

September 30, 1987

Mr. Bill Brown
Trial Attorney
General Litigation and
Legal Advice Section
U.S. Department of Justice
Bond Building, Room 6405
1400 New York Avenue, NW
Washington, DC 20005

Dear Mr. Brown:

In response to your request, the following documents are enclosed:

1. Copy of September 10, 1987, Advanced Medical Systems, Inc. (AMS), hearing before the Honorable Ivan Smith, NRC Administrative Law Judge.
2. Copy of cover letter accompanying September 21, 1987, document return.
3. Copy of [REDACTED] personal record.
4. Copy of service on Eastside Radiology Imaging and Therapy Center (Eastside) unit for "Training Only," by James Cochran.
5. Copy of on-the-job training history for James Cochran.
6. Copy of NRC 10 CFR Part 35.605 with clarifying comments.
7. Copy of AMS Cobalt Service Procedures Manual issued April 1979 with October 1984 revision.
8. Copy of AMS old "obsolete" Cobalt Service Manual.
9. Copy of AMS Cobalt Service Manual approved June 1986.
10. Copy of NRC Cobalt Training Manual (outdated August 1987).
11. Copy of August 10, 1987, Report of Interview with Erich Dreier.
12. Copy of September 21, 1987, Report of Interview with Keith Jordan.
13. Copy of September 22, 1987, Report of Interview with James V. Zelch.

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Act, exemptions 687(c)
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B/S

Mr. Bill Brown

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September 30, 1987

14. Copy of September 22, 1987, Report of Interview with Paul Carani.

15. Copy of September 22, 1987, Report of Interview with Donna Ely.

If you have any questions, please do not hesitate to call me at FTS 388-5686.

Sincerely,

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

Enclosures: As stated

Distribution:

c/f
SAT 3-86-010

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09/30/87

January 13, 1988

Mr. Bill Brown
Trial Attorney
General Litigation and
Legal Advice Section
U.S. Department of Justice
Bond Building, Room 6405
1400 New York Avenue, NW
Washington, DC 20005

Dear Mr. Brown:

As to Howard Irwin's knowledge of 10 CFR 20.102 (the requirement to have a Form NRC-4 prior to entry into a restricted radioactive area) prior to [redacted] overexposure in November 1984, the following information is submitted.

In March 1983, Advanced Medical Systems, Inc. (AMS), was fined \$4,000 by the NRC for an overexposure and other deficiencies. The civil penalty was the result of an inspection effort by J. R. Mullauer, NRC Region III (RIII) Radiation Specialist. In Mullauer's inspection report (Attachment 1), Item 7 addressed the Form NRC-4.

Item 7 of Mullauer's inspection report addressed "Personnel Radiation Protection - External" and stated, in part, "past exposure histories (form NRC-4) have been prepared and are updated quarterly for all personnel involved in the source fabrication, exchange and loading program." The significance of this inspection regarding Irwin is that he was listed as an attendee at the NRC:RIII enforcement conference held at AMS in Cleveland, Ohio, on April 11, 1983.

On June 1, 1983, Seymour S. Stein, Ph.D., AMS President, protested the civil penalty assessed by the NRC. Stein wrote a letter strenuously protesting the civil penalty and citing that the two "employees involved have been suspended without pay" (Attachment 2).

Stein stated that "AMS suspended all hot cell activity until decontamination, equipment changes, and maintenance is performed and is taking steps to reduce future employee exposure. Present radiation safety procedures are under review and an ALARA (as low as reasonably achievable) program is being developed" (Attachment 2).


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Stein further stated, "since the actions of certain employees caused these violations, which were clearly in disregard of company policy, and the company has taken steps to discipline these employees, the company feels that no fine should be levied against the company" (Attachment 2).

A second June 1, 1983, letter from Stein to the NRC stated, "this suspension has the impact of impressing upon all company employees that radiation safety is not to be taken lightly, and that violations will not be tolerated by management" (Attachment 3).

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On July 20, 1983, Irwin, as the AMS Regulatory Compliance Officer, approved Procedure No. 1SP-18, the purpose of which was to "limit the actual exposure to personnel." The significance of this document is that it addressed AMS entry procedures into the radiation field (hot cell) without recognizing whether the entering party is a "volunteer" from the Geneva office or a regular London Road facility employee (i.e., Chaffee) (Attachment 5).

On July 16-17, 1984, a routine safety inspection conducted by Toye Simmons and J. Mullauer again revealed a reference to the use of the Form NRC-4. In paragraph 7 of said inspection report, it is stated, "past exposure histories (form NRC-4) have been prepared and are updated quarterly for all personnel involved in the source fabrication, exchange and loading program." It was also noted by inspectors Simmons and Mullauer that AMS had a shortage of qualified personnel. AMS was asked to "describe how you will maintain your radiation safety program in view of what appears to be a shortage of qualified personnel" (Attachment 6).

Again, Irwin, identified as the Corporate Compliance Manager, is listed as one of the AMS persons contacted by the inspectors for the information provided in said report. Irwin is also identified as being present during the NRC "Exit Interview," wherein the items of noncompliance were discussed. Mullauer stated that Irwin was present throughout the inspection in 1984 and told Mullauer that he (Irwin) was going to be the RSO soon, and that he (Irwin) wanted to know what the NRC reviewed during its inspections. A copy of the inspection report was provided to Irwin.

Item 11 of AMS' License No. 34-19089-01 dated December 13, 1979, to November 30, 1984, states, "the licensee shall comply with" Part 20, "Standards for Protection Against Radiation." Part 20 deals particularly with radiation safety and, in part, with the Form NRC-4 requirement.

6.7C
6.7C part 20

TITLE: ADVANCED MEDICAL SYSTEMS, INC.

ALLEGED WILLFUL ASSIGNMENT OF UNQUALIFIED AND UNLICENSED SERVICE ENGINEERS TO CONDUCT SERVICE REQUIRING A LICENSE AND PROVIDING A FALSE DOCUMENT TO THE NRC; ALLEGED FALSIFICATION OF SEALED SOURCE LEAK TEST DATA; ALLEGEDLY PROVIDING TEST ANSWERS TO APPLICANTS FOR A SERVICE LICENSE, AND ALLEGED FAILURE TO NOTIFY THE NRC OF A DEFECT AFFECTING THE OPERATION OF THE COBALT-60 C-9 TELE THERAPY UNIT

Licensee:

Advanced Medical Systems, Inc.
121 North Eagle Street
Geneva, OH 44041

Docket Nos.: 30-16055; 30-17154

Reported By:

Harold G. Walker

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

Case Number: 3-86-010

Report Date: March 10, 1989

Control Office: OI:RIII

Status: CLOSED

Reviewed By:

Eugene T. Pawlik

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

Approved By:

Ben B. Hayes
Ben B. Hayes
Director
Office of Investigations

Participating Personnel:

Robert E. Burgin, NRC:RIII
Senior Radiation Specialist
George M. McCann, NRC:RIII
Senior License Reviewer

WARNING

The attached document/report has not been reviewed pursuant to 10 CFR Subsection 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."

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SYNOPSIS

On October 8, 1986, NRC Region III (NRC:RIII) requested that an investigation be initiated concerning alleged use of unqualified and unlicensed technicians by Advanced Medical Systems, Inc. (AMS), Geneva, OH, to service teletherapy equipment at hospitals throughout the United States. It was also alleged that an AMS manager directed the falsification of sealed source leak test data and that answers were given in advance to individuals taking the qualifying examination for certification as Licensed Service Engineer (LSE).

As a result of an NRC Order on October 10, 1986, suspending the AMS service license, evidence was developed that AMS had failed to notify the NRC of information indicating a defect which would affect the operation of the Cobalt-60 C-9 teletherapy unit. Further, as a result of a December 23, 1986, NRC hearing at NRC:RIII between AMS and the NRC, it was suspected that information provided to the NRC in the form of an affidavit was false.

This investigation revealed that various unlicensed service engineers were required by the AMS National Service Manager (NSM) to perform licensed service on and installation of cobalt teletherapy units. The investigation revealed that due to the limited number of AMS LSEs, unlicensed service engineers were directed to perform licensed service at facilities throughout the United States. It was revealed that the President of AMS was aware of the shortage of LSEs, but made no apparent attempt to alleviate the matter, preferring to recognize the matter as poor management by the NSM.

It was revealed that the NSM resigned from AMS due to a concern that he was vulnerable as a result of the licensed service activity being performed by unlicensed personnel and his having been responsible for scheduling unlicensed service personnel to conduct licensed services.

The investigation further revealed that when the availability of LSEs diminished from approximately five in early 1984 to one in September 1986, AMS' interpretation of the term "licensed work" changed. Under the new AMS interpretation, unlicensed service personnel were authorized by the new AMS policy to activate cobalt teletherapy units and repair and/or replace cobalt timing units. The conditions for performing these type activities are described in AMS' NRC service license.

The investigation disclosed that AMS unlicensed personnel also conducted cobalt teletherapy unit installation. AMS, through their counsel, provided affidavits to NRC:RIII on December 23, 1986, supporting their position that the unlicensed installation of a cobalt teletherapy unit "head" installation had not occurred. It was subsequently revealed that this documentation was false.

The investigation revealed that the alleged falsification of sealed source leak test data was not substantiated. The perceived "source" referred to by the allegor was in reality a container in which the "source" was transported.

The investigation also revealed that a final examination to become an LSE was made available to an LSE applicant as a "study guide." However, no evidence was developed to support the allegation that the answers to the final test,

which consisted of both fill-in-the-blank and multiple choice questions, were provided to candidates for licensing.

Regarding the failure of AMS to notify the NRC of information indicating a defect which would affect the operation of the cobalt-60 C-9 teletherapy unit, the AMS RSO was aware of such information regarding the timer in use on one particular teletherapy unit model, and intentionally failed to notify the NRC.

ACCOUNTABILITY

The following portions of this Report of Investigation (Case No. 3-86-010) will not be included in the material placed in the PDR. They consist of pages 3 through 53.

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APPLICABLE REGULATIONS

10 CFR 30.34(c)(e), Terms and Conditions of Licenses

10 CFR 21.21, Notification of Failure to Comply or Existence of a Defect

Atomic Energy Act of 1954, as amended, Section 223(a), Violations of Sections Generally

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DETAILS OF INVESTIGATION

Purpose of Investigation

This investigation was initiated to: (1) determine whether or not Advanced Medical Systems, Inc. (AMS), was sending unlicensed service engineers to perform licensed service activities, if this was knowingly done by responsible AMS officials, and relatedly, to determine whether AMS provided false information to the NRC about this allegation in the form of an affidavit; (2) determine whether or not Cobalt-60 sealed source leak test results were being falsified, and if so, by whom; (3) determine whether or not answers to tests certifying service engineers were made available to candidates prior to taking the test; and (4) determine whether or not AMS failed to notify the NRC regarding alleged information indicating a defect which would affect the operation of a Cobalt-60 C-9 teletherapy unit.

Background

AMS, a subsidiary of Advanced Technology Corporation (ATC), is headquartered in Geneva, OH. The President and Chief Executive Officer of both AMS and ATC is Dr. Seymour S. STEIN (Exhibit 1).

AMS purchased the cobalt teletherapy business from Picker International, Inc. (Picker), Highland Heights, OH, in late 1979. AMS operated originally under two licenses (No. 34-19089-01 and No. 34-19089-02) granted by NRC Region III (NRC:RIII) (Exhibits 2 and 3).

License No. 34-19089-01, issued originally on or about November 2, 1979, authorized processing Cobalt-60 for redistribution; installation, dismantling, service, and maintaining teletherapy units; the removal or replacement of sources in teletherapy units; and development and demonstration of equipment, etc.

License No. 34-19089-02, issued originally on or about July 9, 1980, specifically addressed servicing only. The activities authorized by this license included installation, maintenance, dismantling, and servicing of Picker and AMS radiography and teletherapy devices. This particular license is restricted for use in accordance with representations and procedures contained in the original application dated November 5, 1979, and March 10, 1980 (Exhibits 4 and 5).

In March 1983, a routine safety inspection conducted by NRC:RIII inspectors revealed the following noncompliances (Exhibit 6).

1. Under License No. 34-19089-01:
 - a. Whole body exposure in excess of 3 rems in one calendar quarter.
 - b. Failure to follow procedures for periodically checking dosimeters while working in a high dose area.
 - c. Failure to wear required film badges in radiation field.

- d. Failure to evaluate a required extremity dose.
2. Under License No. 34-19089-02: Failure to leak test a calibration source every six months.

AMS was assessed a Civil Penalty of \$4,000 for a Severity Level III violation as a result of the inspection findings (Exhibit 6).

On June 1, 1983, AMS denied corporate responsibility for the March 1983 inspection report findings and reported that management suspended (without pay) the responsible employees (Exhibit 7).

On July 13, 1983, the NRC reconfirmed the imposition of the Civil Penalty of \$4,000, citing the AMS June 1, 1983, response as insufficient to mitigate the NRC imposed penalty (Exhibit 8).

In July 1984, a routine safety inspection of AMS by NRC:RIII revealed excessive radiation levels and a failure to post warnings in a high radiation area. In addition to these two violations, the NRC:RIII inspectors also expressed in the report a concern over the condition of the hot cell window, the recent reduction in the number of adequately trained personnel at the London Road facility (the location where the Cobalt-60 is handled), the shortage of qualified personnel, and the perceived effect that shortage would have on maintaining a radiation safety program (Exhibit 9).

During February 21 through April 25, 1985, a special safety inspection conducted by NRC:RIII inspectors identified four items of noncompliance: (1) external exposures to an individual in excess of the limits; (2) failure to read dosimeters at required intervals; (3) failure to calibrate dosimeters every six months; and (4) failure to perform an adequate survey to evaluate the radiation hazards to workers in a high radiation area (Exhibit 10).

As a result of the findings of this inspection report, on June 28, 1985, a Notice of Violation and Proposed Imposition of Civil Penalties, and an Order Modifying the AMS license was directed. The base civil penalty for these violations (Severity Level III) was \$5,000. However, due to AMS' failure to adequately implement previous corrective actions for prior similar problems, the \$5,000 base civil penalty was increased by 25% to \$6,250 (Exhibit 11).

On July 31, 1985, STEIN categorically denied, via letter each and every violation (Exhibit 12). As a result of this July 31, 1985, letter to the NRC, in which STEIN denied the findings of the NRC:RIII inspector, and in light of subsequent written statements by STEIN in countering the alleged violations, an NRC Office of Investigations (OI) Investigation (Case No. 3-85-015) was requested by the NRC:RIII Administrator.

On June 25, 1986, the NRC, in response to a November 12, 1984, AMS request, combined all AMS NRC licenses into one NRC License No. 34-1901-89-01 (Exhibit 13).

On September 17, 1986, a special safety inspection of AMS was conducted by NRC:RIII. As a result of the findings of that inspection, the NRC:RIII Administrator, on October 8, 1986, requested an additional investigation to address the following allegations: (1) did AMS willfully use unqualified and

unlicensed technicians to service teletherapy equipment; (2) did an AMS manager direct the falsification of sealed source leak test results to indicate a value significantly lower than that counted in order to avoid the decontamination process; and (3) were test answers given in advance to applicants being tested for certification as Licensed Service Engineers (LSEs).

On October 10, 1986, as a result of the NRC:RIII inspection into activities at AMS, STEIN was presented with an NRC Order suspending AMS' service license and an Order to Show Cause (effective immediately). During the ongoing inspection of AMS records following the suspension, an investigation was also undertaken to determine if AMS was in receipt of information suggesting that the Sodeco timer (a cobalt teletherapy unit timing mechanism used as a replacement timer in the C-9 units) was prone to fail, and if sufficient evidence of these alleged failures was available to AMS to prompt a 10 CFR 21.21(b)(1) notification by AMS to the NRC.

