inasmuch as your responses to our prior comments were substantively insufficient, the entirety thereof are incorporated by reference as though fully set forth herein. You are urged to review the prior comments again, because of their importance to maintaining the personal safety of AMS workers and others. For example, to the extent that any preventable accident scenario could impact the efficacy with which the RSO can assist emergency responders, any emergency can have radiological overtones.

---

17. It is noted that in the upper right-hand corner of the September 21, 1995 version of the plan that it is deemed "Revision 0". This is false, as the transmittal letter itself bears out. Insofar as the revisions of the proposed plan reflect the degree to which AMS understands emergency response and

emergency preparedness issues, the proper revision number should be included. Proper revision information may also be required under NRC regulations. If AMS chooses not to report the revision number accurately, no revision number should be reported.

---

18. In section 1-1, it is reported that there are 40 Curies of radioactive material in potentially dispersible form. This number does not agree with prior estimates from AMS and NRC, and therefore is suspect. The basis for determining whether material is dispersible or not should be set forth explicitly, and the amount and location of material deemed not dispersible should be described. Radioactive material presents a hazard to AMS workers and emergency responders whether or not it is dispersible.

---

19. If, however, only 40 Curies of dispersible material remain at the facility, those 40 Curies should be disposed of immediately at a proper nuclear waste facility. Such a facility is presently available, and to fail to dispose of this material is to harbor an unnecessary radiological risk to AMS workers, emergency responders, and potentially the general public.

---

20. In section 1-1, it is reported that the potentially dispersible material consists primarily of "dry solid waste, carbon granules and ion exchange resins," and that it is stored in "55-gallon drums or B-25 (steel) boxes." As 55-gallon drums and B-25 (steel) boxes are not approved for long-term storage of nuclear wastes of any kind, steps should be taken to re-package these wastes in the event that AMS fails to ship them to available nuclear waste disposal facilities.

---

21. Section 1.2 refers to Figure 1 as showing the location of the AMS facility. Figure 1 has too little detail to locate the AMS facility. However, Figure 5, which is appropriately detailed, is of insufficient size to indicate the major highways that may serve the facility. A street map of sufficient size and detail should be provided to accurately locate the facility. In this way, emergency responders can quickly find the facility to minimize the potential for injury to AMS workers and harm to the surrounding neighborhood.

---

22. In section 1.2, the AMS operation is said to occupy 25% of the London Road building. This is known to be inaccurate, insofar as a substantial portion of the warehouse area is taken up by temporary storage bladders holding approximately 400 tons of accumulated wastewater that can contain, according to the NRC, up to 1000 picoCuries/liter of Cobalt-60. It is misleading to ignore this wastewater. Aside from the potential radiological risks (each liter of the wastewater, at the Cobalt-60 levels requested by AMS of the NRC, can contaminate 125 grams of soil to beyond NRC release criteria), there is a risk that AMS workers, emergency responders, or the public could be severely injured in the event that any one or more of these temporary storage bladders failed.

While the water itself may not pose a direct radiological risk, physical injuries to the RSO could impair his ability to respond to radiological issues. Also, a failure of one or more of the temporary bladders could physically wash a (potentially unconscious) AMS worker or emergency responder into more highly contaminated areas, presenting a realistic radiological problem. Further, since AMS has failed to remove so much Cobalt-60 waste from the facility, and has in fact moved into the facility a substantial amount of contaminated soil that had been outside the facility, the physical force of thousands of gallons of wastewater -- whether profoundly radioactive or not -- could well wash significant amounts of highly radioactive material into other areas of the building and even into the surrounding neighborhood. No steps have been taken by AMS to provide spill containment systems, so this is a significant hazard.

---

23. Reference is made in section 1.2 to an irradiation area at the facility. As was pointed out in our comments on the prior revision of the proposed plan, AMS has no authority under its NRC license to conduct irradiation activities. As AMS has no authority to conduct such activities, any equipment or materials related to irradiation should be disposed of at a proper nuclear waste facility, since their presence presents an unnecessary and eliminatable radiological risk.

---

24. Section 1.2.1 contains a potentially misleading description of the Hot Cell and Hot Cell window. Moreover, it does not agree with the description given in the prior revision of the proposed plan which specifically described "Numerous small access ports . . . located on the front and side faces of the cell, and a 20-inch port opens from each side." The prior description also agrees with prior pictorial submissions by AMS to the NRC, one of which was used as an illustration in a presentation by John Grobe of the NRC to the Ohio State Emergency Response Commission. Several questions were posed by the District regarding these openings previously, none of which were answered in AMS' responses.

In this revision, the description is changed. What construction, modification or re-fabrication work eliminated the "numerous small access ports" and the potential radiation-beam and/or dispersion venue potential they presented?

---

25. In the event that no construction, modification or re-fabrication work took place since our comments to the prior revision of this proposed emergency plan, we repeat our request for description of how each access port is sealed.

---

26. It is known that the Hot Cell window broke in the past due to a static discharge within the Hot Cell itself. It is also known that the Hot Cell window is approximately in line with the front door to the facility. Thus, in the event of a fire in the facility, it is reasonable to assume that firefighters may inadvertently direct a cold stream of high-pressure water against the Hot Cell window. According to Hot Cell Services Corporation, as a matter of safety, the Hot Cell window should not

be hit with a direct stream, as it is already under considerable pressure from the zinc bromide solution and could break again.

Since the potential for breakage is created by the proximity and orientation of the Hot Cell window to the other parts of the facility, what measures are available to provide shielding in the opening that would be left in the event of Hot Cell window breakage?

---

27. It is known that in past revisions of the proposed emergency plan that AMS claimed to have lead bricks to stack up in the window in the event of breakage of the window. Since there is no mention of the bricks in the current revision, where are those bricks now?

---

28. As the zinc bromide solution provides a substantial amount of shielding in the Hot Cell window, and such solution would be lost in the event of the Hot Cell window being broken by a foreseeable stream of fire suppression water, what level of shielding against a beam of radiation is supplied by the 8" non-browning glass that might remain after a partial rupture of the window system?

---

29. As the NRC has made it clear that loose Cobalt-60 is present in the Hot Cell, describe the means available to prevent the dispersal (by fire-suppression water or otherwise) of such Cobalt-60 in the event of a foreseeable total rupture of the Hot Cell window.

---

30. The statement is made in section 1.2.1 that "Every item of equipment in the Hot Cell and every item within the cell structure are removable." As they are removable, the Hot Cell should be cleared of all such equipment to an available nuclear waste facility.

---

31. The statement is made in section 1.2.1 that "Because of the structural integrity of the hot cell, this radioactivity [approximately 4,000 Curies of Cobalt-60] is not readily dispersible in the event of a fire, flood or building damage." This statement is erroneous as to dispersibility in a fire event, based on the above concerns raised by the designer of the Hot Cell window. (It must be conceded that the Hot Cell window designer knows more about its properties than the local engineer hired by AMS for overall structural opinions.) Apparently, therefore, any release modelling by AMS for a fire scenario must therefore be increased by at least 4,000 Curies.

---

32. The section 1.2.1 statement that "Because of the structural integrity of the hot cell, this radioactivity [approximately 4,000 Curies of Cobalt-60] is not readily dispersible in the event of a fire, flood or building damage" is also erroneous as to dispersibility in earthquake-related building damage. On page 2-3 of this revision of the proposed emergency plan, AMS concedes that "An

earthquake also has the potential to crack or break the viewing window into the Hot Cell." There could thus be a significant opening made for both beams of gamma radiation and for airborne/waterborne Cobalt-60. Accordingly, it is baselessly optimistic to fail to include the 4,000 Curies of Hot Cell Cobalt-60 in release modelling.

---

33. The section 1.2.1 statement that "Because of the structural integrity of the hot cell, this radioactivity [approximately 4,000 Curies of Cobalt-60] is not readily dispersible in the event of a fire, flood or building damage" is also erroneous as to dispersibility in a flood. At page 2-4 of the present revision of the proposed emergency plan, it is conceded that "Projectiles from a tornado have the potential to crack or break the viewing window into the Hot Cell." Any tornado which could break the Hot Cell window with projectiles could also carry by wind the Cobalt-60 available therein. Moreover, the torrential rains that so frequently accompany tornadoes would also have the potential to carry away Cobalt-60. Accordingly, AMS' modelling of releases from the building should be substantially revised to reflect the 4,000 Curies of dispersible Cobalt-60 it has yet to address.

---

34. The statement is made that "The average ambient exposure rates within the cell are approximately 12 R per hour, with rates up to 200 R per hour on contact with certain surfaces." AMS has endeavored to make much of emergency responders' lack of expertise in radiological matters. Accordingly, statements like the foregoing should be rendered more meaningful to non-radiological personnel.

For example, this statement could be rephrased as follows: "On average, a person in the Hot Cell will receive a full year's radiation exposure in 5 minutes, but may receive that year's worth of exposure in 18 seconds." In this way, in the event of a real emergency involving the Hot Cell (e.g., the RSO collapses from a coronary on the floor of the Hot Cell), emergency responders would have a better idea of how much time they can spend in the cell. Further, an indication of what areas of the Hot Cell produce a year's worth of exposure in 18 seconds should be provided. This rephrasing assumes a maximum annual exposure of 1 R.

If the 100 millirem per year dose limit for members of the general population is assumed (*see* 10 CFR 20.1301 and/or page 2-1 of the September 21, 1995 revision of the proposed Emergency Plan), however, the statement would need to be rephrased thus: "On average, a person in the Hot Cell will receive a full year's radiation exposure in 30 seconds, but may receive that year's worth of exposure in less than two-tenths of a second."

