U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Report No. 030-16055/89001(DRSS)

Docket No. 030-16055 License No. 34-19089-01

Licensee: Advanced Medical Systems, Inc.
1920 London Road
Cleveland, OH 44110

Meeting Conducted: September 18, 1989

Location: NRC Region III Office, Glen Ellyn, Illinois

Prepared By: Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch
Bruce S. Mallett
November 6, 1989
Date

Approved By: Charles E. Norelius, Director
Division of Radiation Safety and Safeguards
Charles E. Norelius
11/6/89
Date

Meeting Summary

Enforcement Conference on September 18, 1989 (Report No. 030-16055/89001(DRSS)
Areas Discussed: Facts contained in NRC Supplemental Inspection Report No. 030-16055/86001(DRSS), regarding an inspection performed on October 10, 1986 through March 4, 1987 to review Sodeco timer failures, facts regarding statements made by a former Radiation Safety Officer (RSO) during an NRC Office of Investigations (OI) interview, apparent violations of NRC requirements and licensee's corrective actions.

DETAILS

1. Individuals in Attendance

NRC

Carl J. Paperiello, Ph.D., Deputy Regional Administrator, Region III
Charles E. Norelius, Director, Division of Radiation Safety and Safeguards, Region III
John A. Grobe, Director, Enforcement and Investigation Coordination Staff, Region III
Bruce S. Mallett, Ph.D., Chief, Nuclear Materials Safety Branch, Region III
George M. McCann, Chief, Materials Licensing Section, Region III
Stephen H. Lewis, Senior Supervisory Enforcement Attorney, Office of the General Counsel
Bruce A. Berson, Regional Counsel, Region III

Licensee

Sherry J. Stein, Esq., Director, Regulatory Affairs
Janet G. Aldrich, Esq., Counsel for AMS

2. Topics Discussed During Conference

Dr. Carl J. Paperiello opened the conference with a general discussion of the purpose of an enforcement conference and the subjects to be covered during the meeting.

NRC staff summarized the apparent violations and concerns. In response, the licensee submitted four procedures for NRC review (Attachments 1, 2, 3, and 4), and stated these procedures were in place at the time of the inspection. The licensee asserted that the procedures cover the requirements of Part 21.

Licensee staff stated AMS' position that (1) the Sodeco timer problems described are not defects, but design characteristics, (2) the NRC was notified of the timer problems since NRC inspectors had access to all licensee committee minutes describing the problems during inspections at AMS, (3) the NRC should not consider the problems as a defect if other licensees did not report these problems, (4) when AMS has discovered timer problems in-house, AMS has sent the timers back for repairs, and (5) it is difficult to determine if timer problems are due to defects or simply due to timer age or user error.

NRC staff informed the licensee that Part 21 specifies notification and reporting mechanisms with timeframes which may be well in advance of any NRC inspection. NRC staff also requested the licensee to provide NRC with answers to the following questions:

a. Could operators cause problems with Sodeco timers, such as setting between numbers and activating units without the timer shutting off unit:

b. What type of problems were exhibited by the timers involved in AMS Event No. 82-08, and did the problems include:

(1) Timers stopping between two numbers and continuing to expose the teletherapy source.

(2) Timers failing to terminate exposure from teletherapy unit sources when set to zero.

NRC staff noted that AMS does not appear to have specific procedures to comply with Part 21. The procedures should include responsibilities of individual AMS staff members and actions to be taken. AMS indicated it would incorporate NRC desired changes to the procedures submitted. NRC staff agreed to review the procedures and respond to AMS on this issue.

Mr. Norelius discussed the AMS May 17, 1989, letter to the NRC regarding AMS' position that there are errors in the NRC Supplemental Inspection Report No. 030-16055/86001(DRSS). The licensee offered four specific errors:

a. On Page 19, Paragraph 5, the C12 Treatment Timer Operating Instructions were written by Picker and not AMS.

b. On Page 5, Part Nos. 81493 and 17086 are Picker part numbers and not AMS.

c. Sodeco timers are electro-mechanical predetermined impulse counters and not electrical timers.

d. On Page 19, Paragraph 4, the Eagle timer was not fully tested at that time.

NRC staff stated that these examples do affect the results of the inspection.

On the issue of the previous AMS Radiation Safety Officer (RSO), and whether he made a material false statement to the NRC, the licensee asserted that the interview of the RSO did not demonstrate that the former RSO made a false statement. The licensee pointed out that the RSO stated his response was to the best of his recollection.

The conference ended after Dr. Paperiello summarized the NRC Enforcement Policy, the options the NRC has and the next steps in the process. The licensee also provided copies of AMS interoffice memoranda dated January 3, 1984, January 27, 1984, and April 13, 1984, which discussed Sodeco timer characteristics and problems (Attachments 5, 6, and 7).

Attachments:

1. AMS interoffice memorandum dated 2/24/83 with attached AMS procedure QA 1000 15.2, dated 1/31/83.
2. AMS Procedure QA 1000 15.3, dated 10/25/79.
3. AMS Procedure QA 1000 15.4, dated 1/28/83.
4. AMS Procedure QA 1000 1.4, dated 11/7/79.
5. AMS interoffice memorandum dated 1/3/84.
6. AMS interoffice memorandum dated 1/27/84.
7. AMS interoffice memorandum dated 4/13/84.

ATTACHMENT 1

INTEROFFICE MEMORANDUM

DATE: February 24, 1983

TO:
Norman Kelbley
Mark Baker
Mike Baruffa
Mike Klozar
Victor Saltenis
Bill Skoch
Red Murray
Tom Kidd
Glenn Siebert
Dwight Puntigan
Perry Edwards
Jim Miller
Dave Krieglein
Denny Walker
Bill Evans
Jim Cochran
Bill Dieffenbachr
Hugh Goodale
Bob Bailey
Jim Ramos
Malcolm Ord
Norbert Johnson
R. Sturgill
D. Driscoll
T. Flora
D. Skowbo
Jack Schuetz
Cecil Cox
Jerry Hill
Terry Cameron
Bill Gammern
Chuck Edgerton
Lee Roy Begin
Cindy Kane
Bob Skrtich
Bob Beauvais
Jean Smith
Jack Lawry

FROM: Howard Irwin
Corporate Safety Officer

COPY TO: S. S. Stein

SUBJECT: Reporting of incidents Incident Reports

Attached to this memo you will find a copy of procedure QA 1000 15.2, 'Procedure for handling of incidents reports', along with five copies of Report Form QA 1000 15.2.

Review of our company employee roster indicates that your position is one in which you may receive a customer complaint that can be classified as an incident. (The term'Incident' is defined in the procedure). This procedure and report form has been developed to instruct you in the proper handling of incidents.

It is important that you understand the definition of an incident. Anytime there is an injury or death involved it is an incident. Anytime there is an overexposure to radiation is is an incident. Hazards-to-safety may not result in an actual injury or death, but have the potential to do so. For instance, exploding field lamps, defective exposure timers and hardware failures are examples of hazards - to - safety that have been classified as incidents in the past. All of these cases require action on the company's part.