Chronology

Allegation 1: Alleged Willful Assignment of Unqualified and Unlicensed Service Engineers to Conduct Service Requiring a License and Providing a False Document to the NRC

Review of AMS License

The AMS license reflects the following employees of AMS were licensed under Licenses No. 34-19089-01 or No. 34-19089-02 to conduct licensed service work (the dates of employment were provided by either AMS or the individual) (Exhibits 3, 4, and 37).

<u>Name</u>	<u>Date Hired</u>	<u>Termination</u>
Norman KELBLEY		
Darwin MURRAY		
Tommy KIDD		
Glenn SIBERT		
Richard DUNCAN		
Bob APNDT		
Victor SALTENIS		
William SKOCH		
James COCHRAN		
Keith JORDAN		

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NRC:RIII Inspection Results

An NRC:RIII unannounced special inspection was initiated upon receipt of an allegation that Jim LESLIE, an unlicensed service engineer for AMS, had been directed to perform installation and repair procedures on a Cobalt-60 teletherapy treatment timer and head at the Munson Medical Center, Traverse City, MI. It was alleged that Paul CARANI, AMS National Service Manager (NSM), directed LESLIE to conduct the licensed activity due to the lack of available LSEs (Exhibit 14, p. 11).

1 to 21

In addition to the above allegations, it was also alleged that Garnett LIGHT, an unlicensed service engineer, conducted licensed service activity while working alone at the Veterans Administration (VA) Hospital, East Orange, NJ (Exhibit 14).

Interview with Keith JORDAN, AMS LSE

INVESTIGATOR'S NOTE: At the time this investigation was initiated in October 1986, JORDAN was the sole remaining LSE in the employ of AMS.

On October 27, 1986, JORDAN was interviewed under oath in the presence of his attorney (provided by AMS), William F. KOLIS, Jr., of Wickens, Herzer, and Panza Co., L.P.A., Lorain, OH. JORDAN provided a sworn statement (Exhibit 15) and stated substantially as follows:

JORDAN stated that on approximately August 29, 1984, he was employed by AMS to do simulator assembly (a simulator is used by physicians in patient treatment). He eventually volunteered to attend AMS' cobalt teletherapy training course to become licensed to service cobalt teletherapy machines (Exhibit 15, pp. 5-7).

According to JORDAN in June 1985, he was approved by AMS' Radioisotope Committee to conduct licensed activity and was eventually placed on AMS' license (No. 34-19089-01) under Amendment No. 5 dated January 10, 1986 (Exhibit 2). JORDAN defined licensed activity as follows: "shielding...anything that has to do with the amount of radiation a patient is to receive per prescription from the doctor" (Exhibit 15, p. 11).

JORDAN identified the following as licensed activity: (1) collimator work; (2) activating the source (turning the source on) by a key switch on the control console (Exhibit 15, pp. 13-14); and (3) work on the timer (contained in the control console).

JORDAN further stated that he was taught that the act of opening up the console (which contains the timing device) was licensed activity. However, JORDAN identified CARANI (Field Service/Production Manager) as not agreeing with that interpretation. According to JORDAN, CARANI never considered service on the timer as licensed activity (Exhibit 15, pp. 14-16). JORDAN explained that upon the departure on or about July 26, 1985, of SIBERT, the former temporary AMS Radiation Safety Officer (RSO), the concept that service on the Cobalt-60 timing device was a licensed activity was no longer enforced by CARANI (Exhibit 15, pp. 16-17).

JORDAN identified the activity associated with Service Report No. 2466 dated February 26, 1985, as a licensed activity. The customer's complaint, according to JORDAN, was "basically that the shutter timing to open is slow." JORDAN acknowledged that at the time of the above stated activity, he was not licensed (Exhibit 14, Attachment X; Exhibit 15, pp. 24-28). JORDAN identified William GAMMERN, the AMS NSM at that time, as the person who would have been responsible for sending him (JORDAN) out on Service Report No. 2466 (Exhibit 15, p. 28).

JORDAN stated that he was unaware at the time he conducted the service as indicated on Service Report No. 2466 that he was conducting licensed activity

(Exhibit 15, p. 28). JORDAN stated that "a technician can always do that (turn on the source) for you." However, JORDAN could not recall whether or not the technologist turned on the source that particular time or not. JORDAN stated that it is not uncommon for the hospital technician to activate the source for AMS personnel (Exhibit 15, p. 30).

JORDAN explained that it was his understanding at the time he was doing the work that a hospital technician could be used by AMS service personnel to activate the source so that unit tests could be conducted (Exhibit 15, p. 30).

INVESTIGATOR'S NOTE: A copy of the AMS Cobalt Service Procedures Manual (SPM) (Exhibit 20) contradicts JORDAN. The SPM states the following regarding AMS policy: "these procedures are to be followed by Advanced Medical Systems, Inc. service technicians when performing service on Advanced Medical Systems, Inc. and Picker Corporation Cobalt-60 Teletherapy and Industrial Radiography Systems." Page 2, paragraph 4 of the SPM states that "the licensee for whom the service is being performed will relinquish control over the use of, and the keys for, the equipment and it's controlled areas to the licensed person in charge until such time as it has been determined by the licensed person that the equipment is in safe operating condition. The licensed person will then return control of the equipment and controlled areas to the licensee."

JORDAN acknowledged that in order to conduct unit tests and demonstrations, one must activate the teletherapy unit, and that activating the unit is a licensed activity. JORDAN acknowledged that he was not licensed at the time of his service at Moses Cone Memorial Hospital on February 26, 1985 (Exhibit 15, p. 31).

JORDAN identified Service Reports No. 2504 and No. 2718 as service reports with which he was associated (Exhibit 15, pp. 31-34; Exhibit 21; Exhibit 22). Service Report No. 2504 dated April 8, 1985, regarding service on a C-12 unit at Bronx VA Hospital, Bronx, NY, indicated "shutter won't open on 180° treatment angle." The "cause" was written as follows: "magnet not holding shutter down on 'on' position" and work carried out was "instructed personnel how to use machine till part can be replaced (Exhibit 21). Service Report No. 2718 dated April 10, 1985, regarding the same C-12 unit and the same field service trip, indicated that the shutter magnet was replaced, the micro switch readjusted, etc., at Bronx VA Hospital, Bronx, NY (Exhibit 22).

JORDAN stated that he was the only AMS representative conducting the service work at the Bronx VA on Service Reports No. 2504 and No. 2718. JORDAN identified the work on Service Reports No. 2504 and No. 2718 as being licensed activity. JORDAN, however, was not licensed at the time the work described on Service Reports No. 2504 and No. 2718 was conducted (Exhibit 15, p. 33).

INVESTIGATOR'S NOTE: JORDAN was first approved to work under AMS License No. 34-19089-02 by the AMS Radioisotope Committee on June 25, 1985 (Exhibit 23).

JORDAN identified GAMMERN as the person responsible for sending him (JORDAN) out to conduct the service calls. JORDAN stated that he was unsure whether he (JORDAN) was aware at the time of the service that what he was doing required a license. JORDAN, however, stated that he was ambitious and just wanted to

do a good job, and that he may have known he was doing licensed activity. JORDAN said he just did as he was told and that he was the only person who worked on the C-12 unit in the entire company, or who had any kind of training whatsoever on the C-12 unit, and that there was no choice as to who AMS would send out to conduct the C-12 service work (Exhibit 15, pp. 34-35).

JORDAN identified as accurate, Service Report No. 3181 dated June 11, 1986, for VA Medical Center, East Orange, NJ, indicating service by JORDAN (Exhibit 24, Attachment K). JORDAN, who was licensed under AMS License No. 34-19089-01 at this point in time, stated that he was sent by CARANI, (AMS NSM during the June 11, 1986, time frame) to conduct this service (Exhibit 15, p. 35).

JORDAN stated that CARANI told him (JORDAN) that the job would take one day. However, JORDAN said that he (JORDAN) worked on Service Report No. 3181 for approximately one week. JORDAN explained that he was unable to concentrate on the service call because [REDACTED] b.7C
JORDAN said that he asked CARANI to send help, which CARANI did. When the help arrived, whom JORDAN identified as LIGHT (an unlicensed service engineer), he (JORDAN) returned to Ohio to be with his [REDACTED]
JORDAN said the service work consisted of installing a new console, which he (JORDAN) could not get to operate properly. JORDAN said, however, that when LIGHT arrived, the console was assembled and that LIGHT had only to get it operating (Exhibit 15, pp. 35-37).

JORDAN stated that on another occasion LESLIE telephoned him from the Munson Medical Center and asked JORDAN's advice because the hospital had requested that he (LESLIE) conduct work that he (LESLIE) knew to be licensed activity. JORDAN said he directed LESLIE to get on the plane and come home (Exhibit 15, pp. 46-57). JORDAN stated that he then went to the Munson Medical Center and completed the service which LESLIE had been asked to do. JORDAN acknowledged that LESLIE, by installing a timer, had already conducted licensed activity work (Exhibit 15, pp. 48-49).

INVESTIGATOR'S NOTE: KOLIS, AMS' attorney present at this interview at the request of JORDAN, attempted to interfere with JORDAN's response affirming that timer replacement was a licensed activity. However, JORDAN maintained that it was his opinion, based upon his training at AMS, that timer replacement was licensed activity. KOLIS attempted to dismiss JORDAN's opinion by saying that the question called for a legal conclusion on the part of JORDAN. JORDAN then stated that the company (AMS) may not perceive timer replacement as licensed activity, but that he did.

Interview with Glenn SIBERT, former AMS LSE and Temporary RSO

SIBERT was interviewed on January 14, 1987, and provided a sworn statement (Exhibit 17) in which he stated substantially as follows:

SIBERT, former AMS LSE and temporary RSO designate, stated that his experience in cobalt processing spanned approximately 14 years, 1971-1985, beginning with Picker. SIBERT related that while with Picker's Therapy Department at 1020 London Road, Cleveland, OH, he processed and built Cobalt-60 sources in the "hot cell." SIBERT said his experience consisted of shipping sources to

clients, installing the sources in the teletherapy units, and servicing the units in the field.

SIBERT stated that in 1979, STEIN purchased the Picker operation and the operation became known as AMS. At that time, SIBERT left the employ of Picker and for three months was employed by Neutron Products in Dickerson, MD.

According to SIBERT on about [REDACTED] he accepted employment with AMS at the London Road facility (the very same operation and location he was associated with before leaving Picker and prior to STEIN's purchase of the operation) to conduct any work required in the laboratory, i.e., processing sources, cleaning the lab, surveying the lab, and doing service work. SIBERT said he was also an instructor under Norman KELBLEY's supervision in the cobalt teletherapy training course at AMS, which ran two continuous weeks (Exhibit 17). 6,7c

According to SIBERT, disconnecting the old timer from the timing system, installing a new timing system, and checking the system to insure proper operation by conducting unit tests and setting the preset timer, etc., "is definitely licensable work" (Exhibit 17, pp. 30-31).

INVESTIGATOR'S NOTE: This corroborates the statement of JORDAN concerning LESLIE'S installation of a timer at Munson Medical Center.

Interview with Garnett C. LIGHT, former AMS Mechanical Assembler

LIGHT was interviewed on October 28, 1986, and provided a sworn statement (Exhibit 26) in which he stated substantially as follows:

LIGHT said he was employed by AMS in approximately [REDACTED] as a "mechanical assembler," assembling the cobalt teletherapy unit. LIGHT, stated that he was not an LSE, but was generally familiar with AMS Licenses No. 34-19089-01 and No. 34-19089-02 and what each license allowed (Exhibit 26, pp. 6-7). 6,7c

LIGHT identified the handwriting on Service Report No. 3181 as his own. LIGHT stated that he was sent by CARANI to assist JORDAN on the job. LIGHT said that JORDAN was having an electrical problem with the console (Exhibit 26, pp. 8-11).

LIGHT acknowledged that it was on or about Monday, June 9, 1986, that CARANI directed LIGHT to travel to East Orange, NJ, to assist JORDAN. However, LIGHT said that he expressed his fear to CARANI that once he (LIGHT) arrived at East Orange, JORDAN would return home, leaving LIGHT alone to repair the unit. LIGHT said that CARANI told him (LIGHT) that he (LIGHT) had to go or he (LIGHT) would be fired (Exhibit 26, pp. 11-12).

LIGHT said that upon arriving at East Orange on the afternoon of June 9, 1986, he and JORDAN worked late into the evening before stopping, and still had not corrected the electrical problem. The next morning, June 10, 1986, JORDAN returned to Ohio, as LIGHT had feared JORDAN would. There was no LSE present during the remaining service call. LIGHT stated that he called CARANI at Geneva, OH, and asked for assistance. CARANI responded to LIGHT's concerns,

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according to LIGHT, by stating that he (CARANI) did not have anybody available to send out (Exhibit 26, p. 13).

LIGHT stated that he personally opened (activated) the source, which he identified as licensed service work. LIGHT, however, stated that it was his understanding that as long as a hospital technologist was present at the time of activation, an unlicensed service engineer (such as he) could conduct licensed work on a unit. The source activation was required, according to LIGHT, in order to set the rotational speed of the unit. LIGHT also stated that he performed unit tests and demonstrations requiring activation of the unit (Exhibit 26, pp. 14-15).

INVESTIGATOR'S NOTE: The AMS SPM (Exhibit 20) clearly states that a licensed AMS person is required to determine if the equipment is in safe operating condition prior to returning control to the licensee, who in this case (Service Report No. 3181) was VA Medical Center, East Orange, NJ.

LIGHT, stated the following when questioned regarding his knowledge of any other circumstances wherein LSEs were unavailable and unlicensed service engineers were required to perform service which involved licensed activity work. LIGHT indicated that such circumstances occurred at Eastside, Willoughby Hills, OH (Exhibit 26, pp. 17-18).

LIGHT stated that CARANI, AMS NSM, directed LIGHT to install a "head" on a cobalt teletherapy C-8 unit, "or else." LIGHT interpreted the "or else" to mean termination if he refused to comply with CARANI's orders. LIGHT said that he (LIGHT) informed CARANI that he (LIGHT) was not licensed and that he (LIGHT) could not accept the responsibility for performing the head installation (Exhibit 25, p. 18).

Interview with James M. LESLIE, former AMS Unlicensed Service Engineer

LESLIE was interviewed on October 29, 1986, and provided a sworn statement (Exhibit 30) in which he stated substantially as follows:

Service Report No. 3172, Munson Medical Center, Traverse City, MI, dated April 28, 1986 (Exhibit 14, Attachment B), revealed service by LESLIE, an unlicensed service engineer.

LESLIE stated that he was employed by AMS on approximately [REDACTED] until September 15, 1986, [REDACTED] 6.7E

[REDACTED] LESLIE stated that on April 28, 1986, he traveled to Traverse City, MI, at the direction of CARANI. CARANI had directed LESLIE to repair an electronic problem on a cobalt teletherapy unit at the Munson Medical Center. LESLIE said that he was not licensed to work on this particular problem, as the work consisted of repairing the unit's control panel timer. LESLIE stated that he had no training in installing the timer, nor had he received any training on the Cobalt-60 teletherapy unit prior to this service. LESLIE said he was directed by CARANI to go to Traverse City because no one else was available (Exhibit 30).

INVESTIGATOR'S NOTE: The AMS criteria of availability over licensed status is again apparent in CARANI's decision to send LESLIE to the Munson Medical Center.

LESLIE stated that at his request, an Eagle Signal Timer was shipped by AMS to the Munson Medical Center and that he (LESLIE) then replaced the faulty timer. The timer was then checked for accuracy by hospital personnel (Exhibit 30).

INVESTIGATOR'S NOTE: The timer checkout (a unit test and demonstration), to be in accordance with AMS' license, should have been performed by an AMS LSE (Exhibit 30, p. 2).