---

35. Throughout the descriptions of building areas in section 1.2, descriptions are made of the exposure levels. However, no indication thereof is made on the building drawings included with this revision of the proposed plan. This forces emergency responders to either expose themselves unnecessarily to radiation in moving through the building to effect a rescue, or to page back and forth between the building drawings and the area descriptions to determine paths wherein acceptable exposures may be encountered. By including exposure information on the drawings, AMS worker

safety would be enhanced and emergency responder access speed and safety would be improved.

This suggestion was made before and was ignored. This suggestion is readily implemented, and AMS' failure to do so is a striking example of AMS' poor understanding of emergency preparedness and how it can affect AMS worker safety and the safety of third parties.

---

36. In section 1.2.2, the Isotope Shop is identified as a "Restricted Area", with quotation marks as if it were a term of art. If "restricted area" is indeed a term of art, its definition should be provided.

---

37. Earlier correspondence and pleadings filed by AMS indicated that the entire facility, with the exception of [the Hot Cell and the Waste Hold-up Tank (WHUT) room], had been decontaminated in the later 1980's. Section 1.2.2 describes significant, measurable contamination in the Isotope Shop. How did this area become re-contaminated? When did this re-contamination occur? Since it appears that decontamination had once taken place, why is the Isotope Shop allowed to remain contaminated now that nuclear waste disposal facilities are available?

---

38. Section 1.2.3 describes a substantial amount of Cobalt-60 stored in the Source Garden. Since it does not appear that AMS is doing anything with this material, and the only utility described -- irradiation -- is not authorized, this material should be shipped to a proper nuclear waste disposal site to reduce or eliminate unnecessary risks.

---

39. Section 1.2.3 includes a description of an irradiation plug. As there is no authority in AMS' NRC license for irradiation activities, this irradiation plug should be removed, along with the associated sources.

---

40. Section 1.2.3 describes the Source Garden as being connected to a "metal container through which cooling air is drawn from the room to the high-efficiency air- (HEPA-) filtered exhaust system." What would occur in the event the source tubes were not cooled? What room is cooling air drawn from? What would occur if air continued to be drawn from the Source Garden in the event of a HEPA filter failure? (For the purposes of the latter question, assume that air did continue to be drawn, notwithstanding a filter failure.)

---

41. The Source Garden is described as harboring 30,000 Curies of Cobalt-60 in sealed form. It is claimed to be non-dispersible because it is in sealed form. At page 2-6, AMS discloses that the natural gas line for the building actually wraps around the Source Garden. It is known that natural gas explosions can be catastrophic. What testing has been performed to demonstrate that sealed sources of the type in the Source Garden can withstand a proximate natural gas explosion? Without

such demonstration, and given the proximity of the natural gas feed line to this large amount of Cobalt-60, it appears unrealistically optimistic to consider it completely unavailable for dispersal.

---

42. Section 1.2.4 describes the Decontamination Room as being equipped with "water outlets and a floor drain, which was used during previous decontamination operations." Are the water outlets still functional? Since the drain is claimed to be sealed, where does runoff from the water outlet go? With what was the drain sealed?

---

43. The Decontamination Room is described as being contaminated and having dispersible activity. However, correspondence and pleadings filed by AMS indicated that the entire facility, with the exception of [the Hot Cell and the Waste Hold-up Tank (WHUT) room], had been decontaminated in the later 1980's. How did the Decontamination Room become re-contaminated? When did this re-contamination occur? Since it appears that decontamination had once taken place, why is the Decontamination Room allowed to remain contaminated now that nuclear waste disposal facilities are available?

---

44. Section 1.2.5 describes drums of waste and spent HEPA filters being stored in the High Level Waste Storage Room. If such wastes may be put into drums, then the wastes can also be shipped to appropriate nuclear waste disposal facilities to reduce unnecessary risk to AMS workers and third parties.

---

45. The only wastes described in the High Level Waste Storage Room are those in drums and spent HEPA filters. Are these a part of the 10 Curies of potentially-dispersible Cobalt-60? If not, what materials do comprise the 10 Curies of potentially-dispersible Cobalt-60?

---

46. Section 1.2.8 describes a drum storage area in the Back Basement. Do these drums contain any of the fifteen Curies of dispersible Cobalt-60? If not, what is the form of the dispersible Cobalt-60 and what is contained in the drums? If the drums do contain Cobalt-60, much as in the case of the High Level Waste Storage Room, if waste can be placed in drums, it can be shipped to appropriate nuclear waste disposal facilities to reduce unnecessary risk to AMS workers and third parties.

---

47. No mention is made in section 1.2.8, 1.2.9 or 1.2.10 of the substantial amount of highly-contaminated soil and highly-contaminated footer drains excavated from around the outside of the facility and now said by counsel for AMS to be stored in the facility basement. This material should be included in the description of the building area radioactive materials.

---

48. No mention is made in sections 1.2.8, 1.2.9 or 1.2.10 of the propensity for the seam where the walls and floor of the basement meet to leak groundwater in and contaminated water out. This should be evaluated expressly.

---

49. In section 1.2.9, discharges into the sewer system are said to have ceased in 1989. Earlier reports by AMS indicated that it stopped discharging Cobalt-60 into the sewer system in 1988. In addition, as late as 1994 Cobalt-60 continued to be discharged from the facility. Explain these inconsistencies in reporting.

---

50. In the event that only 50 Curies of Cobalt-60 remain in the WHUT room, as AMS claims, then it should be decontaminated and those 50 Curies disposed of properly in the available nuclear waste storage facility.

---

51. Where in the footnoted Integrated Environmental Management, Inc., "Evaluation of the WHUT Room Source Term", Report No. 94002/G-3104, June 16, 1995, does it state that the Cobalt-60 contained in the WHUT room is non-dispersible?

---

52. The NRC has indicated that the NRC is not convinced that the "seal" on the WHUT room was adequate to prevent transmission of Cobalt-60 into the water that AMS allowed to accumulate in the facility basement, and that the WHUT room Cobalt-60 could not be considered fully isolated. What steps has AMS taken to fully waterproof the WHUT room to prevent further exchange of Cobalt-60 contamination within the WHUT room to water outside the WHUT room? What steps has AMS taken to dispose of contaminated wastewater that might otherwise accumulate in the basement, once room in the AMS warehouse for temporary storage bladders has run out?

---

53. In section 1.2.10, the Front Basement is said to contain the Blue Tank Room. To what is the Blue Tank connected?

---

54. Are there any drains of any kind in the basement that are not permanently sealed?

---

55. In section 1.2.11, the "air lock, the Isotope Shop warehouse, portions of a caged storage area, and office areas on the second floor" are described as being contaminated. Earlier correspondence and pleadings filed by AMS indicated that the entire facility, with the exception of [the Hot Cell and the Waste Hold-up Tank (WHUT) room], had been decontaminated in the later 1980's. How did the

areas described in section 1.2.11 become re-contaminated? When did this re-contamination occur? Since it appears that decontamination had once taken place, why are these areas allowed to remain contaminated now that nuclear waste disposal facilities are available?

---

56. Section 1.2.11 states that portions of a caged storage area are contaminated, while section 1.2.12 states that portions are not. Why has the caged storage area not been cleaned up to eliminate unnecessary radiological contamination and risk?

---

57. Section 1.3 states that "In the event of a radiological emergency, these locations [80 homes and 7 industrial facilities within two blocks of AMS] may require special consideration." Where are such special considerations set forth?

---

58. Paragraph 2.1 is, as will be shown below, unrealistically optimistic and should therefore be deleted as inaccurate.

---

59. Section 2.1.1 briefly discusses the likelihood of fires at the facility with "significant radiological impact". It is not clear, however, what that phrase means. It must be borne in mind that emergency responders -- whether fire, sewer, medical, or police officials -- are generally not classified as radiation workers. Accordingly, any scenario in which any responder would receive the 100 millirem per year dose limit for members of the general population (*see* 10 CFR 20.1301 and/or page 2-1 of the September 21, 1995 revision of the proposed Emergency Plan) should be characterized as having "significant radiological impact." Anything less is patently misleading to those emergency responders.

---

60. In section 2.1.1, the HEPA filters are described as fire-resistant. From earlier correspondence between AMS and the NRC, it is known that the filters are only rated to 200°F. Even a wastebasket fire can therefore exceed the fire rating of the HEPA filters. It is therefore inaccurate to state, "Minor fires, such as refuse fires, are not likely to result in the release of radioactivity." Higher temperature ratings for the HEPA filters should be secured before AMS can rely on them to resist any fire in the building.

---

61. Section 2.1.1 tends to downplay the possibility of fires at the facility in part because of a fire suppression system. It is known that as of this writing that the fire alarm enunciator panel described and/or promised to various agencies is incomplete, untested, and unapproved.

---

62. Section 2.1.1 speaks of "small quantities of combustibles in the restricted areas". Counsel for AMS has represented that much of the waste materials in storage in the basement of the facility and elsewhere is made up of Tyvek plastic coveralls, plastic gloves, clean rags and other readily flammable material. It is thus overly optimistic to downplay the possibility of a fire because there is not much to burn. All flammable materials should be eliminated from restricted areas; should these materials be contaminated with radioactivity, they should be shipped to the available nuclear waste disposal facility to reduce both the risk of fire and the amount of unnecessary radioactive material on-site.

