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UNITED STATES
 NUCLEAR REGULATORY COMMISSION
 WASHINGTON, D. C. 20555

March 14, 1989

MEMORANDUM FOR: Advanced Medical Defendants
 FROM: Carole F. Kagan
 SUBJECT: MOTION TO DISMISS

On March 8, the U.S. Attorney's office filed the attached Motion to Dismiss on behalf of both the NRC and the individual defendants. We expect that the motion will eventually be granted.

If you have any questions, please call me at FTS 492-1632.

Attachment:
 As stated
 cc: Bruce Berson

File

LP

Ref to CC 9404180304 Release in A/19

9/12/84

Approved by the
NRC Staff
Form N-200 (7)

U. S. NUCLEAR REGULATORY COMMISSION

OCCUPATIONAL EXTERNAL RADIATION EXPOSURE HISTORY

See Instructions on the Back

IDENTIFICATION

1. NAME (PRINT - LAST, FIRST, AND MIDDLE) [REDACTED]	2. SOCIAL SECURITY NO. [REDACTED]
3. DATE OF BIRTH (MONTH, DAY, YEAR) [REDACTED]	4. AGE IN FULL YEARS (M) [REDACTED]

OCCUPATIONAL EXPOSURE - PREVIOUS HISTORY

5. PREVIOUS EMPLOYMENTS INVOLVING RADIATION EXPOSURE - LIST NAME AND ADDRESS OF EMPLOYER	6. DATES OF EMPLOYMENT (FROM-TO)	7. PERIODS OF EXPOSURE	8. WHOLE BODY (REM)	9. RECORD OR CALCULATED (INSERT ONE)
None	N/A	N/A	0	Calculated

10. REMARKS	11. ACCUMULATED OCCUPATIONAL DOSE - TOTAL
	0

12. CALCULATIONS - PERMISSIBLE DOSE WHOLE BODY:	
(A) PERMISSIBLE ACCUMULATED DOSE (50M-18)	50 REM
(B) TOTAL EXPOSURE TO DATE (FROM ITEM 11)	0 REM
(C) UNUSED PART OF PERMISSIBLE ACCUMULATED DOSE (A-B)	50 REM

12. CERTIFICATION: I CERTIFY THAT THE EXPOSURE HISTORY LISTED IN COLUMNS 6, 7 AND 8 IS CORRECT AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

[REDACTED SIGNATURE] 9/12/84
DATE

13. NAME OF LICENSEE
Advanced Medical Systems, Inc. B11

Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 6 & 7 (C)
FOIA 93-236

3-85-015

INSTRUCTIONS FOR PREPARATION OF NRC FORM 4

This form or a clear and legible record containing all the information required on this form must be prepared by each licensee of the Nuclear Regulatory Commission who, pursuant to Section 20.101, proposes to expose an individual to a radiation dose in excess of the amounts specified in Paragraph 20.101(a) of the regulations in Part 20, "Standards for Protection Against Radiation," 10 CFR. The requirement for completion of this form is contained in Section 20.102 of that regulation. The information contained in this form is used for estimating the external accumulated occupational dose of the individual for whom the form is completed. A separate NRC Form 4 shall be completed for each individual to be exposed to a radiation dose in excess of the limits specified in Paragraph 20.101(a) of Part 20 of the Commission's regulations.* Listed below by item are instructions and additional information directly pertinent to completing this form:

Identification

- Item 1. Self-explanatory.
- Item 2. Self-explanatory except that, if individual has no social security number, the word "none" shall be inserted.
- Item 3. Self-explanatory.
- Item 4. Enter the age in full years. This is called "N" when used in calculating the Permissible Dose. N is equal to the number of years of age of the individual on his last birthday.

Occupational Exposure

- Item 5. List the name and address of each previous employer and the address of employment. Start with the most recent employer and work back.

Include only those periods of employment since the eighteenth birthday involving occupational exposure to radiation. For periods of self-employment, insert the word "self-employed."
- Item 6. Give the dates of each employment listed in Item 5.
- Item 7. List periods during which occupational exposure to radiation occurred.
- Item 8. List the dose recorded for each period of exposure from the records of previous occupational exposure

*This form requires the signature of the employee concerned.

of the individual as calculated under Section 20.102. Dose is to be given in rem.

"Dose to the whole body" shall be deemed to include any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of eye.

- Item 9. After each entry in Item 8 indicate in Item 9 whether dose is obtained from records or calculated in accordance with Section 20.102.
- Item 10. Self-explanatory.

Total Accumulated Occupational Dose (Whole Body)

- Item 11. The total for the whole body is obtained by summation of all values in Item 8.

Certification

- Item 12. Upon completion of the report, the employee must certify that the information in Columns 5, 6, and 7 is accurate and complete to the best of his knowledge. The date is the date of his signature.

Calculations

- Item 13. The effective accumulated occupational dose for each individual and the permissible dose under Paragraph 20.101(b) are obtained by carrying out the following steps: The value for N should be taken from Item 4. Subtract 18 from N and multiply the difference by 5 rem. (For example, John Smith, age 32; $N = 32$, $PAD = 5(32 - 18) = 70$ rem.) Enter total exposure to date from Item 11. Subtract (b) from (a) and enter the difference under (c). The value in (c) represents the unused part of the permissible accumulated dose. This value for permissible dose is to be carried forward to NRC Form 5, "Current Occupational External Radiation Exposure (Whole Body)."
- Item 14. Self-explanatory.

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552(a)(2), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-502), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 4. This information is maintained in a system of records designated as NRC-27 and described as Federal Register 48344 (October 1, 1978).

