

Advanced Medical Systems, Inc.

Devenchi

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 FAX (216) 466-0186

May 19, 1994

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

ATTN: Mr. C. E. Norelius, Director
Division of Radiation Safety and Safeguards

RE: Response to a Notice of Violation
Advanced Medical Systems, Inc.
London Road Facility
Docket No. 030-16055
License No. 34-19089-01

Dear Mr. Norelius:

Advanced Medical Systems, Inc. respectfully submits the following reply to the Notice of Violation dated April 20, 1994. Also included are our plans to improve program oversight, particularly our plans to maintain occupational doses within regulatory limits. If you have any questions or need further clarification, please feel free to contact us.

I. RESPONSE TO NOTICE OF VIOLATION REGARDING FIVE OCCUPATIONAL EXPOSURES IN EXCESS OF 20.101(A) LIMITS DURING THE FOURTH QUARTER OF 1993:

(A) Reason for the Violation:

It appears several contributing factors resulted in the five contract workers exceeding the quarterly whole body limit specified in 20.101(a). Specifically, AMS failed to verify that contractor supplied Form NRC-4 information satisfied 10 CFR 20.101(b) and 20.201(b) requirements, and erroneously assumed that the applicable regulatory whole body dose limit for each contract worker was 3 rem for the fourth quarter of 1993.

(B) Corrective Actions Taken and Results Achieved:

Since the quarterly whole body limit specified in 10 CFR 20.101(a) has been eliminated in the new 10 CFR Part 20, no corrective actions are necessary.

(C) Corrective Steps to Avoid Further Violations:

Again, since the quarterly whole body limit has been eliminated, no corrective steps to avoid further violations are necessary.

AMS will address its plans to improve program oversight, particularly in the area of maintaining occupational doses within regulatory limits, later in this response.

9406080038 940531
PDR ADOCK 03016055
C PDR

MAY 20 1994

U.S. Nuclear Regulatory Commission
Mr. C. E. Norelius, Director
May 19, 1994

2. RESPONSE TO NOTICE OF VIOLATION REGARDING FAILURE OF A CONTRACT WORKER TO WEAR REQUIRED TLD/FILM BADGE PER LICENSE CONDITION NO. 19 REQUIREMENT:

(A) Reason for Violation:

Three events contributed to this violation of License Condition No. 19: (1) Failure of the worker to wear his assigned whole body dosimetry device; (2) inadequate contractor supervision of its personnel; and (3) inadequate RSO supervision of daily activities. Specifically when, on the afternoon of October 7, 1993, a contract worker entered the hot cell without his assigned whole body TLD and both the contract supervisor and AMS' RSO failed to notice this discrepancy.

(B) Corrective Actions Taken and Results Achieved:

At present no contract workers have been or will be permitted to enter the controlled areas of the London Road facility until the conditions outlined in response (C) to this violation have been met.

Currently, the only personnel allowed entrance to the London Road facility's restricted areas are the current AMS RSO and a part-time Isotope Handler, who has been employed at the London Road facility since 1991. Both are well acquainted with the dosimetry requirements of ISP-1 Chapter 3 and good health physics practices. These individuals enter the controlled areas under extended Radiation Work Permits (RWP) to conduct routine surveys and perform equipment checks and/or maintenance.

(C) Corrective Steps to Avoid Further Violations:

The RSO, or the RSO's designee, will visually inspect each individual before entering a controlled area on a job-specific RWP. If the individual lacks the proper dosimetry device(s) specified on the job-specific RWP, entry will be denied until the devices are donned.

A form (Attachment A) documenting the visual inspection will be filed with all job-specific RWPs and include: (1) the job-specific RWP number; (2) the date of entry into the controlled area; (3) the name(s) of the individual(s) entering the controlled area; (4) the dosimetry device(s) required on the job-specific RWP; and (5) the initials of the individual conducting the visual inspection.

U.S. Nuclear Regulatory Commission
Mr. C. E. Norelius, Director
May 19, 1994

(D) Date When Full Compliance Will be Achieved:

The visual inspection and documentation, as stated above, are in effect as of the date of this response. AMS is currently revising its ISP manual. The dosimetry checklist will be included as part of the revision.

3. RESPONSE TO A NOTICE OF VIOLATION REGARDING FAILURE TO SET ALARMING DOSIMETER SETPOINTS PER LICENSE CONDITION NO. 19:

(A) Reason For the Violation:

This violation stemmed from the licensee's erroneous assumption that the alarming dosimeter threshold, dictated by ISP-14, could be altered without amending License Condition No. 19.

(B) Corrective Actions Taken and Results Achieved:

No cell entry has been made since the date of issuance of this Notice of Violation. All cell entries will follow the protocol outlined in ISP-14 until the proposed amendment to License Condition No. 19 described in response (C) to this violation is in effect.

(C) Corrective Steps Taken to Avoid Further Violations:

AMS proposes to amend ITEM 5.1.5 of ISP-14 to reflect the occupational whole body dose limit specified in 20.1201(a)(1)(i). The proposed change will read "individual alarming dosimeters will be set to alarm at an accumulated dose equal to (the administrative dose minus the accrued TEDE for the year). The administrative dose shall always be set equal to or less than 4.25 rem". This will provide a 0.75 rem margin for worker dose uncertainty.

(D) Date When Full Compliance Will be Achieved:

AMS is presently in full compliance. The proposed change to ISP-14 will not take effect until License Condition Number 19 is amended.

U.S. Nuclear Regulatory Commission
Mr. C. E. Norelius, Director
May 19, 1994

4. RESPONSE TO NOTICE OF VIOLATION REGARDING FAILURE TO FILE REQUIRED REPORTS UNDER 20.405(A).

(A) Reason For the Violation:

AMS was first advised of the four additional exposures in excess of 20.101(a) limits on Friday, February 25, 1994. One week later, March 4, 1994, the former RSO terminated employment with AMS. The present RSO began employment April 18, 1994. These circumstances led to the failure of AMS to file the required reports within the 20.405(a) time frame.

(B) Corrective Actions Taken and Results Achieved:

AMS is currently in the process of reviewing the circumstances and exposure data associated with the four exposures in excess of 20.101(a) limits and in non-compliance with 20.405(a). These reports will be forwarded to NRC within sixty (60) days.

(C) Corrective Steps Taken to Achieve Avoid Further Violations:

None required.

(D) Date When Full Compliance Will be Achieved:

Within sixty (60) days of the date of this response.

5. AMS' PLANS TO MAINTAIN OCCUPATIONAL DOSES WITHIN REGULATORY LIMITS:


AMS is currently in the process of revising its Isotope Shop Procedures (ISP Manual). The proposed changes will reflect AMS' commitment to maintain occupational doses within regulatory limits. Examples of the proposed changes can be found in the responses (2) and (3).

The 4.25 rem administrative dose limit will be extended to include all projects involving the issuance of a job-specific RWP. This will involve amending Chapter 3 of ISP-1.

When the revisions to the ISP are completed, they will be submitted to NRC as an amendment to the license.

AMS is also considering computerizing occupational exposure data to facilitate timely review.

Respectfully,


Joseph J. Michuta
Radiation Safety Officer

JJM:jmb
Enclosure