---

63. Section 2.1.1 indicates that unrestricted areas of the facility are covered by a sprinkler system, but makes no mention of fire suppression for restricted areas. Mention was made in the prior revision of the proposed Emergency Plan of foam fire suppression systems as being appropriate for use in controlling fires in restricted areas. AMS should therefore install such a system, rather than leaving the areas unprotected and hoping that no emergency occurs.

---

64. The majority of dispersible radioactive material is stated in section 2.1.1 to already be in "drums or boxes that meet the normal conditions of transport described in Subpart F, 10 CFR 71.71." Since such containers are not suitable for long-term storage, if the materials are indeed so packaged, then those materials should be immediately shipped to the available nuclear waste disposal facility to reduce the inventory of unnecessary radioactive material on-site and the entirely avoidable risk such material presents.

---

65. The present packaging of the majority of dispersible radioactive material on-site is stated in section 2.1.1 to meet no more than the requirements of 10 CFR 71.71(c). such criteria are insufficient for long-term storage of nuclear materials at the facility.

---

66. AMS seeks in section 2.1.1 to minimize the danger associated with the large amount of unnecessary Cobalt-60 at its facility by hyperbolizing the storage capabilities of the Source Garden and the Hot Cell. As has been set forth above, the Source Garden is encircled by the facility's natural gas feed line and has not been subject to analysis as to the effect of a proximate explosion thereof. Further, the Hot Cell has been shown to be highly subject to breakage of its large window under a variety of circumstances. Accordingly, it is unrealistic to assume that the thousands of Curies of Cobalt-60 in the Source Garden and Hot Cell will not be involved or released in a fire scenario.

---

67. The discussion on page 2-2 of the exposure rates under a fire scenario is absurdly optimistic and should be rejected in its entirety. The discussion assumes that the criteria under which NUREG 1140 was developed are applicable, and that the amount of radioactive exposure is to be reduced by

a factor of 0.0001. Merely because a calculation is endorsed by an NRC document does not mean that it is realistic.

In the event of a wholesale natural gas explosion, for example, it is much more realistic to assume that the majority of radioactive material would be available, since the walls and ceilings of the facility would likely be entirely destroyed. The release fraction would therefore be far closer to 1.0000 than to 0.0001. Accordingly, the exposure rates would be 10,000 times those reported. The dose to the nearest off-site resident would therefore be 2 R; to the maximally-exposed member of the off-site population within 10,000 meters, 3 R; and to a fire fighter positioned 9 meters from the building, 90 R.

---

68. The discussion on page 2-2 of the exposure rates under a fire scenario discuss the exposure to a fire fighter positioned 9 meters from the building. It is highly unrealistic to assume that a fire fighter would remain outside the building for the duration of a fire event. The anticipated exposures should therefore be much higher, based on the inverse-square law of exposure.

---

69. Because of the erroneous assumptions made in the AMS modelling of exposures, the statement to the effect that countermeasures or recovery actions for protecting members of the general public is incorrect. Because AMS understates the exposure by a factor of approximately 10,000, as discussed above, the actual exposures to off-site individuals is 3 R, or 3,000 mR. This falls into the ICRP early-phase countermeasures range for sheltering.

---

70. The above describes the errors implicit in reducing exposure rates by a factor of 10,000 without reason to believe that the release fraction would be less than 1.0000. However, as indicated in the comments on facility areas, it appears that AMS has gravely understated the amount of Cobalt-60 in dispersible form. From the Hot Cell alone, 4,000 more Curies should be added to the dispersed amount. Both the amount understatement and release fraction errors should be eliminated, and exposure rates recalculated.

---

71. In section 2.1.2, AMS cites its local engineer for the claim that "seismic events in excess of this value [5.2 Richter] in this region is highly improbable. A professional seismologist should be consulted before predictions of earthquake occurrence or magnitude predictions are made a part of any revision of the proposed plan.

---

72. Section 2.1.2 is unrealistic in its assumption that an earthquake would merely expose the Source Garden wall. It is known that standing water alone has caused the foundation of the building to crack and/or to expand pre-existing cracks. As recently as November 13, 1995, counsel for AMS stated to the Honorable Judge John Manos of the Federal District Court of the Northern District of

Ohio that water pressure on the building could endanger its stability. It is unrealistic to assume that the foundation would not crack further, potentially opening a rent below the WHUT room. Similarly, it is known from counsel for AMS that there already exist discontinuities in the seam where the basement walls and floor meet; complete separation of the several structural features could well result, causing exposure of anything in the basement to the environment. As they are not well connected, according to counsel for AMS, it is imprudent to rule out the prospect of the walls shearing away from the floor under the stress of a seismic event. Moreover, no mention is made whatsoever of the 400 tons of radioactive water stored in temporary bladders at the site. If this weight has not already cracked the concrete on which it rests, the weight probably adds significant additional upward force on the internal walls of the facility by virtue of the principal of levers. Any earthquake modelling that does not expressly address the effect of the additional tonnage of water AMS has accumulated should be rejected out of hand.

---

73. What is the specific nature of the damage suffered by the facility during the January 1986 earthquake?

---

74. Section 2.1.2 repeats the erroneous assumption that the release fraction from a seismic event is below 1.0000. No more obvious 1.0000 release could be imagined than a cracking open of the WHUT room and the pouring out of the loose Cobalt-60 therein. The conclusion that no ICRP countermeasures or recovery actions are warranted is thus erroneous and those countermeasures and recovery actions should be set forth.

---

75. As AMS concedes in section 2.1.2 that the Hot Cell window can indeed crack, all release modelling should incorporate the 4,000 Curies of Cobalt-60 known to be harbored therein.

---

76. The section 2.1.2 report of exposure rates in the event of a rupture of the Hot Cell window is misleading and evasive. The exposure rate at the broken window itself should be reported, not the exposure rate at the main building entrance.

---

77. It does not appear that a broken Hot Cell window would be deemed "structural damage" for the purposes of section 2.1.3. However, it is clear that such an event would indeed have serious radiological consequences. Accordingly, the claim that "the radiological impact of a tornado is likely to be minimal" is unrealistic.

---

78. What is the specific nature of the structural damage predicted to occur in the event of a tornado?

---

79. The tornado sequence set forth in the footnote on page 2-4 is absurd. Dispersible Cobalt-60 is found on every floor of the facility, and substantial amounts thereof are not contained in steel drums. (It is not clear, in any case, that such drums can withstand tornadic winds.) The first and second floors are all windowed, hence could all serve as dispersion avenues in the absence of damage to the roof. Similarly, as the basement floor is cracked and said to be of poor connection to the walls, a shearing of the walls could serve to open up portions of the basement. More simply, the doors to the basement could be blown open and the many open pathways on the first floor could be open. There is no indication whatsoever that the doors and windows to the facility are tornado-proof: The latter are not even proof against the stones thrown by passing vandals.

It is equally absurd to assume that any radioactive material dispersed from the facility would be automatically lifted into the tornado and transported between two and twenty miles away. Anyone who has had a tree uprooted in their yard during a tornado knows that the first place to look for it is right next to the hole, not twenty miles away. This baseless supposition is obviously to avoid realistically modelling the more likely local distribution of materials, and consequent higher concentrations of radionuclides.

---

80. Section 2.1.4 is as unrealistic as its predecessor in the prior revision of the proposed plan. As was pointed out previously, vandalism is unrelated to the value of a structures contents. Windows -- including many on the first floor -- are regularly broken at the facility without police notification, and remain broken for months. The fence around the facility parking lot has been breached and vehicles burned in it without current notification to the police. The NRC's own mobile laboratory has been broken into while parked in this lot. Accordingly, AMS' confidence in facility security is baseless. It is also dangerously optimistic in assuming that no one would break in to steal licensed materials. The facility has certainly enough office equipment -- computers, etc. -- to justify a break-in. And, as police notification of the vehicle burned in its parking lot took days rather than minutes, there is certainly enough time to conduct such burglary. Also, the level of animosity toward AMS is quite high, making the prospect of such crimes as arson legitimate considerations. Any such vandalism or break-in creates new openings in the facility, which may serve as added distribution avenues in the event of a conflagration.

---

81. Section 2.1.5 is misleading, insofar as it was AMS' failure to heed the written and oral suggestions of the District in handling the Cobalt-60-contaminated water that the District refused to accept. According to extensive commentary from counsel and consultants for AMS, AMS' failure to secure a simple sump pump led merely to seepage about the seam where the basement walls meet the floor. The only sudden influx of water to occur was due to AMS' failure to plug a standpipe in the basement. Any present or future seepage or flooding of the facility would be due to AMS' unilateral failure to properly handle water around and in the facility.

The District is concerned, however, that AMS' water handling capabilities are in order: At a hearing on November 13, 1995, counsel for AMS argued that AMS needed to dispose of a 3,000

gallon tank of water it had collected from around the facility. In his argument, counsel for AMS stated to the Honorable Judge John Manos of the Federal District Court of the Northern District of Ohio that water pressure on the building could endanger its stability.

---

82. The incursion of 100,000 gallons of water referred to in section 2.1.5 did not occur in 1994, according to multiple representations by counsel and consultants to AMS. It is not clear why AMS would choose to obscure the fact that such water was accumulated primarily during 1995, and that its accumulation was gradual, but it is nonetheless incorrect. Perhaps it is to obscure the fact that such water could well have been evaporated over the course of 1995. Nonetheless, the misstatement should be corrected.

