

SEP 21 1990

Advanced Medical Systems, Inc.
ATTN: Ms. Sherry J. Stein, Director
of Regulatory Affairs
1020 London Road
Cleveland, OH 44110

License No.: 34-19089-01
Docket No.: 030-16055
EA 90-051

Dear Ms. Stein:

Thank you for your letter dated August 15, 1990, informing us of the steps you have taken to correct the violations identified in our Notice of Violation dated July 26, 1990. We have no further questions regarding your response for violations A, G, H and I. We will examine these matters during a future inspection. However, your August 15, 1990 response for violations B, C, D, E and F, and other issues as delineated in our July 26, 1990 letter transmitting the Notice of Violation, must be supplemented to address all required information. A reply to the Notice of Violation is required to include for each violation: (1) the corrective steps that have been taken and the results achieved, (2) the corrective steps that will be taken to avoid further violations, and (3) the date when full compliance will be achieved.

These matters were discussed in a telecon with Mr. McDermott of your staff and Messrs. M. McCann and W. Slawinski of our office on September 13, 1990. Specifically, your response to the July 26, 1990 Notice of Violation must be supplemented to address the issues outlined below.

Violation B:

Your response did not specify the corrective steps taken and the date when compliance will be achieved for the non-bioassayed individual that terminated employment without notice. An evaluation of the non-bioassayed individual must be performed to determine the individual's internal exposure during his employment at your facility.

Violation C:

Your response did not specify the corrective actions to avoid further violations involving unlocked high radiation areas.

Violation D:

Since your amendment request to delete the use of alarming dosimeters was not approved (as described in our August 10, 1990 letter transmitting Amendment No. 18 of your license), please readdress your corrective actions, corrective actions to avoid further violations and the date when compliance will be achieved.

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Violation E:

We acknowledge that you are currently conducting a physical inventory to account for all sources received and possessed under your license. However, your August 15, 1990 response did not specify when full compliance will be achieved nor the corrective actions that will be taken to avoid further violations. Be advised that compliance with the current provisions of your existing license is required until changes are authorized by specific licensing action. We will consider a request for an amendment of your license to change your physical inventory requirements.

Violation F:

Your response did not specify the corrective actions, corrective actions to avoid further violations, and the date when full compliance will be achieved. The evaluation record required by 10 CFR 20.103(b)(2) must be completed and maintained for the April 13, 1989 event. In addition, although your response indicates that you plan to submit a revised bioassay program as part of a future amendment request, be advised that compliance with applicable 10 CFR Part 20 provisions is required unless specific exemption is granted pursuant to 10 CFR 20.501.

In addition to the above supplemental information specified above, we request that you augment your response to certain other issues described in our July 26, 1990 letter as outlined below.

July 26, 1990 Letter, Page 3, Item A:

We acknowledge that you held a special isotope committee meeting and several management meetings following our inspection to discuss the causes of the violations, and that the AMS Management Team has been tasked with performing a review of the AMS license and procedures. However, it is not clear that these actions ensure that your management team fully understands 10 CFR Parts 19, 20 and 30. Please advise us of your actions to enhance the management team's knowledge of these regulations.

July 26, 1990 Letter, Page 3, Items B and C:

Your response concerning your audit program did not address: (1) when the audit program will commence; (2) the scope of the audits; and (3) the time frame that problems identified during the audits will be addressed. Please address these issues.

Although you indicate that AMS is developing a new audit procedure to be submitted as part of a future amendment request, we are concerned that development of the management audit program may not be complete despite that management control problems were identified over 6 months ago during our January 1990 inspection.

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As discussed with Mr. McDermott on September 13, 1990, we ask that you submit a supplemental response letter to address the issues delineated in this letter within 20 days of the date of this letter.

In accordance with 2.790 of the NRC's Rules of Practice, Part 2, Title 10, Code of Federal Regulations, a copy of this letter will be placed in the NRC Public Document Room.

The responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget as required by the paperwork reduction act of 1980, Pub. L. 96-512.

Sincerely,

Carl J. Paper
A. Bert Davis
Regional Administrator

cc: Dr. S. Stein, AMS
DCD/DCB (RIDS)

bcc w/letter dtd 08/15/90:
J. Lieberman, OE
J. Goldberg, OGC
R. Bernero, NMSS

Stawinski/jl
9/17/90

McCann
9/17

Grobe
9/17
CP
9/20/90

Norenius
9/18

Paperjello
9/20/90

Davis
9/21/90