

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Advanced Medical Systems, Inc.
One Factory Row
Geneva, Ohio 44041

License No. 34-19089-01
EA 85-60

An onsite inspection of activities authorized under NRC License No. 34-19089-01 was conducted on February 21 and 22, 1985. The inspection determined that individuals with inadequate training in radiation protection principles were required to enter a hot cell facility where radiation levels as high as 81 R/hr existed. These entries were made without an adequate evaluation of the radiation hazards, without adequate management supervision, and without implementation of an effective radiation safety program. As a result, individuals worked in an area where there was a substantial potential for an exposure in excess of 10 CFR Part 20 limits and an individual received a whole body dose in excess of NRC regulatory limits.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1985), the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1984, as amended ("Act"), 49 U.S.C. 2282, PL 96-255, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

- A. 10 CFR 20.101(a) limits the whole body dose of an individual in a restricted area to one and one quarter rems per calendar quarter, except as provided by 10 CFR 20.101(b). Paragraph (b) allows a whole body dose of three rems per calendar quarter, provided certain specified conditions are met.

Contrary to this requirement, an individual working in a restricted area received a whole body dose of 2.9 rems in the fourth calendar quarter of 1984 and did not meet the conditions specified in 10 CFR 20.101(b).

- B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of 10 CFR Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, adequate surveys were not made to evaluate the radiation hazard incident to the use of radioactive material to assure compliance with 10 CFR 20.201(a). Specifically, the only surveys made by the licensee on November 6 and November 21, 1984 were surveys at the hot cell door showing radiation levels of 17.5 R/hr and 18 R/hr, respectively. These surveys which were used to calculate personnel stay time in the hot cell did not accurately reflect radiation levels inside

the hot cell where individuals were required to work. A survey made by the licensee on April 25, 1985 showed radiation levels of up to 81 R/hr inside the hot cell. This was approximately four times the levels that were used by the licensee to calculate cell stay times. As a result, actual radiation doses to two individuals who were required to enter the hot cell on November 21, 1984 were greater than anticipated and one of these individuals exceeded the whole body dose limit specified in 10 CFR 20.101(a). In addition, neither the Radiation Safety Officer nor his designee adequately supervised the working times of the individuals in the hot cell to ensure that dosimeters were frequently checked for confirmation of the anticipated dose rates.

- C. License Condition No. 16 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in "Radiation Safety Procedures Manual, ISP-1" dated July 1983.

Section 7.2.c "Personnel Monitoring," of ISP-1 states, "Work in high dose areas will be preceded by a survey with appropriate monitoring equipment and an estimated total accumulated exposure determined.... The pencil type dosimeters will be read at intervals consistent with the anticipated dose rate to determine that the actual exposure is not greater than the anticipated exposure."

Contrary to this requirement, dosimeters were not read at intervals consistent with the anticipated dose rate to determine that the actual exposure was not greater than the anticipated exposure. Specifically, on November 21, 1984, two individuals worked in the licensee's hot cell, an area where high radiation levels existed. Individual A remained in the hot cell for 3.65 minutes and Individual B remained for 3.8 minutes without reading their dosimeters. When the individuals read their dosimeters after exiting the hot cell, both 1R dosimeters were off-scale. The licensee estimated the doses by reading the 5R dosimeter that Individual A was wearing. After reading the dosimeter the licensee assigned a 1625 millirem dose to Individual A and a 1600 millirem dose to Individual B. This is more than twice the 750 millirem dose that was anticipated.

- D. License Condition No. 16 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application received July 16, 1979, and in certain referenced letters.

Schedule E of the referenced application states that dosimeters will be calibrated at intervals of 180 days or less or before first use if longer than 180 days since last calibration.

Contrary to this requirement, dosimeters had not, in all cases, been calibrated at intervals of 180 days. Specifically, dosimeters used by individuals who entered the hot cell on November 6 and 21, 1984 had not been calibrated between January 1983 and January 1985.

Collectively, these violations have been categorized as a Severity Level III problem (Supplements IV and VI).

(Cumulative Civil Penalties - \$6,250 assessed equally among the violations.)

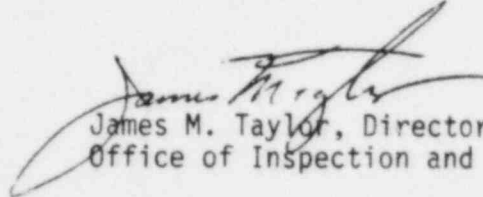
Pursuant to the provisions of 10 CFR 2.201, Advanced Medical Systems, Inc. is hereby required to submit to the Director, Office of Inspection and Enforcement, USNRC, Washington, D. C. 20555, with a copy to the Regional Administrator, USNRC, Region III, 799 Roosevelt Road, Glen Ellyn, IL 60137, within 30 days of the date of this Notice, a written statement or explanation in reply, including for each alleged violation: (1) admission or denial of the alleged violation; (2) the reasons for the violation, if admitted; (3) the corrective steps that have been taken and the results achieved; (4) the corrective steps that will be taken to avoid further violations; and (5) the date when full compliance will be achieved. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, Advanced Medical Systems, Inc. may pay the civil penalties in the amount of Six Thousand Two Hundred and Fifty Dollars or may protest imposition of the civil penalties in whole or in part by a written answer. Should Advanced Medical Systems, Inc. fail to answer within the time specified, the Director, Office of Inspection and Enforcement, will issue an order imposing the civil penalties in the amount proposed above. Should Advanced Medical Systems, Inc. elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, such answer may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the five factors contained in Section V.B of 10 CFR Part 2, Appendix C (1985) should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of Advanced Medical Systems, Inc. is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due, which has been subsequently determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282.

FOR THE NUCLEAR REGULATORY COMMISSION


James M. Taylor, Director
Office of Inspection and Enforcement

Dated at Bethesda, Maryland
this 28 day of June 1985