---

83. Section 2.1.5 states that "the radiological impacts of localized flooding on the off-site population is considered to be inconsequential" is overly optimistic, since environmental testing has not been conducted in the neighborhood. AMS should avoid making claims for which it has no basis.

---

84. A serious flood potential that presently exists at the facility is ignored by AMS in its section 2.1.5. Four hundred tons of radioactively-contaminated water remain at the facility. No engineering assessment appears to have been conducted on the effect of a tornado or earthquake or even a winter freeze rupturing these temporary storage bladders. As the basement of the facility has been described by AMS representatives to be considerably less than 100,000 gallons, this water would not remain in the facility. Also, AMS has failed to install water retaining systems sufficient to contain the runoff. AMS should, therefore, eliminate this water via the NRC-approved evaporation means that is available to it, should ship this water to available nuclear waster disposal facilities, or should construct a runoff retention system sufficient to contain the water it has accumulated.

---

85. No citation is supplied as support for the conclusions of section 2.1.6. Several of the surrounding industrial facilities harbor hazardous materials; accordingly, the engineering analysis leading to the conclusion should be set forth.

---

86. Section 2.1.7 should be revised substantially, as detailed above. The assumption that a natural gas explosion would do no more than disturb the soil around the Source Garden is fatuous, and the assumption that Cobalt-60 released by such an explosion is magically reduced by a fraction of 0.0001 is vacuous.

---

87. Other than the unrealistic treatment of a natural gas explosion in the vicinity of the Source Garden, section 2.1.7 lacks discussion of any other explosions. As the natural gas line runs along the

same side of the building as the majority of the most seriously contaminated areas of the facility, this omission should be corrected and appropriate countermeasures and recovery actions discussed.

---

88. Footnote 20 on page 2-6, in which AMS assumes that "Explosions and/or fires caused by a derailed train will not result in consequences more severe than those presented previously" is absurd. Part of the basis for AMS' prior assumption that explosions and/or fires at the facility would not cause catastrophic consequence was its claim that fuel to feed such a cataclysm could not be found in the facility. As a derailed rail car could carry an abundance of flammable material -- whether natural gas, chemicals, or other materials -- the southern side of the facility could readily be inundated. As the majority of the most seriously contaminated areas of the facility are on the same side of the building as the railroad tracks, and in some cases just inside the wall of the facility, footnote 20 must be rejected.

---

89. Footnote 21 is unsubstantiated and evasive. A railcar of LPG derailing within one hundred feet of the south wall of the facility or a tanker truck of petroleum which jackknives as it attempts to use the circle drive in front of the facility could each potentially supply sufficient concussive force to directly destroy the entire first floor of the facility -- including the Hot Cell. A complete demolition of the first floor should be modeled.

---

90. The assumption in section 2.1.8 that a collapse of the building would enhance shielding is absurd and contrary to AMS' assertions elsewhere in the current revision of the proposed plan that the building's structure itself provides protection against radiological problems. AMS must decide whether the building remaining intact is a good thing or not, and take those steps necessary to ensure that the safest circumstance is maintained.

---

91. No discussion is made in section 2.1.8 of a very serious and immediate problem raised by a train derailment of any type. Both electrical and natural gas feeds come in on the same side of the facility, and would thus be simultaneously compromised. This was pointed out to AMS in the District's prior comments. Such an event would rob the facility of primary and emergency power, causing ventilation and alarm systems to fail. This is a very serious problem and affirmative steps to arrange a tertiary source of power to alarm and other important systems should be developed immediately.

---

92. Section 3.1.3 is somewhat misleading when it speaks of activating "the on-site emergency response team." There are typically only three employees total at the facility, none of whom has demonstrated in-depth training or certification in fire control, first aid, spill control, or Hazardous Waste Operations and Emergency Response ("HAZWOPER") training. Since these individuals do

not appear to have the tools to effectively evaluate emergencies, who else is on the "the on-site emergency response team" that can demonstrate such expertise?

---

93. The comments with respect section 3.1.3 apply with even greater force to section 3.1.4. AMS has failed to document the emergency preparedness training for any of its employees, and has provided no reason whatsoever to assume that any personnel on-site have the capacity to evaluate fires, spills, or other emergencies. Such documentation should be provided as soon as possible, if indeed any personnel have any relevant training at all.

---

94. As AMS has yet to incorporate the many correct telephone numbers for first responders that were provided in comments on the prior revision of the proposed plan, it is not yet in a position to timely notify those first responders in the event of an emergency. This oversight should be corrected immediately.

---

95. Section 3.2 contemplates up to one hour passing before the AMS RSO contacts first responders in an emergency. This is patently and profoundly dangerous, to AMS workers, emergency responders and the public. Such delay would be highly irresponsible; emergency responders should in every case be alerted as soon as possible.

---

96. The statement is made in section 3.2 that the RSO "renders the decision to terminate the emergency." Under a variety of circumstances, the senior fire department official on-site controls the scene. Failure to abide by his decisions or interference with the execution of his duties may lead ultimately to the arrest of the RSO.

---

97. Figure 6, referred to in section 4.1, is an incomplete organization table. No names of any AMS officials are disclosed thereon.

---

98. Reference is made in section 4.1 to a Radiation Protection Program Plan, yet no such entry is found in the table of contents. To what is section 4.1 referring?

---

99. The identities of the Isotope Committee members should be disclosed, along with contact information. In the event of injury to all of the AMS workers in a single accident, fallback personnel to contact should be made known.

---

100. The Isotope Committee is described as being comprised of the vice president of operations, the RSO, the licensed isotope handler, the engineering manager, and a certified health physicist, and as being responsible for review and approval of "all elements of the radiation protection program" and for "confirming that activities are performed safely and in a manner that will protect health and minimize hazards to life, property, and the environment." As there are many obvious deficiencies in this revision of the proposed AMS emergency plan, what individuals of the Isotope Committee reviewed and approved it prior to dissemination to emergency responders for comment?

---

101. Since the RSO is not authorized under AMS' current NRC license to perform all isotope operations, how is he qualified to be responsible for performing product testing?

---

102. Figure 7, referred to in section 4.2, is an incomplete organization table. No names of any AMS officials are disclosed thereon.

---

103. Figure 7, referred to in section 4.2, appears founded on entirely erroneous assumptions. Under no known circumstances are the City of Cleveland Fire Department, Police Department, Emergency Medical Services, Ohio Emergency Management Agency or Ohio Environmental Protection Agency ever subordinate to any private company or individual. This is particularly true in emergency situations. Figure 7 must be completely reconfigured to reflect reality.

---

104. No provision is made in section 4.2 for distribution of tasks in the event one or more of the three AMS workers is not present during an emergency. This is a grave oversight and should be addressed immediately.

---

105. No provision is made for contacting any of the few AMS workers when they are both away from the facility and away from home. As no apparent provision has been made for response with less than complete crew, beepers or other means should be developed to contact these individuals when off-site, twenty-four hours per day. This is a grave oversight and should be addressed immediately.

---

106. AMS' characterization of responders into first responders and secondary responders is willfully ignorant of reality. Accurate information as to the identity and contact information for first responders has been provided to AMS. Its decision to include inaccurate information puts its own workers, emergency responders and the public at grave unnecessary risk. This willful oversight should be corrected immediately.

---

107. Contrary to the assertion in section 4.3, Appendix E of this revision of the proposed emergency plan lacks several first responders' "letters of agreement". It is plain that AMS has failed to incorporate prior comments of several first responders; it is not clear that AMS has even attempted to interact with all relevant first responders. This is a grave oversight and should be addressed immediately.

---

108. Section 4.4 is deficient in many respects. For example, it omits inclusion of the District as a first responder, though AMS' RSO and Vice President are both actually aware of the District's first response activities. Similarly, the Local Emergency Planning Committee is omitted, although it plays a critical role in coordination of first responders. Inappropriate offices are listed for Ohio and federal EPA. This information has been provided to AMS previously; the errors in section 4.4 should be corrected immediately.

---

109. Page 4-4 is false in very material respect as applied to all known first responders.

---

110. Section 5.1 states that emergency notification depends on human efforts, and does not appear to account for emergencies in which AMS workers may be incapacitated and unable to communicate. Automatic notification should be facilitated. In the event that such automatic notification is in place, it should be described in detail for emergency responders' evaluation. This is particularly important in off-hours, since AMS has made no effort to enable mobile communications for its RSO or other employees, and the RSO has a fifty-minute travel time to the facility.

---

111. As stated above, no AMS employee appears to have sufficient training to make the judgments contemplated under section 5.2. Such training should be obtained and documented; until such time as first responders view AMS employees as competent to make such judgments, first responders should be alerted at the first opportunity.

---

112. Section 5.3 is inappropriately optimistic. Restricted areas are not protected by fire sprinklers, even though flammable materials are stored therein. The fire enunciator system is not yet complete, is untested and unapproved.

---

113. Section 5.3 is incorrect when it states that "In the event of a tornado, flood, or severe natural phenomenon, there are no corrective actions that can be taken." See the District's comments on the prior revision of the proposed emergency plan.

---

114. Section 5.3 states that in the event of tornado, flood, or severe natural phenomenon, "appropriate recovery action will be initiated as soon as possible." Where are such recovery actions described?

---

115. Section 5.4.1 does not identify a muster area, nor does it make provision for the RSO being trapped or incapacitated in the facility.