On April 28, 1986 (the second day of service performed by LESLIE), LESLIE said the hospital voiced an additional concern. The concern was described by LESLIE as "a motor problem inside the head." LESLIE said he told the hospital personnel that he had to consult with his service manager (CARANI) regarding any concerns not originally addressed in the service report. LESLIE stated that CARANI instructed him to go ahead and repair the unit. LESLIE said that he told CARANI he did not even know what the doctor was talking about and asked CARANI how he (LESLIE) was supposed to fix the machine. CARANI said he would let JORDAN talk to him (LESLIE) on the telephone (Exhibit 30).

LESLIE stated that JORDAN advised him to inform the hospital that he (LESLIE) was not licensed and to "just get out of there." LESLIE stated that he so informed Doug DAVIS, the hospital's physicist, who, according to LESLIE, became visibly upset. DAVIS informed LESLIE that he was going to complain to CARANI about an unlicensed service engineer being provided by AMS to conduct licensed service (Exhibit 14, Attachments C and D; Exhibit 30).

The following day, upon LESLIE's return to AMS, LESLIE stated that he asked CARANI why he sent him (LESLIE) to Munson Medical Center when he (LESLIE) was not licensed to do the work. CARANI's response, according to LESLIE, was that he (CARANI) was unaware that a license was required (Exhibit 30).

Interview with Russell P. FORTIER, former AMS Electronics Technician

FORTIER was interviewed on October 28, 1986, and provided a sworn statement (Exhibit 31). FORTIER, whose employment at AMS began in [REDACTED] stated the substantially as follows (Exhibit 31): 6, 7

FORTIER indicated that he was hired by AMS as an electronic technician to work on Service Treatment Planners. FORTIER stated that he began learning cobalt from James COCHRAN, an LSE, in an on-the-job training status (Exhibit 31, pp. 6-7).

FORTIER related, however, that his training at AMS was not of great help to him. He did have a vague recall of being trained by AMS. FORTIER stated that most of the people under training were servicemen, and servicemen were needed in the field to work on equipment. According to FORTIER, the manner in which AMS viewed the situation was that the whole service department could not be away from the field for two weeks in order to train in the manner required by AMS' license (Exhibit 31, p. 11). FORTIER stated that AMS' concern "was just money...get the job done" (Exhibit 31, p. 13). FORTIER said that he was never

licensed as a service engineer, but that he was required to do repair work on cobalt teletherapy units (Exhibit 31, pp. 15-16).

Service Report No. 2795 (Exhibit 14, Attachment F) dated May 30, 1985, for Joint Disease Hospital, Harlem, NY, reflects service work by FORTIER. According to FORTIER, he was sent to the Joint Disease Hospital by either GAMMEKN or CARANI.

INVESTIGATOR'S NOTE: GAMMERN was NSM between [REDACTED] CARANI assumed the responsibilities of NSM upon GAMMERN's leaving the employ of AMS (Exhibit 25, p. 7), which would have placed CARANI in the position of NSM during Service Report No. 2795 (May 30, 1985). 6,7C

FORTIER stated that he was informed that the service required him to replace the "head tilt motor," which positions the "head" for a particular patient. FORTIER stated that he was told by CARANI or GAMMERN that the service he was to perform was not licensed work (Exhibit 31, pp. 17-18).

INVESTIGATOR'S NOTE: GAMMERN was not employed at AMS at the time of this service, CARANI was the NSM. NRC:RIII Inspection Report No. 030-16055/86-001, dated November 25, 1986 (Exhibit 14, pp. 27-28), identifies Service Report No. 2795 as licensed activity.

Service Report No. 2978 dated October 16, 1985, addressing service at St. Joseph Riverside Hospital, Warren, OH (Exhibit 14, Attachment G), reflects service conducted by FORTIER. FORTIER indicated that the problem was that the timer would not turn off the source (Exhibit 31, p. 23). FORTIER stated that he basically "tore the timer out of the unit," and cleaned and lubricated it (Exhibit 31, p. 24).

FORTIER stated that after cleaning the timer, he tested the timer. FORTIER described a step by step process by which the teletherapy machine is activated, the time set, and the cobalt source exposed (Exhibit 31, pp. 24-27). FORTIER described the service he conducted as licensed activity and that a hospital technician was present (but not continuously) during this testing (Exhibit 31, pp. 24-27).

INVESTIGATOR'S NOTE: It is STEIN's position that an unlicensed AMS service engineer may conduct licensed activity in the presence of hospital personnel who routinely operate the unit. This practice, however, is not in accordance with AMS' license. In FORTIER's aforementioned case, the hospital technologist was not present throughout the process, thereby violating even AMS' alleged policy.

Service Report No. 2949 dated October 21, 1985, reflects service at St. Joseph Riverside Hospital, Warren, OH, by FORTIER (Exhibit 14, Attachment H). FORTIER described the service at the hospital as a repair of the "key switch" on the unit. The hospital technologist was allowed by FORTIER to conduct quality checks.

INVESTIGATOR'S NOTE: This service was identified in NRC:RIII Inspection Report No. 030-16055/86-001 (Exhibit 14, pp. 27-28) as a licensed activity.

Service Report No. 1721 dated October 23 and 24, 1985, reflects service at Ball Memorial Hospital, Muncie, IN, by FORTIER (Exhibit 14, Attachment I). FORTIER described problems associated with the Sodeco timer used on C-9 units as follows: "it would not always stop and turn the shutter off, the source would stay open and just continue" (Exhibit 31, p. 31). FORTIER replaced the Sodeco timer with a Sodeco timer.

FORTIER stated that he (FORTIER) was the only available serviceman at AMS the day the service request (No. 1721) was received. CARANI, according to FORTIER, asked him (FORTIER) to go to Ball Memorial. FORTIER stated that he recalled approaching CARANI with the concern that the service required was licensed activity, at which time CARANI "acted" as if he did not know for sure whether the required service was a licensed activity (Exhibit 31, p. 34).

FORTIER stated that regardless of CARANI's response to his (FORTIER's) inquiry regarding licensed work, he (FORTIER) thought the requested service required a license. FORTIER stated that he felt confident in his ability to conduct the work, but was uncomfortable with the thought that he was not licensed to perform the required service (Exhibit 31, p. 34).

FORTIER related that the day following the service conducted at Ball Memorial (Service Report No. 1721), COCHRAN, an LSE, informed him that the service he performed was "definitely licensable work" and that he (FORTIER) should not have done it. FORTIER stated that had he refused to do the requested service, he felt he might have lost his job, because "there was never any job security at AMS" (Exhibit 31, p. 35).

FORTIER stated that he and Victor SALTENIS, both unlicensed service engineers, were sent to China to install a cobalt teletherapy unit. FORTIER stated that both he and SALTENIS knew that if they had been performing the same service in the United States, it would have been illegal. However, according to FORTIER, AMS management told him that the NPC had no jurisdiction over the work done outside the country (Exhibit 31, pp. 40-41).

FORTIER stated that he eventually left AMS because of [REDACTED] and the problem of unlicensed versus licensed activity. As according to FORTIER, 417c
as he gained knowledge as to what constituted licensed and unlicensed work, conflict developed between what he was required to do and what he felt he could legally do (Exhibit 31, p. 43). FORTIER described his frustrations as a result of poor training and ambiguous guidelines. The training, according to FORTIER, consisted of "a shot here and a shot there" (Exhibit 31).

Interviews with Erich H. DREIER, AMS Assistant Service Manager

DREIER, Assistant Service Manager under CARANI was initially interviewed on October 16, 1985, and stated that he never, on his own, assumed the responsibility of sending out service personnel (Exhibit 33). DREIER provided a telephone call report for review (Exhibit 34) dated September 19, 1986, which, according to DREIER, initiated Service Report No. 1991. DREIER identified himself as the person who received the service call as revealed in Exhibit 34, and stated that CARANI was the person responsible for sending Rick SPEER to Allen Park, MI, on this particular service request.

DREIER was subsequently interviewed under oath on December 8, 1986, in the presence of KOLIS, and AMS-retained attorney, whom DREIER requested be present during the interview (Exhibit 35). DREIER stated substantially as follows:

DREIER's attorney (KOLIS) read into the record the report of interview dated October 16, 1986, which stated, "CARANI was the person responsible for sending SPEER" (on Service Report No. 1991). DREIER acknowledged that the report of interview as read by KOLIS was accurate (Exhibit 35, p. 8). DREIER stated that he would have called CARANI to ask who should be sent on the service call if CARANI were not physically present to send someone. DREIER further stated that CARANI, during this time frame, was overseeing work being conducted at Eastside Radiology Imaging and Therapy Center (Eastside), Willoughby Hills, OH (Exhibit 35, p. 9).

DREIER stated that it was determined that Service Report No. 1991 was not licensed activity service, therefore SPEER could be sent. DREIER identified CARANI as the person being responsible for determining licensed work and sending out service personnel (Exhibit 35, p. 10).

Interview with Mark BAKER, former AMS Unlicensed Service Engineer

BAKER was interviewed on December 17, 1986. BAKER provided a sworn statement (Exhibit 36) and stated substantially as follows:

A review of Service Reports No. 2219, No. 2294, and No. 2814 reflect licensed work performed by BAKER, an unlicensed service engineer (Exhibit 14, Attachments V, S, and CC).

According to BAKER, he was employed at AMS from [REDACTED] 6,7C
BAKER stated that he originally began working at AMS in the quality control field and transitioned into the production area within three or four months building cobalt and simulator machines. BAKER said that during the period he worked in production, it got to the point where they started needing service on the equipment, and because he (BAKER) had built them, he began going out on service calls starting with simulators (not licensed by NRC) (Exhibit 36, p. 8).

BAKER said that both he and SALTENIS (a production employee who also conducted service work on simulators) began to get involved in cobalt. BAKER stated that as the volume of AMS service requests increased, he attended the AMS cobalt teletherapy training class, where he received instruction regarding what constituted licensed and unlicensed service work (Exhibit 36, p. 9).

BAKER identified service work on the following components as licensed activity: (1) shutter; (2) collimator; and (3) treatment timer on the control console.

BAKER further stated that if a component, integrated into the control console, was in any manner associated with the shutter control portion of the teletherapy unit, an unlicensed individual would be prohibited from work on that component (Exhibit 36, p. 10).

Service Report No. 2219 dated October 5, 1984, reflects work conducted by BAKER at Monroe Radiology Associates, Rochester, NY (Exhibit 14, Attachment V). BAKER described the work as inspecting and tightening the collimator bearing ring. BAKER, however, did not feel that he had conducted licensed activity because shielding was not removed from the unit. BAKER identified GAMMERN as the person responsible for sending him out on Service Report No. 2219 (Exhibit 36, pp. 12-13).

INVESTIGATOR'S NOTE: The collimator work was judged to be licensed activity by NRC:RIII Inspection Report No. 030-16055/86-001 (Exhibit 14).

Service Report No. 2294 dated November 29, 1984, reflects work conducted by BAKER at VA Medical Center, Bronx, NY (Exhibit 14, Attachment S). BAKER stated that the the VA Medical Center's complaint was that the shutter would not work. This service would have required BAKER to open the shutters in order to conduct a unit test. BAKER stated that such service would have required a licensed person to activate, or demonstrate the unit was operable (Exhibit 36, p. 12).

Service Report No. 2814 dated July 5, 1985, reflects service by BAKER at St. Joseph Hospital, Joliet, Illinois (Exhibit 14, Attachment CC). BAKER stated that he conducted a preventive maintenance inspection at St. Joseph Hospital consisting of: (1) adjusting the light to the radiation field; and (2) tightening the gain to rotation chain and gear box, and repairing burned wires (Exhibit 36, p. 12). Upon completing the work required by a preventive

maintenance inspection, BAKER stated that it was necessary to activate the unit, which according to BAKER, requires a license (Exhibit 36, p. 14).

BAKER stated that he and other unlicensed service engineers were instructed to activate the cobalt teletherapy unit if alone, with no one else available to activate the machine for them. Otherwise, if possible, to have the radiation therapy technician activate the unit. BAKER could not recall specifically who directed this action. However, BAKER stated that GAMMERN was the NSM and Howard IRWIN was RSO when this policy was in effect (Exhibit 35, pp. 15-16).

BAKER stated, regarding the three previous Service Reports (No. 2219, No. 2294, and No. 2814), that he was aware at the time of the service that he was conducting licensed activity, and that on each job he conducted the required unit tests, which required activation of the unit (Exhibit 36, p. 5).

Interviews with Rick SPEER, AMS Mechanical Assembler

SPEER was interviewed on January 2, 1987 (Exhibit 48), and stated substantially as follows:

SPEER said he was sent to perform service on occasions identified by the NRC:RIII unannounced special inspection as service requiring a license (Exhibit 14). Those instances were Service Report No. 1796 dated December 20, 1985 (Exhibit 14, Attachment N), and Service Report No. 1856 dated January 16, 1986 (Exhibit 14, Attachment M).

SPEER, a mechanical assembler for AMS beginning in [REDACTED] was interviewed by NRC inspectors on October 1, 1986. SPEER stated that he witnessed LIGHT reinstall a "head" at Eastside without supervision by COCHRAN, a contracted LSE (Exhibit 14, Attachment L). 6, 7c

On January 2, 1987, SPEER was interviewed telephonically and contradicted his previous statement to NRC inspectors given on October 1, 1986 (Exhibit 14, Attachment L), by stating that COCHRAN was present at all times when he (SPEER) was at Eastside (Exhibit 47).

INVESTIGATOR'S NOTE: SPEER would not grant NRC:OI an in-depth interview.

On January 26, 1987, SPEER, was interviewed telephonically by NRC inspectors and stated that he did not recall his October 1, 1986, interview. However, upon further thought, he vaguely recalled the statement, but maintained that he does not now recall LIGHT's alleged reinstallation of the head (Exhibit 48).

INVESTIGATOR'S NOTE: SPEER was one of several employees [REDACTED] following the October 10, 1986, suspension order. All of SPEER's statements contradicting his October 1, 1986, statement occurred [REDACTED] SPEER was also characterized by KOLIS on December 23, 1986, as [REDACTED] when KOLIS was attempting to discredit SPEER's statement to the NRC regarding unlicensed service activity (Exhibit 39). SPEER, [REDACTED] performed three service calls, Service Reports No. 1796, No. 1856, and No. 1991 (Exhibit 14, Attachments M, N, and O), which were all identified in the NRC:RIII inspection report (Exhibit 14) as licensed 6, 7c

work conducted by an unlicensed service engineer. These service calls were performed December 1985 through September 1986.

Interview with James F. COCHRAN, former AMS LSE

COCHRAN was interviewed on February 6, 1987. COCHRAN provided a sworn statement (Exhibit 40) and stated substantially as follows:

COCHRAN, an LSE, who was employed by AMS from [REDACTED] stated that his formal cobalt training was conducted by KELBLEY who was assisted by Darwin MURRAY and SIBERT. Following his formal training and approximately six to eight months of on-the-job training, he was approved for an O1 license. AMS Radioisotope Committee meeting minutes of December 5, 1985, paragraph 2, reflects that COCHRAN was incorporated by Amendment No. 2 to AMS License No. 34-19089-01 (Exhibits 37, 40, and 41). 6,7C

COCHRAN stated that upon leaving AMS in [REDACTED] he became a contract employee. COCHRAN stated that he was requested by AMS to conduct all licensed activity associated with the installation of a C-8 cobalt teletherapy unit at Eastside, Willoughby Hills, OH (Exhibit 40). 6,7C

COCHRAN stated that he and LIGHT unloaded the "head" containing the cobalt source off the delivery truck. The cobalt teletherapy unit "stand" was already in place (Exhibit 40).

INVESTIGATOR'S NOTE: The stand, having already been set up as of COCHRAN's first appearance, corroborates SPEER's and LIGHT's recollection that the work was conducted during the summer of 1986. Service Report No. 1959 reveals COCHRAN's first day as August 18, 1986. KOLIS attempted to discredit SPEER's statement that the installation took place in July 1986, prior to Eastside's having a license.