1. **AUTHORITY** Sections 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2012, 2032, 2036, 2111, 2132, 2134, 2201 (a), and 2201(d)). The authority for collecting the social security number is 10 CFR Part 20.
2. **PRINCIPAL PURPOSE(S)** The information is used by the NRC in its evaluation of the risk of radiation exposure associated with the licensed activity and in exercising its statutory responsibility to monitor and regulate the safety and health practices of its licensees. The data permit a meaningful comparison of both current and long-term exposure experience among types of licensees and among licensees within each type. Data on your exposure to radiation is available to you upon request.
3. **ROUTINE USES** The information may be used to provide data to other Federal and State agencies involved in monitoring and/or evaluating radiation exposure received by individuals employed as radiation workers on a permanent or temporary basis and exposure received by monitored visitors. The information may also be disclosed to appropriate Federal, State, or local agency in the event the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** It is voluntary that you furnish the requested information, including social security number; however, the licensee must have a completed NRC Form 4 on each individual whom the licensee proposes to expose to a radiation dose in excess of the amounts specified in 10 CFR 20.101(a). Failure to obtain the requested information before permitting such exposure may subject the licensee to enforcement action in accordance with 10 CFR 20.801. The social security number is used to ensure that NRC has an accurate identifier not subject to the confounders of similar names or birthdates among the large number of persons on whom data is maintained.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission, Washington, D.C. 20555

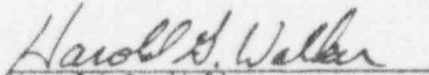
Title: ADVANCED MEDICAL SYSTEMS, INC.
ALLEGED MATERIAL FALSE STATEMENT

Licensee:

Advanced Medical Systems, Inc.
Geneva, OH 44041

Docket No. 030-16055

Reported by:



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

Case Number: 3-85-015

Report Date: JUNE 24, 1986

Control Office: OI:RIII

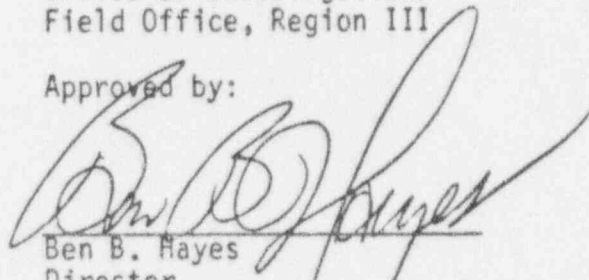
Status: CLOSED

Reviewed by:



Eugene T. Pawlik
Director
Office of Investigations
Field Office, Region III

Approved by:



Ben B. Hayes
Director
Office of Investigations

Participating Personnel:
D. J. Sreniawski, Chief, Nuclear
Materials Safety Section 2, RIII

WARNING

The attached document/report has not been reviewed pursuant to 10 CFR 5/2.790(a) exemptions nor has any exempt material been deleted. Do not disseminate or discuss its contents outside NRC. Treat as "OFFICIAL USE ONLY."

Information in this record was deleted
in accordance with the Freedom of Information
Act, exemptions b7(c)
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SYNOPSIS

On August 16, 1984, NRC Region III (RIII) requested that an investigation be initiated concerning a July 31, 1985, response by the President of Advanced Medical Systems, Inc. (AMS), to a February 21-22, 1985, RIII inspection and subsequent report dated May 17, 1985, and the resulting Notice of Violation and Proposed Civil Penalty dated June 28, 1985.

The Office of Investigations (OI) investigation revealed that the July 31, 1985, response in question, which addressed each of four findings originally addressed in the RIII inspection report, contained multiple material false statements.

One false statement considered to be material indicated that information required on a NRC Form-4 was available at the time of an overexposure occurrence. The purpose of the NRC Form-4 is to document an individual's previous radiation exposure history.

The OI investigation revealed that the individual having received the overexposure (November 1984) had no NRC Form-4 or its equivalent on file at the time of the overexposure. In January 1985, the overexposed individual was required by the Corporate Radiation Safety Officer (RSO) to sign a post-dated NRC Form-4 to cover the time frame in which the subject had been exposed.

On October 1, 1985, the President of AMS stated in affidavit form that several witnesses had seen the NRC Form-4 or its equivalent on which he based his July 31, 1985, response to the NRC. Investigation revealed that said witnesses did not support the affidavit as purported by the President of AMS, and in fact, one of the witnesses was coached by the AMS President to falsely support the President's affidavit alleging the NRC Form-4 existed in November 1984.

Another material false statement made to the NRC was that a complete hot cell survey was completed by a remote probe prior to entry into the cell by AMS personnel. The OI investigation revealed that the remote probe was both erratic and uncalibrated, and used only to determine "hot spots" within the cell. Air monitoring and radiation levels at the entrance door of the hot cell were revealed to have been the basis for the determination of stay time, not a "complete survey by a remote probe."

An AMS secretary made a material false statement to NRC investigators during the investigation of the incidents in question. The material false statement by the secretary was prompted by the President of AMS in order to provide support to the President's previous written material false statements to the NRC.

ACCOUNTABILITY

The following portions of this Report of Investigation (Case No. 3-85-015) will not be included in the material placed in the PQR. They consist of pages 2 through 27.

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APPLICABLE REGULATIONS

Chapter 16, Section 186, of the Atomic Energy Act: Material False Statement

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DETAILS OF INVESTIGATION

Purpose of Investigation

This investigation was initiated to determine the accuracy and intent of Dr. Seymour STEIN's July 31, 1985, response to a NRC Region III (RIII) inspection report dated May 17, 1985, and the subsequent Notice of Violation and Proposed Civil Penalty dated June 28, 1985.

Background

On August 16, 1985, the Regional Administrator of RIII requested an OI investigation following the receipt of a July 31, 1985, response by STEIN to a Notice of Violation and Proposed Civil Penalty action dated June 28, 1985. On July 31, 1985, STEIN, President of Advanced Medical Systems (AMS), forwarded a letter to the NRC taking exception with the findings of RIII Radiation Specialist, Toye L. SIMMONS, and alleging evidence was available which, if properly inspected, would discount SIMMONS' findings in said inspection report.