---

116. Section 5.4.2 states that "radiation monitoring devices will be made available to survey evacuated personnel and off-site personnel that have responded to the emergency." This is much more vague than the prior revision of the proposed emergency plan, and evades the many questions posed by the District regarding location, calibration, operation, etc. The questions raised in the District's earlier comments remain pending.

---

117. Questions regarding location, calibration, operation, etc., relevant to section 5.4.3 remain pending.

---

118. Entry/exit procedures should be established prior to actual emergencies, rather than during emergencies as contemplated by section 5.4.3.

---

119. Section 5.4.3 assumes that fire control runoff will return to the basement of the facility. This assumption is faulty in many respects. AMS has represented in correspondence and in various parts of this revision of the proposed plan that drains have been plugged; accordingly, it is not immediately obvious that all runoff from the first and second floors would indeed reach the basement. Also, according to counsel for AMS, the basement is filled with contaminated soil and excavated footers, cutting into the volume available for runoff. Finally, even an empty basement could be insufficient to hold the contaminated water presently stored in temporary rubber bladders on site. As the bladders are temporary storage only, and AMS has taken no protective measures to ensure their integrity or provide runoff control, section 5.4.3 must assume that the bladders remain intact. This does not appear well-founded. Alternative runoff protection for the facility should be provided.

---

120. Footnote 26 on page 5-2 recommends that non-liquid fire suppression systems be used in restricted areas. As AMS has not installed such available suppression systems, where has AMS stored these fire control materials on-site?

---

121. It is irresponsible for AMS to state in section 5.4.3 that "Radioactive materials dispersed due to a tornado or other severe natural phenomenon cannot be controlled but can be monitored and collected after the fact." AMS is aware that its present store of Cobalt-60 can be removed to a proper and available nuclear waste disposal facility. Thus, the materials at the facility that could be dispersed by severe natural phenomena can indeed be controlled before the fact. Disposal activities should commence immediately.

---

122. It is unclear that the exposure levels discussed in section 5.5 have been discussed with any first responders, or that they have agreed to be so exposed at any time. Since the Cobalt-60 contamination at the site can be removed to available nuclear waste disposal facilities, and thus exposure levels at the AMS facility can be brought down, this failure to communicate and/or discuss exposure levels with emergency responders can be eliminated as an issue.

---

123. In the District's comments on the prior revision of the proposed emergency plan, questions were raised about the number, type, calibration, location and operation of monitoring devices as described in section 5.5, all of which remain pending.

---

124. Section 5.6 does not state by whom radiation training is provided. In the event the training is supplied by anyone other than AMS, AMS should supplement such training, since no other licensee in the area served by Cleveland Emergency Medical Services handles loose Cobalt-60.

---

125. Neither Cleveland Emergency Medical Service nor University Hospitals appear to have provided a "letter of agreement". Have they affirmatively communicated an agreement of any kind to the statements set forth in sections 5.6 or 5.7?

---

126. As stated in prior comments, a second alternate location for the "command center" described in section 6.1 should be selected.

---

127. As stated in prior comments, the location of the nearest public telephone should be set forth in section 6.2.

---

128. Section 6.3 speaks of "facilities with which AMS has arrangements", yet no "letters of agreement" may be found. How is that AMS can claim to have "arrangements" with facilities, yet fail to provide written documentation thereof?

---

129. The equipment listed in section 6.4 is insufficient to properly monitor a full contingent of responders to a major emergency (e.g., fire) at the facility. Supplemental equipment should be secured immediately to avoid rescue or fire suppression activities being impaired by lack of monitoring.

---

130. Section 6.4 refers to "ISP-23" for calibration and operability information, yet no such "ISP-23" is contained in this revision of the proposed plan. "ISP-23" should be supplied to emergency response organizations immediately, and made a part of subsequent revisions of this proposed plan.

---

131. Section 6.4 states that protective clothing may be found "In the locker room or storage room". Which room has the protective clothing? Where is the "storage room"?

---

132. Footnote 25 on page 5-2 states that only self-contained breathing apparatus are suitable for fire response. Why, then, does AMS state in section 6.4 that only particulate respirators are stored for emergencies? The present equipment should be replaced with self-contained breathing apparatus as are appropriate for emergency response.

---

133. As to review and update of this proposed emergency plan, section 7.1 is incorrect when it states that such review and update is annual. Were section 7.1 true, several more revisions of the proposed plan would have been made available over the years. As the plan as presently set forth requires substantial improvement, annual review is insufficient.

---

134. Section 7.2 states that "applicable management personnel participate in comprehensive annual and refresher training" in the area of emergency response and notifications. Since the AMS staff is so small, these applicable management personnel should be identified to emergency responders as potential information resources in the event that AMS workers are incapacitated.

---

135. Section 7.2 is wholly incorrect when it states that "AMS also provides annual radiation safety training for first responders." No such training has ever taken place even once, much less annually. AMS should only make such claims once it has undertaken such training efforts. The remainder of section 7.2 is also wholly false.

---

136. Section 7.3 is wholly false as it relates to emergency exercises. In its entire history, AMS has never once conducted an emergency exercise with off-site responders, and does not even have such

an exercise scheduled currently. AMS should actually undertake cooperative activities before it claims credit for them.

---

137. Section 7.3 appears to be false as it relates to communication drills, insofar as AMS' list of responders is incomplete and numbers that are listed are in some cases incorrect.

---

138. Section 7.4 is speculative, inasmuch as no exercises have been conducted in AMS' history. It may also be incorrect, as it does not appear that an audit was prepared after AMS called the fire department to have them pump water into the foundation around the building under circumstances they classified as emergent, claiming that the building was otherwise in danger of collapse. Similarly, it does not appear that an audit was prepared after AMS allowed groundwater to build up around its building to such an extent that the compression plug in its lateral was blown out. While there were several thousand gallons of water quickly drained from around the facility -- a circumstance that AMS has characterized as potentially precipitating a collapse of the building -- and the District responded to this spill, it does not appear that any follow-up was conducted.

---

139. It does not appear that an independent audit has ever been conducted as contemplated under section 7.5. Inasmuch as AMS' Isotope Committee is the group to whom audit reports would be made, no member thereof could belong to both the auditing group and the Isotope Committee and still be called independent. Who, then, will perform the independent audit, should one ever be conducted?

---

140. Quarterly inventory of emergency supplies, as contemplated under section 7.6, is insufficient to supply assurance that such supplies would be operable. Operational checks should be conducted with the same regularity. To leave operational checks until "prior to use" is fatuous in the context of emergency equipment.

---

141. Section 7.7 is incorrect when it states that "letters of agreement" are "solicited once per year". Such letters have been solicited once in the entire history of AMS, and solicited of an incomplete and sometimes incorrect list of emergency responders. The misstatements of section 7.7 are reflected in Appendix E, which itself is incomplete.

---

142. As stated above, it does not appear that any follow-up documentation has been prepared with respect to emergency responses by the Fire Department and the District. Thus, while section 8.1 may describe a potentially acceptable reporting procedure, it does not reflect the actual activities of AMS. AMS should not claim to follow procedures unless it actually does so.

---

143. Section 8.2 contemplates the saving of certain documents for three years. As AMS' NRC licensure period is five years, an interval longer than five years should be established to ensure that NRC has the opportunity to review AMS' compliance with applicable regulations and its claims. This is important, insofar as the contemplated record retention period could interfere with NRC's identification of the extent to which AMS has exaggerated its emergency preparedness. For example, under the three-year scenario, NRC could be unaware that AMS has never provided training to emergency responders, never conducted emergency exercises, never audited emergency procedures or responses, etc. The NRC would only know that AMS had not conducted such activities in the past three years and would refuse to opine on earlier periods. AMS would thus not receive appropriate feedback from which it could improve its performance.

---

144. Chapter 9, Recovery and Plant Restoration, does not address emergencies in which AMS workers are entirely incapacitated or unable to communicate. This omission should be addressed immediately.

---

145. Chapter 9, Recovery and Plant Restoration, does not address emergencies in which both natural gas and electrical power are lost, in which case the facility would be without alarm and ventilation control. This grave omission should be addressed immediately, with the immediate installation of a fully autonomous emergency back-up generator.

---

146. Chapter 9, Recovery and Plant Restoration, does not address emergencies in which contamination is widespread, in which the facility is no longer operable, in which plant equipment (e.g., ventilation) is destroyed, in which neighborhood sheltering-in-place or evacuation are appropriate. These omissions in emergency preparedness should be addressed immediately.

---

147. Section 9.1 is potentially incorrect. Under many circumstances, the senior fire department official on-site controls an emergency scene and determines whether or not a facility may be re-entered. Failure to abide by his decisions or interference with the execution of his duties may lead ultimately to the arrest of the RSO.

---

148. Section 10 contains a variety of inaccuracies of which AMS has actual knowledge. For example, AMS is presently under the jurisdiction of the Cuyahoga County Local Emergency Planning Committee ("LEPC") by order of the Ohio State Emergency Response Commission, an order which was issued without opposition by the NRC. AMS has yet to demonstrate compliance with LEPC requirements, hence cannot claim to be in compliance.

---

149. Table 1 is vague as to location of the materials described, their actual physical form, the basis for estimated activity and basis for dispersibility determinations. Each aspect of Table 1 should be detailed to avoid wasting emergency responders' time cross-referencing other parts of the proposed plan for further information.

---

150. The 29.4 Curies of "packaged waste" listed on Table 1 should be immediately sent to the available nuclear waste disposal facility to reduce unnecessary radiological risk at the facility.

