UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

DCS

December 27, 1989

Docket No. 030-16055
License No. 34-19089-01
EA 89-86

Advanced Medical Systems, Inc.
ATTN: Seymour S. Stein, Ph.D
1020 London Road
Cleveland, OH 44110

Gentlemen:

SUBJECT: NOTICE OF VIOLATION

This refers to the NRC inspection conducted on October 10, 1986 through March 4, 1987, at Advanced Medical Systems, Inc. (AMS) in Cleveland, Ohio, to review problems associated with the installation and servicing of teletherapy machines and related components. During the inspection, a violation of NRC requirements was identified. The inspection report addressing these matters was sent to you on January 26, 1989.

This also refers to the investigation conducted by the NRC Region III Office of Investigations (OI). The investigation, which was conducted during the period October 15, 1986 through March 10, 1989, included, among other things, 1) a review of the circumstances that led to your failure to make the notification and report described in 10 CFR 21.21(b) regarding significant defects in Sodeco timers which you routinely installed and serviced on cobalt-60 teletherapy units used by your customers for medical treatment of humans, and 2) a review of the circumstances surrounding the preparation and submission to NRC of Service Report No. 1959 which addressed work performed by AMS at the Eastside Radiology Imaging and Therapy Center in Willoughby Hills, Ohio. These matters are addressed in the investigation report that was sent to you on November 7, 1989.

On September 18, 1989, an enforcement conference was conducted in the NRC Region III office with Ms. Sherry Stein, Director of Regulatory Affairs, AMS, and Ms. J. G. Aldrich, Attorney for AMS, to discuss, among other things, the significance and extent of the potential violations involving your failure to adopt procedures and make notifications required by 10 CFR 21.21, their causes, and your corrective steps to prevent recurrence. The enforcement conference report addressing these matters was sent to you on November 9, 1989.

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Your representatives maintained that you had established company procedures that address product defects and presented a copy of those procedures at the Enforcement Conference; however, those procedures do not fulfill the requirements of 10 CFR 21.21. Among other things, procedures established to fulfill the requirements of 10 CFR 21.21 must include provisions to assure that a director or responsible officer (as defined in 10 CFR 21.3) is informed if a component supplied for a licensed facility or activity contains a defect. Your representatives further maintained at the Enforcement Conference that the problems with the Sodeco timer were design characteristics and not defects. In our view, if AMS had had appropriate Part 21 procedures and had followed those procedures, these problems would have been evaluated and identified as defects, a responsible officer or director would have been notified, and he in turn would have made the required reports to NRC.

The following are examples of matters known to AMS that, under appropriate Part 21 procedures, should have been reported to NRC:

1. An AMS interoffice memorandum from Mike Baruffa to Ed Svigel, dated January 3, 1984, documents that the [Sodeco] Model RP112E timer has the ability to enable shutter operation [exposing the teletherapy source] with the timer set at 000.00 minutes.

   In its memorandum dated January 27, 1984, "Minutes of Safety Committee Meeting 1/25/84," AMS documented that it was aware that Sodeco timers allow the counter to function [exposing the teletherapy source] with the counter set at 000.00; and that it is standard operating procedure for C/12 [teletherapy unit] users to set the counter to 000.00 at the end of the day. The minutes further document concern that: "when a replacement [Sodeco] timer becomes necessary, this procedure will create a potential safety hazard."

2. In its memorandum dated September 13, 1983, "Minutes of Safety Committee Meeting 8/24/83," AMS described Incident 82-08, "Defective treatment timer," and stated that one of a lot of 10 timers installed in a teletherapy machine delivered to a customer was detected to be defective. The memorandum also states that eight of the 10 were further tested and several were found to be defective and were returned to the vendor for repairs. The memorandum further states that one of the 10 was installed at St. Catherine's Hospital, Kenosha WI, and that a follow up letter was sent to St. Catherine's.

   According to records, a Sodeco timer was installed at St. Catherine's on November 6, 1982.

The December 10, 1982 follow up letter from AMS to St. Catherine's Hospital states: "There exists the possibility that the treatment timer recently installed in your C/9 Cobalt teletherapy unit may malfunction and either continue counting down past zero or stop counting altogether, without signalling the source to return to the off position. This occurrence could result in the overexposure of the patient being treated."

3. In its memorandum dated April 16, 1984, "Minutes of Safety Meeting 4/11/84," AMS described Incident 84-05, which occurred at the VA Medical Center, Allen Park, Michigan, and noted that a patient was overexposed by a teletherapy machine due to a Sodeco timer failure which occurred when the timer jammed between 1.50 and 1.49 during countdown. The memorandum further stated that an AMS engineer responded and was able to repeat the failure by tapping the reset button during countdown. The memorandum then concludes, "this is true for all Sodeco units."

While your representatives maintained at the Enforcement Conference that this information was available to NRC inspectors, the reporting requirements of 10 CFR 21.21(b) were not fulfilled. The type of report required, the NRC offices to which the report must be sent, and the contents of the report are explicitly described in 10 CFR 21.21(b)(1) - (b)(3).

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1986) (Enforcement Policy), the violation described in the enclosed Notice has been classified as a Severity Level III problem because it contributed to your failure to make a required notification to NRC under 10 CFR Part 21. Since the failure to notify does not appear to have been the result of a knowing and conscious act by a director or responsible official as defined in 10 CFR 21.3, a civil penalty is not being proposed. However, you should be aware that this matter is of serious regulatory concern and that a recurrence will not be tolerated. More significant enforcement action, including modification, suspension, or revocation of your license, is available to NRC should related violations occur in the future.

The OI investigation also addressed the circumstances surrounding AMS' preparation and submission to NRC officials of Service Report No. 1959 which addressed work performed by AMS at the Eastside Radiology Imaging and Therapy Center in Willoughby Hills, Ohio. This report was submitted to NRC on December 23, 1986, and the OI investigation did not establish that the responsible AMS managers had knowledge of erroneous information in the report at that time. Under the circumstances of this case, we do not intend to issue a citation. Nevertheless, this is a serious matter. The NRC regulatory framework requires reasonable assurance that licensees will maintain and provide only complete and accurate information concerning licensed activities. In this and other regards, licensees are held accountable for the acts of their employees and contractors at all levels. On February 1, 1988, 10 CFR 30.9, "Completeness and Accuracy of Information," became effective.

This regulation codifies the requirement that information provided to the Commission by a licensee and NRC-required records be complete and accurate in all material respects.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. NRC Region III has reviewed the Part 21 procedures that you submitted by letter dated November 1, 1989. Those procedures are deficient in some respects. A letter describing the specific deficiencies will be sent to you under separate cover from Charles Norelius, Director, Division of Radiation Safety and Safeguards, NRC Region III. We encourage you to work closely with Mr. Norelius and his staff to resolve the deficiencies. You should then submit your revised procedures along with your response to the enclosed Notice. To accommodate this process, an additional 60 days has been added to the usual response time provided in the enclosed Notice. The Notice further provides that, where good cause is shown, consideration may be given to extending the response time. After reviewing your response to the Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Sincerely,

A Bert Davis

A. Bert Davis
Regional Administrator

Enclosures:
1. Notice of Violation
2. Inspection Report
   No. 030-16055/86001
3. Investigation Report Synopsis
   No. 3-86-010

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