



Advanced Medical Systems, Inc.

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October 23, 1989

Mr. Jack Grobe
USNRC, Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: In the Matter of:
ADVANCED MEDICAL SYSTEMS, INC.
By Product Material License No. 34-19089-01
Docket No. 30-16055-SP; EA-86-155; ASLBP No. 87-545-01-SP
Suspension Order

Dear Mr. Grobe:

This letter will serve as an update to you from my September 22, 1989, letter. Our Engineering Manager, Mr. Ed Svigel has returned on a part-time basis following his hospitalization for a gallbladder operation and has provided me with the following information:

1. Factual errors contained in Inspection Report #030-16055 (86-001 DRSS).

Some of this information has been previously provided to Mr. Norelius. Because we are in the midst of litigation, any additional information may be obtained by the NRC Staff through normal discovery channels.

2. Whether operator error could cause the Sodeco Counter to go from 000.00 to 999.99.

Mr. Svigel and his staff believe that the teletherapy operator could set the Sodeco Impulse Counter to 000.00 and start treatment. However, this would happen only if the operator failed to follow the written instructions for the proper use of the counter. Since no treatment time is 000.00, the operator would deliberately have to set the counter to 000.00 to cause this improper use of the counter.

3. Whether the counters that were "improperly manufactured" duplicated the 000.00 to 999.99 problem, or contained another problem.

Mr. Svigel and his staff have indicated that AMS has no way of knowing if any Sodeco impulse counters were "improperly manufactured". The rejected counters did not pass our incoming quality control inspection. Another problem per the material disposition report, number I.D. 3560, references a jamming during reset and non-stop counting after time out.

Again, the 000.00 to 999.99 counting when set to 000.00 is a design characteristic of the counter, not a defect.

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4. Whether the counters that were "improperly manufactured" stopped counting altogether, and whether this was the same problem which was manifest in Ball Memorial Hospital's and St. Catherine's Hospital's problems.

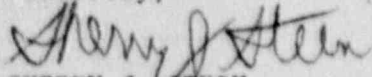
Mr. Svigel and his staff again indicated that AMS had no way of knowing whether the rejected counters were improperly manufactured. The rejected counters only stopped counting when they were "jammed", usually at resets. Pulses were still there, but the unit did not index. The counters at Ball Memorial and St. Catherine's Hospitals had a headswitch position problem, which was totally different.

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. [i.e., what is the purpose of the reset button?].

Mr. Svigel and his staff have indicated that yes, the Counter will operate when manually set to 000.00. They have also indicated that the reset button serves two (2) functions: (A) when pressed it returns the counter to the previously entered number; (B) when continuously depressed, it allows selection of a new time.

Although it remains our position that these technical issues were resolved in 1986, I hope this additional information satisfies your inquiries. Should you have any additional questions, please do not hesitate to contact me.

Sincerely,



SHERRY J. STEIN
Director, Regulatory Affairs

SJS/cjc

cc: Seymour S. Stein, Ph.D., P.E.
Administrative Judge Robert M. Lazo
Administrative Judge Ernest E. Hill
Administrative Judge Harry Foreman
Director, Office of Enforcement
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