

9347



UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

RELATED CORRESPONDENCE

DOCKETED

October 18, 1989

'89 OCT 23 P3:09

Sherry J. Stein, Esq.
131 North Eagle Street
Geneva, OH 44041

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

Dear Ms. Stein:

Your letter dated October 6, 1989 regarding the documents Ms. Aldrich and you requested during your review of the AMS license file was received in Region III on October 12, 1989. As indicated in my September 27, 1989 letter to you, only documents relevant to your interrogatories and the issues in this proceeding were provided. With the exception of the March 9, 1987 letter from the Department of Justice to NRC, the documents not produced were withheld because they are not relevant. The Department of Justice letter was not provided because I understand it is already part of the record of this proceeding. However, after further review, three additional documents you requested appear to be relevant to the proceeding and are enclosed. These pertain to the Notice of Violation issued to AMS by the State of Mississippi in October, 1986.

You may wish to file a Freedom of Information Act request for the remaining documents. I assume you can determine which documents you are interested in by comparing the list you prepared while in Region III with the documents provided. I am enclosing a copy of the list in the event you misplaced it.

Please contact Colleen Woodhead or Mitzi Young if you wish to discuss this matter further.

Sincerely,

Bruce A. Berson

Bruce A. Berson
Regional Counsel

Enclosures: As stated

cc w/enclosures:
Service List

8910310124 891018
NMSS LIC30
34-19089-01 PDR

DS07



Mississippi State Department of Health

P.O. Box 1700 - 2428 North State Street
Jackson, Mississippi 39205
601/354-6618

Alton B. Cobb, M.D., M.P.H.
State Health Officer

October 1, 1986

Mr. S. S. Stein, President
Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio 44110

Dear Mr. Stein:

This letter is to serve as "Official Notice of Violation" concerning your activities authorized under reciprocal recognition of U.S. NRC License No. 36-19089-01. This notice regards work performed at the Oxford-Lafayette County Hospital, Oxford, Mississippi, on August 14 and 15, 1986.

Certain aspects of these activities appeared to be in a state of noncompliance with conditions of Radioactive Material License No. 36-19089-01, Advanced Medical Systems, Inc. Operating Procedures, and the Mississippi State Board of Health Environmental Regulations, Part 801-Radiation.

1. Section 801.D.203(f)(1) of the Mississippi State Board of Health Environmental Regulations states in part that each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above, the authorized personnel responsible for source exchange unknowingly failed to exchange the old teletherapy source during the source exchange procedure. However, the teletherapy head was labeled with the new source information following the final survey. This item is classified as a violation.

2. Section 801.C.100(a)(1) of the Mississippi State Board of Health Environmental Regulations states in part that no licensee shall deliver any radioactive material for transport unless the licensee complies with the applicable requirements of the U.S. Department of Transportation Regulations regarding packing, monitoring, labeling and marking.

Contrary to the above, after unknowingly failing to exchange the old teletherapy source, authorized personnel transported the shipping cask (containing two new teletherapy sources) to a second job site in Tennessee. The actual curie content of the shipping cask must therefore have greatly exceeded the curie content required on the D.O.T. shipping labels. This item is classified as a violation.

Mr. S. S. Stein, President
October 1, 1985
Page 2

In addition to the above, the following items were noted by the hospital personnel during the source exchange:

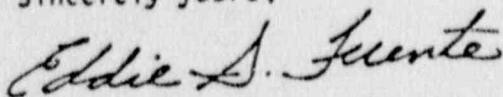
1. Advanced Medical Systems' (AMS) survey meter was inoperable prior to beginning work. Your personnel attempted to borrow the hospital's survey meter which was not suitable for their purposes. Finally a hospital employee managed to locate spare batteries for the AMS survey meter.
2. A five year maintenance check failed to note a problem with the drive motor for the teletherapy head rotation. The unit was supposedly rotated during the survey that followed the second source exchange by your personnel. However, immediately following the source exchange, the hospital's consultant found the head rotation to be inoperable. The problem with the drive motor had been particularly stressed by the hospital representatives prior to the source exchange and servicing.
3. At the conclusion of the second source exchange, one of the AMS representatives expressed an interest in exactly how thorough the hospital's consultant is regarding unit survey and calibrations. This Agency finds such remarks both curious and distressing. Any doubts concerning either the survey of the teletherapy unit or the services of the consultant should be addressed to this Agency.

This Agency finds an error of this magnitude and the circumstances surrounding this incident very disturbing. In the very least, it would appear that an investigation by the licensee and subsequent retraining of personnel is in order. At the very most, it would appear that the AMS radiation safety program and procedures should be reviewed by the licensing Agency.