Please note the distribution list at the bottom of Form QA 1000 15.2A. Incident reports on AMS manufactured equipment are to be filed with Norm Kelbley. Incident reports on ATC Med. Tech. manufactured equipment are to be filed with Lee Roy Begin.

continued

ATTACHMENT 1

INTEROFFICE MEMORANDUM

DATE: February 24, 1983

TO:

FROM: Howard Irwin HRI
Corporate Safety Officer

COPY TO: S. S. Stein

SUBJECT: Reporting of Incidents, cont'd.

The addresses of the listed individuals are as follows:

Norm Kelbley
1020 London Road
Cleveland, OH 44110

Howard Irwin
5463 Horning Road
Pittsburgh, PA 15236

Lee Roy Begin
570 Del Rey
Sunnyvale, CA 94086

Fred Kafer
2775 S. Moreland
Cleveland, OH 44120

Dwight Miller
1604 Illuminating Bldg.
55 Public Square
Cleveland, OH 44113

It is extremely important that incidents be handled correctly, as they may result in a product liability lawsuit. You are the key person in the process if you take a customer call regarding an incident. If you do not notify the proper management personnel to coordinate further action, the company may be vulnerable to legal action.

PROCEDURE FOR HANDLING OF INCIDENT REPORTS	ATTACHMENT 1
	Revision:
	Date Issued: 1 - 31 - 83

Purpose: This procedure has been established to define the method of handling a customer complaint which can be classified as an Incident.

Definition: "Incident" - This is a complaint pertaining to patient or operator injury or death, or to a hazard-to-safety condition. Hazards-to-safety include malfunction of any components related to radiation generating and attenuating, malfunction of any components which might create an uncontrolled radiation situation, and malfunction of any components whose failure could physically harm someone. This type of complaint requires formal investigation.

Scope: This procedure applies to all Incidents involving ATC Medical Group Manufactured equipment.

Instruction: A. Responsibilities of company employees

1. Notification of an Incident
Any company employee may report an incident. The incident may occur in the factory as well as in a customer's facility.
Upon learning of an incident, immediately contact either the facility manager or the corporate safety officer Howard Irwin (412) 655-3737).
No statements regarding company responsibility should be made to a customer. No action is to be taken without authorization from the facility manager or corporate safety officer.

2. A preliminary investigation by telephone should be conducted using Incident Report form QA 1000 15.2A. This form should be filled out in its entirety and distributed as marked. This form itemizes the appropriate questions to be asked and provides space for responses.

B. Responsibilities of Facility Manager and/or Corporate Safety Officer

1. Acknowledgement of Incident
The customer shall be contacted by the Facility Manager or his appointee in a timely fashion. The customer should be assured that the complaint is being acted on.

2. Notification of Insurance Carrier and corporate counsel
All incidents are to be reported to our product liability insurance agent (Mr. Fred Kafer, Pinkerton Insurance (216) 751-7222).
All incidents involving an injury or death are to be verbally reported to corporate counsel (Dwight Miller or Tony Stavole (216) 771-0011) before further action is taken.

Prepared by	Approval	Revisions
	Howard R Irwin 1-31-83	

3. Field investigation
All incidents on newly manufactured or remanufactured equipment will be field investigated by a qualified field service engineer.
Incidents on Picker Manufactured equipment should be reported to Picker International, Mr. Bill Ashby, (216) 449-3000.
Field investigation is to be limited strictly to the equipment involved.
Where component failure has occurred, photographs should be taken. Defective components should be returned to the factory for further examination.
A written report of findings is to be made, stamped Confidential and the original copy filed in the Incident file.
No other copies are to be made or distributed.

4. Correspondence
All company correspondence related to an incident shall be reviewed by corporate counsel prior to release.

5. Incident file
An incident report file will be maintained at each manufacturing facility by an individual designated by the Corporate Safety Officer. The file will contain a copy of form QA 1000 15.2A, the results of investigations performed, notice of corrective action and any other pertinent data.
The file will be marked "Company Confidential" and maintained in a locked cabinet.
Only two copies of the incident file will be maintained. Corporate counsel will retain the original documents with a copy in the plant file.
No other persons are authorized to maintain any copies of the report or findings.

COMPANY CONFIDENTIAL

INCIDENT REPORT

ATTACHMENT 1

FROM: Name_____
Division_____
Office_____
Date of Report_____

INSTRUCTIONS FOR USE:

This form is to be completed in the event of an incident involving equipment manufactured and/or sold by the ATC Medical Group companies which resulted or could have resulted in an injury, death, or hazard to safety.

1. Please complete as much of the information requested as possible.
2. State factual information only - do not editorialize or state opinions unless they are opinions or conclusions of persons unconnected with the ATC Medical Group companies and are identified as such.
3. Attach additional pages if necessary to fully describe the incident.
4. Preserve broken parts or other evidence which would aid in determining the cause of the incident. The Corporate Safety Officer will notify you with directions for the disposition of this evidence.

INCIDENT DESCRIPTION

1. Date of Incident_____ Time of Incident_____
2. Name of Account_____

   _____
   Address City State
3. Where did incident occur?_____
4. Was anyone injured (even slightly?)_____
5. If so, please complete information on lines (a.) through (c.) below:
   a. Injured person's name_____
   b. Injured person's address_____
      City_____ State_____
   c. Sex_____ Age_____ Marital Status_____
6. Give complete details of the incident. (Use additional page if necessary).

   _____

   _____

   _____
7. Was person examined by physician after injury?_____ Physician's name_____
8. Unit operated by_____ (Name & Title) at time of incident.
9. Names and addresses of other witnesses (if any) to incident:

   _____

   _____
10. Was there any property damage other than the equipment involved?_____
11. If so, please describe_____
12. Sources of above information_____

EQUIPMENT DESCRIPTION

1. Name of equipment_____ Cat. #_____ Ser. #_____
2. Date of installation_____
3. Service Contract_____ Serviced on call_____ Serviced by_____ Branch Off._____
4. Date of last service call_____ Date of last safety inspection_____
5. Has preventive maintenance been performed at suggested intervals?_____
   Specify dates_____
6. Any comments on misuse or alterations by customer.
   a. Misuse - _____
   b. Alterations - _____
   c. Was above misuse or alteration called to the attention of customer in writing prior to incident?_____
7. Was part (involved in incident) previously serviced?_____

_____
Signature of Person Preparing Report

DISTRIBUTION: Send this original report to:

AMS - Norm Kelbley
ATC - LeeRoy Begin

and copies to:

Howard Irwin
Fred Kafer
Dwight Miller

Form QA1000 15.2A

INTEROFFICE MEMORANDUM

DATE: February 24, 1983

TO:

FROM: Howard Irwin
Corporate Safety Officer

COPY TO: S. S. Stein

SUBJECT: Reporting of incidents, cont'd.

The addresses of the listed individuals are as follows:

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Cleveland, OH 44110

Howard Irwin
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Pittsburgh, PA 15236

Lee Roy Begin
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Sunnyvale, CA 94086

Fred Kafer
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Cleveland, OH 44120

Dwight Miller
1604 Illuminating Bldg.
55 Public Square
Cleveland, OH 44113

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PROCEDURE FOR HANDLING OF INCIDENT REPORTS	Procedure No. QA 1000 15.2
	ATTACHMENT 1
	Revision:
	Date Issued: 1 - 31 - 83

Purpose: This procedure has been established to define the method of handling a customer complaint which can be classified as an Incident.