---

151. If only 53 Curies of Cobalt-60 remain in the WHUT room, as is claimed on Table 1, it is certainly feasible to remove such wastes to the available nuclear waste disposal facility to reduce unnecessary radiological risk at the facility.

---

152. Table 1 states that there exists "Uncharacterized surface activity in the restricted areas of the facility", yet limits the amount of such uncharacterized contamination to only 11 Curies. What is the basis for this limitation?

---

153. Table 2, as has been discussed above, is riddled with errors. These include the following: The NRC does not provide first response services. University Hospitals of Cleveland does not provide first response services. The Ohio Department of Health in Columbus, Ohio generally, does not provide first response services. The Ohio Environmental Protection Agency in Columbus, Ohio, provides first response services through its regional offices. The Columbus phone number is incorrect, this phone number will not connect you with OEPA Emergency Response Services. The Northeast Ohio Regional Sewer District does provide first response services, but is omitted from the list of first responders. Additionally, the emergency number listed for the Northeast Ohio Regional Sewer District is also incorrect. It should be listed as 641-6000 8 to 4:30, M-F and 641-3200 at all other times. The Cuyahoga County Local Emergency Planning Committee does provide first response services, but is omitted from the list of first responders. Several of the phone numbers listed for responders are not the 24-hour emergency response numbers including the number for the Cuyahoga County Local Emergency Planning Committee.

---

154. Table 3 does not provide sufficient emergency supplies to address an emergency at the facility. See comments above and in the District's comments on the prior revision of the proposed emergency plan.

---

155. Figure 1 is not sufficiently detailed.

---

---

156. The "note" on each of facility drawings is troubling. Why is equivocation on facility dimensions necessary? Who prepared the drawings, and when?

---

157. Figure 2 lacks depictions of several doors, piles of concrete blocks, contaminated soil and excavated footer drains, 55-gallon drums filled with wastes, and other features that could impact access to various parts of the facility. Such details should be provided to ensure that rescue efforts are not impeded.

---

158. Figure 4 lacks depiction of doors that are said to be electrically locked or interlocked, does not show the many windows, does not show the location of the 400 tons or more of contaminated water stored adjacent to the features shown on Figure 4, does not show the location of any fire extinguishers, or the location of the natural gas line. These features should be added to ensure that rescue efforts are not impeded.

---

159. Figure 5 does not show any doors or windows, any fire extinguishers, or fire alarm pulls. These features should be added.

---

160. Actual names and contact information should be added to Figure 6 to enable backup contacts to be established in the event that AMS workers including the RSO are incapacitated or out of communication.

---

161. The unacceptability of Figure 7 has been documented earlier.

---

162. As to the Security and Fire Systems described in Appendix A, at this writing, the fire enunciator system for the facility is incomplete, untested and unapproved. The burglar alarm system appears to ignore broken windows, hence cannot be considered reliable. Fire extinguisher locations are not shown on facility drawings, and it is not clear that there are sufficient hand-held dry chemical extinguishers on hand to appropriately protect the facility.

---

163. A variety of questions were raised in the District's comments on the prior revision of the proposed emergency plan regarding the Air Handling System, most of which remain pending in light of Appendix A in the current revision, particularly those related to the absence of back-up dampers, gamma alarms for neighborhood notification, and temperature ratings for the equipment. Moreover, the description from the last revision to the current revision of the Air Handling System itself has

changed. What modifications have taken place since the prior revision?

---

164. As set forth in the Emergency Power and Lighting section of Appendix A, AMS is without means to control air handling, monitoring, or other electrical systems in the event both electricity and natural gas supplies are cut off. As both are commonly lost in severe storms, etc., this is a grave oversight and should be addressed immediately.

---

165. It is not clear that additional back-up power is supplied to the Alarm Systems described in Appendix A, hence they are subject to complete failure in the absence of natural gas and electricity. This is a grave oversight in light of the importance of alarm function, and should be addressed immediately.

---

166. Additional back-up power, whether electrical or hydraulic, should be provided for Hot Cell door operation, since as described in Appendix A a worker could be trapped if power were lost while inside the Cell.

---

167. Since the gamma alarm described on page 13-5 is dead when electricity and natural gas are discontinued, it is not properly called "fail-safe". Were tertiary back-up power supplies installed, it may then be accurate.

---

168. As discussed above, the Appendix C dose estimate for Ruptured Hot Cell Window is misleading because it assumes that persons do not approach the window. A more accurate report of the exposure rate at the broken cell window would be simply that inside the cell: 12 R/hr.

---

169. Several of the assumptions made in the Major Building Fire dose estimate in Appendix C were criticized above and in the District's comments on the prior revision of the proposed plan. Few, if any, of those earlier criticisms have been addressed. The exposure rates currently estimated by AMS are off by a factor of at least 10,000. A new model, based on a full release of the entire Cobalt-60 inventory and realistic in-plant locations of fire fighters, should be conducted.

---

170. The Earthquake Damage in the Vicinity of the Source Garden in Appendix A is also unreal, as set forth above. It should be re-done with realistic assumptions (e.g., cracking or shearing of walls).

---

171. Appendix D, ISP-37, repeats many of the errors set forth above, and appears to reflect intentions rather than actions. It contains additional problems, moreover. For example, it is not clear that the AMS Vice President is appropriately trained to conduct the activities set forth in section 5.1. It is not clear that the RSO is qualified to perform the activities described in sections 5.2.5 and 5.5.2.3. Section 5.3.2 is cumbersome and time-consuming to a dangerous degree. Section 5.6 omits the obvious action of turning on the emergency generator. Section 5.8 does not appropriately contemplate major spills that could well occur (i.e., up to 400 tons of contaminated wastewater). Section 5.11.5 does not appear to be good fire suppression practice. Section 5.11.6 is untimely notification: Location of radioactive material should be detailed in the proposed plan, as detailed building drawings as available should be provided to emergency responders before an emergency arises, and all unnecessary radioactive material should be removed from the facility. Attachment 1 to Appendix D summarizes, and thus propagates, several of these errors. Attachment 2 also propagates errors already discussed.

---

172. Attachment 1 to Appendix D refers to airborne activity in terms of "DAC". What is meant by this unit?

---

173. Appendix E suffers from deficiencies previously discussed. See above.

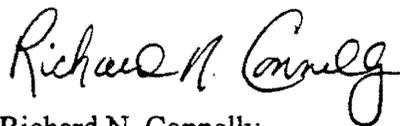
---

174. Because of errors made by AMS in creating a list of emergency responders, its Chapter 14 Distribution List is incomplete.

Should you have any questions about the foregoing, please call (216) 641-6000 and speak to the undersigned.

Please do not fail to act on the above comments merely because you do not understand the comment or because you intend to claim that you do not understand the comment.

Very truly yours,



Richard N. Connelly  
Manager, Water Quality and Industrial Surveillance

att.

cc: Chief Thomas Root, Cleveland Fire Prevention Bureau  
Robert Staib, AMS Task Force  
Martha McCorkle, City of Cleveland Law Department

Mayor Kathleen Edwards, Newburgh Heights, Ohio  
Michael S. Kalstrom, Secretary, Cuyahoga County LEPC  
James Williams, Ohio Emergency Management Agency  
Jane Harf, Ohio State Emergency Response Commission  
James L. Caldwell, Nuclear Regulatory Commission, Region III  
Henry Billingsley, II, Arter & Hadden  
Dwight Miller, Stavole & Miller



DIVISION OF FIRE  
1645 SUPERIOR AVENUE  
CLEVELAND, OHIO 44114-2984  
(216) 664-6800  
FAX (216) 664-6816

# City of Cleveland

MICHAEL R. WHITE, MAYOR

WILLIAM E. LEE  
CHIEF OF FIRE

RECEIVED  
WATER QUALITY & INDUSTRIAL  
SURVEILLANCE

NOV 27 1995

NORTHEAST OHIO REGIONAL  
SEWER DISTRICT

November 21, 1995

Mr. Robert Meschter  
Radiation Safety Officer  
Advanced Medical System, Inc.  
121 North Eagle St.  
Geneva, Ohio 44041

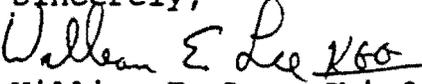
Re: 1020 London Rd.  
Advanced Medical Systems, Inc.  
Emergency Plan

Dear Mr. Meschter,

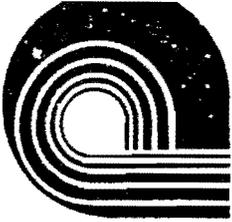
This letter is to inform you that the Cleveland Fire Department considers the Northeast Ohio Regional Sewer District (NEORS) as a first responder type organization within the City of Cleveland.

The supervisory staff and field personnel of NEORS are highly professional. NEORS personnel are trained and equipped to respond to emergencies and investigations, including hazardous material type incidents. NEORS has assisted the Cleveland Fire Department on many occasions with spills and releases that have affected the sewer system and potentially the health and safety of the citizens of the City of Cleveland.

If you have any questions, you may contact Lt. Mark Scott of the Cleveland Fire Prevention Bureau Hazardous Material Section at 664-6664.