COCHRAN stated that the "head" sat in a crate for a period of time while the "stand" was readied to accept the "head." COCHRAN said that following installation of the "head," installation of the "collimator," and upon conducting unit tests, "slop" was found in the "yoke" bearing. Upon observing the "slop," COCHRAN and LIGHT removed the "head" and sat it in the corner. COCHRAN stated that he then instructed LIGHT to repair the yoke (an unlicensed activity) and left Eastside (Exhibit 40).

COCHRAN stated that he was told by CARANI, AMS NSM, that he (COCHRAN) would be recalled when the repair on the bearing (yoke) was completed. It was upon COCHRAN's return to Eastside four or five days later that he found the "head" had already been reinstalled. COCHRAN stated that he inquired of CARANI, "who installed the head?" CARANI, according to COCHRAN, informed COCHRAN that LIGHT had done the work. COCHRAN stated that he told CARANI he should not have had LIGHT do the work, because LIGHT was not licensed. COCHRAN said that CARANI's response was to shrug his shoulders and, according to COCHRAN, CARANI exhibited no concern that LIGHT was not licensed to perform head installation. COCHRAN said that he then proceeded to install the collimator and conduct unit tests (Exhibit 40).

INVESTIGATOR'S NOTE: COCHRAN's statement contradicts AMS' presentation to the NRC on December 23, 1986, and corroborates the statements of LIGHT and SPEER.

COCHRAN stated that after completing the appropriate quality checks, he completed a service report, installation papers, and other required documents, which he left at Eastside (Exhibit 40).

INVESTIGATOR'S NOTE: Attempts to locate the original service report referred to by COCHRAN were unsuccessful.

COCHRAN stated that on or about October 15, 1986, Theodore HEBERT called him and requested that he come to AMS' office and complete another service report to cover his (COCHRAN's) work at Eastside.

INVESTIGATOR'S NOTE: The request by AMS of COCHRAN came five days after AMS was served the service suspension order by the NRC.

COCHRAN stated that he was directed by Donna ELY to complete a second service report, which stated that all work at Eastside was done in accordance with AMS' license and that he (COCHRAN) supervised LIGHT throughout the installation. COCHRAN said that he was told by LIGHT that CARANI directed LIGHT to reinstall the "head." LIGHT, according to COCHRAN, said that he (LIGHT) told CARANI he (LIGHT) was not licensed to install the head by himself (Exhibit 40).

INVESTIGATOR'S NOTE: The above statement regarding LIGHT's informing of CARANI that he (LIGHT) was not licensed corroborates LIGHT's sworn statement (Exhibit 26).

COCHRAN stated that SPEER, while at Eastside, assisted as necessary in the installation of the cobalt teletherapy machine and an accelerator being installed during the same period.

INVESTIGATOR'S NOTE: COCHRAN's above statement corroborates Despina MAVRAKIS' (Exhibit 42) recollection that other AMS employees Mark (MEETIN) were present installing a linear accelerator when the "head" was installed by LIGHT.

In a followup telephone call by NRC inspectors on February 9, 1987, COCHRAN stated that he informed ELY and HEBERT, in addition to CARANI, that he (COCHRAN) was not present when LIGHT reinstalled the "head." COCHRAN stated that he had no second thoughts about writing the document as directed, that he was just doing as he was told (Exhibit 44).

COCHRAN further related via telephone on February 26, 1987, that ELY had called him on or about February 24, 1987. According to COCHRAN, ELY wanted to know if COCHRAN had informed the NRC that he had reinstalled the "head" at Eastside. COCHRAN said that he told ELY that he had informed the NRC that he had not reinstalled the "head," at which time ELY questioned COCHRAN as to why he had so informed the NRC. COCHRAN stated that he reminded ELY that at the time he completed the service report (No. 1959), he made her aware that he (COCHRAN) had not reinstalled the "head." ELY then told him that what he was telling the NRC did not correspond with the service report (No. 1959) he

completed. COCHRAN said he reminded ELY that the words on the service report were not his words, at which time ELY told COCHRAN, "we didn't put words in your mouth." COCHRAN said he told ELY that he was not stupid, at which point the conversation concluded (Exhibit 45).

Receipt of Documents from William F. KOLIS, Attorney Representing AMS

On December 23, 1985, AMS, represented by KOLIS, the attorney representing AMS provided a brief to NRC:RIII, supporting affidavits, and oral arguments to support AMS' request that the NRC rescind the October 10, 1986, suspension of AMS' service license (Exhibits 38 and 39).

In KOLIS' written brief, it is stated, "since Mr. COCHRAN is licensed, work involving source material by unlicensed persons, provided it is done under his supervision and in his physical presence, is not a violation of AMS' license" (Exhibit 38, p. 35).

KOLIS further presented documents (HEBERT's affidavit) establishing COCHRAN as a licensed subcontractor who was paid for three trips to Eastside and who, according to KOLIS, must have been present on all trips to Eastside (Exhibit 38, p. 35). KOLIS, during his oral presentation of AMS' brief to the NRC, presented Service Report No. 1959, attached to HEBERT's affidavit (Exhibits 38 and 39) to support AMS' position that evidence of licensed supervision by COCHRAN at Eastside was available to NRC investigators/inspectors had they chosen to look for said documentation (Exhibit 39).

INVESTIGATOR'S NOTE: It appears that the copy of Service Report No. 1959 presented to the NRC by KOLIS was the one prepared by COCHRAN upon being directed to do so by ELY. The information contained in this service report has been acknowledged by COCHRAN to be at least partially false.

Interview with Despina MAVRAKIS, Radiation Therapy Manager, Eastside

On September 30, 1986, MAVRAKIS, Radiation Therapy Manager of Eastside, Willoughby Hills, OH, provided a written statement to NRC inspectors. MAVRAKIS stated that over a two week period, COCHRAN, LIGHT, and SPEER installed (at Eastside) a cobalt C-8 unit and console. MAVRAKIS stated that to the best of her knowledge, on the day the "head" was installed, COCHRAN was not present. According to MAVRAKIS, LIGHT and SPEER conducted the installation. COCHRAN, according to MAVRAKIS, returned another day to perform unit tests (Exhibit 42).

MAVRAKIS identified MEETIN, an ATC employee working on installing a linear accelerator at Eastside during the same time period, who, according to MAVRAKIS, told her that the Cobalt-60 installation had been conducted by unqualified personnel. MAVRAKIS also stated that she was told by MEETIN that a three month delay by AMS to install the Cobalt-60 teletherapy machine was due to the unavailability of licensed personnel (Exhibit 42).

INVESTIGATOR'S NOTE: MAVRAKIS' statement corroborates the statements of SPEER, LIGHT, and COCHRAN, and contradicts AMS' presentation to the NRC on December 23, 1986. The lack of available LSEs as allegedly related to MAVRAKIS by MEETIN corroborates CARANI's statement that he had no one from whom to choose.

Memorandum prepared by George McCANN, Senior License Reviewer, NRC:RIII

McCANN stated that on September 30, 1986, while conducting a special inspection of Eastside, he was provided an AMS service report by CARANI, which bore the signature of COCHRAN. This report, according to McCANN, prompted him to ask questions of CARANI regarding COCHRAN's presence during the head installation (Exhibit 43).

service report presented by KOLIS to the NRC (Service Report No. 1959) on October 23, 1986, was dated October 15, 1986, and signed by COCHRAN (Exhibit 38, HEBERT's affidavit).

INVESTIGATOR'S NOTE: The period of work covered by Service Report No. 1959 is August 18 to September 5, 1986. COCHRAN stated that upon completion of the installation at Eastside, he prepared the service report which would indicate an approximate date of September 5, 1986. The service report presented by KOLIS to the NRC was dated October 15, 1986, following the October 10, 1986, AMS service license suspension imposed by the NRC.

Interview with William GAMMERN, former AMS NSM

GAMMERN was interviewed on October 29, 1986. GAMMERN provided a sworn statement (Exhibit 19) and stated substantially as follows:

GAMMERN, [redacted] and that he was employed by AMS as the NSM from [redacted] and is now retired. He stated that given the complaint as written on Service Report No. 2466, he would have sent out an LSE. GAMMERN denied that he would have sent out anyone other than a licensed man because the problem was working with the timer, and it (working with the timer) requires a licensed man. GAMMERN related that his first year and a half at AMS he was the NSM, and thereafter he was Assistant NSM to Bill EVANS and Dean ABRAHAM. GAMMERN identified his responsibilities as "in charge of service for cobalt accelerators" and sending service personnel to the field to repair equipment (Exhibit 19, pp. 5-6 and 27-28). 6, 7C

GAMMERN identified Service Reports No. 2504 and No. 2718 to NRC:OI as work requiring a license. GAMMERN also stated that he vaguely remembered sending JORDAN out to do this service work (Exhibit 19, p. 36).

GAMMERN further stated that when a C-60 source had to be turned on, he would send an LSE to do the work. However, GAMMERN stated that there was always a physicist or a "biomed" person present who was authorized to turn on (activate) the source and to work with the AMS LSE (Exhibit 19, p. 16).

GAMMERN acknowledged after reviewing Service Report No. 2219, that he would have provided a licensed individual to conduct the service work as stated on Service Report No. 2219. In response to the question of why would he (GAMMERN) have sent an unlicensed service engineer (BAKER) to perform the required work as reflected on Service Report No. 2219, GAMMERN stated, "I can't answer that" (Exhibit 19, p. 22).

GAMMERN, upon reviewing Service Report No. 2294, stated it was licensed activity (Exhibit 19, p. 31), and that he would not have sent out an

unlicensed person even though he feels there are "gray areas," which may not have required a license (Exhibit 19, p. 32). Gammern stated further that the "Fault/Symptom" as indicated on Service Report No. 2294 originated following BAKER's arrival at the Bronx VA Medical Center, and further, that the servicemen are routinely sent out in the field based upon telephone requests, prior to the service report being completed (Exhibit 19, p. 34).

INVESTIGATOR'S NOTE: On November 14, 1986, a request of all telephone call reports, including Service Report No. 2294, was requested of AMS. In response, HEBERT, General Manager of ATC Medical Group, responded. HEBERT stated in his December 8, 1986, response that, "usually faults/symptoms are the record of indicated problems by the customer in their telephone request for service." There was no "telephone call report" for Service Report No. 2294. Therefore, according to HEBERT's explanation, Service Report No. 2294's faults/ symptoms as stated was carried by BAKER to the service site, VA Medical Center, Bronx, NY (Exhibit 37). The words "faults/symptoms" as used by Gammern in his statement do not appear on the telephone call report as evidenced by AMS' December 8, 1986, submittal. This information contradicts Gammern's statement.

Interview with Paul CARANI, former AMS NSM

CARANI was interviewed on October 15, 1986. CARANI provided a sworn statement (Exhibit 25) and stated substantially as follows:

CARANI, stated that he was placed in the position of AMS NSM as a result of Gammern leaving AMS' employ on [REDACTED] CARANI was also Production Supervisor for AMS, supervising the manufacture and remanufacture of cobalt teletherapy machines. As Production Supervisor, CARANI was in charge of all production. CARANI left AMS' employ on or about October 10, 1986 (Exhibit 25). 6, 7C

CARANI, at the time of his interview, briefly identified service work which requires an LSE as follows (Exhibit 25, pp. 21-22): (1) work on the source, including source exchange; (2) work on the shutter and the motor mechanisms; and (3) work on the collimator.

CARANI stated that work on the timer was not licensed activity as a result of an AMS Radioisotope Committee decision. CARANI further stated that he saw the minutes from the Radioisotope Committee which stated this decision (Exhibit 25, pp. 22-23).

INVESTIGATOR'S NOTE: A thorough review of AMS' Radioisotope Committee minutes revealed no such decision. CARANI was unable to provide a copy of the alleged minutes reflecting the alleged vote.

CARANI stated that the cobalt service at VA Medical Center, East Orange, NJ, in June 1986 (Service Report No. 3181) was begun by JORDAN and completed by LIGHT. CARANI stated that he was the responsible person "theoretically" for having LIGHT remain and finish the work on Service Report No. 3181, but not "physically." CARANI said that STEIN and ELY, AMS' Administrative Assistant (AD), were involved in the decision (Exhibit 25, pp. 30-32).

According to CARANI, STEIN and ELY elected to send LIGHT to East Orange, NJ, to do the work with JORDAN and to remain at East Orange following JORDAN's departure (Exhibit 25, p. 32). CARANI stated that STEIN discussed with him (CARANI) via telephone who would be qualified to help JORDAN. CARANI said that he recommended LIGHT because of LIGHT's expertise. CARANI said that it was STEIN's intent to suspend JORDAN, and have LIGHT remain at East Orange and complete the job. CARANI stated that STEIN indicated he would terminate CARANI if CARANI refused to send LIGHT to East Orange (Exhibit 25, pp. 33-35). CARANI stated that STEIN knew that LIGHT was not licensed and that LIGHT's unlicensed status was discussed with STEIN. CARANI stated that at that time it was not known, of course, whether JORDAN would return to Ohio upon LIGHT's arrival, leaving LIGHT alone (without licensed supervision) to complete the service work (Exhibit 25, p. 37).

CARANI stated that STEIN was aware that LIGHT was alone at East Orange, NJ, upon JORDAN's departure, and that STEIN's concern was "when the machine was going to be fixed." CARANI said that STEIN directed CARANI to suspend JORDAN because he (STEIN) did not feel that JORDAN was qualified to do anything (Exhibit 25, pp. 39-40).

CARANI said that LIGHT "might have" told him (CARANI) that he (LIGHT) was doing licensed work. Under questioning, CARANI acknowledged that as a matter of course, unit tests and emergency checks would be conducted, and in order to accomplish these tests, the unit must be activated, thereby exposing the source. However, CARANI stated that he did not know if the checks were performed. All he (CARANI) knew was that the hospital physicist, Dr. OHANYON (no further identification (NFI)) was present (Exhibit 25, pp. 43-44).

INVESTIGATOR'S NOTE: CARANI appears to contradict himself on numerous occasions. CARANI stated that he was directed by STEIN to send LIGHT to assist JORDAN under threat of termination and that STEIN and ELY elected to send LIGHT to East Orange to do the work with JORDAN and to stay even though JORDAN had left. CARANI further stated that STEIN was well aware of LIGHT's unlicensed status, as he (CARANI) discussed with STEIN (via telephone) LIGHT's qualifications prior to sending LIGHT to East Orange. CARANI then stated that the work LIGHT was conducting at East Orange was not licensed work, even though CARANI admits that LIGHT may have informed him (CARANI) that the work required a license. CARANI acknowledged that the unit tests require a licensed individual and CARANI justified LIGHT being alone at East Orange by citing that the hospital physicist was there. The purpose in sending JORDAN in the first place was apparently because the service required an LSE, and according to LIGHT, the reason he remained was not because the service he was conducting was not licensed work, but because as CARANI told LIGHT, there was no one else available.

CARANI stated that LESLIE was sent to Traverse City (Service Report No. 3172) because no one else available. CARANI stated that he did not consider the activity conducted by LESLIE as licensed activity at the time (Exhibit 25, p. 55). CARANI said that LESLIE had not wanted to go to Traverse City, and that he (CARANI) did have some concern about sending LESLIE, considering LESLIE was not familiar with the cobalt control to be serviced. CARANI stated that he felt LESLIE could, however, do the servicing with the proper schematics available to him (Exhibit 25, pp. 55-56).

INVESTIGATOR'S NOTE: CARANI sent an unlicensed service engineer (LESLIE) to service a cobalt control console with which he (LESLIE) was unfamiliar, because no one else was available. This incident contradicts the East Orange argument, which was offered by STEIN. At East Orange, the alleged determination by STEIN based upon was who was qualified to help JORDAN. In the Munson Medical Center service, the criteria utilized by CARANI was only availability, disregarding the service engineer's license status.

