

NOTICE OF VIOLATION

Advanced Medical Systems, Inc.
Cleveland, Ohio

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

During an NRC inspection conducted on July 6-7, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1994), the violations are listed below:

License Condition 19 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated November 12, 1984; and various dated letters including letter dated December 4, 1986 (with Revised ISP-1 Manual, Appendices A and B), and letters dated March 29, 1989 and July 23, 1990.

1. Appendix A of Revised ISP-1 Manual, Procedure No. ISP-2, requires that restricted areas be surveyed at least monthly and that loose surface contamination be maintained less than 40,000 dpm/100 cm². Similarly, Chapter 3 of ISP-1 Manual entitled "Safety & Health," forwarded by letters dated March 29, 1989 and July 23, 1990, require in Section 3.3.2 that surface contamination in restricted areas exceeding 40,000 dpm/100 cm² be reduced ALARA.

Contrary to the above, from October 1993 and continuing to the date of this inspection, various restricted areas within your facility have exhibited loose surface contamination levels in excess of 40,000 dpm/100 cm², and these levels have not been reduced ALARA. Specifically, floor surfaces in the isotope shop, decontamination room and back basement have loose surface contamination levels ranging from several hundred thousand to over three million dpm/100 cm².

This is a Severity Level IV violation (Supplement VI).

2. Chapter 3 of ISP-1 Manual, entitled "Safety and Health," forwarded by letter dated July 23, 1990, states in Section 3.5.5, that a radiation survey of the sanitary sewer will be conducted quarterly.

Contrary to the above, sanitary sewer surveys have not been conducted at required intervals. Specifically, in 1994 to the date of this inspection, only one radiation survey was conducted in the sanitary sewer.

This is a Severity Level IV violation (Supplement VI).

3. Chapter 3 of ISP-1 Manual, entitled "Safety and Health," forwarded by letter dated July 23, 1990, states in Section 3.5.7, that fixed station air sample flowmeters will be calibrated annually.

Contrary to the above, fixed station air sample flowmeters have not been calibrated at required intervals. Specifically, as of the date of this inspection, the last calibration of the two fixed air sample flowmeters located in the isotope shop was March 1990.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Advanced Medical Systems, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Lisle, Illinois
this 31 day of August 1994