

April 10, 1987

U.S. Department of Justice
General Litigation and
Legal Advice Section
ATTN: Marty Carlson
Attorney
Bond Building
1400 New York Ave., NW
Room 6124
Washington, DC 20530

Dear Mr. Carlson:

In response to your request regarding Advanced Medical Systems, Inc. (AMS), I have attached the following:

1. A list of service activities performed by unauthorized and unqualified AMS employees is attached. Those activities identified by an asterisk (*) reflect incidents which fall outside of AMS' own definition of what is allowable under their license. Their assertion is that unlicensed service personnel can perform licenseable activity if they are in the presence of a technologist or someone who ordinarily operates the cobalt teletherapy unit. However, their assertion is not supported by their license requirements. Ten of 16 documented incidents are outside of AMS' own definition. (Attachment 1)
2. A routine unannounced safety inspection conducted at AMS by J. R. Mullauer, Radiation Specialist, Region III (RIII), on March 1-3, 1983, and issued on May 5, 1983, revealed in part the following:
(a) body exposure (overexposure) of an individual; (2) failure to follow procedures while working in a high dose area; and (3) failure to wear required radiation detection devices in radiation fields. (Attachment 2)

As a result of the findings of the inspection, AMS was assessed a civil penalty in the amount of \$4,000.00. (Attachment 2)

On June 1, 1983, AMS filed a letter protesting the assessed civil penalty. Their stated position was that the employee action giving rise to the findings and subsequent civil penalty were intolerable to AMS and in violation of AMS' stated policy. As a result, AMS instituted measures to insure that its stated policy is understood by its employees and to insure that such an incident does not recur. (Attachment 3)

AMS' stated action was to suspend without pay the employees involved and to generate, clarify, etc., new radiation safety procedures and submit said changes to the NRC as an amendment to their license.

On June 22, 1983, the NRC upheld the \$4,000.00 civil penalty stated that AMS' reasons why the civil penalty should not be imposed were insufficient. (Attachment 4)

9404130366 940614
PDR FOIA
WENDLING93-236 PDR

A/B

Regarding Howard Irwin, he is at the time of this action in the position of Corporate Compliance Officer (page 3 of the inspection report).

3. On August 10, 1984, AMS submitted information to the NRC, signed by Howard Irwin, regarding AMS' "Cobalt Teletherapy Training Course." Howard Irwin is named as an instructor in the training course and is referred to as the Manager of "Regulatory Affairs," whose topic of instruction is "Radiation Theory, Federal and State Regulations." (Attachment 5)
4. On August 29, 1984, the results of a routine safety inspection conducted by T. S. Simmons and J. R. Mullauer on July 16-17, 1984, documented NRC concern over the condition of the "hot cell" at the London Road facility and the "reduction in the number of adequately trained personnel." (Attachment 6)

The persons contacted (page 2 of the inspection report) indicate Howard Irwin's presence at the exit meeting. Paragraph 7 on page 3 of said report addresses the procedures in place at AMS to protect personnel from external contamination/overexposure. The report specifically addresses that "past exposure histories (NRC Form-4) have been prepared and are updated quarterly for all personnel involved in the source fabrication, exchange and loading program. Therefore, personnel are permitted to receive whole body exposures of up to three (3) rem per quarter."

The above reference to AMS' NRC Form-4 policy would appear to contradict Howard Irwin's professed puzzlement (in Case No. 3-85-015) concerning how the regulation affects "volunteers" going into the hot cell.

5. The Isotope Committee meeting minutes obtained from AMS on October 10, 1986 (the day of the NRC revocation of AMS' service license), has been reviewed and copies are attached. (Attachment 7)

The minutes in NRC's possession are dated October 20, 1981, through April 14, 1986. Dr. Stein is always a member. Irwin is on distribution until he shows up regularly as recorder of the minutes on September 4, 1984.

The following minutes reflect Quarterly Exposure Reports which indicate "readings exceeding action levels" (an administrative level which would alert the company may be approaching regulatory limits). All of these reports were recorded by Howard Irwin.

- (a) August 10, 1984
- (b) December 14, 1984
- (c) April 1, 1985
- (d) June 28, 1985
- (e) August 8, 1985
- (f) March 11, 1985

April 10, 1987

Minutes dated November 18, 1985, reflect exposures down considerably, apparently because no "hot cell" entries were made during this period.

6. Regarding the service license requirement under which AMS' operates, the following documents are presented:
- (a) License No. 34-19089-02 dated July 9, 1980, through July 31, 1985 (they have been operating on a month by month license since expiration of the license on July 31, 1985), paragraph 14 states, "except as specifically provided otherwise, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated November 15, 1979 and letter dated March 10, 1980." (Attachment 8)
 - (b) Under cover letter dated November 16, 1979, is the November 15, 1979, "Application for Byproduct Material License" signed by N. Kelbley. In paragraph 6, schedule "B," it is stated by AMS that "all work requiring a specific license which does not involve removal of a sealed source from its shielded container but does include operation of our exposure device, will be performed by persons formally approved to do so by the AMS Isotope Committee." (Attachment 9)
 - (c) The March 10, 1980 letter referred to by the AMS license on page 9 states (Attachment 10):

"The following operations must be performed only by a person certified on the license."

- (1) Contamination checks
- (2) Waste disposal
- (3) Emergency closing of a stuck shutter
- (4) Surveys
- (5) Collimator removal and installation
- (6) Head installation or removal
- (7) Shutter service and cleaning
- (8) Shutter bearing lubrication
- (9) Unit tests and demonstration

The above described license requirements were violated on numerous occasions by AMS. This will be detailed in the Case No. 3-86-010 currently being written.

7. The AMS license file has been reviewed and material bearing directly on the findings in this investigation have been identified and placed in a secure area.
8. I have also provided in the attachments to this letter the following documents:

April 10, 1987

- (a) the "AMS Factory Training Course" describes licensed operations on page 9, paragraph 4, which states, "licensed operations include work involving the source or parts of the unit which could result in increased exposure to the source." (Attachment 11)

The above cited paragraph is very specific regarding work requiring a license.

9. I have provided for your information an NRC review of AMS as presented at a meeting regarding AMS' inspection history. (Attachment 12)
10. For background purposes, I am providing you with a copy of AMS' License No. 34-19089-01, which allows them to conduct any activity associated with the cobalt teletherapy machine. License No. 34-19089-02 is service license only. These two licenses have since been combined under License No. 34-19089-01 as of June 25, 1985. (Attachment 13)

If there are any further questions, please do not hesitate in contacting me.

Sincerely,

Harold G. Walker
Senior Investigator
Office of Investigations
Field Office, Region III

Attachments:

1. List of Service Activities
2. Safety Inspection of 03/01-03/83
dtd 05/05/83
3. AMS Response to Attachment 2
dtd 06/01/83
4. NRC Response to AMS dtd 06/22/83
5. AMS ltr to NRC dtd 08/10/84
6. Safety inspection of 07/16-17/84
dtd 08/29/84
7. Isotope Committee minutes
dtd 10/20/81 - 04/14/86
8. License No. 34-19089-02
9. 11/16/79 correspondence
containing 11/15/79 ltr
10. Ltr dtd 03/10/80
11. AMS' Factory Training Course
12. AMS Inspection History
13. License No. 34-19089-01
dtd 11/02/79

Distribution: c/f, ~~3-86-010~~

01
HWalker:nh
04/10/87