CARANI stated, regarding the incident, that LESLIE telephoned him (CARANI) from the Munson Medical Center, expressing concern about checking "something" up in the shutter area of the cobalt unit. CARANI said that he told LESLIE to determine only if the switch was good or bad. CARANI said he told LESLIE not to remove anything. CARANI further stated that LESLIE stated that he (LESLIE) did not know what he was doing (Exhibit 25, pp. 60-61).

CARANI was asked to address Service Report No. 1991 (Exhibit 14, Attachment O) dated September 18, 1986, wherein SPEER performed service on a C-9 teletherapy unit at the VA Medical Center, Allen Park, MI. The "Fault/Symptom" on the service report indicated the "shutter fails to shut off," and the "Cause" revealed a "broken shutter spring." CARANI initially stated that this service call (No. 1991) would not require an LSE. However, upon closer review, CARANI stated that the "Fault/Symptom" and related "Cause" would, on the face of it, appear to require an LSE (Exhibit 25, p. 64).

CARANI, the NSM during Service Report No. 1991, stated that based upon the information provided by the service report, he would not have sent SPEER, because SPEER was not licensed. CARANI drew the distinction that SPEER, however, was qualified to perform the service required by Service Report No. 1991 (Exhibit 25, p. 65).

CARANI, upon denying that he would have been responsible for sending SPEER on Service Report No. 1991, suggested that any number of other people could have been responsible for sending SPEER out on the service call (Exhibit 25, p. 65).

INVESTIGATOR'S NOTE: CARANI, upon reviewing Service Report No. 1991, initially referred to the service work as not licensed activity. However, upon closer review, he altered his position. CARANI stated that he would not have sent SPEER on this service call because SPEER was not licensed. DREIER contradicts CARANI's statement and corroborates past practices acknowledged by CARANI of providing available service engineers. Attempts to interview SPEER regarding this issue were unsuccessful.

CARANI, stated that he assumed the duties of NSM in addition to his regular duties as Production Manager following GAMMERN's departure. CARANI stated that his knowledge of the AMS service license parameter was that the AMS service license allows them (AMS) to service the teletherapy machines in various installations and that the type of work required determines who is allowed to do the work (Exhibit 25, pp. 7-8).

CARANI explained that AMS had two types of licenses (No. 34-19089-01 and No. 34-19089-02). CARANI defined an "02" licensed person as having the

ability to do work without removing the source (Cobalt-60). CARANI further defined the "02" work as doing calibration tests, wipe tests, linkage tests, and the removal of some shielding material. CARANI described "01" work as work involving source exchange and removal. CARANI also stated that following his becoming NSM, he became a member of the AMS Radioisotope Committee. CARANI stated, however, that he was unfamiliar with AMS' definition of licensed activity (Exhibit 25, pp. 8-20).

CARANI related that he was able to determine what was considered licensed activity work if he had any questions, through the help of IRWIN (RSO). CARANI also related that he reviewed an AMS manual, which described licensed activity. However, other than by asking the RSO (IRWIN) or by referring to AMS' manual, CARANI had no formal training in making this determination (Exhibit 25, pp. 20-21).

In response to questions asked by NRC:RIII Senior Radiation Specialist BURGIN regarding licensed activity, CARANI acknowledged that work on the source, including source exchanges, work on the collimator, work on the shutter, and the motor mechanism involved in exposing the source was licensed activity. He denied, however, that work on the control unit was licensed activity. CARANI, at this point, stated, "I knew you were going to get to the timer mechanism here pretty quick. The isotope committee voted before I took over and maybe before I was employed that work on the timer was not licensable work" (Exhibit 25, pp. 21-22).

INVESTIGATOR'S NOTE: There is no record of any such policy adopted by the Radioisotope Committee (Exhibit 41).

CARANI stated that he "thought" he witnessed a letter or Radioisotope Committee minutes regarding the alleged policy that timer service was not subject to being licensed activity. CARANI also claimed that Ed SVIGEL, AMS Engineering Manager, informed him (CARANI) of this policy (Exhibit 25, p. 23).

CARANI acknowledged that he had provided unlicensed service engineers to perform service on cobalt teletherapy unit timers, knowing that a hospital technician was available to open and close the source and to test the operation of the timer. CARANI stated that it was his understanding that as long as a technician or someone else that knew how to run the unit was present, an unlicensed service person could perform service on the timer (Exhibit 25, p. 26). CARANI stated that he discussed this policy with IRWIN and SVIGEL and it was their opinion that the timer work was not licensed activity.

INVESTIGATOR'S NOTE: The unannounced special inspection conducted by NRC:RIII specifically addressed the timer issue and use of hospital personnel to conduct unit tests (Exhibit 14, pp. 8-9). Unit tests and demonstrations, according to the AMS manual, "must be performed only by a person certified on the license." This information was available to CARANI through AMS manuals, which he claimed he had reviewed.

In CARANI's statement, while discussing LIGHT's unlicensed work at VA Hospital, East Orange, NJ, Service Report No. 3181, CARANI acknowledged that an emergency bar test "emergency switch" would routinely have been conducted by LIGHT. CARANI further acknowledged that testing the emergency switch would

require the unit to be activated and exposure of the source (Exhibit 25, p. 43).

CARANI, when asked if he was personally aware of whether or not LIGHT activated the unit, or whether the routine checks were conducted, stated, "no, I don't. I don't know if they were performed. All I know is that the physicist, Dr. OHANYON, was there" (Exhibit 25, p. 44).

INVESTIGATOR'S NOTE: CARANI's apparent lack of concern regarding the unit tests and demonstrations to assure quality servicing of the VA machine at East Orange, reflects STEIN's (Exhibit 28) policy of allowing unlicensed personnel to conduct unit tests/demonstrations in the presence of hospital personnel.

CARANI expressed his frustration about having an inadequate amount of LSEs available to send out on service calls. CARANI stated (upon reflecting about sending LESLIE, an unlicensed service engineer, to the Munson Medical Center, Traverse City, MI, Service Report No. 3172 (Exhibit 14)), that he sent LESLIE only because no one else was available.

CARANI acknowledged that he had approached STEIN with his concerns and that STEIN would counsel him by saying, "you're not utilizing the people that you have." CARANI stated, "I tried to tell him if I have someone in New York and in Florida, how am I going to send--(sic)--what am I going to do about those people in New York? Do I just pull them out of there?" STEIN's only response, according to CARANI, was that CARANI was not properly utilizing his people (Exhibit 25, p. 57).

CARANI stated that STEIN counseled him (CARANI) to "train them" (service engineers). CARANI said he told STEIN, "how am I going to train them if you don't allow me to train them." CARANI said that STEIN "expressed a great concern at why I would send two people out to do a job when it takes only one." CARANI said he tried to tell STEIN, "if I send LESLIE out with COCHRAN, he can observe how to do the work." STEIN, according to CARANI, did not want CARANI setting up on-the-job training because STEIN felt the training provided by AMS was adequate (Exhibit 25, p. 58).

INVESTIGATOR'S NOTE: See Exhibit 14, the NRC:RIII unannounced special inspection, where the AMS training program was found to be inadequate.

CARANI, [REDACTED] immediately following the NRC's October 10, 1986, suspension order, acknowledged that he had expressed his concerns to STEIN and IRWIN, and that he (CARANI) had the responsibility of sending out service personnel and that his questions of IRWIN and STEIN had not been satisfied, which left him vulnerable. CARANI said that the response he received was "that's tough." CARANI concluded by stating "That's why I'm no longer employed there" (Exhibit 25, pp. 74-75). 617C

Reinterview with CARANI

CARANI, was interviewed telephonically on January 13, 1987, regarding the Eastside cobalt teletherapy unit installation (Exhibit 46). CARANI acknowledged that he was present during the cobalt teletherapy unit installation at Eastside. CARANI said he recalled LIGHT and COCHRAN

installing and then removing the "head" to repair a yoke bearing and that COCHRAN was only working half days. CARANI acknowledged that it was he that recalled COCHRAN once the yoke bearing repair had been completed by LIGHT. However, CARANI "drew a blank" when asked if LIGHT reinstalled the "head" by himself without COCHRAN. CARANI further stated that he would not have allowed LIGHT to install the head, however, he "absolutely" had no recall of the reinstallation (Exhibit 46).

INVESTIGATOR'S NOTE: CARANI corroborates the statement of COCHRAN, in that COCHRAN worked only half days at AMS. CARANI further corroborates the statement of LIGHT, COCHRAN, SPEER, and MAVRAKIS regarding the faulty yoke bearing and that there was a reinstallation, and his total lack of recall regarding LIGHT having reinstalled the "head" alone does not contradict or corroborate the statements COCHRAN, LIGHT, SPEER, or MAVRAKIS regarding this point.

Interview with Donna ELY, AMS AD

ELY was interviewed on December 9, 1986. ELY provided a sworn statement (Exhibit 27) and stated substantially as follows:

ELY, AD to STEIN since January 7, 1985, stated that regarding East Orange, NJ, and specifically Service Report No. 3181 dated June 1986, she recalled telling CARANI, "we needed to send someone to work with Keith (JORDAN). And, eventually, Garnett LIGHT went in (sic)." ELY stated that LIGHT "did not want to go, because he just didn't want to go." ELY further stated that LIGHT was not threatened with termination in order to force him to assist JORDAN (Exhibit 27, pp. 7-8).

INVESTIGATOR'S NOTE: ELY contradicts CARANI's statement as presented to LIGHT. LIGHT stated that CARANI told him (LIGHT) that he (CARANI) was directed by ELY to fire LIGHT if he (LIGHT) refused to go to East Orange NJ. However, this alleged threat was prior to JORDAN's leaving LIGHT alone at East Orange, NJ.

ELY stated that STEIN was aware of the events of that weekend prior to LIGHT's arrival at East Orange, and that during that weekend, she had conversations with CARANI. ELY noted that her concern was that the facility (East Orange) had a problem, JORDAN was there, and JORDAN was a licensed person. The hospital was still down (out of service), and they needed their machine repaired and they were becoming increasingly annoyed. ELY recalled that her conversation with CARANI addressed the need to get someone to help JORDAN, and the usual procedure, according to ELY, was to send whoever was available. ELY said that an attempt was made to get COCHRAN (an LSE) to assist JORDAN, but COCHRAN, according to ELY, was unavailable (Exhibit 27).

ELY stated that she was unaware of whether the service work was licensed activity or not.

INVESTIGATOR'S NOTE: ELY's comments corroborate LIGHT's statement that CARANI told him (LIGHT) that there was no one else available to send to East Orange. ELY also stated that the work, licensed activity or not, was not a deciding factor; all that, availability was the determining factor. CARANI's justification that LIGHT was not doing licensed work

was an apparent after-the-fact attempt to legitimize the decision to send LIGHT. According to CARANI, the original determination was not based upon whether LIGHT was or was not licensed, but that he was qualified. It was not apparently suspected by anyone other than LIGHT that JORDAN would leave him alone. LIGHT's protests and subsequent requests to CARANI following JORDAN's departure, however, went unheeded.

ELY stated that attempts were made to obtain the services of COCHRAN, a former AMS employee whose name appears on the AMS license and who was available on a contract basis. It would appear that the attempts to obtain an LSE prior to sending LIGHT corroborates CARANI's statement, that the service was known by STEIN and ELY to be a licensed activity.

Interview with Dr. Seymour S. STEIN, AMS President

STEIN was interviewed on December 9, 1986, and provided a sworn statement (Exhibit 28). STEIN stated substantially as follows:

STEIN, stated that he was aware there were some problems with JORDAN regarding the service conducted at East Orange. STEIN recalled that JORDAN's [REDACTED] during that time period and that someone was needed to go out and help on the control system of the unit being serviced (Exhibit 28, pp. 19-21). 6,7C

STEIN acknowledged that LIGHT had been sent to assist JORDAN, because "apparently...he (JORDAN) was having problems with the electrical work." STEIN stated that he and ELY "chatted" about JORDAN's problem, which STEIN characterized as [REDACTED] and the need to send someone (LIGHT) to "back him (JORDAN) up" (Exhibit 28, pp. 20-21).

STEIN acknowledged that JORDAN was an LSE and that Service Report No. 3181 required work associated with a timer. It was because the unit was exhibiting an electrical problem, according to STEIN, that LIGHT was sent to East Orange. STEIN stated that he could not recall, however, to what extent LIGHT was there. STEIN stated, I don't know the exact period of time that he (JORDAN) was there and when LIGHT was there and when LIGHT was alone. STEIN said that CARANI was responsible for the service call (Exhibit 28, pp. 21-22).

STEIN stated that he would have sent LIGHT on this service call (Service Report No. 3181), and (hypothetically) disregarding licensed or unlicensed service, LIGHT, according to STEIN, was the better electronics person, and he (STEIN) would have sent LIGHT. LIGHT, according to STEIN, was far superior to JORDAN because of LIGHT's experience from day one with the timer. STEIN said LIGHT, according to STEIN, was familiar with the console and the new system. LIGHT had been particularly involved with installing and testing the console on cobalt teletherapy machines, whereas JORDAN was trained more as a serviceman on the cobalt teletherapy machine itself (Exhibit 28, p. 23). JORDAN, according to STEIN, was suspended from work following the East Orange, NJ, service call due to a decrease in service requests (Exhibit 28, p. 25).

INVESTIGATOR'S NOTE: STEIN's statement that LIGHT was the most appropriate person to assist JORDAN during Service Report No. 3181 was allegedly based upon STEIN's knowledge of LIGHT's expertise in the field of electronics and LIGHT's involvement at AMS with testing and installing the console. This would apparently corroborate CARANI's statement that

CARANI and STEIN discussed, prior to sending LIGHT, who was best qualified to help JORDAN, and that CARANI recommended LIGHT because of LIGHT's expertise. STEIN's statement that he has no recall of the extent of JORDAN's stay or when LIGHT was at East Orange without JORDAN conflicts with CARANI statements that: (1) both STEIN and ELY directed that LIGHT remain at East Orange even though JORDAN had left [REDACTED] and (2) that STEIN was aware of LIGHT remaining alone at East Orange, and STEIN's only concern being "when the machine was going to be fixed." STEIN's statement that JORDAN was laid off due to a work slow down was contradicted by CARANI, who stated that STEIN directed JORDAN's suspension because STEIN felt JORDAN was unqualified to conduct service activity. 6, 7C

STEIN was questioned, "would you have sent Mr. Garnett LIGHT by himself to conduct a service call such as is indicated on the Service Report No. 3181?" STEIN responded, "strictly a timer problem, I would have sent Garnett LIGHT" (Exhibit 28, p. 23).

STEIN indicated earlier that service work on timers is not a licensed activity (Exhibit 28, p. 12). STEIN further stated that if an unlicensed person in the field was required to turn on the cobalt teletherapy unit in order to conduct a unit test, "there should be licensed hospital personnel there. According to our--(sic) in fact, we had checked this out with the NRC many years ago when we first took over, and it was not indicated to be necessary to have a licensed person in our employ at the time that licensed work is done" (Exhibit 28, pp. 15-16).

STEIN acknowledged as correct and in accordance with AMS policy, the practice of unlicensed personnel activating a cobalt teletherapy unit to conduct quality checks as long as hospital personnel who normally operate the unit are in the presence of the AMS unlicensed personnel. STEIN reiterated that this practice had been verified with the NRC many years ago (Exhibit 28, p. 16).

STEIN could not recall the time period that AMS received the alleged NRC approval for the stated practice, but thought it was NRC:RIII, "because this is one of the early things that we worked on at the time we acquired the business from Picker" (Exhibit 28, p. 17). STEIN was asked to conduct a search of his records to find any support for AMS' position.