Please respond to the above cited items within ten (10) days of your receipt of this Notice. Upon determination that a violation did in fact exist, please state in your response the corrective steps that have been taken by you and the results achieved, corrective steps that will be taken, and the date when full compliance is achieved. If, in your judgement, a violation did not in fact exist, describe the circumstances whereby the cited item was not a violation including producing those records substantiating such claim.

If you should have any questions or comments, please contact this agency.

Sincerely yours,



Eddie S. Fuente, Director
Division of Radiological Health

ESF:0226K:2

cc: U. S. Nuclear Regulatory Commission
Region III Offices



Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 456-4677 FAX 810-4272-183

October 16, 1986

OCT 20 1986

VIA EXPRESS MAIL

RADIOLOGICAL HEALTH

Mr. Eddie S. Fuente, Director
Division of Radiological Health
Mississippi State Department of Health
P.O. Box 1700
2423 North State Street
Jackson, Mississippi 39205

Dear Mr. Fuente:

Mr. Ed Svigel, Chief of AMS Engineering, and Mr. Theodor Hebert, Manager of Facilities and Operations, conducted a thorough in-house investigation and interview of Mr. Keith Jordan, AMS Service Engineer, regarding the Oxford Lafayette County Hospital, Mississippi August 14 and 15, 1986 source exchange. We find that Mr. Jordan, while conducting the source exchange, did remove the source from the teletherapy unit. Having conducted the prescribed preventative maintenance, he then proceeded with the installation of the new teletherapy source. However, as noted by Mr. Jordan, he had difficulty with the procedures involved with the trapping and orientation of the new source within the exchange container. Through his efforts to reposition the sources, a disorientation occurred whereby the same source removed from the teletherapy head was inadvertently replaced within the head. The sources are identified; but when contained within the source exchange unit, observation of this identification number is impossible. They can be observed in the teletherapy unit head, but only at the risk of exposure. Source exchanges are normally verified by meter readings taken at the top of the teletherapy head. Mr. Jordan indicated that he had moved the meter in its proximal location on the head. Our engineering staff indicated that they believe the change in location of the meter may have affected the readings. With sources such as this, meter reading changes of 5mR are significant to indicate that the exchange has been effective.

We have implemented the following as remedial action:

1. Service engineers will mark the exact position of the meter on the teletherapy head when taking readings to determine if an effective exchange has taken place. This procedure will immediately become part of the AMS standard operating procedure.

It should be noted that Mr. Jordan has conducted about 10 field source exchanges without error or procedural discrepancies. We feel that in this instance, he followed the AMS procedures manual exactly, even though a source disorientation did occur.

In response to your letter as Official Notice of Violation, we have enclosed the following information:

1. Section 801.D.203(f)(1). Mr. Jordan did affix the new labels to the teletherapy unit after conducting what he believed to be a source exchange. The final survey is not final conclusive evidence that a source transfer has taken place. The final conclusive evidence is always up to the hospital physicist who conducts the new source calibration within the teletherapy unit. Our serviceman affixes the labels for the new source when he finishes the transfer exchange. The hospital physicist confirms that the new source conforms to the new labels, often after AMS has left the job site.
2. Section 801.C.100(a)(1). Mr. Jordan did not knowingly or unknowingly transport two new teletherapy sources to a primary or secondary job site in a single shipping cask. The shipping cask and source exchange container are one and the same unit. Although other companies may utilize a single cask to ship two sources, our cask is specifically designed to carry only one source at a time and cannot be secured for transport with a two-source content. The only time two sources may be placed in this exchange unit is when it is physically in place for an exchange with a teletherapy unit.

The AMS shipping and exchange unit is approved to carry up to 13,680 curies. A combination of all of the sources involved in the Mississippi and Tennessee transfers would not have exceeded 13,680 curies. The fact remains that the new source for the Tennessee exchange was shipped in its own source exchange unit as was the Mississippi source.

Reference Your Letter, Page 2, Paragraph 1

The primary tool kit carried by the AMS service personnel weighs in excess of 60 pounds. Mr. Jordan had the option of returning to his temporary base of operations and procuring his secondary kit which contained spare batteries and spare meter, or the procurement of 4 D cell batteries (available in nearly every store in the U.S.) to fix the meter in his primary kit. Borrowing 4 D cell batteries from the hospital was not necessary, but did expedite the service.

Reference Your Letter, Page 2, Paragraph 2

Mr. Jordan stated that he had checked the head rotation for allowable angles and that the motor was operating properly. However, following the second and proper source exchange, the hospital representative rotated the head beyond the maximum allowable angles causing gear tooth damage within the motor. As an end result, AMS sent a new motor to the hospital which was installed by their personnel.

Reference Your Letter, Page 2, Paragraph 3

As a routine, AMS representatives always express an interest in exactly how thorough the hospital consultant is regarding unit survey and calibrations. AMS will not install a machine or cobalt source if it is not satisfied that the hospital is properly licensed and has adequate personnel to conduct the subsequent surveys and calibrations.

