

NOTICE OF VIOLATION

Advanced Medical Systems, Inc.
Cleveland, Ohio

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

During an NRC inspection conducted on February 22 and 25, 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 (1993), the violations are listed below:

1. 10 CFR 20.101(a) requires that the licensee limit the whole body radiation dose of an individual in a restricted area to one and one quarter rem per calendar quarter, except as provided by 10 CFR 20.101(b). 10 CFR 20.101(b) allows a licensee to permit an individual in a restricted area to receive a whole body radiation doses of three rem per calendar quarter provided specified conditions are met.

Contrary to the above, the licensee did not limit the whole body radiation dose of individuals working in its hot cell, a restricted area, to one and one quarter rem per calendar quarter and the conditions of 10 CFR 20.101(b) were not met. Specifically, five contract workers each received whole body doses between 1.53 and 3.075 rems while performing hot cell decontamination and equipment repair/installation activities during the fourth calendar quarter of 1993.

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

2. License Condition No. 19 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including any enclosures. A referenced letter, dated December 4, 1986, transmitted a revised Isotope Facility Safety Procedures Manual (ISP-1). Chapter 3.4 of ISP-1, Hot Cell Entry and Action Levels, requires that a job specific RWP be used for each hot cell entry. Chapter 7.2 of ISP-1, Personnel Monitoring, requires that all personnel entering controlled areas wear approved film badges.

The RWPs for the hot cell decontamination and hoist installation project which took place in the fourth quarter of 1993 (RWP No. 93-26 and No. 93-30), required that TLD/film badges be used to monitor whole body exposures.

Contrary to the above, TLD/film badges were not always worn by workers entering the hot cell, a controlled area, and involved in the hot cell decontamination and hoist installation project. Specifically, on the afternoon of October 7, 1993, a contract worker performed decontamination work in the hot cell and failed to wear his assigned whole body TLD dosimetry device.

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

3. License Condition No. 19 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in referenced documents, including any enclosures. A referenced letter, dated December 4, 1986, transmitted a revised Isotope Facility Safety Procedures Manual (ISP-1), which includes procedure ISP-14, Entering The Hot Cell.

Item 5.15 of ISP-14 requires that alarming dosimeters be set to alarm at an accumulated dose equal to $\frac{1}{4}$ (2400 mrem minus the total dose for the quarter).

Contrary to the above, on several occasions during the fourth quarter hot cell decontamination and hoist installation project, alarming dosimeters worn by individuals while working in the hot cell were set at alarm thresholds exceeding the value calculated using the ISP-14 equation. For example, on November 11, 1993, a hot cell worker's alarming dosimeter was set to alarm at about 600 mrem, rather than 110 mrem calculated using the required equation.

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

4. 10 CFR 20.405(a) requires, in part, that within 30 days, each licensee make a written report to the Commission concerning each exposure to radiation in excess of any applicable limit in Part 20 or in the NRC License.

Contrary to the above, as of April 8, 1994, the licensee had not made a report to the Commission of four whole body occupational doses in excess of 10 CFR 20.101(a) limits. Specifically, four contract workers each received whole body exposures between 1.53 and 2.17 rem while involved in hot cell activities during the fourth quarter of 1993, and the licensee failed to submit the required written report to the Commission.

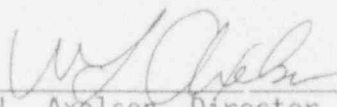
This is a Severity Level IV violation (Supplement IV).

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.

APR 20 1994

Dated _____



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