In response to the above request, AMS, through their attorney KOLIS, provided a copy of a March 8, 1979, memorandum from R.W. ARNDT to J.D. STICKNEY (NFI) regarding a visit to NRC in Silver Springs, MD, on March 7, 1979 (Exhibit 29). The memorandum references a meeting between STEIN, W. ASHBY (NFI), and ARNDT representing AMS, and N. BASSIN (NFI) and Earl WRIGHT (NFI) of the NRC. The point of reference in the memorandum states, "N.R.C. does not require that people named on a license be on the payroll of the licensee as long as the licensee has supervisory control over the licensable operations" (Exhibit 29).

INVESTIGATOR'S NOTE: The memorandum provided by AMS' counsel as justification for AMS' corporate position as stated by STEIN appears to have no bearing on the point in question. The memorandum states that the licensee (AMS) must have control over licensed activity operation. This memorandum does not permit AMS' apparent policy of providing unlicensed personnel to conduct licensed activity in the presence of hospital

employees who normally operate the teletherapy unit. It should also be noted that the hospital personnel/ technologist who normally operate the units are not licensed by the NRC. The hospital holds the license, not the individual technologist/physicist. AMS' own SPM, upon which a portion of AMS' license is based, requires "unit tests and demonstrations" be performed only by a person certified on the license (AMS' NRC license) (Exhibit 5, p. 9). The memorandum (Exhibit 29) states only that it is not required that people named on a license be on the payroll of the licensee. This would appear to accommodate the use of contract personnel, i.e., COCHRAN. While COCHRAN, an LSE, left AMS, his name remained on AMS' license. COCHRAN is no longer on AMS' payroll as a regular employee; he is utilized on an as-needed basis by contract. Therefore, the point "NRC does not require that people named on a license be on the payroll." However, the licensee (AMS) has supervisory control over the licensed activity operation. It is apparent that LIGHT was not on the AMS license therefore, his activity at East Orange cannot be recognized as licensed service. ARNDT, the author of the March 8, 1979, memorandum, also disputes STEIN's assertion (Exhibit 24).

Regarding Service Report No. 3181 (Exhibit 14, Attachment K), the form reflects only the LSE's name (JORDAN). Nowhere on the form is the name of LIGHT (the unlicensed service engineer) noted. JORDAN also could not identify the handwriting on Service Report No. 3181. Therefore, to the uninformed, it would appear that the service was performed by/or under the supervision of an LSE, i.e., JORDAN.

STEIN stated in response to questions, that "head" removal and installation did require an LSE (Exhibit 28, p. 12).

INVESTIGATOR'S NOTE: The response by STEIN that head removal and installation require a licensed service representative is in agreement with AMS' December 23, 1986, brief to the NRC regarding Eastside, Willoughby Hills, OH.

STEIN, however, responded in the negative to the question of whether work on timers was licensed activity (Exhibit 28, p. 12). STEIN was asked the following hypothetical question: "If it would be necessary for an unlicensed person who is in the field, for some reason to have to turn on the machine to see if everything is working properly, who would be allowed to do that under your rules, that you work under?" STEIN responded, "there should be a licensed hospital personnel there." STEIN stated that AMS, many years ago, had addressed this situation with NRC and found "it was not indicated to be necessary to have a licensed person in our employ at the time that licensed work is done" (Exhibit 28, pp. 15-16).

INVESTIGATOR'S NOTE: Hospital employees, however, are not on AMS' license and normally are not licensed by the NRC. The use of unlicensed hospital staff to conduct unit tests/demonstrations for unlicensed AMS service personnel is a violation of AMS' license condition. STEIN stated in his response to questions that "there should be licensed hospital personnel there" (emphasis added), leaving open the possibility that a unit test and demonstration may also take place if a hospital staff member were not there, thus allowing an unlicensed AMS service person the necessary latitude to conduct unit tests and demonstrations in the

absence of hospital personnel. Such activity was documented in the NRC:RIII inspection report (Exhibit 14; Exhibit 28, p. 15).

STEIN stated that it was he (STEIN) that pushed to have as many people licensed as possible, but that no one was licensed before they were sufficiently trained. STEIN stated that the real problem was people sitting around doing nothing, and that they were "under utilized" (Exhibit 28, p. 36).

INVESTIGATOR'S NOTE: STEIN's statement and CARANI's observations directly contradict one another. However, STEIN's statement that the real problem was "under utilization" corroborates CARANI's recall of STEIN counseling him that he (CARANI) was not utilizing his resources properly. At the time in question (October 14, 1985, to October 10, 1986), there were three LSEs available at that time: SALTENIS, COCHRAN, and JORDAN (Exhibits 3 and 4).

STEIN denied there were any situations wherein unlicensed service engineers were forced to do work for which they were unlicensed. STEIN stated that he held more than one meeting wherein he told the service engineers that they would be terminated if they did anything that violated any NRC requirement.

INVESTIGATOR'S NOTE: In response to an OI:RIII request for information pertaining to LSE affidavits, AMS, through their attorney, KOLIS, on December 17, 1986, provided copies of affidavits signed by JORDAN, COCHRAN, and SALTENIS, all three of which were LSEs during the time frame in question. These affidavits affirmed that the LSE's would abide by the rules and regulations of the NRC with no deviations. However, the concern is not that LSE's were doing unlicensed work, but that unlicensed service engineers were doing licensed work (Exhibit 49).

Interview with R.W. ARNDT, former Picker Corporate Officer and former AMS General Manager

ARNDT was interviewed on April 5, 1988 (Exhibit 24), and stated substantially as follows:

ARNDT, the author of the March 8, 1979, memorandum produced by AMS, contradicted STEIN's interpretation of the memorandum and stated further that the memorandum was never discussed with STEIN, as it was produced while ARNDT was employed by Picker (Exhibit 24).

Interview with Norman KELBLEY, former AMS Manager and RSO

KELBLEY, former AMS RSO and Manager of AMS' London Road facility from [REDACTED] was interviewed on December 9, 1986 (Exhibit 50). At that time, KELBLEY was employed by Picker, Cleveland, OH. KELBLEY stated substantially as follows: 6,7C

KELBLEY stated that "licensable work would be anything that would cause a radiation level to go higher around the machine if you had to turn the source on, or anything along those lines" (Exhibit 50, p. 5). Responding directly to AMS' definition of licensed activity service work (Exhibit 14, pp. 8-9) regarding "unit test and demonstration," KELBLEY stated, "this means you must turn the source on and, by turning the source on, you are increasing the

radiation level and, in my opinion, the way I interpret the regulation, that was licensable work" (Exhibit 50, p. 10). Regarding service work on timers, KELBLEY stated, "the timer by necessity is part of testing the shutter. Without a timer, the shutter cannot be kept on." KELBLEY described the timer as the heart of the control activity. KELBLEY stated that "anytime you have to turn the source on to test, it is a licensed activity. When I worked there (AMS), we used licensed people for that" (Exhibit 50, p. 13).

INVESTIGATOR'S NOTE: KELBLEY, in his capacity as AMS' first RSO, described his responsibilities in part as assuring AMS' compliance with NRC regulations, conducting training classes, and policing all activities under AMS' license (Exhibit 50, p. 4).

KELBLEY stated that in order to conduct a unit test, one must activate the source and that any time one activates the source, that is a licensed activity which must be performed by licensed people under AMS' license. He said page 9 of the Cobalt SPM (Exhibit 14, pp. 8-9) states, "unit tests and demonstrations must be performed only by a person certified on the license (AMS' license)."

KELBLEY further stated that the AMS policy as of his leaving AMS was that only licensed personnel were to be sent out to conduct timer replacements (Exhibit 50, pp. 18-20).

INVESTIGATOR'S NOTE: KELBLEY's statement contradicts STEIN's assertion that AMS relied upon the March 1979 memorandum as justification to send out unlicensed personnel to conduct licensed activity under the supervision of hospital personnel. The policy as stated by STEIN apparently came into effect upon KELBLEY's departure (April 1984) and STEIN used the March 1979 memorandum to justify AMS' change in policy without an NRC license amendment.

KELBLEY acknowledged frustration in that two training classes between October 1979 and April 1984 were conducted from which only three individuals received an "02" license.

KELBLEY denied any knowledge of an acknowledgement or acceptance by the NRC that someone other than an LSE under AMS' NRC license could activate a cobalt teletherapy unit for purposes of unit testing. KELBLEY stated that a service operation is always licensed activity if that service requires unit testing (Exhibit 50, p. 28).

INVESTIGATOR'S NOTE: KELBLEY apparently was unaware of the March 1979 memorandum purported by STEIN to justify the AMS policy of allowing unlicensed personnel to conduct licensed activity in the presence of hospital personnel. KELBLEY left AMS on April 30, 1984.

KELBLEY also stated that he was involved with AMS in obtaining their NRC license as early as July 1979. The sale of Picker to AMS, according to KELBLEY, was contingent upon AMS having a license to possess the nuclear material, which was in the London Road facility that AMS was purchasing (Exhibit 50, p. 15).

Interview with Darwin MURRAY, former AMS LSE

MURRAY was interviewed on February 5, 1987. MURRAY provided a sworn statement (Exhibit 51) and stated substantially as follows:

MURRAY, stated that he was employed by AMS from [REDACTED] and with prior employment at Picker from [REDACTED]. He said he is currently employed by Adam Mechanical, an enterprise which services cobalt teletherapy units.

MURRAY stated that upon transferring from Picker to AMS, there was no deviation in the manner in which the servicing department was operated. MURRAY described his duties as the original AMS Service Manager (Exhibit 51, p. 12). MURRAY stated that the only change that occurred between Picker and AMS was the name.

MURRAY described a point in time wherein the service department was moved from the London Road facility to Geneva, OH. According to MURRAY, GAMMERN, working out of the AMS Geneva office, ultimately became the AMS Service Manager. MURRAY stated that upon GAMMERN being appointed Service Manager, he (MURRAY) was not necessarily aware of the service activities being conducted out of Geneva. MURRAY stated that activation of the source (unit) had always required a licensed person (Exhibit 51, pp. 14-18). MURRAY, however, had no knowledge of any unlicensed activity during his employment at AMS from November-2, 1979, to February 24, 1984.

Interview with Victor SALTENIS, former AMS LSE

SALTENIS was interviewed telephonically on November 6, 1986 (Exhibit 52), and provided the following information in substance.

SALTENIS, a former LSE at AMS from [REDACTED] stated that he was trained at AMS by KELBLEY and SIBERT. SALTENIS further stated that it was always his understanding that work with the source, including the timer, required a license (Exhibit 52). 617C

INVESTIGATOR'S NOTE: SALTENIS, an AMS LSE, contradicts STEIN's statements regarding AMS' alleged policy of allowing unlicensed service personnel to service timers in the presence of hospital personnel.

Interview with Howard IRWIN, former AMS RSO

IRWIN was interviewed on December 8, 1986, and provided a sworn statement (Exhibit 53). IRWIN stated substantially as follows:

IRWIN said he began working for STEIN in 1971 as a machinery equipment appraiser. IRWIN stated that he has been associated with regulatory affairs, licenses, permits, and other regulations of a number of Federal agencies prior to becoming AMS RSO in November 1984. IRWIN stated that he also is an instructor in AMS' cobalt teletherapy classes. IRWIN stated that he, as RSO, had not directed unlicensed service personnel to service cobalt teletherapy units. IRWIN referenced the AMS SPM as defining licensed activities, specifically identifying source exchange, bearing lubrication, collimator

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removal or installation, and loaded head installation or removal, as service requiring an LSE (Exhibit 53, pp. 35-36).

INVESTIGATOR'S NOTE: Exhibit 14, pp. 8-9, references the AMS SPM and identifies those items identified by IRWIN, including head installation (Eastside) and unit tests and demonstrations as requiring an LSE. It should be noted that CARANI stated he would, on occasion, consult with IRWIN if he (CARANI) had any questions.

IRWIN stated, "activating a timer...I consider a licensable activity...turning a source on." IRWIN identified the AMS SPM as a "comprehensive list, carried from the days of Picker International, when they were performing licensable service, AMS didn't delete anything from that" (Exhibit 53, pp. 39-40). IRWIN further stated, "it's been my policy that if we send a non-licensed person on a job to do a timer replacement, he's not allowed to activate the shutter by himself." IRWIN stated that only a "licensable service engineer" would be allowed to activate the shutter (Exhibit 53, p. 42).

However, in the event that an AMS licensed person is not available to activate the unit, IRWIN stated that he has, in the past, "instructed (sic) our people to ask a hospital personnel person to do...a normal machine operator, someone who is familiar with the machine." IRWIN responded that whether the hospital person was licensed or unlicensed would not be a consideration. IRWIN further clarified his policy by stating, "my policy has been that we may replace the timer, but the hospital person should actually activate the shutter, not the AMS person. Okay, that's my policy" (Exhibit 53, pp. 43-44).

IRWIN acknowledged that CARANI, former AMS NSM, would ask questions of him (IRWIN) questions regarding what is and is not licensed service activity, and that his (IRWIN's) response to CARANI was the same as his responses to OI investigators during this interview (Exhibit 53, p. 45).

INVESTIGATOR'S NOTE: The apparent change in AMS policy regarding licensed activity appeared with IRWIN's designation as RSO following KELBLEY and SIBERT leaving AMS. CARANI's direction regarding what is and is not licensed activity was influenced by IRWIN, as IRWIN acknowledged. IRWIN contradicts himself, however, when on the one hand he states that unit tests require a license as reflected in AMS' SPM, and then institutes his policy in direct contradiction of the SPM.

Interview with Theodore HEBERT, ATC Medical Group, General Manager

HEBERT was interviewed on December 8, 1986, and provided a sworn statement (Exhibit 54). HEBERT stated substantially as follows:

HEBERT, currently General Manager of ATC Medical Group, was originally employed by ATC in January 1986 as ATC Facilities Manager. HEBERT stated that he has no formal training in regulatory affairs associated with the NRC, nor has he attended a cobalt teletherapy training class. HEBERT further stated that he is not involved with the AMS field service operation. HEBERT stated that he knows that "if the work directly involves an increased exposure to the source it would be classified as licensable work. If the work on the shutter did not increase exposure to the source, then it would not be non-licensable" (Exhibit 54).

In HEBERT's December 23, 1986, affidavit package presented by KOLIS to NRC:RIII, a document dated March 8, 1979, from "ARNDT to STICKNEY," subject line: "Visit to NRC, Silver Spring, MD on March 7, 1979," was presented as justification for AMS' policy of allowing other than AMS licensed service personnel to conduct unit tests and demonstrations (Exhibit 38, Attachment B). The document's last paragraph stated, "N.R.C. does not require that people named on a license be on the payroll of the licensee as long as the licensee has supervisory control over the licensable operation."

INVESTIGATOR'S NOTE: The March 8, 1979, document would, it appears, allow a contracted person, i.e., COCHRAN, to have supervisory control over licensed activity operations. COCHRAN is an example of a person who is not on AMS' payroll (COCHRAN's regular employment is Coca-Cola foods). However, COCHRAN is named on AMS' license due to his previous employment with AMS. COCHRAN, in accordance with documents filed by AMS (HEBERT's affidavit), is contracted as necessary to conduct licensed activity work for AMS, i.e., Eastside.

Willfulness/Intent

The NRC:RIII unannounced special inspection of AMS, Geneva, OH, identified 18 unlicensed service calls on cobalt teletherapy units by AMS field service engineers (Exhibit 14). A review of AMS' LSEs revealed a total of ten LSEs on AMS' license since it beginning in late 1979 through September 1986. The highest number of LSEs available at any one time was five in April 1984, after which the number diminished to only one by March 1986 (Exhibits 24 and 37).

