

APR 20 1994

Advanced Medical Systems, Inc.
ATTN: Sherry J. Stein
Director of Regulatory Affairs
121 North Eagle Street
Geneva, OH 44041

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

Dear Ms. Stein:

This refers to the special safety inspection conducted by Mr. Wayne Slawinski of this office on February 22 and 25, 1994 with continuing review through March 11, 1994, of activities authorized by NRC Byproduct Material License No. 34-19089-01, and to the discussion of our findings with you and Mark Loeser on March 1, 1994.

The special, limited scope inspection was conducted to review a whole body occupational exposure in excess of regulatory limits to a contract worker involved in hot cell decontamination activities at your London Road facility. The exposure was reported to the NRC by your former Radiation Safety Officer, Mr. Loeser, in a telecon on November 19, 1993 and in a written report dated December 7, 1993.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, and interviews with personnel.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

As described in the NRC's Enforcement Policy delineated in 10 CFR Part 2, Appendix C, Supplement IV, a cumulative worker exposure above regulatory limits can be classified as a Severity Level III problem under certain circumstances. Severity Level III problems normally result in escalated enforcement action. However, after consideration of the circumstances associated with this case, we have determined that escalated enforcement action is not appropriate at this time. The violations have been classified individually as Severity Level IV problems. We have arrived at this decision because: (1) the breakdown in your radiation protection program which led to the overexposures was primarily administrative in nature and (2) NRC whole body occupational exposure limits were revised in 1994 to 5 rem per year from external and internal exposures, eliminating the quarterly 1.25 and 3 rem external dose limits.

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The NRC expects licensees to achieve and maintain compliance with regulatory requirements and license conditions and conduct its activities with due regard for health and safety. In this instance, we are concerned that you did not exercise the necessary management and administrative controls over your program to maintain whole body exposures within applicable regulatory limits.

The principal violations identified during this inspection relate to inadequate control of worker exposures while involved in hot cell activities and failure to adequately complete Form NRC-4s for several workers. We are particularly concerned about these problems because an exposure in excess of regulatory limits occurred in 1984 during a hot cell entry, and also involved Form NPC-4 issues.

In addition to your response to the specific violations noted, please also describe your plans to improve program oversight, particularly your plans to maintain occupational doses within regulatory limits during all future activities.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

The response directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards

Enclosures:

- 1. Notice of Violation
 - 2. Inspection Report
- No. 030-16055/94001(DRSS)

bcc w/enclosures:

PUBLIC

P. Santiago, OE

J. Lieberman, OE

RIII

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RIII

Slawinski/bt

Madera

Caniano

DeFayette

Berson

Axelson

04/13/94

4/13/94

4/13/94

4/15/94

4/18/94

4/18

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Handwritten initials and signatures: w/z, Madera, 4/13/94

Handwritten initials and signature: Caniano, 4/13/94

Handwritten initials and signature: DeFayette, 4/15/94

Handwritten initials and signature: Berson, 4/18/94

Handwritten initials and signature: Axelson, 4/18