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Advanced Medical Systems, Inc.
ATTN: Sherry J. Stein, Director
Regulatory Affairs
1020 London Road
Cleveland, OH 44110

EA 89-086
License No. 34-19089-01

Dear Ms. Stein:

This refers to the enforcement conference held in the Region III office on September 18, 1989, and responds to your May 17, 1989, September 22, 1989 and October 23, 1989 letters. The enclosed report documents the discussions between our respective organizations during the conference.

In your May 17, 1989 letter, you noted inaccuracies in the NRC Supplemental Inspection Report No. 030-16055/86001(DRSS) sent to you on January 26, 1989. We discussed these inaccuracies during the conference and NRC staff has determined that they are not significant and do not affect the results of the inspection. It was our understanding from the conference and your September 22, 1989 letter that you would provide us with additional examples of inaccuracies that you have identified in the Supplemental Report. Your October 23, 1989 letter, however, indicates that you will not provide this information because of the ongoing suspension proceeding. As we have stated on several occasions, and you have acknowledged in your letter dated May 17, 1989, matters related to the Sodeco timer and Inspection Report No. 030-16055/86001(DRSS) are not in litigation in that proceeding. Therefore, based on the examples provided during the enforcement conference and your failure to provide additional examples, we are proceeding to a decision on appropriate enforcement action.

In your September 22, 1989 letter, you indicate that NRC agreed at the conference to investigate:

1. Whether a safety risk existed with Sodeco timer use and whether the NRC exacerbated that safety risk by notifying only the end user;

2. Whether the NRC staff created a health and safety risk by mandating a retrofit timer;

3. Whether NRC inspectors who visited the AMS facility from 1982 to the present were negligent in failing to properly review AMS' procedures and records and whether their supervisors were also negligent; and

4. Why NRC inspectors failed to make note of any procedural deficiencies with respect to AMS' compliance with 10 CFR Part 21.

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Although we discussed these items during the conference, we did not agree to investigate them further. We have reviewed the staff's actions in light of NRC's policies and procedures and find no basis for concluding that the staff created health and safety risks in regard to timers nor for concluding the staff was negligent in reviewing procedures or records during inspection of AMS.

Your September 22, 1989 letter also raises a concern about Ms. B. J. Holt, currently an NRC Region III employee and formerly a private consultant with RAD Services, a contractor to AMS. You ask that the NRC investigate why Ms. Holt did not detect any alleged deficiencies in AMS' procedures during an audit of your radiation program in March of 1987. The audit was performed while Ms. Holt was under contract with AMS; she was not under contract or employed by the NRC. Since her audit activities were independent of NRC's review of your procedures, I find no basis for initiating such an investigation.

During the conference, you asserted that AMS did not have to make a report to the NRC pursuant to 10 CFR 21.21(b)(1) because AMS had actual knowledge that the Commission has been adequately informed of a defect. This assertion is based on the fact that the scope of the NRC inspections of AMS included minutes of the Radiation Safety Committee meetings. Reports of problems with the Sodeco timer were addressed in some of these minutes. An NRC inspection, however, involves a review of a representative sample of a licensee's records. Merely having records available for inspection does not mean that NRC inspectors will have reviewed particular records. Thus, there is no sound basis for your assertion that AMS did not have to make a report pursuant to Section 21.21(b)(1). This matter will be considered in determining what additional enforcement action is warranted.

You submitted procedures during the conference that you claim satisfy the requirements of 10 CFR Part 21. A copy of each of these procedures is enclosed. We have reviewed these procedures and have concluded that they do not meet the requirements of 10 CFR 21.21. In general, they do not:

1. Assure that an AMS director or responsible officer will be informed if a basic component supplied to customers by AMS contains a defect;

2. Specify or contain procedures for an AMS responsible officer to notify the Commission as specified in Section 21.21(b)(1); and

3. Contain procedures for indicating who will review the information and prepare and submit a written report as specified in Sections 21.21(b)(2) and (3).

This failure by AMS to have had Part 21 procedures will also be considered in determining what enforcement action is warranted.

Regarding future compliance with Part 21 we have received the procedures you submitted with your November 1, 1989 letter. We will review them and let you know whether they satisfy the requirements of Section 21.21.

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In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosed conference report will be placed in the NRC Public Document Room.

Sincerely,

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

Enclosure: Conference Report
No. 030-16055/89001(DRSS)

cc w/ltrs dtd 09/22/89,
10/23/89 and 05/17/89
w/enclosure:
DCD/DCB(RIDS)

bcc w/ltrs dtd 09/22/89,
10/23/89 and 05/17/89
w/enclosure:
J. Lieberman, OE
J. Goldberg, OGC
S. Lewis, OGC
R. Bernero, NMSS

RIII	OGC	RIII	RIII	RIII	RIII
Mallett/jl	Lewis	Berson	Grobe	Norelius	Paperiello
11/1/89	OK per Lewis 11/9/89	11/1/89	11-1-89	11/6/89	11/6/89