NOTICE OF VIOLATION

Advanced Medical Systems, Inc.
Cleveland, Ohio

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

During an inspection conducted on January 23-26, 1990, 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 (1990) the violations are listed below:

A. License Condition No. 17 of Amendment No. 17, which became effective on December 13, 1989, 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 ISP-1 Manual which describes the hot cell supporting facilities and equipment. Page 12 of ISP-1 states, "The operation of the air handling equipment, the monitoring facilities and the liquid waste facilities is insured in the event of electrical power failure by a natural gas burning emergency generator with automatic rapid changeover. An emergency lighting system is also powered by this generator."

Contrary to the above, as of January 24, 1990, the operation of the air handling equipment, monitoring facilities, and liquid waste facilities was not insured by rapid automatic changeover to the emergency generator. Specifically, 1) on that date, a power outage occurred at the licensee's facility and the emergency generator failed to start automatically; and 2) the licensee's records revealed that on January 6, 1990 and January 19, 1990, the licensee had checked this system for startup and noted that the generator did not automatically start upon initial attempts and that a possible battery problem existed; however, no action was taken to correct the apparent problem.

B. License Condition No. 19 of Amendment No. 16, which became effective on January 19, 1989, requires that the licensee conduct its program in accordance with statements, representations, and procedures contained in referenced documents, including any enclosures. A referenced letter, dated December 4, 1986, transmitted a revised ISP-1 Manual which includes the licensee's bioassay program. Item H of the bioassay program requires, among other things, that all personnel who have extended employment at the London Road facility and who routinely enter bioassay areas for routine operation or maintenance be assayed annually and prior to employment termination. Also, a special bioassay is required when there is an internal exposure in excess of 40 MPC-Hrs in seven consecutive days.

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Contrary to the above, the licensee failed to perform:

1. Annual bioassays in 1989 for two individuals who had extended employment at the London Road Facility and who routinely entered bioassay areas for routine operations or maintenance.

2. A special bioassay for one of these two individuals who had received an internal exposure of 66.7 MPC-hrs on April 13, 1989.

3. A bioassay prior to employment termination (in early 1989) of at least one individual who routinely entered bioassay areas for operation or maintenance at the London Road facility.

C. 10 CFR 20.203(c)(2)(i)-(iii) requires that each entrance or access point to a high radiation area be equipped with certain control devices or be maintained locked except during periods when access to the area is required, with positive control over each individual entry.

Contrary to the above, during the January 23-26, 1990 inspection period, the access point to the decontamination room, a high radiation area, was not equipped with a control device pursuant to 10 CFR 20.203(c)(2)(i) or (c)(2)(ii); the lock on the decontamination room door was broken; and the door was not locked during periods when access to the area was not required.

D. License Condition No. 19 of Amendment No. 16, which became effective January 19, 1989, requires that the licensee conduct its program in accordance with statements, representations, and procedures contained in referenced documents including any enclosures. A referenced letter, dated December 4, 1986, transmitted a revised ISP-1 Manual which includes ISP-31 and attachment 10.6 to ISP-1. Attachment 10.6 to ISP-1 requires that alarming dosimeters be calibrated at a frequency of "six months per ISP-31 or before the first use if greater than six months since last calibration."

Contrary to the above, an alarming dosimeter that was last calibrated on July 27, 1987, was used during a hot cell entry in April 1989.

E. License Condition No. 14 of Amendment No. 14, which became effective on January 26, 1988, requires that the licensee conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

Contrary to the above, during the period January 1988 through January 26, 1990, the licensee did not conduct a physical inventory to account for all sources and/or devices received and possessed under the license.

F. 10 CFR 20.103(b)(2) requires, in part, that whenever the intake of radioactive material by any individual exceeds the specified 40-hour control measure, the licensee make such evaluations and take such actions as are necessary to assure against recurrence, and further requires that the licensee maintain records of such occurrences, evaluations, and actions taken in a clear and readily identifiable form suitable for summary review and evaluation.

Contrary to the above, although the licensee asserted that an evaluation was made after a worker exceeded the 40-hour control measure on April 13, 1989, records of this evaluation and action to assure against recurrence were not maintained.

G. License Condition No. 19 of Amendment No. 14, which became effective on January 26, 1988, requires that the licensee conduct its program in accordance with statements, representations, and procedures contained in referenced documents, including any enclosures. A referenced letter, dated May 7, 1987, transmitted the ATC Medical Group's Management Plan, revised April 30, 1987. The management plan provides that external audits of the isotope handling facilities, source manufacturing procedures, and documentation will be conducted on a semiannual basis by a third party quality assurance auditing service.

Contrary to the above, no semiannual external audits of the isotope handling facilities, source manufacturing procedures, and documentation were performed by a third party quality assurance auditing service during the period January 1, 1989 through December 13, 1989.

(Repeat violation from November 1988 inspection.)

H. License Condition No. 17 of Amendment No. 17, which became effective on December 13, 1989, requires that the licensee conduct its program in accordance with statements, representations, and procedures contained in referenced documents including any enclosures. A referenced letter, dated December 4, 1986, transmitted a revised ISP-1 Manual which describes the Master Alarm Panel operation. Page 18 of ISP-1 states that the Master Alarm Panel shows a warning light for the basement door in the Isotope Shop Area, which will indicate a steady bright red light when the door has been opened and indicate to the hot cell operator that personnel are in this area. Page 20 of ISP-1 states that when the basement door is opened, a steady red light turns on above the door.

Contrary to the above, during the January 23-26, 1990 inspection period, the Master Alarm Panel did not indicate any light when the basement door in the Isotope Shop Area was opened and no warning light existed above the basement door.

I. 10 CFR 20.203(b) requires that each radiation area be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words: Caution Radiation Area.

Contrary to the above, on January 24, 1990, the roof area above the equipment room, a radiation area, was not conspicuously posted in that the radiation area sign was face down on the roof and partially covered with roofing material.

Collectively, these violations represent a Severity Level III problem (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, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, U.S. Nuclear Regulatory Commission, 799 Roosevelt Road, Glen Ellyn, IL 60137, 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 may be issued to show cause 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. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 26th day of July 1990