The inspection report (Exhibit 1), authored by SIMMONS, revealed several areas of noncompliance from which RIII proposed a Notice of Violation and Imposition of Civil Penalty and an Order Modifying AMS' license (Exhibit 2).

On July 31, 1985, STEIN forwarded to the Director, Office of Inspection and Enforcement, NRC, a reply for the June 28, 1985, Notice of Violation (Exhibit 3).

In STEIN's response, he addresses Items A through D of the Notice of Violation by responding to each particular violation.

1. Item A of STEIN's response dated July 31, 1985, addresses the NRC finding that an individual working in a restricted area received a whole body dose of 2.9 rems in the fourth calendar quarter of 1984 and did not meet the condition specified in 10 CFR 20.101(b) (Exhibits 2, 3).

STEIN, in his July 31, 1985, letter, denied the alleged violation. STEIN states that, "the individual referenced as having the overexposure had been scheduled for the Radiation Safety Course earlier in the year. Prior to taking the course, the information required on Form NRC-4 was determined and was available before the cell entries were made in November 1984" (Exhibit 3, page 1).

[REDACTED] the individual in question, was interviewed on September 3, 1985. [REDACTED] stated that he had been notified by Howard IRWIN, Manager of Regulatory Affairs and Radiation Safety Officer (RSO) for AMS, in January 1985 that he [REDACTED] had received an overdose and was at that time asked to sign the NRC Form-4 (Exhibit 4, page 37).

IRWIN, the Manager of Regulatory Affairs and RSO for AMS, was interviewed on September 4, 1985. IRWIN stated that the film badge company (Radiation Detection Company, California) reported overexposures on [REDACTED] and

[redacted] of AMS. IRWIN stated that the NRC Form-4 on [redacted] was dated September 12, 1984, because "that's a date that would have been prior to the work we performed in September on our hot cell window, which is the point at which this information was known to us" (Exhibit 1, page 3, paragraph 5; Exhibit 5, page 12, lns. 4-10).

INVESTIGATOR'S NOTE: [redacted] initial involvement with the hot cell was that he assisted in changing the hot cell window in September 1984 (Exhibit 4, page 27, line 4).

Regarding the information on [redacted] NRC Form-4, [redacted] stated that the form was typed and ready for his signature when he signed his name in January 1985 with no input of information from [redacted] (Exhibit 4, page 23, line 5, and page 28, line 2).

[redacted] stated that at the time he signed the NRC Form-4, he "noticed the date was a little funny, and that it (September 12, 1984) wasn't the date that I signed it." [redacted] further stated that he did not know the meaning of the NRC Form-4 (Exhibit 4, page 24, line 2).

In response to questions regarding AMS' alleged knowledge of [redacted] exposure history as reflected on the NRC Form-4, [redacted] stated the following: to his [redacted] knowledge, AMS would not have known his [redacted] previous exposure history (Exhibit 4, page 24, line 20).

IRWIN stated that the information on the NRC Form-4 regarding [redacted] was "known to us." However, IRWIN states that the information known was [redacted] name, birthdate, and social security number (Exhibit 5, page 11, line 19).

IRWIN later states that the NRC Form-4 information was obtained from [redacted] through prior work that he [redacted] had done. However, IRWIN acknowledged that he did not have [redacted] previous radiation exposure history in written form for inspection at the time of the overexposure (November 1984) (Exhibit 5, pgs. 13-14). IRWIN emphatically stated that the exposure history was based on his memory of a previous discussion he allegedly had with [redacted] (Exhibit 5, pgs. 13, 14, and 16).

[redacted] also, when interviewed, was unaware of his allegedly having been scheduled by AMS to attend a Radiation Safety Course, as indicated by STEIN (Exhibit 4, page 22, line 11).

Glen SIBERT, former Manager of the AMS London Road facility, located in Cleveland, Ohio, stated that IRWIN took care of the NRC Form-4, and that he (SIBERT) had no responsibility to initiate a NRC Form-4 (Exhibit 6, page 18, line 15, and page 19, line 5).

Norman KELBLEY, former RSO of AMS (October 2, 1979, through April 30, 1984), stated that he had not prepared a NRC Form-4 on [redacted] prior to his (KELBLEY's) leaving the employ of AMS, nor would he have had the necessary information from [redacted] with which to prepare a NRC Form-4 (Exhibit 7, pgs. 18-19).

10 - portions

Ed SVIGEL, current Engineering Manager of AMS since January 1982, stated that he is [redacted] supervisor. SVIGEL acknowledged upon questioning that he also had not completed a NRC Form-4 on [redacted], nor would the initiation of said form be within his operational responsibility (Exhibit 8, page 6).

SVIGEL further stated that any initiation of a NRC Form-4 would be done at the London Road facility because that location is where the radioactive material was maintained (Exhibit 8, page 7).

In responding to questions regarding STEIN's letter to the NRC dated July 31, 1985, specifically Item A, STEIN stated that "the information for this form [redacted] NRC Form-4) was actually given to Norm KELBLEY by Ed SVIGEL when Keith was first called down to do some work at the facility." STEIN maintained that the NRC Form-4 information was in a retrievable system at the time of [redacted] November 1984 exposure (Exhibit 9, page 20).

STEIN, when questioned regarding the discrepancy between the typed September 12, 1984, NRC Form-4 and the subsequent January 1985 signing by [redacted] offered no reason for the discrepancy stating only that KELBLEY (former RSO of AMS) was the responsible party for maintaining the NRC Form-4 (Exhibit 9, page 21).

INVESTIGATOR'S NOTE: KELBLEY stated in his October 1, 1985, sworn statement that he had not prepared a NRC Form-4 on [redacted] nor did he have the necessary information from [redacted] to prepare the required form (Exhibit 7, pgs. 18-19).

STEIN stated in support of his July 31, 1985, letter that he thought he saw "a handwritten sheet of this (the NRC Form-4 of [redacted] exposure, dated September 12, 1984), something handwritten, one of these, that was in the file." STEIN was adamant that the document he saw was handwritten (Exhibit 3; Exhibit 9, pgs. 22-24; Exhibit 10).

