DCB

JAN 05 1990

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

License No. 34-19089-01
EA No. 89-86

Dear Ms. Stein:

This refers to your November 1, 1989 letter, which forwarded a copy of Advanced Medical System's (AMS) newly established 10 CFR Part 21 procedures. As indicated in our December 27, 1989 letter to AMS, we have reviewed the procedures and conclude that they are not adequate to fulfill all the requirements of Section 21.21 of 10 CFR Part 21. The procedures should be modified and resubmitted to include the following provisions:

1. A description of the process for evaluating deviations to determine if a defect or failure to comply exists, or informing the licensee or purchaser of the deviation. The description should include who will perform the evaluation and the items considered.

2. A description of the process for assuring that a director or responsible officer is informed if it is determined that an activity or component failure is a reportable defect or failure to comply. The description should include the name (or position title) of the director or responsible officer.

If you have any questions regarding this matter, please contact Bruce Mallett or George McCann of my staff at (708) 790-5500.

Sincerely,

ORIGINAL SIGNED BY C. E. NORELIUS

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

cc w/ltr dtd 11/01/89:
S. S. Stein, AMS
DCD/DCB (RIDS)

bcc w/ltr dtd 11/01/89:
J. Lieberman, OE
J. Goldberg, OGC
R. Bernero, NMSS

IE07
1/1

RIII	NMSS	RIII	RIII	RIII	RIII
McCann/jl	Glenn	Grobe	Berson	Mallett	Norelius
01/5/90	per phone 1/3/90	1/5	1/5	01/5/90	1/5/90

9001300162 900105
REG3 LIC30
34-19089-01 PDC