Mr. Eddie S. Fuente

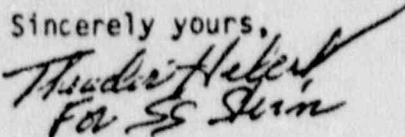
-3-

October 14, 1986

In our judgment, no violation of any regulatory compliance existed. In fact, we look upon the disorientation of sources and the inadvertent loading of the teletherapy unit with its old source as an inconvenience for both the hospital and ourselves, but nevertheless, a learning experience which directed our Engineering Department to further improve our standard operating procedures.

I have enclosed specific drawings and documents supporting the above facts. Should your office require additional information, please contact AMS.

Sincerely yours,



S.S. STEIN
President

SSS/mz
Enclosures

CERTIFIED MAIL #P185486105
RETURN RECEIPT REQUESTED



Mississippi State Department of Health

P.O. Box 1700 - 2423 North State Street
Jackson, Mississippi 39205
601/854-6612

Alton B. Cobb, M.D., M.P.H.
State Health Officer

October 24, 1986

Mr. S. S. Stein, President
Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio 44110

Dear Mr. Stein:

This Agency received your response to the Official Notice of Violation concerning the August 14 and 15, 1986, licensed activities authorized under reciprocal recognition of U.S. NRC Radioactive Material License No. 36-19089-01. It is noted that those actions which you have instituted toward correction appear to be satisfactory. Future inspections by this Agency will be utilized to determine the effectiveness of said corrections.

However, this Agency cannot agree with your position regarding the ultimate responsibility for verifying the sealed source exchange. Your company is licensed to conduct activities for which it bears the ultimate responsibility for performing the licensed activity safely and correctly. The consulting physicist is responsible for calibration after servicing and source exchange.

Our Agency must also take issue with your explanation regarding two shipping casks rather than one. Regardless of the number of casks involved, the undisputed fact remains that, during the trip into Tennessee, two casks possessed new sealed sources. In this case, assuming an old source in one cask, the cask had to be either unlabelled or labelled incorrectly. Both alternatives violate the U.S. DOT Regulations.

Thank you for your response.

Sincerely yours,

Eddie S. Fuente

Eddie S. Fuente, Director
Division of Radiological Health

ESF/bkf

Mississippi State Health Department

DEC 31 1986

FILE A

- ✓ 1. Qualifications for the Radiation Safety Officer Genl.
7 pages book
- ✓ 2. Semi Annual Independent Audit - Dec 27, 1988
by Joseph M. Harman - 7 pages

FILE C

- ✓ 1. D.S. Schemanski letter - Dec 6, 1984 13 pages
plus inspection report
- ✓ 2. Nature of Violation - Appendix - Aug 9, 1984
13 pages
- ✓ 3. PICKER International Letter - Oct 22, 1982
2 pages
- ✓ 4. NRC letter May 5, 1983 - inspection & fine
7 pages
- ✓ 5. Feb 19, 1982 - to AMS - Inspection &
Report 8 pages
- ✓ 6. ~~May 1982~~ ^{Sept 29, 1980} - to AMS - 10 pages (inspection)
- ✓ 7. Sept 12, 1984 to Maurine Moriarty, FOIAS
2 pages
- ✓ 8. Dec 21, 1984 letter & list from James D. Koppeler
3 pages
- ✓ 9. Conversation Record March 26, 1984 2 pages
- ✓ 10. AMS letter from Howard Cleving August 10, 1984
4 pages

FILE C. CONTINUED

- ✓ 11. June 22, 1984 AAS letter by Mandelstein 1 page
- ✓ 12. 2. Communication Records 1/22/83 & 7/4/83 2 pages
- ✓ 13. Communication Record 3/9/83
- ✓ 14. p 242 ^{THROUGH} 246 functions to be performed by licensed personnel only 5 pages
- ✓ 15. 249 - 250 functions to be performed by licensed personnel 2 p.

WORK
1/85-2/86

"B"