Definition: "Incident" - This is a complaint pertaining to patient or operator injury or death, or to a hazard-to-safety condition. Hazards-to-safety include malfunction of any components related to radiation generating and attenuating, malfunction of any components which might create an uncontrolled radiation situation, and malfunction of any components whose failure could physically harm someone. This type of complaint requires formal investigation.

Scope: This procedure applies to all Incidents involving ATC Medical Group Manufactured equipment.

Instruction: A. Responsibilities of company employees

1. Notification of an Incident
Any company employee may report an incident. The incident may occur in the factory as well as in a customer's facility.
Upon learning of an incident, immediately contact either the facility manager or the corporate safety officer (Howard Irwin (412) 655-3737). No statements regarding company responsibility should be made to a customer. No action is to be taken without authorization from the facility manager or corporate safety officer.

2. A preliminary investigation by telephone should be conducted using Incident Report form QA 1000 15.2A. This form should be filled out in its entirety and distributed as marked. This form itemizes the appropriate questions to be asked and provides space for responses.

B. Responsibilities of Facility Manager and/or Corporate Safety Officer

1. Acknowledgement of Incident
The customer shall be contacted by the Facility Manager or his appointee in a timely fashion. The customer should be assured that the complaint is being acted on.

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Prepared by	Approval	Revisions
	Howard R Irwin 1-31-83	

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A written report of findings is to be made, stamped Confidential and the original copy filed in the Incident file.
No other copies are to be made or distributed.

4. Correspondence
All company correspondence related to an incident shall be reviewed by corporate counsel prior to release.

5. Incident file
An incident report file will be maintained at each manufacturing facility by an individual designated by the Corporate Safety Officer. The file will contain a copy of form QA 1000 15.2A, the results of investigations performed, notice of corrective action and any other pertinent data.
The file will be marked "Company Confidential" and maintained in a locked cabinet.
Only two copies of the incident file will be maintained. Corporate counsel will retain the original documents with a copy in the plant file.
No other persons are authorized to maintain any copies of the report or findings.

COMPANY CONFIDENTIAL

ATTACHMENT 1

INCIDENT REPORT

FROM: Name_____
Division_____
Office_____
Date of Report_____

INSTRUCTIONS FOR USE:

This form is to be completed in the event of an incident involving equipment manufactured and/or sold by the ATC Medical Group companies which resulted or could have resulted in an injury, death, or hazard to safety.

1. Please complete as much of the information requested as possible.
2. State factual information only - do not editorialize or state opinions unless they are opinions or conclusions of persons unconnected with the ATC Medical Group companies and are identified as such.
3. Attach additional pages if necessary to fully describe the incident.
4. Preserve broken parts or other evidence which would aid in determining the cause of the incident. The Corporate Safety Officer will notify you with directions for the disposition of this evidence.

INCIDENT DESCRIPTION

1. Date of Incident_____ Time of Incident_____
2. Name of Account_____
   Address City State
3. Where did Incident occur?_____
4. Was anyone injured (even slightly?)_____
5. If so, please complete information on lines (a.) through (c.) below:
   a. Injured person's name_____
   b. Injured person's address_____
      City_____ State_____
   c. Sex_____ Age_____ Marital Status_____
6. Give complete details of the incident. (Use additional page if necessary).
7. Was person examined by physician after injury?_____ Physician's name_____
8. Unit operated by_____ (Name & Title) at time of incident.
9. Names and addresses of other witnesses (if any) to incident:
10. Was there any property damage other than the equipment involved?_____
11. If so, please describe_____
12. Sources of above information_____

EQUIPMENT DESCRIPTION

1. Name of equipment_____ Cat. #_____ Ser. #_____
2. Date of installation_____
3. Service Contract_____ Serviced on call_____ Serviced by_____ Branch Off._____
4. Date of last service call_____ Date of last safety inspection_____
5. Has preventive maintenance been performed at suggested intervals?_____
   Specify dates_____
6. Any comments on misuse or alterations by customer.
   a. Misuse - _____
   b. Alterations - _____
   c. Was above misuse or alteration called to the attention of customer in writing prior to incident?_____
7. Was part (involved in incident) previously serviced?_____

_____
Signature of Person Preparing Report

DISTRIBUTION: Send this original report to:

AMS - Norm Kelbley
ATC - LeeRoy Begin

and copies to:

Howard Irwin
Fred Kafer
Dwight Miller

Form QA1000 15.2A

ATTACHMENT 1

ATC

INTEROFFICE MEMORANDUM

DATE: February 24, 1983

TO:

Norman Kelbley	Jim Ramos
Mark Baker	Malcolm Ord
Mike Baruffa	Norbert Johnson
Mike Klozar	R. Sturgill
Victor Saltenis	D. Driscoll
Bill Skoch	T. Flora
Red Murray	D. Skowbo
Tom Kidd	Jack Schuetz
Glenn Siebert	Cecil Cox
Dwight Puntigan	Jerry Hill
Perry Edwards	Terry Cameron
Jim Miller	Bill Gammern
Dave Krieglein	Chuck Edgerton
Denny Walker	Lee Roy Begin
Bill Evans	Cindy Kane
Jim Cochran	Bob Skrtich
Bill Dieffenbachr	Bob Beauvais
Hugh Goodale	Jean Smith
Bob Bailey	Jack Lawry

FROM: Howard Irwin HHI
Corporate Safety Officer

COPY TO: S. S. Stein

SUBJECT: Reporting of incidents Incident Reports

Attached to this memo you will find a copy of procedure QA 1000 15.2, 'Procedure for handling of incidents reports', along with five copies of Report Form QA 1000 15.2.

Review of our company employee roster indicates that your position is one in which you may receive a customer complaint that can be classified as an incident. (The term'Incident' is defined in the procedure). This procedure and report form has been developed to instruct you in the proper handling of incidents.

It is important that you understand the definition of an incident. Anytime there is an injury or death involved it is an incident. Anytime there is an overexposure to radiation is is an incident. Hazards-to-safety may not result in an actual injury or death, but have the potential to do so. For instance, exploding field lamps, defective exposure timers and hardware failures are examples of hazards - to - safety that have been classified as incidents in the past. All of these cases require action on the company's part.

Please note the distribution list at the bottom of Form QA 1000 15.2A. Incident reports on AMS manufactured equipment are to be filed with Norm Kelbley. Incident reports on ATC Med. Tech. manufactured equipment are to be filed with Lee Roy Begin.

continued

ADVANCED MEDICAL SYSTEMS, INCORP.	QUALITY ASSURANCE DEPARTMENT FAILURE INVESTIGATION POLICY	NUMBER ATTACHMENT 2 QA 1000 15.3 DATE ISSUED
Operating Practice	Test	Other

1.0 SCOPE:

This procedure has been established to indicate the practice which will be used to process reported field failures for equipment which was produced by AMS, Inc. All written and oral field reported failures are to be directed to the Q.A. Manager.

2.0 PROCEDURE:

2.1 Upon receipt the Q.A. Manager will review the reported failures. Those which do not require further investigation will be marked indicating his evaluation, dated, signed then put into a closed failure investigation file.

2.2 Those requiring further investigation will be forwarded to the Engineer by the Q.A. Manager.

2.4 The data sheet will be used for investigational results. Once complete it will be dated and signed by the Engineer then forwarded to the Q.A. Manager.