The procedures guiding the licensed service are identified in AMS' license conditions as the "Cobalt Services Procedures Manual" (Exhibit 20). This manual identifies what service constitutes licensed activity and was adhered to by AMS' first RSO, KELBLEY (Exhibit 50). GAMMERN, the AMS NSM, also abided by the SPM (Exhibit 19). However, upon IRWIN assuming responsibilities as RSO in November 1984, the common practice of what constitutes licensed activity in the SPM was changed. IRWIN stated, contrary to AMS' license, that an unlicensed service engineer could conduct licensed activity provided a hospital person was present during said activity who routinely operated the equipment (Exhibit 53, pp. 43-44).

STEIN asserts that the policy adopted by IRWIN was discussed with the NRC in March 1979, and that the NRC was aware of this practice (Exhibit 28, p. 16). STEIN, in addition, stated that the service work on "timers," considered licensed activity by KELBLEY, GAMMERN, and the NRC, was not licensed activity (Exhibit 14). The memorandum alluded to by STEIN was a Picker International memorandum originated by ARNDT. ARNDT, a former Picker employee prior to working for AMS as General Manager, stated that STEIN was in error, and furthermore, that he had never discussed the memorandum with STEIN (Exhibits 24 and 29).

IRWIN, AMS RSO and instructor in AMS' cobalt teletherapy classes, stated that he considered the activation of a timer a licensed activity. However, IRWIN professed a policy of instructing unlicensed AMS service personnel to allow the hospital personnel familiar with the cobalt unit to activate the unit to conduct unit tests (Exhibit 53).

The professed policy by STEIN and its implementation by IRWIN is a clear violation of AMS' license as reflected in the NRC inspection reports (Exhibits 2, 3, 4, 5, 6, 9, 10, 16, 17, 28, and 53).

CARANI, the AMS NSM directly responsible for providing service personnel to clients, stated that upon assuming the position of NSM, he was able to determine AMS' definition of licensed activity by asking IRWIN and referring to the AMS manual. CARANI acknowledged that service work on the collimator, shutter, and motor mechanisms, which could expose the source (C-60), was licensed activity. CARANI's professed knowledge of a licensed activity was in concert with that of IRWIN and STEIN (Exhibits 14, 25, 28, and 53).

CARANI admitted having provided unlicensed service engineers to perform service on cobalt teletherapy unit timers, knowing that a hospital technician was available to activate the unit to test the operation. This policy was in direct conflict with AMS' NRC license (Exhibits 2, 3, 4, 14, and 25).

In regard to installation activity, STEIN stated that "head" removal and installation was a licensed service activity. However, CARANI directed LIGHT, an unlicensed service engineer, to install a "head" on a cobalt teletherapy C-8 unit, "or else." LIGHT, in fear of being terminated, installed the "head" by attaching the "head" to the unit. The licensed service representative contracted by AMS to conduct the installation, COCHRAN, had been told by CARANI, he would be notified when to return and install the unit. Upon COCHRAN's return, he discovered the "head" had been installed. Upon approaching CARANI, CARANI simply shrugged his shoulders to COCHRAN's concerns regarding the unlicensed installation (Exhibits 26, 28, and 40).

On several occasions, CARANI provided unlicensed service personnel to conduct service requiring a license, and when confronted by the service people, would claim ignorance of the licensed activity. CARANI provided unlicensed service personnel to conduct service on control consoles/panels, "head" tilt motors, timers, "key switches," "shutters," and installations, all of which are considered licensed service work by the NRC (Exhibits 14, 15, 25, 30, 31, and 32).

CARANI stated that he was frustrated in his job because of an inadequate amount of available licensed service engineers. CARANI stated that he sent unlicensed service persons when no one else was available. ELY, AMS AD, stated that an attempt to obtain a contract LSE on one occasion was made, but when that person was unavailable, an unlicensed person was sent. This occasion resulted in an unlicensed person conducting work on a console alone, a violation of AMS' license. NRC routine inspection dated July 16-17, 1984, addressed the shortage of qualified personnel at AMS as a safety concern (Exhibits 9, 25, and 27).

CARANI stated that he had approached STEIN with his concerns regarding a lack of licensed service personnel only to be told that he (CARANI) was not utilizing his resources properly. CARANI stated that he was told by STEIN to train more people. However, CARANI stated that STEIN would not allow him to train people because STEIN did not want two people (one licensed, one unlicensed) to go on a service call. CARANI's attitude was to conduct on-the-job training by allowing an unlicensed person to observe and assist a licensed person. STEIN, according to CARANI, would not allow that, because

STEIN felt AMS had a sufficient training program. The NRC inspection of September 17 through November 12, 1986, found AMS' training program to be insufficient (Exhibits 9, 14, 25, and 28).

CARANI [REDACTED] the NRC October 10, 1986, suspension of AMS' service license. CARANI cited his vulnerability due to his being responsible for sending out unlicensed service personnel and STEIN's alleged response to him upon voicing his concerns as, "that's tough" as his reasons [REDACTED] (Exhibit 25). 617C

The change in policy regarding licensed and unlicensed service occurred around the time of the termination of KELBLEY, the original RSO who left AMS on April 30, 1984. It was determined that STEIN's policy regarding unlicensed versus licensed service began with KELBLEY's departure. KELBLEY stated that throughout his employment with AMS, there was no question as to what service activity constituted licensed service. KELBLEY stated that throughout his tenure at AMS, the timer, by necessity, was part of testing the shutter. Without a timer, the shutter could not be activated. KELBLEY further stated that any time the source was activated, this constituted licensed activity. KELBLEY stated that during his tenure at AMS, licensed people were used for service work on timers and whenever activation of a unit was necessary. KELBLEY denied knowledge of an acceptance by the NRC, as asserted by STEIN, that someone other than an LSE named on AMS' NRC license could activate a unit for purposes of unit testing (Exhibit 50).

In regard to the submittal of a service report to the NRC on December 23, 1986, in support of AMS' assertion that the installation of a C-8 teletherapy unit was done under the supervision of an LSE, the following was submitted (Exhibit 38). AMS, through their attorney KOLIS, presented an affidavit of HEBERT, General Manager of ATC Medical Group. Among the documents presented to the NRC was a copy of Service Report No. 1959 dated August 18 to September 5, 1986, signed by COCHRAN and dated October 15, 1986. The service report addressed Eastside in Willoughby Hills, OH (Exhibits 38 and 39).

The work carried out by COCHRAN was described in part as reinstalling the "head and collimator." COCHRAN wrote that he (COCHRAN) reinstalled the "head." COCHRAN, a former employee of AMS and a licensed person whose name appears on AMS' license, was contracted by AMS to conduct the licensed activity portions of the installation of the C-8 unit (Exhibits 38, 39, and 40).

LIGHT, an unlicensed service engineer, stated that he was directed to reinstall a cobalt teletherapy unit C-8 "head" by CARANI, NSM, "or else." LIGHT interpreted the "or else" to mean termination. LIGHT said he told CARANI that he (LIGHT) was not licensed to perform the task, but did as directed. Subsequently, COCHRAN, the LSE, was called back to the Eastside project by CARANI. COCHRAN said he confronted CARANI, who responded with a "shrug." On October 15, 1986, five days following the NRC suspension of AMS' NRC service license, COCHRAN stated he was called to AMS and required to complete Service Report No. 1959, which was false. COCHRAN alleged that he was just doing as he was told when he prepared the false document. COCHRAN alleged that both HEBERT and ELY directed he prepare the false statement (Exhibits 25, 26, 40, 42, 43, 44, and 45).

The information that HEBERT and ELY directed COCHRAN to prepare a false document which was provided to the NRC under affidavit, was presented to the U.S. Department of Justice (DOJ). At which time all further investigation under the authority of the NRC halted and a criminal investigation with DOJ ensued (Exhibits 38 and 39).

Agent's Conclusions

Based on the testimonial and documentary evidence developed during the investigation, it is enclosed:

- (1) that STEIN, AMS President, IRWIN, AMS RSO, and CARANI, AMS NSM, knowingly and willfully provided unlicensed field service engineers to repair and test cobalt teletherapy units a licensed activity.
- (2) that CARANI knowingly and willfully required an unlicensed field service engineer to install a cobalt teletherapy unit, a licensed activity.
- (3) and that AMS, through an affidavit, provided a false service report to the NRC in support of their position that no unlicensed installation occurred. There is insufficient evidence to conclude, however, that AMS corporate officers were aware of the false nature of the document.

Allegation 2: Alleged Falsification of Sealed Source Leak Test Data

Interview with Eric Van ROBY, AMS Engineering Technician

ROBY (employed by AMS, Geneva, OH, as an engineering technician beginning February 1984), whose main duties consisted of building, maintaining, and servicing radiation treatment planning computers, and additional duties of running the AMS computer, was interviewed on October 16, 1986 (Exhibit 55). ROBY stated substantially as follows:

ROBY stated that it is his responsibility to input values received from the London Road facility into a computer, which calculates leak test data (wipe tests) on custom designed C-60 cobalt sources.

INVESTIGATOR'S NOTE: AMS' license allows cobalt source construction at the London Road facility.

ROBY identified a computer read out sheet (Exhibit 56) dated August 8, 1986, reflecting a "first run" on "3320" (Exhibit 56, p. 6). ROBY identified IRWIN, AMS RSO, as the person from whom he (ROBY) received the data (radiation readings). ROBY believed the values received from IRWIN were associated with a "wipe test" of a cobalt source (Exhibit 56, p. 7).

ROBY stated that the leak test is conducted in order to avoid contamination at hospital sites, to avoid contamination of equipment used to transport the cobalt sources, to ensure the weld is solid on the source container, and to assure that no radioactive material can escape (Exhibit 55, p. 7). Simply stated, the leak test is a check of the exterior of the source container to assure that radioactivity is not above prescribed standards.

According to ROBY, based upon the information provided by IRWIN and inputted into the computer by ROBY, the test results were found to be unacceptable, and ROBY so informed IRWIN (Exhibit 55, p. 8; Exhibit 56). IRWIN, according to ROBY, upon being informed of the unacceptable results, immediately provided ROBY with a second set of data (Exhibit 55, p. 9).

ROBY further stated that upon informing IRWIN of the unacceptability of the 3320 test data, IRWIN stated, "just a second, try this set of numbers." ROBY, in accordance with IRWIN's instructions, input a second set of data (Exhibit 57). The data received by ROBY from IRWIN was unchanged except for the "Activity for Standard," which remained the same (.0481). The resulting computer generated analysis was found to be acceptable, at .00174 microcuries. ROBY stated that he so informed IRWIN, at which time IRWIN provided a third set of numbers for what ROBY believed was a third set of data for 3320 (Exhibit 55, pp. 10-11).

INVESTIGATOR'S NOTE: ROBY was not certain that the third set of wipe test data was for 3320, however, 3320 was handwritten at the top right corner of the sheet and identified by ROBY (Exhibit 55, p. 11).

ROBY identified the third input received from IRWIN on 3320 as acceptable (Exhibit 58). ROBY stated that he had a vague recall of asking IRWIN about the second set of data provided and that IRWIN responded that the values had been miscalculated, so everything was proportionally changed.

In response to an NRC:OI request, AMS, through their attorney KOLIS, made available a list of sources shipped to clients by AMS from January 1 through November 5, 1986 (Exhibit 59). The AMS response did not reveal a source numbered 3320.

Information Developed during Interview with IRWIN (Exhibit 53)

During his interview, IRWIN stated that he was present during the manufacture of the sources. IRWIN addressed the three computer read out sheets in question (Exhibits 56, 57, and 58) and he identified the 3320 as the model number of a source exchange container and the 2558 as a source serial number. According to IRWIN, there are a "dozen" 3320 containers (Exhibit 53, pp. 9-11).

IRWIN described the intricate process by which a completed source is transferred via several shielded containers and 3320 containers from the hot cell to a "machine head" (Exhibit 53, pp. 14-27). IRWIN stated that several wipe tests are performed throughout this process, but he could not recall the August 8, 1986, data (Exhibits 56, 57, and 58).

INVESTIGATOR'S NOTE: The NRC concern was that the test data represented sources processed by AMS and sent to clients. The IRWIN interview clarified that the 3320 was not a source, as suspected by ROBY, but a source container.

Willfulness/Intent

The allegation of falsification of sealed source leak test data was not substantiated. The data 3320 was found to be a source container and not a cobalt-60 source manufactured by AMS (Exhibits 53, 55, 56, 57, 58, and 59).

Agent's Conclusions

The allegation that C-60 sealed source leak data was being falsified by AMS was not substantiated.

Allegation 3: Allegedly Providing Test Answers to Applicants Being Tested for Certification as LSE

Information Developed during Interview with LIGHT (Exhibit 26)

During his interview, LIGHT stated that he had attended the cobalt teletherapy training classes, but refused to take the licensing examination. Upon further questioning, LIGHT acknowledged that he was presented a completed quiz by CARANI, but that he refused to accept the completed quiz. LIGHT stated that he had no knowledge of CARANI doing this for other people. LIGHT stated that the quiz he was presented with was not the final licensing examination (Exhibit 26, pp. 19-21).

Information Developed during Interviews with CARANI (Exhibit 25)

CARANI stated that when the AMS Radioisotope Committee agreed that LIGHT was qualified, LIGHT would take the test qualifying him to be placed on the license. The test, as described by CARANI, consists of multiple choice and fill-in questions (Exhibit 25).

Information Developed during Interview with SPEER (Exhibit 47)

SPEER corroborated LIGHT's statement in his (SPEER's) October 1, 1986, interview (Exhibit 14, Attachment L), when he stated, "the only other comment I want to make is that Dr. STEIN is short of licensed service engineers and has given tests with the answers already filled in to people to get them licensed. I personally know Garnett LIGHT was given one by Paul CARANI and told to sign it. Garnett said he wouldn't, and didn't."

Information Developed during Interview with FORTIER (Exhibit 31)

FORTIER acknowledged in his sworn statement dated October 28, 1986 (Exhibit 31, p. 16), that he had found a blank "Final Exam B" on his desk upon arriving at work one day. FORTIER acknowledged that he thought the blank test was a study guide to use prior to officially taking the final exam.

INVESTIGATOR'S NOTE: Neither LIGHT nor FORTIER were ever certified as a LSE.

Willfulness/Intent

LIGHT, an unlicensed service person, stated that he was provided a quiz which was complete with answers. LIGHT identified CARANI as the person responsible

for providing him the quiz. FORTIER, an unlicensed service person, also stated that he found a blank final exam on his desk upon arriving at work one day, but he did not know who provided the test. The two unlicensed service people, LIGHT and FORTIER, never were certified as LSEs (Exhibits 14, 26, and 31).

Agent's Conclusions

The allegation that certification test answers were provided to aspiring applicants wishing to be certified as LSEs was not substantiated.

Allegation 4: Alleged Failure by AMS to Notify the NRC of a Defect Affecting the Operation of a Cobalt-60 C-9 Teletherapy Unit

Background

On October 10, 1986, the NRC issued an Order Suspending AMS' service activities associated with teletherapy units. The order also required that AMS make available for NRC retention, inspection or copying, specifically itemized records relevant to the conduct of licensed activities. It was during the NRC's review of AMS' records on October 10 and 11, 1986, that the possibility of problems associated with Picker and/or ATC cobalt teletherapy units was first made known to NRC representatives (Exhibit 60).

A supplemental special inspection was initiated by NRC:RIII, the specific purpose of this inspection being (1) the extent to which AMS was aware of possible defects in the operation of Sodeco timers, and (2) AMS' actions in regard to notifying the NRC and/or their clients of any identified defects which could result in a substantial unplanned exposure of an individual (Exhibit 60).

On October 10, 1986, the review of AMS' safety Radioisotope Committee meeting minutes revealed the topics of a July 31, 1984, meeting (document dated August 10, 1984) (Exhibit 60, Attachment H), as follows:

"Sodeco Timers

"Picker, in letter of June 4, 1984, will not endorse Sodeco timer in C/9 timer kit. Therefore, we may not install Sodeco timer in any Picker unit, whether remanufactured or not. New digital Eagle Signal timer has been submitted to Picker. Timer accuracy testing has been done in house."