Sincerely,  
  
William E. Lee, Chief  
Division of Fire

cc: Capt. Glauner, Acting Fire Marshal  
Lt. Scott, FPB Haz Mat  
William Gruber, Law Dept.  
Rich Connelly, NEORS  
James L. Caldwell, USNRC, Region III  
1020 London Rd. File



COUNTY OF  
CUYAHOGA

**Cuyahoga Emergency Management  
Assistance Center (CEMAC)**

**Commissioners**

Mary O. Boyle  
Timothy F. Hagan  
Lee C. Weingart

November 1, 1995

Robert Meschter, RSO  
Advanced Medical Systems, Inc.  
1020 London Rd.  
Cleveland, Ohio 44110

**RECEIVED**  
WATER QUALITY & INDUSTRIAL  
SURVEILLANCE

NOV - 3 1995

NORTHEAST OHIO REGIONAL  
SEWER DISTRICT

Dear Mr. Meschter:

The Northeast Ohio Regional Sewer District ("NEORS") is a member of the Cuyahoga County Local Emergency Planning Committee ("LEPC"), because it is a first responder for emergencies involving discharges of hazardous substances to sewers and public water courses within the District's drainage area. NEORS staff members are well trained emergency responders and provide invaluable on-scene guidance and assistance to Fire, Police, EMS, County Health Department, Ohio EPA, Ohio EMA, NRC, County Emergency Management and other officials during emergency incidents.

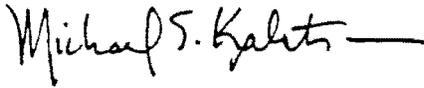
The NEORS is also on the LEPC's 24-hour call list for spills involving sewers or public water courses, because its emergency responders are prepared and have responded to hundreds of local emergency incidents.

In your September 22, 1995 letter to Richard Connelly of the NEORS, regarding your Emergency Plan, you said that the "NEORS is not an emergency responder to emergencies at AMS." The NEORS not only could respond, but has responded to emergencies at AMS. Since you were apparently misinformed about the NEORS's emergency response role, the LEPC thought it important to set the record straight. The NEORS could most definitely be involved in an emergency response at Advanced Medical Systems, Inc., notwithstanding your comments to the contrary.

Emergency response participation is a responsibility of local government officials. Furthermore, emergency incidents, not AMS, determine the level of response and the participants necessary for effective emergency mitigation. An emergency plan is an effort to identify possible levels of

response and the responders needed to meet these anticipated needs. We believe it is in your best interest to cooperate with any and all interested emergency response organizations, and to make your emergency plan compatible with their response protocols.

Sincerely,



Michael S. Kalstrom  
Secretary, Cuyahoga County LEPC

- cc: Reggie Brown, Ohio EPA  
James Caldwell  
~~Richard Connelly, NEORS~~  
Martha McCorkle  
Edmund M. Mecklenburg  
Edwin C. Price  
Chief Thomas Root, Cleveland Fire Department  
Ken Schultz, Ohio SERC



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

June 8, 1995

Northeast Ohio Regional Sewer District  
ATTN: Lawrence K. English  
Assistant General Counsel  
3826 Euclid Avenue  
Cleveland, Ohio 44115-2504

Dear Mr. English:

This responds to your letters dated April 6, 1995 and May 4, 1995, regarding Advanced Medical System's (AMS's) submittal of its radiological emergency plan (EP) to the Northeast Ohio Regional Sewer District (NEORSD) for review and comment. Your April 6, 1995 letter informed us that NEORSD is a first responder to emergencies including fires, floods and spills. The NEORSD's radiological emergency response status was not known to our organization prior to your April 6, 1995 letter.

On May 12, 1995, our office was informed by AMS that its EP was delivered via certified mail to the NEORSD on April 26, 1995, and a return receipt was obtained. This information was confirmed in a May 22, 1995 letter from AMS.

Based on your May 22, 1995 telecon with Mr. Madera of my staff, we understand that the NEORSD received the AMS EP. Pursuant to 10 CFR Part 30.32(i)(4), AMS is required to allow offsite response organizations, expected to respond in case of an accident, 60 days to comment on its EP. Comments received within the required time frame shall be provided to the NRC. Accordingly, should the NEORSD have comments on the AMS EP, please provide them to AMS within 60 days of your receipt of the plan.

If you have any other questions regarding this matter, please do not hesitate to contact Messrs. John Madera or Wayne Slawinski of my staff.

Sincerely,

A handwritten signature in cursive script that reads "James L. Caldwell".

James L. Caldwell, Deputy Director  
Division of Radiation Safety and Safeguards

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

See Attached Distribution

Distribution

cc w/ltrs dtd 4/6/95; 5/4/95  
and 5/22/95:

D. Cesar, Treasurer  
Advanced Medical Systems, Inc.  
121 N. Eagle Street  
Geneva, OH 44041

Marian Zobler  
U.S. Nuclear Regulatory Commission  
Rockville, MD 20852

Robert Meschter  
Radiation Safety Officer  
Advanced Medical Systems, Inc.  
121 N. Eagle Street  
Geneva, OH 44041

Robert E. Owen, Administrator  
Department of Health  
246 North High Street, 3rd Floor  
P.O. Box 118  
Columbus, OH 43266

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  
Cleveland, OH 44115

Erv Ball, Deputy Director  
Cuyahoga County Board of Health  
1375 Euclid Avenue, Suite 524  
Cleveland, OH 44115

Michael Kalstrom, Secretary  
County of Cuyahoga  
Cuyahoga Emergency Management  
Assistance Center  
1255 Euclid Avenue, Room 102  
Cleveland, OH 44115-1807

Jane Harf, Chairperson  
Ohio State Emergency Response  
Commission  
1800 Watermark Drive  
P.O. Box 163669  
Columbus, OH 43219-3669

JUN 25 1993

MEMORANDUM FOR: Richard E. Cunningham, Director, Division of Industrial and Medical Nuclear Safety, NMSS

Richard L. Bangart, Director, Division of Low-Level Waste Management and Decommissioning, NMSS

James Lieberman, Director, Office of Enforcement

FROM: Charles E. Norelius, Director, Division of Radiation Safety and Safeguards, Region III

SUBJECT: STRATEGY CONCERNING ADVANCED MEDICAL SYSTEMS, INC. (AMS) NRC LICENSE NO. 34-19089-01

Enclosed for your review and comment is a medium to long term strategic plan for dealing with AMS. This plan has been developed to allow for the gradual decommissioning of the AMS facility and the restructuring of its NRC license to reflect limited activities. These activities would involve the possession of less than 5,000 curies of licensed material for storage only incident to decontamination of the facility and/or until manufacturing operations are re-authorized. This plan also includes provisions for conducting a hazard assessment at the AMS site, with emphasis on internal as well as external hazards which could lead to a large release of radioactivity.

We would appreciate your input and comments concerning this strategy as soon as possible. The concepts of this strategy have been discussed with Tim Johnson and Fred Combs, and indications are that NMSS could support our efforts.

If you have any questions or require clarification on any of the information stated above, you may contact Mr. Roy J. Caniano of my staff at FTS 388-5612.

ORIGINAL SIGNED BY W. L. WELDON

Charles E. Norelius, Director  
Division of Radiation Safety  
and Safeguards

Enclosure: AMS Strategy

cc w/enclosure:

J.B. Martin, RIII

H. Miller, RIII

J. Glenn, NMSS

J. Austin, LLWM

J. Goldberg, OGC

F. Combs, NMSS

T. Johnson, NMSS

C. Paperiello, NMSS

B.J. Holt, RIII

W. Slawinski, RIII

9307280224 930625  
PDR ADOCK 03016055  
C PDR

B-57

RIII  
Madera  
6/24/93

RIII  
Caniano  
6/24/93

RIII  
Norelius  
6/24

38  
ML  
AF  
F

REGION III OBJECTIVES/STRATEGY CONCERNING  
ADVANCED MEDICAL SYSTEMS, INC. (AMS)  
34-19089-01

DRAFT

- A. Complete and reduce physical inventory of all sealed and bulk radioactive sources in AMS possession as soon as possible. The immediate goal would be to reduce the inventory below the activity requiring an Emergency Plan (5,000 curies Co-60) pursuant to 10 CFR 30.72 (Schedule C).
1. Consider enforcement action to compel AMS to achieve compliance as promptly as possible without causing abandonment by AMS.
  2. Evaluate regulatory impediments that may hinder AMS from transferring licensed material such as; contacting other Regional Offices or Agreement States in order to facilitate necessary license amendments for AMS contractors to receive the material.
  3. Following the removal of all sealed/bulk sources from the AMS inventory, characterize the facilities remaining source term to determine if it is below 5,000 curies of Co-60.
  4. Work with licensee to ensure that all sealed and bulk sources are transferred and, through the inspection program, verify that they have been properly removed.
- B. Monitor future AMS discharge operations regarding liquid waste into the sanitary sewer to assure compliance with 10 CFR Part 20.
1. Work with licensee to evaluate current system used to seal all basement floor drains and possible modifications to that system to prevent inadvertent releases of contaminated liquid effluents. Obtain an agreement from the licensee that in the event a discharge needs to be made to the sanitary sewer, the NRC would be notified prior to the discharge to allow for confirmatory sampling.
  2. Assure that the licensee is cognizant of the new Part 20 requirements regarding disposal by release into sanitary sewerage (10 CFR 20.2003). This should be accomplished through a meeting with the licensee.
  3. Evaluate the licensees plan for compliance with the new Part 20 requirements (i.e., liquid waste holdup or solidification in concrete).