2.5 If the Q.A. Manager concurs with the report, he will sign it then file it in the closed failure investigation file. If he doesn't agree with the contents, it will be returned to the Engineer with notations for reprocessing. A copy of the approved report will be returned to the Engineer.

PREPARED BY	APPROVAL	CATALOG#	REVISIONS
	M O'Kelley 10/25/79		

FAILURE INVESTIGATION DATA SHEET

PROBLEM: _____

_____

_____

_____

_____

_____

CAUSE: _____

_____

_____

_____

_____

☐ Isolated Case ☐ Generic Problem

FACTORY CORRECTIVE ACTION: _____

_____

_____

ENGINEER: _____

DATE: _____

Q.A. MANAGER: _____

COMPANY CONFIDENTIAL

ATTACHMENT 2

INCIDENT REPORT

FROM: Name_____
Division_____
Office_____
Date of Report_____

INSTRUCTIONS FOR USE:

This form is to be completed in the event of an incident involving equipment manufactured and/or sold by the ATC Medical Group companies which resulted or could have resulted in an injury, death, or hazard to safety.

1. Please complete as much of the information requested as possible.
2. State factual information only - do not editorialize or state opinions unless they are opinions or conclusions of persons unconnected with the ATC Medical Group companies and are identified as such.
3. Attach additional pages if necessary to fully describe the incident.
4. Preserve broken parts or other evidence which would aid in determining the cause of the incident. The Corporate Safety Officer will notify you with directions for the disposition of this evidence.

INCIDENT DESCRIPTION

1. Date of Incident_____ Time of Incident_____
2. Name of Account_____
   Address City State
3. Where did incident occur?_____
4. Was anyone injured (even slightly?)_____
5. If so, please complete information on lines (a.) through (c.) below:
   a. Injured person's name_____
   b. Injured person's address_____
      City_____ State_____
   c. Sex_____ Age_____ Marital Status_____
6. Give complete details of the incident. (Use additional page if necessary).
7. Was person examined by physician after injury?_____ Physician's name_____
8. Unit operated by_____ (Name & Title) at time of incident.
9. Names and addresses of other witnesses (if any) to incident:
10. Was there any property damage other than the equipment involved?_____
11. If so, please describe_____
12. Sources of above information_____

EQUIPMENT DESCRIPTION

1. Name of equipment_____ Cat. #_____ Ser. #_____
2. Date of installation_____
3. Service Contract_____ Serviced on call_____ Serviced by_____ Branch Off._____
4. Date of last service call_____ Date of last safety inspection_____
5. Has preventive maintenance been performed at suggested intervals?_____
   Specify dates_____
6. Any comments on misuse or alterations by customer.
   a. Misuse -
   b. Alterations -
   c. Was above misuse or alteration called to the attention of customer in writing prior to incident?
7. Was part (involved in incident) previously serviced?_____

_____
Signature of Person Preparing Report

DISTRIBUTION: Send this original report to:

AMS - Norm Kelbley
ATC - LeeRoy Begin

and copies to:

Howard Irwin
Fred Kafer
Dwight Millar

Form QA1000 15.2A

PURPOSE:

This procedure has been established to define a uniform method of handling written and verbal complaints from users of ATC Medical Group products.

SCOPE:

This procedure applies to all devices (current & obsolete) manufactured by ATC.

APPLICABILITY:

This procedure applies to all company personnel who, in the normal course of their duties, receive customer complaints.

DEFINITIONS:

"Complaint" - FDA, in 21 CFR 820.198 (a), defines a complaint as a written or oral expression of dissatisfaction with the identity, quality, durability, safety, effectiveness, or performance of a device.

For the purposes of this procedure, the company deems that the following are not to be considered as complaints:

1) Request for routine service, repairs, or maintenance.
2) Requests for operator instructions.
3) Complaints regarding back orders, shipping damage, billing, schedules, etc.
4) Any other complaints not related to device performance or malfunction.

CLASSIFICATION:

All complaints shall be classified in one of the following three categories. Based upon the category, the method of handling the complaint varies.

1. "Incident"
   This is a complaint pertaining to patient or operator injury or death, or to a hazard-to-safety condition. Hazards-to-safety include the malfunction of any components related to radiation generating and attenuating which might create an uncontrolled radiation situation, and/or the malfunction of any components whose failure could physically harm someone. This type of complaint requires a formal investigation.

2. "Major Complaint"

This is a complaint which relates to a malfunction causing the system to be inoperative in a safe manner. In general, it results in customer down-time. This type of problem requires an immediate solution.

3. "Minor Complaint"

This is a complaint which relates to a malfunction that creates a problem that is undesirable but does not impair the safe operation of the system. Solution of the problem in a timely manner is recommended.

INSTRUCTIONS FOR HANDLING COMPLAINTS:

A. Routing the complaint to the proper personnel

1. Written

Any company employee receiving a written communication of a complaint shall notify the appropriate Field Service Manager by telephone. Copies of the complaint shall be forwarded to the Field Service Manager, the facility manager, and the corporate safety officer. In the event that the complaint can be classified as an Incident, then the facility manager and corporate safety officer shall be notified by telephone also.

2. Verbal

Any company employee receiving a verbal complaint shall forward the complaint call to the appropriate Field Service Manager, if at all possible. If this is not possible, then the caller should be advised to call back and provided with the information as to who to call, when and where. Non-service personnel who receive a complaint call for whatever reason should only take a message and see that it is relayed as soon as possible. No attempt should be made to diagnose a problem and no solutions should be offered by non-service personnel.

B. Acknowledgement of Complaints

1. Receipt of all complaints, either written or verbal, shall be acknowledged. For "Minor" and "Major Complaints", acknowledgement will be by telephone from the Field Service Manager or a field service engineer - Acknowledgement would simply be supplying your name and company position. Incidents should be acknowledged by the facility manager with an explanation that an investigation will follow.

C. Complaint Reporting Form

Each customer complaint must be recorded on standard report form QA 1000 15.4A. The person taking the complaint must fill this form out completely and sign it.

D. Field Service Complaint Response

The field service manager or engineer who receives a complaint must do the following:

1. Fill out Form QA 1000 15.4A while taking the complaint.

2. Classify the complaint as either "Minor","Major", or "Incident". In case of an Incident, advise the customer to shut down the system and wait for further instructions. Notify the General Manager immediately to discuss appropriate action.
Remember, there could be legal ramifications involved.

3. Response to minor/major complaints:
   a) Suggest methods to correct the problem.
   b) Schedule a service call.
   c) Work with engineering and material control to solve the problem.

4. Recordkeeping requirements:
   a) Maintain report in open complaint file until problem has been solved.
   b) Maintain a log of all open complaints. Forward a monthly summary of open complaints to the facility manager.
   c) Once a complaint is closed, forward copies to QC and Engineering.
   d) File completed report in customer file.

E. Engineering Response

1. Engineering is responsible for auditing all open and closed QA 100015.4A reports with regard to determining design and component problems. A data bank should be generated to spot trends in device failures.

F. Quality Assurance Response

1. Quality Assurance has the responsibility to maintain the complaint files as required by regulation. For the purposes of FDA inspections and annual reports, the complaint file should be organized into three major catagories.

   a) Written and verbal complaints organized by device type.
   b) Incidents
   c) All other complaints organized by device type.

