

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of

ADVANCED MEDICAL SYSTEMS, INC.
One Factory Row
Geneva, Ohio 44041

Docket No. 30-16055
License No. 34-19089-01
EA 85-60

ORDER MODIFYING LICENSE

I

Advanced Medical Systems, Inc., One Factory Row, Geneva, Ohio, 44041 (the "licensee") is the holder of byproduct material License No. 34-19089-01 issued by the Nuclear Regulatory Commission (the "NRC") pursuant to 10 CFR Part 30. The license authorizes, among other things, possession and use of 150,000 curies of cobalt-60 as solid metal for processing, for redistribution to authorized recipients, and research and development of sealed sources. This license was issued on November 2, 1979 and was due to expire on November 30, 1984. The license has continued in effect because the licensee submitted a timely renewal application which is currently being reviewed by the NRC.

II

The NRC conducted a special onsite safety inspection on February 21 and 22, 1985 in response to an apparent overexposure that the licensee reported to the NRC by letter dated January 24, 1985. The licensee provided additional information in letters dated April 17 and 25, 1985. The inspection also addressed telephone allegations received by the NRC Region III office on January 22, 1985. Four violations of NRC regulatory requirements and license conditions were identified. The violations which are described in the Notice of Violation and Proposed Imposition of Civil Penalties issued on this date

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involved: (1) a 2.9 rem whole body dose to an individual who entered the licensee's hot cell facility during the fourth quarter of 1984; (2) failure to read dosimeters at appropriate intervals to assure that actual doses did not exceed anticipated doses (a measure which the licensee had specifically proposed as corrective action following a previous overexposure); (3) failure to calibrate dosimeters at required intervals; and (4) failure to make such surveys as were necessary to adequately evaluate the radiation hazards incident to the use of radioactive materials in the licensee's hot cell facility. Specifically, the only surveys were made at the hot cell door and showed radiation levels of 17.5 R/hr and 18 R/hr. These surveys did not accurately reflect the 81 R/hr radiation levels inside the hot cell.

An Enforcement Conference was held on March 13, 1985, in the NRC Region III office between the licensee's Radiation Safety Officer (RSO) and the Region III staff. A Enforcement Conference was held by telephone on April 12, 1985 between the licensee's President, the RSO, and the NRC Region III staff. During the conferences the licensee agreed to take interim corrective actions until the radiation safety program could be upgraded. The conferences included a discussion of a previous similar overexposure that occurred during the fourth quarter of 1982 and resulted in the imposition of a \$4,000 civil penalty on July 13, 1983. The NRC Region III staff concluded that the licensee had not adequately implemented corrective actions to prevent another overexposure after the previous enforcement action. The licensee agreed to discontinue all entries into the hot cell facility until improvements, acceptable to the NRC Region III staff, had been made in the licensee's radiation

safety program. The NRC Region III office issued a Confirmation of Action letter, dated March 15, 1985, to document the NRC's understanding of the licensee's commitment. The licensee agreed to expand on these proposals and submit them in writing to the NRC Region III Administrator for review and approval.

By letters dated March 27 and April 4, 1985 and a telephone conversation on April 3, 1985, the licensee submitted proposed revisions to Procedure No. ISP-14, "Entering the Hot Cell." Based on this submittal and further conversations with licensee representatives, the licensee agreed that:

1. No individual shall enter the hot cell unless that individual has been adequately trained in accordance with Draft Procedure No. ISP-14, "Entering the Hot Cell," dated March 27, 1985.
2. No individual shall enter the hot cell without an alarming dosimeter. When an alarming dosimeter alarms, an individual shall immediately leave the hot cell, retreat to the Isotope Shop Area, and shall not reenter the cell until the exposure is assessed and a determination is made that reentry is allowable.
3. The in-cell monitor (Victoreen 500 electrometer with remote probe, Model 550-6A) that was calibrated by Victoreen and a new probe that was recently purchased will both be calibrated on a six month basis.
4. Each time the hot cell door is opened and before individuals are permitted to enter the hot cell a complete radiation survey of the hot cell will be performed remotely using a calibrated instrument and probe.

5. The RSO shall be physically present to supervise the operation and to verify that the hot cell entry operation is reasonably safe to prevent an overexposure.

The NRC Region III Staff has reviewed the licensee's submittal. To provide reasonable assurance that the potential for significant personnel exposure will be reduced and to ensure continued implementation of the licensee's commitments, I have determined that the public health, safety, and interest require the licensee's commitments be confirmed by an immediately effective Order.

III

Accordingly, pursuant to Sections 81 and 161b of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204, Parts 20 and 30, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, that:

The licensee shall implement the radiation safety program described in numbered paragraphs 1 through 5 of Section II of this Order.

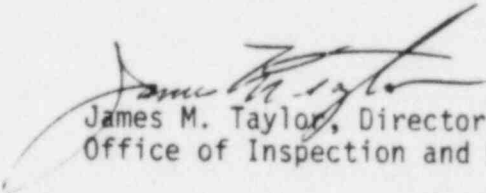
The Regional Administrator may relax or rescind any of the above conditions for good cause upon written application by the licensee.

IV

The licensee or any other person adversely affected by this Order may request a hearing on this Order within 25 days of the date of issuance of this Order. Any request for hearing shall be submitted to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D. C. 20555. Copies of any request shall also be sent to the Executive Legal Director at the same address and the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137. A REQUEST FOR HEARING SHALL NOT STAY THE EFFECTIVENESS OF THIS ORDER.

If a hearing is to be held, the Commission will issue an Order designating the time and place of hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION



James M. Taylor, Director
Office of Inspection and Enforcement

Dated at Bethesda, Maryland
this 28 day of June 1985