3419085-01 "B"
1/85-12/86

started together

- ✓ Dec 16 86 memo ~~Bill~~ Billing 1 pg
- ✓ Dec 16 86 memo Hand 3 pg
- ✓ Dec 4 86 memo Burgin 12 pgs
- ✓ Dec 11 86 Mallett - Albert conversation record 1 pg
- ✓ Oct 24 86 Mississippi State Dept Health 1 pg
- ✓ Oct 16 86 letter to "Mansapi" 3 pgs
- ✓ Oct 1 86 letter from Mississippi Dept Health 2 pgs
- ✓ Oct 22 86 Bruce Mallett note to "Bill" 1 pg (initials)
- ✓ Oct 10 86 Bruce Mallett conversation record 1 pg
- Oct 10 86 Mallett conversation record - UN Bronx 1 pg
- Oct 10 86 Mallett conversation record VA Eastmore 1 pg
- Oct 10 86? Mallett conversation record - UN Central 1 pg
- Oct 10/14/86 Mallett conversation record OSP 1 pg
- Oct 10 86 Mallett conversation record UN all parts 1 pg
- Oct 10 86 Mallett conversation record outside 1 pg
- Oct 10 86 Mallett conversation record Ball Memorial 1 pg
- Oct 10 86 Mallett conversation record VA Eastmore 1 pg
- Oct 10 86 Mallett conversation record UN Bronx 1 pg
- Oct B 86 Mallett event notes within attached Ball Memorial 1 pg
- Oct 17 86 conversation Mallett in front 1 pg
- Oct 21 86 conversation record Red therapy Ball Memorial 1 pg
- Oct 22 86 Ball Memorial conversation record 1 pg
- Oct 22 86 Ball Memorial conversation record 1 pg
- Oct 22 86 E J Memorial conversation record 1 pg
- ✓ Home written notes white note pad front + back

341989-01 "B"
1/85-12/86

~~Letter of license: Malta Feb 20 86 1 pg~~
~~Jan 21 86 letter from Andy 4 pgs~~
~~Oct 14 85 Oak Ridge letter 6 pgs~~
~~Apr 31 85 re: letter from the 2885 4 pgs~~
~~Nov 4 85 letter to Keppeler 2 pgs 1 PG. + 3/27~~
~~Mar 13 85 Notice of syn agreement between me & 1 pg~~
~~Feb 28 85 letter to Toye summons 2 pgs~~
~~Jan 29 85 letter 5 pgs~~

~~License + related pgs 60 pgs~~

SHIPPED
TOGETHER

~~Sept 10 86 letter re: beam 14 pgs~~
~~Apr 15 86 letter to Alan 1 pg~~
~~July 15 86 letter 4 pgs~~
~~July 23 86 letter 1 pg~~
~~June 13 86 letter to Keppeler 20 pgs~~
~~June 3 86 letter 10 pgs~~
~~June 5 86 letter 1 pg~~
~~Conversations re: beam BU/TUT/AT 1 pg~~
~~May 30 86 McCann conversation re: beam 1 pg~~

Tranny file \emptyset
Hightal release Tranny \emptyset
Pleasurp \emptyset

Readup - Document :: 9/10/87-9/89 \emptyset
~~10/86-9/4/89~~ ✓ 10/30/87 letter Lantz 1 pg
✓ 1/9/87 letter to Murray from Benjamin 3 pgs
✓ 1/21/87 conversation record Kelly-Mallett 2 pgs
✓ 1/5/87 conversation record Mallett-Helant 1 pg

~~10/86-9/4/87~~

✓ AHS response dated 1-23-87 "confidential"
letter - 7 pgs.
✓ meeting notes of 12/23/86 3 pgs

ATI file

✓ Brennan memo Nov 15 '88 4 pgs
✓ Sheer to Burgin Dec 5 '86 14 pgs
✓ Burgin from Candiano Dec 16 '86 7 pgs
✓ Mullaver to Burgin Dec 18 '86 8 pgs
✓ Walker's interview of Setho 5 pgs
✓ Draft license 40 pgs + Back
✓ Region II license fee transmittal 1 pg
✓ Region 3 license fee transmittal 5/29/86 9 pgs
✓ Conversation record Walker-Ely 12/1/88 1 pg
✓ Conversation record Walker-Benson 11/30/88 1 pg

- ✓ Conversation record Modera - Ely 4/14/88 1 pg
- ✓ Conversation record Modera - FDR 11/10/88 1 pg
- ✓ Mallett from Lewis Sept 19 1988 3 pgs
- ✓ Conversation record 9/15/88 Modera - FDR 1 pg
- ✓ Conversation record 9/13/88 Modera - Baggett 2 pgs
- ✓ Conversation record 9/9/88 Modera - DK 1 pg
- ✓ Conversation record 9/8/88 Modera - Ely 2 pgs
- ✓ Conversation record 9/6/88 Modera - Lewis 1 pg
- ✓ McCann from Miller July 6 88 4 pgs
- ✓ Modera letter June 6 1988 2 pgs
- ✓ Conversation record Modera - Robert 6/1/88 4 pgs
- ✓ Mallett letter to Robert 1/22/88 2 pgs
- ✓ McCann letter re April 20 88 re conversation with Robert 4 pgs

✓ Ruben dated 5/27/86

13 pgs.

AZ. 3419089-01

ROSENBERG audit

23 pp

✓

34-19089-02 - Pg 9 Intro, Pg 10 - isotopes, ✓
Radionuclides, etc