Regarding [redacted] having been scheduled for a Radiation Safety Course as alleged in Item A of STEIN's July 31, 1985, letter, STEIN stated that prior to every training course, a list of all the possible people who might take the course is made. [redacted] according to STEIN was on one of those lists. STEIN further states that potential course attendees "would have been aware they were under consideration" and "anyone taking the course would have a form (NRC Form-4) prepared for him."

INVESTIGATOR'S NOTE: [redacted] stated that he had no knowledge of ever having been scheduled to attend a training class, nor had he provided any previous exposure history to AMS (Exhibit 10).

STEIN further stated that SVIGEL would have been responsible for furnishing [redacted] NRC Form-4 information to KELBLEY (Exhibit 9, page 26).

INVESTIGATOR'S NOTE: SVIGEL, when interviewed on October 1, 1985, denied having any responsibility to provide or obtain NRC Form-4 information and

stated in fact that he had not provided any such information regarding [REDACTED] (Exhibit 8).

On September 4, 1985, STEIN was asked by OI:RIII Investigator Walker to conduct a search of the AMS files in an attempt to locate the NRC Form-4 information alleged by STEIN in his July 31, 1985, letter to have been on file at AMS in November 1984 (Exhibit 9, page 27).

On October 1, 1985, the results of STEIN's search was hand carried to Investigator Walker by SVIGEL. STEIN's findings consisted of a typed statement in the form of an affidavit dated October 1, 1985, and signed by STEIN. The statement read as follows:

"I have checked our files for a copy of a handwritten Form-4 for [REDACTED]. Although several people have indicated to me that they did see this handwritten form, it cannot be located. All that we have in our records is the typewritten form signed by [REDACTED]."

"It has been indicated to me that as our files were reviewed, anything that appeared to be extraneous or repetitive was discarded in our attempt to organize the files in an efficient manner" (Exhibit 11).

Following the receipt of the aforementioned statement, D. J. SRENIAWSKI, RIII Chief, Nuclear Materials Safety Section 2, and Investigator Walker traveled to AMS headquarters in Geneva, Ohio, to obtain clarification of the "affidavit."

STEIN was questioned as to the identity of the "several people" referred to in his October 1, 1985, "affidavit." Both STEIN and his Administrative Aide, Donna ELY, stated that the "several people" having seen the alleged handwritten NRC Form-4 were Josephine POWELL, Secretary, and IRWIN (Exhibit 12).

STEIN stated that IRWIN had, the previous evening (September 30, 1985), admitted having seen the document in question and had further assumed that it was discarded during an organization of the AMS office files in anticipation of the February 21-22, 1985, NRC inspection. ELY, when questioned, denied any direct knowledge of the form. However, ELY corroborated STEIN's assertions regarding the witnesses in the "affidavit" (Exhibit 12).

POWELL, when initially interviewed on September 3, 1985, had stated under oath that she recalled having completed [REDACTED] previous occupation/exposure (NRC Form-4) record "last year." POWELL stated that [REDACTED] NRC Form-4 was completed prior to the November 1984 time frame. She also stated that she recalled IRWIN had provided her the information to type (Exhibit 13, pgs. 14-15).

INVESTIGATOR'S NOTE: IRWIN stated on September 8, 1985, that he did not have [REDACTED] NRC Form-4 information in written form during the November

1984 overexposure time frame as stated by POWELL (Exhibit 5, pgs. 13-14, 16).

On October 9, 1985, IRWIN reaffirmed his September 1985 statement that he had not seen a documented record of [REDACTED] previous exposure history prior to the initiation of the January 1985 form dated September 12, 1984, and signed by [REDACTED]. IRWIN also denied that a rough document (handwritten) of the [REDACTED] typewritten NRC Form-4 prepared by IRWIN, was available in November 1984. IRWIN's recollection was that he (IRWIN) prepared a handwritten form to be typed for [REDACTED] signature no more than a week prior to [REDACTED] actually signing the form. IRWIN acknowledged that the earliest possible time frame that the handwritten copy would have been in existence was in late December 1984 (Exhibit 16, page 5).

IRWIN acknowledged that had a NRC Form-4 or its equivalent been in existence previous to the January 1985 initiated form, it would have been initiated by either SIBERT or KELBLEY (Exhibit 16, page 10, lns. 12-17).

INVESTIGATOR'S NOTE: Both KELBLEY and SIBERT deny any knowledge of a NRC Form-4 having been prepared for [REDACTED] (Exhibits 6-7).

IRWIN stated that POWELL would have been the secretary responsible for typing the [REDACTED] NRC Form-4 and would have typed the original based on information provided her by IRWIN (Exhibit 16, pgs. 10-11).

INVESTIGATOR'S NOTE: POWELL, in her September 4, 1985, statement, said unequivocally that she had typed [REDACTED] NRC Form-4 prior to the November 1984 entries resulting in an overexposure to [REDACTED].

On October 9, 1985, POWELL was re-interviewed regarding her previous September 4, 1985, statement in light of the STEIN affidavit and IRWIN's statements. POWELL stated that she types any material required of her by IRWIN including any NRC Form-4s, if necessary. POWELL stated that her routine procedure is to destroy the handwritten form once the typewritten form is generated (Exhibit 15, page 4).

POWELL identified the [REDACTED] NRC Form-4 dated September 12, 1984, as having been typed by her. POWELL insisted that she recalled having typed the [REDACTED] NRC Form-4 document prior to the November 1984 hot cell entries (Exhibit 10; Exhibit 15, pgs. 5-6).

POWELL, upon being informed of IRWIN's statements that the form in question was not in existence prior to November 1984, stated that she was likely confused. POWELL stated that she had not typed but one form for [REDACTED] during her employment at AMS and that he [REDACTED] signed the form in her presence (Exhibit 15, pgs. 7-8).