2. Auditing

Quality assurance should audit the Field Service complaint system on a bi-weekly basis to assure that complaints are being classified properly and that written reports of complaints are being generated and distributed properly.

G. Facility Manager Action

1. Review monthly summaries of open complaint file.

ATTACHMENT 3

TELEPHONE CALL REPORT NO._____

TAKEN BY:_____

FACILITY:_____ DATE:_____
FACILITY ADDRESS:_____ EQUIPMENT:_____
_____ REVISION LEVEL:_____

PHONE #:_____ CONTACT (FULL NAME):_____

P.O. # (REQUIRED):_____ TIME:_____

BILL TO ADDRESS: _____
_____

TOPIC:
_____ REQUEST FOR SERVICE
_____ TELEPHONE ASSISTANCE
_____ CONTRACT
_____ OTHER
_____ WARRANTY
_____ TIME AND MATERIAL
_____ PART ORDER

PROBLEM (DETAIL DESCRIPTION):_____
_____
_____
_____
_____
_____

DIAGNOSIS:_____
_____
_____
_____
_____
_____

PARTS OR TOOLS (IF REQUIRED):

PART NUMBER	DESCRIPTION

IF SHIPPED: SHIPPER NO.:_____ DATE_____

TENTATIVELY SCHEDULED FOR:_____ SERVICE PERSONNEL SCHEDULED:_____

_____ _____ _____ _____
SERVICE TECHNICIAN DATE ENGINEERING DATE

ADVANCED MEDICAL SYSTEMS, INC.	QUALITY ASSURANCE DEPARTMENT QUALITY ASSURANCE POLICY FOR COMPLIANCE WITH 10 CFR PART 71 APPENDIX E	NUMBER QA 1000 1.4
		DATE ISSUED
Operating Practice	Test / Other	November 7, 1979

I. ORGANIZATION

The final responsibility for the Quality Assurance (QA) Program for Part 71, requirements rests with ADVANCED MEDICAL SYSTEMS, INCORPORATED.

The Q.A. function is developed about the concept that all products are produced and controlled to comply with all specified and implied standards of performance and quality, at the most economical cost. In essence, the quality assurance function can be considered a coordinated responsibility aimed at eliminating defective work, which can be generated as the result of poor design, poor production workmanship, and vendor and customer errors.

Because of the magnitude of such a function, the responsibility of coordinating this has been given to the Quality Assurance Department. The Q.A. Department being an independent reporting group, is responsible to the General Manager.

All Design and Fabrication shall be conducted under this Q.A. Program. The Q.A. Program is implemented as shown on the attached organization chart.

The Radiation Safety Officer/Q.A. Manager is responsible for overall administration of the program, training and certification, document control, and auditing.

Q.A. individuals, via the Q.A. Manager, have the responsibility and authority to stop unsatisfactory work and control further processing, delivery, or installation of non-conforming material.

II. QUALITY ASSURANCE PROGRAM

The management of ADVANCED MEDICAL SYSTEMS, INCORPORATED, establishes and implements this Q.A. Program. Training, prior to engagement, for all Q.A. functions is required according to written procedures. Q.A. Program revisions will be made according to written procedures with Isotope Committee approval. The Q.A. Program will ensure that all defined Q.A. Procedures, Engineering Procedures, and Specific Provisions of the package design approval are satisfied. The Q.A. Program will emphasize control of the characteristics of the package which are critical to safety.

The ADVANCED MEDICAL SYSTEMS, INCORPORATED Isotope Committee regularly reviews the total Q.A. Program.

The Q.A. manual is a confidential publication containing proprietory information for ADVANCED MEDICAL SYSTEMS, INCORPORATED. It's distri-

bution is, therefore, limited to corporate Q.A., the General Manager, Engineering Manager, Manufacturing Manager, and Quality Assurance.

Revisions to the Q.A. manual must be approved by management, as outlined below, and will become effective immediately upon approval.

Document Control requires the approval of the Manager, Engineering.

All sections also require the approval of the Manager, Quality Assurance.

The manual will be reviewed every 12 months to verify all revisions are contained.

The General Manager will communicate to all departments and individuals that quality policies, Q.A. manuals, and procedures are mandatory requirements which must be implemented and enforced.

All items purchased, manufactured, or used by ADVANCED MEDICAL SYSTEMS, INCORPORATED, in the manufacturing or service of its products are subject to Q.A. control.

Any disputes involving quality, between Q.A. personnel and other department personnel, will be resolved by the General Manager.

An indoctrination and training program is established such that:

1. Personnel responsibility for performing quality-related activities are instructed as to the purpose, scope and implementation of the Q.A. manuals, instructions, and procedures.

2. Personnel performing quality-affecting activities are trained and qualified in the principles and techniques of the activity being performed.

3. The scope, the objective, and the method of implementing the indoctrination and training program are documented.

4. Proficiency of personnel performing quality-affecting activities is maintained by re-training, re-examining, and/or re-certifying.

Quality-related activities are performed with specific equipment under suitable environmental conditions, and prerequisites have been satisfied prior to inspection and test.

III. DESIGN CONTROL

1. Measures are established to carry out design activities in a planned, controlled, and orderly manner.

2. Measures are established to correctly translate the applicable regulatory requirements and design bases into specifications, drawings, written procedures, and instructions.

3. Quality standards are specified in the design documents, and deviations and changes from these quality standards are controlled.

4. Designs are reviewed to assure that (1) design characteristics can be controlled, inspected, and tested, and (2) inspection and test criteria are identified.

5. Proper selection and accomplishment of design verification or checking processes such as by design reviews, alternate calculations, or qualification testing are performed. When a test program is used to verify the adequacy of a design, a qualification test of a prototype unit under design conditions shall be used.

6. Individuals or groups responsible for design verification are other than the original designer and the designer's immediate supervisor.

7. Design and specification changes are subject to the same design controls and approvals that were applicable to the original design, unless the licensee designates another qualified responsible organization.

8. The positions or groups responsible for design reviews and other designs verification activities and their authority and responsibility are identified and controlled by written procedures.

IV. PROCUREMENT DOCUMENT CONTROL

1. Procedures are established that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents.

2. Procurement documents identify the applicable 10 CFR Part 71, Appendix E requirements, which must be complied with and described in the supplier's Q.A. Program.

3. Procurement documents contain or reference the design basis technical requirements including the applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instructions.

4. Procurement documents identify the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedures qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted to the purchaser for review and approval.

5. Procurement documents identify those records to be retained, controlled, and maintained by the supplier, and those delivered to the purchaser prior to use or installation of the hardware.

6. Procurement documents contain the procuring agency's right of access to supplier's facilities and records for source inspection and audit.

7. Changes and revisions to procurement documents are subject to at least the same review and approval as the original document.

V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

1. Activities affecting quality are prescribed and accomplished in accordance with documented instructions, procedures, or drawings.

2. Provisions are established which clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures, and drawings.

3. The Q.A. organization reviews and concurs with inspection plans; test, calibration, and special process procedures; drawings and specifications; and changes thereto.

VI. DOCUMENT CONTROL

1. The review, approval, and issue of documents and changes thereto, prior to release, are procedurally controlled to assure they are adequate and the quality requirements are stated.

