



# Advanced Medical Systems, Inc.

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DESIGNATED ORIGINAL

Certified By *J. L. ... Secretary*

September 22, 1989

Mr. Jack Grobe  
U.S. Nuclear Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellyn, IL 60137

RE: In the Matter of: Advanced Medical Systems, Inc.; Byproduct Material License No. 34-19089-01; Docket No. 30-16055-SP; EA-86-155; ASLEP No. 87-545-01-SP (Suspension Order)

Dear Mr. Grobe:

This will confirm several points raised during the Monday, September 18, 1989 Enforcement Conference attended by Mr. Papparillo, Mr. Norelius, Mr. McCann, Dr. Mallett, Attorney Lewis, Attorney Berson and yourself of the NRC and Attorney Aidrich and myself, wherein we presented evidence to dispute Sodeco impulse counter charges Numbers One and Three. All of these documents were either in your files or reviewed by NRC inspectors from 1979 on. These documents clearly outline incident reporting, incident evaluation, handling of defects, and handling of deviations. They are all in accordance with 10 CFR Part 21.

At the meeting, you confirmed the fact that no hospital, clinic or other customer of AMS filed a complaint or a 10 CFR Part 21 notice concerning the Sodeco pre-determining impulse counter utilized by AMS. The fact that the NRC failed to contact the manufacturer of the Sodeco counter for verification of any design characteristics as well as the NRC's failure to contact other service organizations concerning the NRC's view that the Sodeco was defective was also discussed. As agreed, it will be the responsibility of the NRC to investigate whether a safety risk existed and, if so, whether the NRC staff exacerbated that safety risk and created an additional health risk by notifying only the end user, the hospital and/or clinic, of the perceived defect.

As further agreed, the NRC will be responsible for investigating whether its staff created a health and safety risk by mandating as a retrofit timer, a timer which the NRC knew had approximately a fifteen percent (15%) failure rate and was not fully tested. As discussed, at least three (3) of these timers have failed, causing overexposures. Perhaps the NRC will explain, in writing, why it has taken the position that the Atom Mechanical timer contained a "design characteristic" whereas the AMS Sodeco was "defective".

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It was agreed that, if the NRC wishes to maintain its position that the Sodeco counter was defective, then the NRC will be responsible for investigating whether its inspectors who visited AMS from 1982 on were grossly negligent in failing to properly review AMS procedures, Isotope Committee Meeting Minutes, Safety Committee Meeting Minutes, and interoffice memoranda made available to them. In that case, proper investigation by these inspectors would have eliminated what the NRC considered to have been a health and safety risk. It is our hope that the NRC will also investigate the negligent supervision of these employees.

Similarly, the NRC will determine why their inspectors failed to properly review AMS' procedures and make note of any perceived deficiencies in our procedures with respect to 10 CFR Part 21, if it is your position that deficiencies existed. Further, as discussed with Attorney Lewis, Attorney Barson and Mr. McCann, at the December 23, 1986 Enforcement Conference attended by Mr. Axelson, Dr. Mallett and Mr. McCann, where the Sodeco counter was first discussed, 10 CFR Part 21.21 requirements were resolved at that time. See, T. Hebert letter of January 23, 1987. If it is determined that AMS procedures were deficient, why did the NRC management agree that this matter was resolved?

It must also be noted that B.J. Holt and Rodney Johnson of RAD Services, Inc. conducted an audit of AMS' Radiation Safety Program in March of 1987. With respect to records maintenance, it was stated in that report: "The RSO maintains a clear, legible set of records in the London Road Office." Because Ms. Holt is currently an NRC Region III employee, it is our hope that the matter of any alleged deficiencies in our procedures which were not detected by her as a RAD Services employee will be investigated. This report may also be found in your files.

Similarly, as set forth in our management plan, which is also contained in your files, the Isotope Committee meets quarterly and reviews field service reports involving Cobalt unit installation, dismantling and maintenance. These audit reviews are conducted primarily to conform to 10 CFR. As you are aware, special Isotope Committee meetings are held to review incidents occurring during the interim. It is demonstrated by the copies of letters forwarded to you concerning incidents of which AMS was aware, anytime AMS is aware of an incident which requires reporting pursuant to 10 CFR Part 21, a report is made regardless of who the service organization is.

Also, with respect to your questions concerning what Mr. Irwin was thinking at the time his deposition was taken and what he was able to recall in that deposition in 1986, it was agreed that had the NRC had questions about certain documents, Mr. Irwin should have been asked about those documents at that time. It continues to be our position that AMS should not be required to answer three-year-old questions that proper investigation by NRC investigators would have resolved. Again, AMS is not responsible for the failure of the NRC management. This continued harassment is unwarranted. Neither Mr. Irwin nor anyone else at AMS should be made to bear the brunt of an attempt to cover up negligence on the part of the NRC.

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Finally, this will confirm that Mr. Ed Svigel who, due to illness, was unable to attend the September 18, 1989 meeting, has been hospitalized for a gall bladder operation. Upon his recovery, I will again provide you with answers to the following questions:

- 1) Factual errors contained in Inspection Report No. 030-16055/86-001 (DRSS);
- 2) Whether operator error could cause the Sodeco counter to go from 000.00 to 999.99;
- 3) Whether the counters that were improperly manufactured duplicated the 000.00 to 999.99 problem, or contained another problem;
- 4) Whether the counters that were improperly manufactured stopped counting altogether, and whether this was the same problem which was manifest in the Ball Memorial Hospital and St. Catharine's Hospital problems;
- 5) Whether the Sodeco counter only opens at 000.00 when manually set or whether it could be opened if reset by the reset button or manually? (i.e., what is the purpose of the reset button?)

It is, of course, still our position that these technical issues were resolved in 1986.

Sincerely,



SHERRY J. STEIN  
Director of Regulatory Affairs

EJS/mz

cc: Service List