Regarding STEIN's October 1, 1985, "affidavit" and STEIN's and ELY's subsequent comments to Investigator Walker and SRENIAWSKI regarding POWELL and IRWIN having witnessed the Form-4 information prior to the November 1984 hot cell entries, POWELL stated the following: "This (the

affidavit) has been brought to my attention, that a written--there has been a written one on [REDACTED] I have never seen it. The only one I have seen is the one that Howard handed me, and I destroy every one of them after I type in the information on the original one" (Exhibit 15, pgs. 9-10).

POWELL was asked the identity of the person telling her that a form had previously been on file at AMS for [REDACTED] POWELL responded "Dr. STEIN" (Exhibit 15, page 10).

INVESTIGATOR'S NOTE: STEIN's October 1, 1985, affidavit supporting his July 31, 1985, letter to the NRC (specifically Item A) was not supported by POWELL as stated in STEIN's and ELY's October 1, 1985, interview with Investigator Walker and SRENIAWSKI (Exhibits 12, 15).

IRWIN, in his October 9, 1985, statement, said contrary to STEIN's October 1, 1985, "affidavit" and subsequent interview of the same date that he "stated to him (STEIN) that it is my (IRWIN's) practice that when I have a final document from rough documents, that I discard the rough documents." IRWIN further acknowledged that he did not leave the impression with STEIN that the rough document discarded was available in November (1984) when the overexposure of [REDACTED] occurred (Exhibit 11; Exhibit 12; Exhibit 16, page 11).

INVESTIGATOR'S NOTE: STEIN's "affidavit" and subsequent interview suggests that IRWIN as AMS' RSO had destroyed the document referred to by STEIN in his July 31, 1985, letter, and IRWIN's alleged act would therefore support STEIN's alleged recollection of [REDACTED] NRC Form-4 information having been available in November 1984 (Exhibits 11-12).

IRWIN stated, in his September 4, 1985, interview that he (IRWIN) had been confused as to how the NRC Form-4 requirement applied to a part-time employee, a one-time employee or a volunteer, as opposed to full-time employees (Exhibit 5, pgs. 14-15).

INVESTIGATOR'S NOTE: [REDACTED] referred to himself as a volunteer, in that he was hired as a draftsman, not a hot lab worker. STEIN acknowledged that [REDACTED] was a volunteer (Exhibit 4, page 26; Exhibit 11, page 21).

2. Item B of STEIN's July 31, 1985, letter addressed Item B of the Notice of Violation and Proposed Imposition of Civil Penalty dated June 28, 1985 (Exhibits 2-3).

STEIN stated, in part, in his response (Exhibit 3):

"AMS denies the allegation. The survey procedure used on November 6 and November 21, 1984, was adequate. A complete cell survey was made with our remote probe prior to these dates and prior to entry. The statement made by NRC that we relied only on the hot cell door survey is not only absolutely untrue, but ridiculous. Had the inspector conducted a proper review, this statement would never have been made. Prior to any survey at the door, a complete survey by a remote probe is always performed."

"The work performed on November 21, 1984, involved two cell openings and multiple individual trips into and out of the cell. The RSO designate did instruct Individuals A and B to read their dosimeters after each trip. The individuals made four trips during the total entry time of 3.65 and 3.80 minutes."

"The RSO designate monitored the work so that exposures did not exceed this limit (1700mR). The dosimeters were read by the individuals prior to cell re-entry."

"All three individuals involved in the November cell entries were interviewed separately. All three indicated that dosimeters were read prior to cell entry. The RSO designate was further interviewed regarding the cell survey being made prior to cell entry. He verified in front of four witnesses that such a survey was made prior to cell entry. I do not understand how the NRC inspector could have reached such an erroneous conclusion that a survey was not made. The RSO designate specifically stated in front of four witnesses that the NRC inspector was informed that such a survey was made."

SIBERT, a former employee of AMS as an isotope engineer and later the manager of the AMS London Road facility, was interviewed on September 3, 1985. SIBERT stated that following KELBLEY as RSO, he (SIBERT) was appointed the RSO by STEIN (Exhibit 6, page 9).

INVESTIGATOR'S NOTE: SIBERT was referred to in STEIN's July 31, 1985, letter as the RSO designate (Exhibit 3).

SIBERT expressed his displeasure toward STEIN for having appointed him (SIBERT) the AMS RSO designee, stating that he (SIBERT) "wanted no part of it." IRWIN, according to SIBERT, was subsequently appointed RSO by STEIN (Exhibit 6, pgs. 10, 18).

SIBERT (who was present during ~~the~~ November 6 and 21, 1984, hot cell entries) recounted the step-by-step process by which a hot cell entry is made. SIBERT stated that:

- a. Prior to going into the cell, the cell was checked for stray cobalt pellets. This process would, according to SIBERT, require two or three days. This was accomplished through the use of a Victoreen 500 meter, an in-cell remote monitor by the manipulators. This process, according to SIBERT, was done in order to get the [radiation] level as low as possible (Exhibit 6, page 25).

On March 13, 1985, at the RIII enforcement conference, IRWIN (the AMS RSO) stated that the in-cell probe (Victoreen 500 Electrometer) had been used for the detection of stray cobalt-60 pellets during decontamination procedures. Because the instrument was erratic and uncalibrated, it was not used for cell radiation level surveys (Exhibit 1, page 9).

- b. Protective clothing was then put on which consisted of shoes, shoe covers, rubber gloves (two pair), respirators, and a plastic bag over the top of the head. A dosimeter, 5R and 1R chamber, and a film badge were placed into a plastic bag and taped to one's shoulder to enable one to monitor the dosimeter.
- c. Once suited up, an air sample would be taken. The sample would then be put in a well counter. The information derived would then be fed into a computer that determines how much "stay time" one had (Exhibit 6, pgs. 25-26).

SIBERT states that the stay time in the hot cell was determined from the air sample (airborne contamination). However, according to SIBERT, airborne contamination had no bearing on the radiation level inside the hot cell (Exhibit 6, page 26, line 18).