2. Changes to documents are reviewed and approved by the same organizations that performed the original review and approval or by other qualified responsible organizations delegated by the applicant.

3. Approved changes are included in instructions, procedures, drawings, and other documents prior to implementation of the change.

4. Documents are available at the location where the activity will be performed prior to commencing the work.

5. A master list, or equivalent, is established to identify the current revision number of instructions, procedures, specifications, drawings, and procurement documents.

VII. CONTROL OF PURCHASED MATERIALS, PARTS, AND COMPONENTS

1. Qualified personnel evaluate the supplier's capability to provide acceptable quality services and products.

2. The evaluation of suppliers is based on one or more of the following:

    1. The supplier's capability to comply with the elements of Appendix E to 10 CFR Part 71, that are applicable to the type

of material, equipment, or service being procured.

2. A review of previous records and performance of suppliers who have provided similar articles of the type being procured.

3. A survey of the supplier's facilities and Q.A. Program to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

3. The results of supplier evaluations are documented and filed.

4. Surveilance, if required, of suppliers during fabrication, inspection, testing, and shipment of materials, equipment and components, is planned and performed in accordance with written procedures to assure conformance to the purchase order requirements.

5. The supplier furnishes the following records as a minimum to the purchaser:

1. Documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items.

2. Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances dispositioned "accept as is" or "repair".

6. Receivng inspection of the supplier-furnished material, equipment, and services is performed to assure:

1. The material, component, or equipment is properly identified and corresponds with the identification on receiving documentation.

2. Material, components, equipments, and acceptance records are inspected and judged acceptable in accordance with predetermined inspection instructions, prior to installation or use.

3. Inspection records or certificates of conformance attesting to the acceptance of material and components are available prior to installation or use.

4. Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further work.

VIII. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

1. Procedures are established to identify and control materials, parts, and components including partially fabricated subassemblies.

2. The identification and control procedures assure that identification is maintained either on the item or on records traceable to

the item to preclude use of incorrect or defective items.

3. Identification of materials and parts important to the function of safety-related systems and components can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.

4. The location and the method of identification do not affect the fit, function, or quality of the item being identified.

5. Correct identification of materials, parts, and components is verified and documented prior to release for fabrication, assembling and installation.

IX. CONTROL OF SPECIAL PROCESSES

1. Special processes such as welding, heat treating, nondestructive testing, and cleaning are procedurally controlled.

2. Procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards, and specifications.

3. Qualificaiton records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

X. INSPECTION

1. An inspection program which verifies conformance of quality-affecting activities with requirements is established, documented, and accomplished in accordance with written and controlled procedures.

2. Inspection personnel are independent from the individuals performing the activity being inspected.

3. Inspectors are qualified in accordance with applicable codes, standards, and company training programs; and their qualifications and certifications are kept current.

4. Modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements, or acceptable alternatives.

5. Provisions are established that identify mandatory inspection hold points for witness by an inspector.

XI. TEST CONTROL

1. A test program to demonstrate that the item or component will perform satisfactorily in service is established, documented, and accomplished in accordance with written controlled procedures.

2. Modifications, repairs, and replacements are tested in accordance with the original design and testing requirements or acceptable alternatives.

3. Test results are documented, evaluated, and their acceptability determined by a qualified, responsible individual or group.

XII CONTROL OF MEASURING AND TEST EQUIPMENT

1. Measuring and test instruments are calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

2. Measuring and test equipment is identified and traceable to the calibration test data.

3. Measures are taken and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.

4. Reference and transfer standards are traceable to nationally recognized standards; or where national standards do not exist, provisions are established to document the basis for calibration.

XIII. HANDLING, STORAGE, AND SHIPPING

1. Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by qualified individuals in accordance with predetermined work and inspection instructions.

2. All conditions (operations, tests, inspections, specifications, etc.), of the NRC package approval and the U.S. Department of Transportation shipping requirements are satisfied prior to shipment.

3. All necessary shipping papers will be prepared, as required.

4. Departure, arrival time, and destination of a package will be established and monitored to a degree consistent with the safe transportation of the package.

XIV. INSPECTION, TEST, AND OPERATING STATUS

1. Identification of the inspection, test, and operating status of packages and components is known by affected organizations.

2. The application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps, are procedurally controlled.

3. Bypassing of required inspections, tests, and other critical operations is procedurally controlled.

4. The status of nonconforming, inoperative, or malfunctioning packages or components is identified to prevent inadvertent use.

XV. NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

1. The identification, documentation, segregation, review disposition, and notification to affected organizations of nonconforming materials, parts, components, or services are procedurally controlled.

2. Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition.

3. Nonconforming items are segregated from acceptable items and identified as discrepant until properly dispositioned.

4. Acceptability of rework or repair of materials, parts, components, and systems is verified by reinspecting and retesting the item as originally inspected and tested or by a method which is at least equal to the original inspection and testing method.

XVI. CORRECTIVE ACTION

1. Evaluation of conditions adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective material and equipment) is conducted to determine the need for corrective action in accordance with established procedures.

2. Corrective action is initiated following the determination of a condition adverse to quality to preclude recurrence.

3. Follow-up reviews are conducted to verify proper implementation of corrective actions and to close out the corrective action documentation.

XVII. QUALITY ASSURANCE RECORDS

1. Sufficient records are maintained to provide documentary evidence of the quality and safety of items and the activities affecting quality and safety.

2. Q.A. records include operating logs; results of reviews, inspections, tests, audits, and material analyses; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports; and corrective

action reports.

3. Records are identifiable and retrievable.

4. A list of the required records and their storage locations will be maintained.

5. Design related records (e.g., drawings, calculations, etc.), are maintained for a minimum of two years.

6. Inspection and test records contain the following, where applicable:

   1. A description of the type of observation.

   2. Evidence of completing and verifying a manufacturing, inspection, or test operation.

   3. The date and results of the inspection or test.

   4. Information related to conditions adverse to quality.

   5. Inspector or data recorder identification.

   6. Evidence as to the acceptability of the results.

XVIII. AUDITS

1. Audits are performed in accordance with pre-established written procedures or check lists and conducted by personnel not having direct responsibilities in the areas being audited.

2. Audit results are documented and the reviewed with management having responsibility in the area audited.

3. Responsible management takes the necessary action to correct the deficiencies revealed by the audit.

4. Deficient areas are reaudited on a timely basis to verify implementation of corrective actions which minimize recurrence of deficiencies.

5. Audits of the Q.A. program are performed at least annually, based on safety significance of the activity being audited.

INTEROFFICE MEMORANDUM ATTACHMENT 5

DATE: January 3,1984

TO: Ed Svigel

LOCATION:

FROM: Mike Baruffa

LOCATION:

COPY TO: Howard Irwin
Norm Kelbley
Pat Harrison

SUBJECT: SODECO RP112E PULSE COUNTERS USED ON OUR VG8 CONTROL FOR TREATMENT COUNTERS

Per my conversation with Mike Marks, Product Engineer at Landis & GYR/Sodeco, the model RP112E predetermining pulse counter we currently use as a treatment timer in our VG8 has now and has always had the ablility to set time at 000.00 min. while enabling shutter operation. This is a design characteristic, not a malfunction as recently suspected by AMS Engineering.