4. Following NRC implementation of the new Part 20, verify, through the inspection program, that the licensee is in compliance with their liquid effluent disposal plan.
- C. Conduct a hazard assessment of the AMS facility. This assessment would require contractor support and would include the following:
1. Assessment of WHUT room integrity, including concrete stability, migration potential of radioactive materials, and consequences from basement flooding or internal hazards which could produce flooding;
  2. Assessment of hot cell integrity, including hot cell window (static discharge problem), and hot cell ventilation system;
  3. Assessment of the reliability of the AMS facility controls and structure during the occurrence of unforeseen catastrophic events (fires, floods, tornadoes, etc.);
  4. Reassessment of licensee's Emergency Plan and Fire Protection Plan in light of the findings from the hazard assessment; and
  5. Determine facility modification needs based on hazard assessment.
- D. Assure with OGC and NMSS that an adequate DFP for the AMS licensed facility is established.
1. Determine financial stability of AMS to determine the merits of the DFP.
  2. Meet with licensee in conjunction with NMSS to review specific requirements for the submission of a proper DFP (NRC expectations). Initial meeting should take place in December 1993 and should include discussions on future plans of AMS.
  3. Once an adequate DFP is established, the license should be renewed to clearly reflect AMS' activities.
- E. Assure proper decontamination of AMS facility.
1. Prior to license renewal, request and work with licensee on submitting an adequate plan for site decontamination. Request LLWM to provide technical assistance in reviewing any plans for decontamination. Major areas of consideration in the decontamination plan are:

\* Decontaminate isotope shop and source garden (1-2 curies Co-60);

- \* Decontaminate basement storage area and drain piping (1-2 curies Co-60);
  - \* Decontaminate ventilation room (millicurie quantities of Co-60);
  - \* Remove all accumulated radwaste - no interim storage of radwaste (millicurie to curie quantities of Co-60); and
  - \* Decontaminate sewerage drain pipes (inside and outside the facility)
2. Evaluate the licensee's plan for the WHUT room prior to license renewal. Major areas of consideration are:
- \* Evaluate ALARA options for the WHUT room;
  - \* Evaluate the possible migration of radioactive materials from the WHUT room to the environment; and
  - \* Evaluate WHUT room decontamination plan or plan to safe-store the WHUT room (man-rem cost, environmental monitoring, stabilization, security, etc.).
3. Evaluate the licensee's plan for the hot cell prior to license renewal. Major areas of consideration are:
- \* Evaluate hot cell redesign or procedural methods used to limit the levels of contamination and to decontaminate the hot cell;
  - \* Evaluate hot cell maintenance program (lighting, manipulator arm replacement, zinc-bromide solution regeneration, etc.); and
  - \* Evaluate with NMSS Sealed Source and Device Registry engineers the equipment, sealed source design, and procedures for the fabrication of sealed sources containing radioactive material.
4. Impress on AMS that it would be to their advantage to cleanup their facility so that the cost estimate for final decommissioning will be reduced.
5. Strongly encourage AMS to dispose of all currently held waste. The sooner they ship waste, the lower the cost.



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

DEC 05 1995

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

Dear Mr. Cesar:

We have received your letter dated October 30, 1995, with attached application for renewal of License Number 34-19089-01, dated October 27, 1995. As we understand, and as stated in your letter, the application supersedes previously submitted renewal applications.

During a telephone conversation between Mr. Robert Meschter of your staff and Mr. Michael Weber of our office on November 15, 1995, Mr. Weber explained to Mr. Meschter that the NRC needs to review AMS' procedures that are referenced in the October 27 application. According to Mr. Meschter, the procedures have not yet been completed. Mr. Meschter also indicated that the procedures would be submitted to our office for review. Please note that we only want to review the final versions of the procedures. Do not submit draft copies.

It is our understanding your goal is to have the final versions completed by the end of December. Please submit the procedures for our review as soon as possible.

If your understanding of any of the above differs from ours, please contact me immediately at 708-829-9854.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin G. Null".

Kevin G. Null  
Senior Materials Licensing Reviewer

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



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

DEC 05 1995

Advanced Medical Systems, Inc.  
ATTN: Mr. David Cesar  
Vice President  
121 North Eagle Street  
Geneva, OH 44041

Dear Mr. Cesar:

We have completed our review of your revised Trust Agreement for Advanced Medical Systems (AMS), Inc's financial assurance dated July 27, 1995.

Advanced Medical Systems, Inc. in Cleveland, Ohio, submitted a "modified and restated" standby trust agreement to replace one that was previously submitted to NRC. The agreement modifies a decommissioning funding plan that uses an amended letter of credit in the amount of \$1,800,000. It assures decommissioning costs for License Number 34-19089-01. Upon review of the financial assurance mechanisms, we ask that AMS modify the submission in the following way:

Submit evidence indicating that the party signing the standby trust agreement for the licensee is authorized to represent the company (Regulatory Guide 3.66, page 3-14).

The standby trust agreement, dated July 5, 1995, is signed for the licensee by its Treasurer. The submission does not, however, provide any evidence indicating that the Treasurer is authorized to enter into a standby trust agreement for the licensee, as recommended in 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), page 3-14.

In a prior submission, AMS provided such evidence in the form of a certified corporate resolution from its board of directors that granted to the Treasurer the authority to execute the standby trust agreement. That authority explicitly applied to the execution of a standby trust dated March 30, 1995, however, and does not extend to the standby trust agreement in the current submission. Evidence of authority to represent AMS is necessary to ensure the validity and enforceability of the mechanism. Therefore, please submit a copy

of the corporate by-laws or other evidence (e.g., another certified corporate resolution) indicating that the party signing the standby trust agreement is authorized to do so.

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 00209.

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

Sincerely,



Kevin G. Null  
Licensing Reviewer

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



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

December 6, 1995

Advanced Medical Systems, Inc.  
ATTN: David Cesar  
Vice President  
121 North Eagle Street  
Geneva, OH 44841

Dear Mr. Cesar:

This letter refers to: (1) the matters discussed at the exit meeting between NRC and AMS on August 29, 1995, (2) the Demand for Information (DFI) subsequently issued by NRC on September 17, 1995, and (3) your response to the DFI, dated October 11, 1995.

We have completed our preliminary review of your response to the DFI, and find that we need additional information and/or clarification on several issues.

We note that your response discussed several initiatives which were not raised in the DFI. Examples of these initiatives include auditing the AMS radiation protection program and upgrading the standard operating procedures. We are encouraged by these positive initiatives.

At the exit meeting, both NRC and AMS were in agreement that definite emphasis should be placed on the reduction of the radioactive material inventory located at the AMS facility. This requires that AMS restore its hot cell to operability for inventory reduction efforts. In your response, 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. In addition, you should describe the actions taken to date and planned, to identify a market for the sealed and bulk sources.

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.

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. Please note that for materials licensees, NRC does not consider storage as a

substitute for disposal (see Information Notice 90-09). Low level waste should be stored only when disposal capacity is unavailable and for no longer than is necessary. The only exception to this is storage for decay, which is generally authorized for radionuclides with half-lives of 120 days or less. This issue has direct bearing on your Decommissioning Funding Plan, and will be addressed, with comments regarding the "Conceptual Decommissioning Plan," in a separate correspondence from Region III.

We request specific justification if the actions discussed in the above three paragraphs are not designated as high priority actions with specific schedules assigned.

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.

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.

Regarding Item E (decontamination of the facility), in your response you state: "AMS is not operating under a decommissioning order, therefore this item is not applicable. Further, the contamination in the referenced areas is adequately controlled such that workers and members of the public do not incur 'avoidable risks' merely by its presence." As we stated in the DFI, 10 CFR 20.1101(b) requires a licensee to use, to the extent practicable, procedures and engineering controls to achieve radiation doses to workers and members of the public that are as low as is reasonably achievable (ALARA). Moreover, 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<sup>2</sup>).<sup>1</sup> 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.

Regarding the disposition of the 100,000 gallons of treated water, we note that this is a low priority action. Please provide us information regarding the expected long term (3-5 years) integrity of the collapsible storage tanks.

---

<sup>1</sup> Letter from S. J. Stein to NRC, dated July 23, 1990.

We also wish to inform you that 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 Funding Plan). Therefore, in your response to this letter, please address the issues discussed in the structural integrity inspection report.

A response to this letter is requested within thirty days after receiving the aforementioned structural integrity inspection report.

Questions concerning this letter should be addressed to Mr. James L. Caldwell, Deputy Director, Division of Nuclear Materials Safety, Region III, who can be reached at (708) 829-9801.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter will be placed in the NRC's Public Document Room.

Sincerely,



Hubert J. Miller  
Regional Administrator

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

See Attached Distribution

Distribution

Robert Meschter  
Radiation Safety Officer  
Advanced Medical Systems, Inc.  
121 N. Eagle Street  
Geneva, OH 44041

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

Erwin J. Odeal, Executive Director  
Northeast Ohio Regional Sewer District  
3826 Euclid Avenue  
Cleveland, OH 44115

Michael Kalstrom, Secretary  
County of Cuyahoga  
Cuyahoga Emergency Management  
Assistance Center  
1255 Euclid Avenue, Room 102  
Cleveland, OH 44115-1807

Marian Zabler  
U.S. Nuclear Regulatory Commission

Robert E. Owen, Administrator  
Department of Health  
246 North High Street, 3rd Floor  
P.O. Box 118  
Columbus, OH 43266

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

Erv Ball, Deputy Director  
Cuyahoga County Board of Health  
1375 Euclid Avenue, Suite 524  
Cleveland, OH 44115

Jane Harf, Chairperson  
Ohio State Emergency Response  
Commission  
1800 Watermark Drive  
P.O. Box 163669  
Columbus, OH 43216-3669