"Decision was made to use on our units once we have confidence in its performance."

INVESTIGATOR'S NOTE: The above quoted portions of AMS' July 31, 1984, safety meeting gave rise to further questioning of AMS personnel and Picker on the timer issue along with an intensive NRC:RIII inspection effort (Exhibit 60). The July 31, 1984, Radioisotope Committee meeting minutes were apparently prepared by IRWIN (Exhibit 60, Attachment H).

Information Developed during Interview with IRWIN (Exhibit 53)

IRWIN stated that he recalled the meeting which gave rise to the minutes described. IRWIN indicated that AMS' concerns regarding the Sodeco timer involved a question of liability. According to IRWIN, AMS' agreement with Picker was that they (Picker) would retain liability for machines they (Picker) had manufactured (Exhibit 53, pp. 27-30).

IRWIN stated, "we (AMS) did not assume the liability of the machines manufactured by Picker from an electrical/mechanical standpoint." However, according to IRWIN, AMS, in the course of servicing Picker machines, would periodically have to work on timing units and replace various components. IRWIN further stated, "the particular timer that was installed in a Picker manufactured machine was unavailable to us (AMS) as a replacement part, it has been discontinued" (Exhibit 53, p. 30).

IRWIN identified the "Liebel Florshiem" (L-F) timer as the timer which discontinued manufacture, and that AMS had customers who owned Picker manufactured machines that needed timers replaced, and since L-F was not available, AMS offered a Sodeco as a timer replacement. Therefore, according to IRWIN, to do this (replace an L-F with a Sodeco) and to stay within the agreement to which AMS and Picker had agreed, "we (AMS) had to get their (Picker) approval to make a change on the machine" (Exhibit 53, p. 31).

IRWIN described the referenced minutes as a summary of previous discussions with Picker, and the minutes simply state that Picker had described that they would not endorse the Sodeco timer as a replacement part in machines of their manufacture (Exhibit 53, p. 31).

Regarding the phrase, "therefore we may not install Sodeco timer in any Picker unit, whether remanufactured or not," IRWIN stated, "if we did not want to assume the liability for that machine, we could do that." IRWIN acknowledged that if AMS did install a Sodeco timer following Picker's refusal to sanction the use of a Sodeco as a replacement timer, AMS/ATC would assume any liability attached thereto (Exhibit 53, pp. 31-32).

IRWIN responded, "to my direct knowledge, I don't know. I'm not in the manufacturing aspect of the business," to the question, "to your knowledge, did you install additional Sodeco timers either remanufactured or not in Picker C-9 units?" (Exhibit 53, p. 32). IRWIN stated that he had no knowledge of a Sodeco timer being installed in a Picker machine following the July 31, 1984, meeting. However, IRWIN stated that the Sodeco timer was being used as a replacement on AMS/ATC machines (Exhibit 53, p. 33). IRWIN stated that he had no reservations about installing the Sodeco timer, that the July 31, 1984, meeting was not related to the reliability of the Sodeco timer, and that AMS/ATC had made a decision to use the Sodeco timer in ATC manufactured units (Exhibit 53, p. 34).

IRWIN was asked, "did you as the RSO have knowledge of any concern regarding the timer not functioning properly when placed in the appropriate unit? Was there a history of problems with the Sodeco timer?" He responded, "No. We had one to the best of my recollection. We had one incident where we consider an incident regarding the Sodeco timer, and we investigated that and

determined it was an isolated case for one particular hospital and it wasn't a generic problem to the timer itself." The problem, as explained by IRWIN, was "the source, machine source, could be turned on if the timer had counted down to zero, but had not been reset" (Exhibit 53, pp. 33-35).

INVESTIGATOR'S NOTE: The NRC:RIII supplemental inspection (Exhibit 60) revealed that IRWIN, on more than one occasion, was aware of concerns related to the Sodeco timer. The following occasions have been documented in the NRC:RIII supplemental inspection (Exhibit 60, p. 39):

1. AMS' Safety Committee meeting on August 24, 1983, written by IRWIN, reflect a defective treatment timer (Exhibit 60, Attachment A).
2. AMS' Safety Committee meeting on January 25, 1984, written by IRWIN, reflect the Sodeco timer being able to initiate source exposure and count down when reset to 000.00 (Exhibit 60, Attachment B).
3. AMS' Safety Committee meeting on April 11, 1984, written by IRWIN, referencing two patient overexposure incidents due to Sodeco timer failures (Exhibit 60, Attachment E).
4. An AMS Radioisotope Committee meeting of April 1984, on whose distribution list IRWIN's name appears, states, "the timer used in the C-9 units has been causing some problems recently..." (Exhibit 60, Attachment E).
5. AMS' Radioisotope Committee meeting of July 31, 1984, written by IRWIN, references Picker's decision not to endorse Sodeco timers (Exhibit 60, Attachment H).
6. IRWIN is named on the distribution list for two of AMS' incident reports referencing patient overexposure incidents caused by timer's failure to close source (Exhibit 60, Attachments I and J).

INVESTIGATOR'S NOTE: The information noted in the NRC:RIII special inspection report indicates that IRWIN was not being totally truthful in his responses to questions concerning the Sodeco timer.

Information Developed during Interview with STEIN (Exhibit 28):

STEIN was interviewed on in reference to the AMS July 31, 1984, Radioisotope Committee meeting minutes (Exhibit 60, Attachment H).

STEIN stated that on the C-9 machines, Picker manufactured them with an L-F timer. STEIN said when Picker came out with the C-12 unit (a more advanced machine), the timer used on the C-12 was a Sodeco timer. STEIN related the Sodeco timer was, therefore, the original timer for a C-12 unit. According to STEIN, when the L-F began to fail on the C-9 units because L-F's were no longer being manufactured, no L-F's were available as replacement timers, and Sodeco timers were historically used as replacement timers in the C-9 unit (Exhibit 28, p. 29).

STEIN further stated that the ATC agreement with Picker is "they (Picker) would retain product liability on all of the machines that they (Picker) designed and manufactured unless we (ATC) made a modification without their approval" (Exhibit 28, p. 29). STEIN further stated when ATC found out that L-F timers were no longer available, Picker was formally asked by ATC to use the C-12 timer, a Sodeco timer, as a replacement on the C-9 unit (Exhibit 28, p. 30). STEIN asserted that Picker never said the Sodeco timer was bad, because they (Picker) never told ATC that the Sodeco should not be used on the C-12 unit.

Information furnished by Andrew R. MORSE, Attorney Representing Picker

In response to an NRC:OI request, Picker, Highland Heights, OH, on March 17, 1987, responded through their attorney, MORSE (Exhibit 61). MORSE's correspondence contained an affidavit from Kenneth J. DRAGMEN, the Senior Product Review Engineer at Picker.

DRAGMEN's affidavit stated that in late 1983, he was notified by AMS of a need to have an alternate timer available for the L-F timer used in Picker therapy products. DRAGMEN stated that he called KELBLEY in early 1984 and asked if AMS had any alternate timer/counter available. According to DRAGMEN, KELBLEY indicated that AMS had a timer that could be used and indicated he (KELBLEY) would send DRAGMEN documentation on the proposed replacement timer (Exhibit 61).

DRAGMEN's affidavit further stated that in a letter dated February 14, 1984, AMS forwarded information to DRAGMEN on the proposed L-F replacement timer. DRAGMEN stated that a thorough review of the documents by various individuals within Picker, including DRAGMEN, indicated that the proposed Sodeco timer was not acceptable as a replacement for the L-F timer. It was concluded, according to DRAGMEN, that the proposed Sodeco timer had a peculiarity that might produce unsatisfactory performance under certain conditions (Exhibit 61).

On June 4, 1984, DRAGMEN stated that he sent a letter recommending that AMS discontinue selling the Sodeco timer as a replacement for the L-F timer (Exhibit 60, Attachment LL).

INVESTIGATOR'S NOTE: The Radioisotope Committee meeting of July 31, 1984, dated August 10, 1984 (Exhibit 60, Attachment H), refers to the June 4, 1984, DRAGMEN letter and states AMS' decision, "we may not install Sodeco timers in any Picker unit, whether remanufactured or not." Following this decision, AMS routinely used the Sodeco timer as a replacement timer (Exhibit 60).

DRAGMEN further related in his March 16, 1987, affidavit that on or about July 25, 1984, he sent AMS a letter, which stated, in part, the following:

"The Sodeco Timer Kit (200037), when installed, has an operating peculiarity which we feel presents the possibility of operator error. When the time is at "all zeros," an exposure can be made. We believe this is a problem even though the operator's instructions clearly state the problem."

DRAGMEN further related that following his June 4 and July 25, 1984, letters, AMS did not request authority to install the Sodeco timer in any of the Picker therapy units, or ever ask Picker for methods or possible conditions under which the Sodeco timer could be safely installed in the therapy unit.

INVESTIGATOR'S NOTE: This information contradicts STEIN's assertion that they were never told by Picker that they could not use the Sodeco timer in Picker Units.

Willfulness/Intent

IRWIN stated under oath that he could recall only one instance where AMS' had a problem with the Sodeco timer. According to information extracted from AMS Safety Committee meetings on August 24, 1983, January 25, 1984, April 11, 1984, April 1984, and July 31, 1984, Sodeco timers had been involved in several incidents. This puts in serious question the veracity of IRWIN's statements.

STEIN claims that Picker never told them that AMS could not use a Sodeco timer as a replacement for the L-F timers in Picker units. The affidavit of DRAGMEN clearly contradicts the statement of STEIN and outlines what Picker felt was the problem with the Sodeco timers. This same problem was apparently identified in the AMS January 24, 1984, Safety Committee Meeting.

AMS was aware of several failures associated with the use of a Sodeco timer as a replacement timer on the Picker C-9 unit as revealed in notes, memoranda, and meeting minutes. IRWIN, AMS RSO, however, in sworn testimony admitted knowledge of only one incident which, according to IRWIN, was not found to be a generic problem with the Sodeco timer. AMS made no attempt to notify the NRC of the Sodeco timer failures (Exhibits 28, 53, 60, and 61).

Agent's Conclusion

Based on the testimonial and documentary evidence developed during the investigation it is concluded that the allegation that AMS was aware of defects in the replacement timer (Sodeco) used in Picker C-9 units and failed to notify the NRC was substantiated. IRWIN, AMS RSO, made a false statement to NRC inspectors/investigators regarding the extent of his knowledge. STEIN, AMS President, wrongfully defined the problems associated with the Sodeco timer as legal problems. STEIN and IRWIN knowingly and willfully attempted to down play the extent of the problems associated with the Sodeco timer.

Status of Investigation

Upon determining that material presented to the NRC on December 23, 1985, was false, and further that an AMS employee had allegedly been directed by AMS management to falsify said document, the DOJ was notified. All further investigation under the authority of the NRC halted and a criminal investigation with DOJ ensued. By letter dated August 1, 1988, DOJ declined prosecution of this matter. This case is closed.

LIST OF EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
1	Copy of ATC Organization Chart
2	Copy of AMS License No. 34-19089-01, in part.
3	Copy of AMS License No. 34-19089-02, in part.
4	Copy of Application for Byproduct Material License dated November 16, 1979.
5	Copy of AMS Procedures Manual dated March 10, 1980.
6	Copy of NRC Inspection Report No. 30-16055/83-01(DRMS); 30-17154/83-01(DRMS) with Notice of Violation and Proposed Imposition of Civil Penalty dated May 5, 1983.
7	Copy of AMS Protest of Civil Penalty dated June 1, 1983.
8	Copy of NRC letter to AMS reaffirming Civil Penalty dated July 13, 1983.
9	Copy of NRC Inspection Report No. 30-16055/84-01(DRSS) dated August 29, 1984.
10	Copy of NRC Inspection Report No. 030-16055/85001(DRSS) dated June 28, 1985.
11	Copy of Notice of Violation and Proposed Imposition of Civil Penalty dated June 28, 1985.
12	Copy of AMS letter to NRC dated July 31, 1985, denying violations.
13	Copy of NRC letter to AMS combining licenses under License No. 34-19089-01.
14	Copy of NRC Inspection Report No. 030-16055/86-001(DRSS) dated November 25, 1986.
15	Sworn statement of Keith JORDAN dated October 27, 1986.
16	Copy of AMS Basic Training Program.
17	Sworn statement of Glenn SIBERT dated January 14, 1987.
18	Copy of AMS Service Report No. 2466.
19	Sworn statement of William GAMMERN dated October 29, 1986.

<u>Exhibit No.</u>	<u>Description</u>
20	Copy of AMS Cobalt Service Procedures Manual.
21	Copy of AMS Service Report No. 2504.
22	Copy of AMS Service Report No. 2718.
23	Copy of AMS Radioisotope Committee Meeting Minutes dated June 28, 1985.
24	Report of Interview with R. W. ARNDT dated April 5, 1988.
25	Sworn statement of Paul CARANI dated October 15, 1986.
26	Sworn statement of Garnett C. LIGHT dated October 28, 1986.
27	Sworn statement of Donna ELY dated December 9, 1986.
28	Sworn statement of Dr. Seymour S. STEIN dated December 9, 1986.
29	Copy of AMS memorandum from R. W. ARNDT to J. B. STICKNEY dated March 8, 1979.
30	Sworn statement of James M. LESLIE dated October 29, 1986.
31	Sworn statement of Russell FORTIER dated October 28, 1986.
32	Report of Review of Records of Russell P. FORTIER's Ohio unemployment records on October 29, 1986.
33	Report of Interview with Erich DREIER dated October 16, 1986.
34	Copy of Telephone Call Report dated September 19, 1986.
35	Sworn statement of Erich DREIER dated December 8, 1986.
36	Sworn statement of Mark BAKER dated December 17, 1986.
37	AMS response to an OI:RIII Request for Information dated December 8, 1986.
38	Copy of AMS brief with affidavits of Theodore HEBERT and Donna ELY presented to NRC:RIII on December 23, 1986.
39	Copy of NRC:RIII Hearing transcript in the matter of AMS dated December 23, 1986.
40	Sworn statement of James F. COCHRAN dated February 6, 1987.
41	Copy of AMS Radioisotope Committee Meeting Minutes from October 20, 1981, through April 14, 1986.

<u>Exhibit No.</u>	<u>Description</u>
42	Written statement of Despina V. MAVRAKIS dated September 30, 1986.
43	NRC memorandum from George M. McCANN to Harold G. Walker dated August 17, 1987.
44	Copy of Conversation Record dated February 9, 1987 (COCHRAN).
45	Conversation Records dated February 26, 1987 (COCHRAN).
46	Report of Interview with Paul CARANI dated February 13, 1987.
47	Report of Interview with Rick SPEER dated January 2, 1987.
48	Copy of Conversation Record dated January 26, 1987 (SPEER).
49	Copy of AMS Response to OI:RIII Request dated December 17, 1986.
50	Sworn statement of Norman KELBLEY dated December 9, 1986.
51	Sworn statement of Darwin MURRAY dated February 5, 1987.
52	Report of Telecon with Victor SALTENIS dated November 5, 1986.
53	Sworn statement of Howard IRWIN dated December 8, 1986.
54	Sworn statement of Theodore HEBERT dated December 8, 1986.
55	Sworn statement of Eric Van ROBY dated October 16, 1986.
56	Computer generated data sheet, Ref: 3320, first run, dated August 8, 1986.
57	Computer generated data sheet, Ref: 3320, after 2558, dated August 8, 1986.
58	Computer generated data sheet, Ref: 3320, dated August 8, 1986.
59	Copy of AMS Responses to an NRC:OI request, Ref: Sources, dated October 31 and November 5, 1986.
60	NRC Supplemental Inspection Report No. 30-16055/86-001(DRSS).
61	Copy of Picker correspondence dated March 17, 1987.