A course of action has been adopted to remedy this situation by adding the Eagle Signal counter as a replacement kit.

Thank You,

Mike Baruffa

MB/bt

ATTACHMENT 6

AMC

INTEROFFICE MEMORANDUM

DATE: January 27, 1984

TO: Norman Kelbley
Dick Brees
Ed Svigel

FROM: Howard R. Irwin HRI

COPY TO:

SUBJECT: Minutes of Safety Committee meeting 1/25/84

1. Incident 84-01 Glen Falls table

Committee reviewed facts of incident, prior service records. Filled out incident report. Examined part.

Determination that this was an isolated incident. There are no existing procedures for inspection of C/8 tables.

H. Irwin verbally notified D. Miller & F. Kafer of incident, written report to follow.

Actions to be taken

Generate C/8 table rebuild procedure utilizing knowledge of Red Murray.

2. Sodeco RP112E Pulse Counters

N. Kelbley assures us that it is standard operating procedure for C/12 users to set the counter to 000.00 at end of day. Is concerned that when a replacement timer becomes necessary, this procedure will create a potential safety hazard.

Engineering has verified with Sodeco that the counters as we receive them today have not been changed and have always allowed the counter to function when manually reset to 000.00

Counters are AMS part #81493, are sold individually as a part of kits 200037 (C/9) and 170786 (C/12)

Instruction sheets 200025 and T60B-153 exist as part of the kits to describe to the user the method of operation using the Sodeco counter.

Until the Eagle digital counter has been fully designed and tested, it may not be offered as a replacement.

Instruction sheets 200025 and T60B-153 have been reviewed, re - vised and reformatted as supplemental pages to the operators manuals, T55B-170, T55B-28 (Rev.A). They will continue as a part of the timer kit. In addition, the sheet will be stocked with the counters so as to insure it accompanies a counter ordered as an individual part.

A copy of the new instruction sheet should be issued to all customers who have already purchased a counter or timer kit.

3. RadSim TV Arm Service note.

The service note was issued on 12/23/83
Receipt has been verified. Field Implementation of the note is proceeding well.

ATTACHMENT 6

INTEROFFICE MEMORANDUM

DATE: January 3,1984

TO: Ed Svigel

LOCATION:

FROM: Mike Baruffa

LOCATION:

COPY TO: Howard Irwin
Norm Kelbley
Pat Harrison

SUBJECT: SODECO RP112E PULSE COUNTERS USED ON OUR VG8 CONTROL FOR TREATMENT COUNTERS

Per my conversation with Mike Marks, Product Engineer at Landis & GYR/Sodeco, the model RP112E predetermining pulse counter we currently use as a treatment timer in our VG8 has now and has always had the ablility to set time at 000.00 min. while enabling shutter operation. This is a design characteristic, not a malfunction as recently suspected by AMS Engineering.

A course of action has been adopted to remedy this situation by adding the Eagle Signal counter as a replacement kit.

Thank You,

Mike Baruffa

MB/bt

CHERYL PAPUGA
HOWARD IRWIN
ED SVIGEL

ATTACHMENT 7

TO: ISTOPE COMMITTEE

FROM: NORMAN KELBLEY

DATE: APRIL 13, 1984

SUBJECT: MINUTES OF APRIL ISOTOPE COMMITTEE MEETING.

FILM BADGES AND EXPOSURES

Exposures are within required A.L.A.R.A. limits. The badges of some service personnel are reporting zero in spite of the fact that they have been helping on colbalt jobs. The R.S.O. will send a general memo to let monitored personnel know that the exposure reports are reviewed.

Remove Dieffenbacher and Goodale from issue of badges. We will issue if used for jobs again.

Remind Gammern to advise service persons that badges are to be worn, not kept in tool or brief cases. This is as a result of Jack Juras accidently exposing his body and wrist badge to radiation while testing an accellerator.

A quarterly report is attached.

EXCESSIVE LEAKAGE

The problem of excessive leakage, previously reported with the source exchange at Jennie Edmunson Hospital, was resolved by the physisit reading of an average of 2.0 and the checking of our instrument also agreed with this. The the source stays in the unit.

181375 AND 181361 OVERPACKS

It is mandatory that the inspection and repair of these overpacks be documented and records be maintained. This is required by 10 CFR 71.

None are to be used unless they pass Q.A. Inspection.

DEPLETED URANIUM PATTERNS

The D U Patterns have been received from the previous vendors, per Cheryl Papuga. R. Brees will verify and inventory prior to storing in the controlled storage area.

Nuclear Metals Co. has a problem with the C/9 saddles (C 46879). Ed Svigel will get drawings and call to resolve the problem.

COBALT 60

We have received our bulk shipment of cobalt 60 but need personnel to be able to clean the cell and put the cobalt into the cell. We also need our survey meters and electrimeters back from calibration before this can be even started.

ATTACHMENT 7

TRAINING

Those persons who have taken the formal training course must be used on service calls so that we can qualify them for - 2 licensing.

We do not have a whole lot of people to do licensed service since the loss of Mr. Kidd and Mr. Murray.

The following is a list of those who successfully completed the training course and their status.

NAME	STATUS
W. SKOCH	LICENSED ON -2
J. COCHRAN	MINIMALLY QUALIFIED FOR -2 SERVICE
H. GOODALE	NOT QUALIFIED - INSUFFECIENT ON JOB TRAINING
W. DIEFFENBACHER	NOT QUALIFIED - INSUFFECIENT ON JOB TRAINING
M. ORD	NOT QUALIFIED - INSUFFECIENT ON JOB TRAINING
OTHERS	
M. KLOZAR	DID NOT PASS WRITEN TEST, COULD POSSIBLY PASS IF GIVEN AGAIN.

ROTOR & HEADS

No further D.U. pieces will be sent to the licensed vendors until all on hand D.U. parts are used up and sent to A.M.S.. Parts will then be sent only on an as required basis and coordinated with the vendor, purchasing and regulatory affairs.

BIO - ASSAY

Will be scheduled for early May. Skoch , Baruffa, Sibert, and Kelbley will be tested.

RAD - WASTE

Our first load of waste, since AMS was established, has been shipped and accepted at the Barnwell, SC site.

Since allocations are 3 months in the future we should plan our next disposal.

It was agreed that the next shipment should be a large volume low level shipment in, if possible, a shielded van.

The paper, etc will be compacted and placed into 55 gallon drums. These drums will be cleaned and removed from the lab and stored in the former radiography (shielded) room.

The next shipment will be planned for the end of the 3rd quarter of 1984.

NEUTRON PRODUCTS

NPI has been able to successfully remove their source from the head from University of Oregon. The empty head has been returned to AMS.

A.M.S. also successfully removed the stuck NPI source from the head from Glens Falls Hospital. This was done using hardened pins on the source holder and driving using an air impact wrench.

CHINA HEAD

The head has been returned from China and we can not move the rotor. We have tried carbon dioxide and various techniques to no avail.

It was recommended, and accepted by the committee, that AMS build another head and source for replacement to the customer. This will allow for installation of this head congruent with the new unit to be shipped in May 1984.

SUPPLIES

We, at the London Road Facility, are still waiting for many supplies that have been requisitioned and some had orders placed as long as a year ago.