- d. Once stay time is determined, SIBERT stated that the next step involved a reading of the radiation level. SIBERT would open the hot cell wall far enough to stick his arm in and get a reading inside the cell (Exhibit 6, pgs. 27-28).

If, according to SIBERT, the reading is over 20R, the door is closed. Anything 20R and under, the entry proceeds (Exhibit 6, page 28, lns. 5-9).

- e. If, according to SIBERT, the radiation level is over 20R/hr, a search for stray cobalt pellets would begin again, and another air sample is obtained until acceptable limits (under 20R) are the result (Exhibit 6, page 29, line 1).

INVESTIGATOR'S NOTE: STEIN stated in his July 31, 1985, letter that a complete cell survey was made with a remote probe prior to cell entry, and that prior to any survey at the door, a complete survey by a remote probe is always performed. SIBERT, the RSO designee, stated that only airborne contamination is measured inside the cell prior to entry, at which time a radiation reading is obtained at the cell door. Radiation level and airborne contamination being different measurements of activity, STEIN's statement that a complete cell survey was made prior to entry is inaccurate. Radiation levels at the cell door may be significantly different than the space inside the hot cell where workers will be stationed. The airborne contamination has no direct correlation to radiation levels (Exhibit 6, page 26, lns. 18-25, and page 27, line 4).

For cell door survey results less than 20 R/hr, a cell stay time was calculated. This stay time would be compared to the earlier stay time calculated from air sample measurements with the more restrictive value chosen for the entry. Past practices showed the stay time calculated from the cell door survey to be the most restrictive.

SIBERT expressed dissatisfaction with the employees of AMS, stating that they "don't know how to read dosimeters" and that "if I'm over there I've got to worry about myself. I've also got to worry about somebody else" (Exhibit 6, pgs. 26-31).

SIBERT stated that he did the calculations for [redacted] as far as stay time. A stopwatch was utilized and as the individual went into the cell, that stopwatch went on so it was known exactly how much time was spent in the cell. SIBERT stated that the individuals in the hot cell would be notified by POWELL, and also through checking the individual's dosimeter.

As to the November 6, 1984, entry by [redacted] SIBERT acknowledged that these two individuals were not routinely involved in the hot cell operations before this incident (Exhibit 6, page 39).

On November 6, 1984, according to SIBERT, two jobs had to be completed. [redacted] each did one. According to SIBERT, each individual made only one entry that day (November 6, 1984). Following the entry and subsequent exit, [redacted] read their dosimeter, recording the information at the London Road facility (Exhibit 6, page 40).

[redacted] stated that November 6, 1984, was the first time that he and [redacted] entered the hot cell. [redacted] described in detail the preparation for entry into the hot cell. [redacted] described SIBERT's taking of an air sample and also taking a reading at the door of the hot cell. [redacted] described two entries into the hot cell by [redacted] and one by himself (Exhibit 4, page 16).

[redacted] stated that November 6, 1984, was the first exposure experience he had entering the hot lab. [redacted] stated that he and [redacted] both entered the lab that day. [redacted] said that he entered the hot lab two separate times and [redacted] entered once. [redacted] also stated that between entries he did not read his dosimeter (Exhibit 17, pgs. 12-13).

Regarding November 21, 1984, SIBERT stated that two entries by each person, [redacted] were made into the hot cell.

According to [redacted] on November 21, 1984, three or four entries were made into the hot cell. As to the dosimeter readings, [redacted] stated that he did not take dosimeter readings after each entry, nor does he believe he was so instructed. [redacted] said that the "radiation was fairly high" and that "things were happening fast" (Exhibit 17, pgs. 25-26).

[redacted] stated that three entries were made on November 21, 1984. [redacted] stated that the dosimeters were read following his entries and upon leaving the decontamination room (Exhibit 4, pgs. 20-21).

INVESTIGATOR'S NOTE: The July 31, 1985, letter signed by STEIN to the NRC stated in Item B, Paragraph 3, that "the dosimeters were read by the individuals prior to re-entry" (Exhibit 3). SIBERT stated that he had to worry about himself while in the hot cell (Exhibit 6, pgs. 26-31).

STEIN stated that his July 31, 1985, letter, Item B, reflected his understanding of events as received from SIBERT. STEIN stated that SIBERT was monitoring the exposure of [redacted] and seeing that "their reading

didn't become excessive." STEIN further acknowledged that each time they [redacted] came out of the hot cell, a reading was made, and that the reading was the individual's responsibility (Exhibit 9, page 33, line 23).

STEIN stated in his July 31, 1985, letter to the NRC that "all three individuals were interviewed separately," and that "all three indicated that dosimeters were read prior to cell entry." STEIN also stated that prior to "cell re-entry" dosimeters were read (Exhibit 3).

[redacted] stated that he and [redacted] approximately a week before this interview (September 12, 1985), were in a meeting with STEIN. At this meeting, STEIN went over with both men the Notice of Violation and Proposed Imposition of Civil Penalties. According to [redacted] STEIN requested that [redacted] read item by item the notice and then read item by item STEIN's July 31, 1985 response. [redacted] stated that during this meeting, he [redacted] voiced no objections, although he mentally objected to various conclusions arrived at by STEIN (Exhibit 4, pgs. 46-49).

Regarding the meetings with STEIN, the review of STEIN's response to the NRC, and the review of NRC notices, [redacted] said, "he did not ask us any questions pertaining to the incident," and "we sat there and listened to him" (Exhibit 4, page 50, line 12).

According to [redacted] IRWIN (the RSO designee) conducted individual interviews with [redacted] (Exhibit 17, page 31, lns. 5-14).

INVESTIGATOR'S NOTE: [redacted] statement corroborates STEIN's assertion in the July 31, 1985, letter that "all three individuals involved in the November cell entries were interviewed separately" (Exhibit 3; Exhibit 17, page 50).

STEIN stated (regarding his interviews as stated in his July 31, 1985, letter) that he talked with both [redacted] in the presence of ELY, the Administrative Assistant. STEIN reasoned that he had ELY with him because she was "a very gentle lady" and that he (STEIN) has a "tendency to come on a little stronger." STEIN said that ELY, Dean ABRAHAM, and Tony SANTORO were present when he (STEIN) talked with SIBERT (Exhibit 6, page 38).

3. Item C of Seymour STEIN's July 31, 1985, letter to the NRC stated in part:

"Four entries were made by each individual on November 21, 1984. Between visits, dosimeters were checked to ascertain actual exposure" (Exhibit 3, Item C, page 3, paragraph 1).

[redacted] both deny that dosimeters were read between visits (Exhibit 4, pgs. 20-21; Exhibit 17, pgs. 18, 25).

STEIN stated in responding to questions regarding his statement that "these are things people do automatically." STEIN also stated "they don't have to be told to read them; they will do them automatically" (Exhibit 9, page 46).

STEIN, when specifically asked if his (STEIN's) discussions with [REDACTED] revealed they had checked their dosimeters between visits into the hot lab stated as follows: "I'm certain that [REDACTED] would automatically check his; he told me he did" (Exhibit 9, page 46).

As to [REDACTED] checking his dosimeter, STEIN stated, "if one did it, the other would automatically do it." STEIN said that "I wasn't there, I'm just going by the way people are" (Exhibit 9, page 47).

4. Item D of STEIN's July 31, 1985, response to the NRC Notice of Violation and Proposed Imposition of Civil Penalties, in part, states the following:

"The procedure for calibration submitted in 1979 was found to be unworkable in that it did not produce repeatable results. The technique adopted as an alternative was the comparison of dosimeter readings with film badge reports on a monthly basis."

The procedure adopted by STEIN is not in accordance with AMS License Condition No. 16 contained in the July 16, 1979, license application (Exhibit 2, page 2; Exhibit 9, pgs. 49-55).

SANTORO, a former employee of AMS, was interviewed on September 3, 1985, at which time SANTORO corroborated STEIN's statement on page 2 of the July 31, 1985, letter that a hot lab operation was cancelled at one time due to excessive readings of radiation (Exhibit 18, page 10).

SANTORO also recalled that on November 6, 1984, [REDACTED] entered the hot cell and logged in the final dosimeter reading. SANTORO could recall only one entry that date (Exhibit 18, page 8).

SANTORO also recalled that on November 21, 1984, [REDACTED] took dosimeter readings on two occasions. SANTORO stated that he recalled [REDACTED] discussing the dosimeter readings of two entries that day (Exhibit 18, page 13).

Willfulness/Intent

STEIN, in his July 31, 1985, response to the NRC's Notice of Violation and Proposed Imposition of Civil Penalties, addressed four separate items referred to in said notice.

Item A

STEIN, President of AMS, located in Geneva, Ohio, made a material false statement to the NRC when he originally responded by letter dated July 31, 1985, to the RIII inspection dated May 17, 1985, and the subsequent June 28, 1985, Notice of Violation and Proposed Civil Penalty. STEIN stated that "the information required on form NRC-4 was determined and was available before the cell entries were made in November 1984" (Exhibit 3).

The investigation revealed that the NRC Form-4 information was initiated in January 1985 by IRWIN, AMS Corporate RSO, following receipt of an overexposure

reading from the film badge company (Radiation Detection Company, California) in January 1985 (Exhibit 5, page 12).

IRWIN, the AMS Corporate RSO, by requiring [redacted] signature in January 1985 on a NRC Form-4 dated September 12, 1984, effectively falsified the existence of said form. The motive for this action, as stated by IRWIN, was to cover the times when [redacted] had previously entered the hot cell without the necessary form on file. The existence of the NRC Form-4 or its equivalent as of November 1984 would have allowed [redacted] to experience an increased exposure due to his previous history of no exposure. Also, the existence of said form or its equivalent would have brought AMS into compliance with NRC requirements 10 CFR 20.101(b) (Exhibit 5, pgs. 12, 14-15; Exhibit 1; Exhibit 2).

[redacted] stated that he was required to sign a NRC Form-4 in January 1985 dated September 12, 1984. [redacted] had, to his knowledge, never before been required to sign a NRC Form-4, nor had he given previous exposure history data to AMS with which to complete a NRC Form-4 (Exhibit 4, pgs. 23-24, 28, and 37).

STEIN, upon OI's request, conducted a search of the AMS files to locate NRC Form-4 equivalent information. He stated that it was available in his July 31, 1985, letter, and responded by submitting a statement in affidavit form indicating that the information could not be found. However, STEIN stated that several witnesses had seen the information in question (Exhibit 11; Exhibit 12).

An interview with STEIN on October 1, 1985, revealed that the several witnesses were IRWIN and POWELL. However, IRWIN and POWELL had not seen the document in question in November 1984 or prior thereto. Further, IRWIN stated that he in no way had left STEIN with the impression that he (IRWIN) had seen any such document during that time period (Exhibit 12; Exhibit 15; Exhibit 16).

POWELL, the AMS secretary, made false statements under oath to Investigator Walker and SRENIAWSKI on September 3 and October 9, 1985, when she stated that she remembered having completed the [redacted] NRC Form-4 prior to November 1984. POWELL subsequently, upon learning of IRWIN's admission, reversed her previous statement and stated that she had only seen one NRC Form-4 for [redacted] and that one was the one given her by IRWIN. STEIN told her that there was one previously, but that she had never seen it (Exhibit 13, page 15; Exhibit 15, pgs. 5-7 and 9-10).

POWELL stated that she had never seen any document other than the one dated September 1984, initiated by IRWIN and signed by [redacted] in January 1985 (Exhibit 15, page 10).

Item B

STEIN's July 31, 1985, letter stated in part in Paragraph 1 of STEIN's Item B response, that "a complete cell survey was made with our remote probe prior to these dates [November 6 and 21, 1984] and prior to entry." He also stated "prior to any survey at the door, a complete survey by a remote probe is always performed" (Exhibit 3).

SIBERT, AMS RSO designee, revealed that prior to cell entry, a search of the hot cell was accomplished by use of a Victoreen 500 probe to detect and dispose of Cobalt-60 pellets. The Victoreen 500 was controlled by a "manipulator" (Exhibit 6, pgs. 25-29).

The Victoreen 500 probe, according to IRWIN, who appeared at the March 13, 1985, RIII enforcement conference, was erratic and uncalibrated, and not used for cell radiation level surveys (Exhibit 1, page 9).

STEIN, in his September 4, 1985, deposition stated, in support of his July 31, 1985, letter, that a remote probe was used to monitor "hot spots" within the hot cell (Exhibit 9, pgs. 27-28).

It is apparent that STEIN's July 31, 1985, statement regarding a "complete survey by a remote probe" of the hot cell prior to entry was false. As stated by SIBERT, the probe was utilized only to determine hot spots and to recover stray Cobalt-60 pellets. As stated by IRWIN, the AMS RSO, the probe (Victoreen 500) was erratic and uncalibrated, and for that reason, not used for cell radiation level surveys.

Item C

STEIN stated in part in Item C of his July 31, 1985, response to the NRC, that "between visits, (on November 21, 1984) dosimeters were checked to ascertain actual exposure" (Exhibit 3).

[REDACTED] one of those entering the hot cell that date, stated that three or four entries were made into the hot cell on November 21, 1984. As to dosimeter readings, [REDACTED] stated that he did not take dosimeter readings after each entry, nor does he recall having been instructed [by the RSO designee] to do so (Exhibit 17, pgs. 25-26).

[REDACTED] stated that three entries were made on November 21, 1984, and that dosimeter readings were taken following his entries and upon leaving the decontamination room (Exhibit 4, pgs. 20-21).

SANTORO stated that on November 21, 1984, he recalled that both [REDACTED] took dosimeter readings on two occasions during the entries (Exhibit 18, page 13).

The conflicting recollections by both the participants and witness of the cell entries on November 21, 1984, prevent a determination of the Item C response by STEIN as being truthful or false. Apparently, the entry was not monitored closely by the RSO designee, as revealed by SIBERT's following statements.

SIBERT stated that he "wanted no part of it" when referring to his designation by STEIN as the AMS RSO, and that the employees of AMS "don't know how to read dosimeters" (Exhibit 6, pgs. 10, 18, and 26-31).

SIBERT expressed further displeasure at being designated the AMS RSO in that when entering the hot cell, he had to "worry about myself," and also "worry about somebody else" (Exhibit 6, pgs. 26-31).

Item D

STEIN stated in Item D of this July 31, 1985, response to the NRC that "the procedure for calibration submitted in 1979 was found to be unworkable," therefore, the procedure was changed. This item was addressed as a licensing violation in that AMS was clearly in noncompliance with their July 16, 1979, license application (Exhibit 3; Exhibit 9, pgs. 49-55).

The Item D response in STEIN's July 31, 1985, letter to the NRC was based upon apparent confusion by STEIN as to what his 1979 license application required.

Agent's Conclusion

IRWIN, Corporate RSO of AMS, falsified the existence of an NRC Form-4 by post-dating said document. STEIN, President of AMS, provided material false information in response to the NRC via a July 31, 1985, letter. POWELL, a secretary employed by AMS, made a material false statement to the NRC while under oath during the investigation of the incident in question.

STATUS OF INVESTIGATION

Evidence developed during this investigation is sufficient to demonstrate that Howard IRWIN, Corporate RSO of Advanced Medical Systems, Inc., falsified a NRC Form-4, and also that material false statements were made to the NRC by STEIN, President of AMS, and POWELL, a secretary for AMS. In addition, it was established that STEIN prompted witness testimony to support his false statement to the NRC.

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SUPPLEMENTAL INFORMATION

This investigation has developed information indicating possible violations of Federal criminal law by Seymour S. STEIN, Howard R. IRWIN, and Josephine POWELL. Under the circumstances, a copy of the final Report of Investigation has been referred to the Department of Justice.

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LIST OF EXHIBITS

1. Copy of NRC Inspection Report No. 030-16055/85001 dated June 28, 1985.
2. Copy of Advanced Medical Systems, Inc. Notice of Violation and Proposed Imposition of Civil Penalties and Order Modifying License dated June 28, 1985.
3. Copy of Letter from Seymour S. STEIN to the USNRC in response to the Notice of Violation and Proposed Imposition of Civil Penalties dated July 31, 1985.
4. Copy of sworn statement of [REDACTED] dated September 3, 1985.
5. Copy of sworn statement of Howard IRWIN dated September 4, 1985.
6. Copy of sworn statement of Glenn SIBERT dated September 3, 1985.
7. Copy of sworn statement of Norman KELBLEY dated October 1, 1985.
8. Copy of sworn statement of Ed SVIGEL dated October 1, 1985.
9. Copy of sworn statement of Seymour S. STEIN dated September 4, 1985.
10. Copy of [REDACTED] NRC Form-4 dated September 12, 1985.
11. Copy of Seymour S. STEIN's affidavit dated October 1, 1985.
12. Copy of Report of Interview with Seymour S. STEIN and Donna ELY dated October 1, 1985.
13. Copy of sworn statement of Josephine POWELL dated September 3, 1985.
14. Copy of sworn statement of Josephine POWELL dated September 4, 1985.
15. Copy of sworn statement of Josephine POWELL dated October 9, 1985.
16. Copy of sworn statement of Howard IRWIN dated October 9, 1985.
17. Copy of sworn statement of [REDACTED] dated September 4, 1985.
18. Copy of sworn statement of Anthony SANTORO dated September 3, 1985.