Cheryl Papuga will follow up on the items to be presented in a list

TIMERS

The timer used in the C/9 units has been causing some problems, recently. A new design is in the works and shoul be released for field installation in about 2 or 3 weeks. Ed Svigel will keep everyone advised of the progress. VA Allen Park, MI is to be replaced A.S.A.P. a schedule for replacements will be prepared at a later date.

INTEROFFICE MEMORANDUM

ATTACHMENT 7

DATE: January 3,1984

TO: Ed Svigel

LOCATION:

FROM: Mike Baruffa

LOCATION:

COPY TO: Howard Irwin
Norm Kelbley
Pat Harrison

SUBJECT: SODECO RP112E PULSE COUNTERS USED ON OUR VG8 CONTROL FOR TREATMENT COUNTERS

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A course of action has been adopted to remedy this situation by adding the Eagle Signal counter as a replacement kit.

Thank You,

Mike Baruffa

MB/bt

BODY

QUARTERLY EXPOSURE REPORT

DATED: APRIL 10, 1989

	KELLEY	KIDD	MURRAY	SIMERT	SKOCH	COCHRAN	DIEFFENBACHER	GOODALE	KLOZAR	STORMER	JURAS	BARUFFA	BAKER, M	
FIRST	130	275	340	495	420	0	0	0	0	0	270	0	10	
SECOND														
THIRD														
FOURTH														
TOTAL														

ATTACHMENT 7

1 WRIST

QUARTERLY EXPOSURE REPORT

DATED: APRIL 10, 1984

	KELBLEY	KIDD	MURRAY	SIBERT	SKOCH	COCHRAN	DIEFFENBACHER	GOODALE	KLOZAR	STORMER	JURAS	RARUFFA	BAKER, M	
FIRST	25	0	510	90	315	0	0	0	0	0	465	0	5	
SECOND														
THIRD														
FOURTH														
TOTAL														

ATTACHMENT 7

PART 21

REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISIONS

Authority: Secs. 161i and 161o, Pub. L. 83-703, 68 Stat. 949 and 950, as amended, sec. 234, Pub. L. 91-161, 83 Stat. 444, secs. 201 and 206, Pub. L. 93-438, 88 Stat. 1242 and 1246, as amended (42 U.S.C. 2201(i), 2201(o), 2282, 5841, 5846).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

§ 21.2 Scope.

The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 40, 60, 61, 70, or 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, and/or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel, or to construct, manufacture, possess, own, operate and/or transfer within the United States, any production or utilization facility or independent spent fuel storage installation, and to each director (see § 21.3(f)) and responsible officer (see § 21.3(j)) of such a licensee. The regulations in this part apply also to each individual, corporation, partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs (see § 21.3(c)) a production or utilization facility licensed for manufacture, construction or operation (see § 21.3(h)) pursuant to Part 50 of this chapter or an independent spent fuel storage installation for the storage of spent fuel licensed pursuant to Part 72 of this chapter, or supplies (see § 21.3(l)) basic components (see § 21.3(a)) for a facility or activity licensed, other than for export, under Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter. Nothing in these regulations should be deemed to preclude either an individual or a manufacturer/supplier of a commercial grade item (see § 21.3(a-1)) not subject to the regulations in this part from reporting to the Commission a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure.[1]

§ 21.3 Definitions.

As used in this part:

(a)(1) "Basic component," when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 100.11 of this chapter.

(2) "Basic component," when applied to other facilities and when applied to other activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter, means a component, structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect (see § 21.3(d)) or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (see § 21.3(k)).

(3) In all cases "basic component" includes design, inspection, testing, or consulting services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others.

[1] NRC Regional Offices will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers (for nights and holidays as well as regular hours) are listed below:

Region		
I	(Philadelphia)	(215) 337-5000
II	(Atlanta)	(404) 221-4503
III	(Chicago)	(312) 790-5500
IV	(Dallas)	(817) 860-8100
IV	Uranium Recovery Field Office (Denver)	(303) 234-4232
V	(San Francisco)	(415) 943-3700

(4) A commercial grade item is not a part of a basic component until after dedication (see § 21.3(o-1)).

(o-1) "Commercial grade item" means an item that is (1) not subject to design or specification requirements that are unique to facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (2) used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example a catalog).

(b) "Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

(c) "Constructing" or "construction" means the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are important to safety.

(c-1) "Dedication" of a commercial grade item occurs after receipt when that item is designated for use as a basic component.

(d) "Defect" means:

(1) A deviation (see § 21.3(e)) in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation (see § 21.3(g)), the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (d)(1) of this section; or

(3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 of this chapter provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to Part 50 of this chapter.

(e) "Deviation" means a departure from the technical requirements included in a procurement document (see § 21.3(i)).

(f) "Director" means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, "director" means the individual.

(g) "Evaluation" means the process accomplished by or for a licensee to determine whether a particular deviation could create a substantial safety hazard.

(h) "Operating" or "operation" means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are important to safety.

(i) "Procurement document" means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

(j) "Responsible officer" means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

(k) "Substantial safety hazard" means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.

(l) "Supplying" or "supplies" means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

§ 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 21.5 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or to the Director of a Regional Office at the address specified in Appendix D of Part 20 of this chapter. Communications and reports also may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 7920 Norfolk Avenue, Bethesda, Md.; or at a Regional Office at the location specified in Appendix D of Part 20 of this chapter.

§ 21.6 Posting requirements.

(a) Each individual, partnership, corporation or other entity subject to the regulations in this part, shall post current copies of the following documents in a conspicuous position on any premises, within the United States where the activities subject to this part are conducted (1) the regulations in this part, (2) Section 206 of the Energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in this part.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) The effective date of this section has been deferred until January 6, 1978.

§ 21.7 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial grade items.

[47 FR 57446]

§ 21.8 Information collection requirements: OMB approval.

[49 FR 19623]

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0035.

(b) The approved information collection requirements contained in this part appear in §§ 21.21 and 21.51.

NOTIFICATION

§ 21.21 Notification of failure to comply or existence of a defect.

[42 FR 28891]

(a) Each individual, corporation, partnership or other entity subject to the regulations in this part shall adopt appropriate procedures to:

(1) Provide for: (i) Evaluating deviations or (ii) informing the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated unless the deviation has been corrected; and

(2) Assure that a director or responsible officer is informed if the construction or operation of a facility, or activity, or a basic component supplied for such facility or activity:

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect. The effective date of this paragraph has been deferred until January 6, 1978.

[47 FR 57446]

(b)(1) A director or responsible officer subject to the regulations of this part or a designated person shall notify the Commission when he obtains information reasonably indicating a failure to comply or a defect affecting (i) the construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and that is within his organization's responsibility or (ii) a basic component that is within his organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter. The above notification is not required if such individual has actual knowledge that the Commission has been adequately informed of such defect or such failure to comply.

[42 FR 28891]

(2) Initial notification required by this paragraph shall be made within two days following receipt of the information. Notification shall be made to the Director, Office of Inspection and Enforcement, or to the Director of a Regional Office. If initial notification is by means other than written communication, a written report shall be submitted to the appropriate Office within 5 days after the information is obtained. Three copies of each report shall be submitted to the Director, Office of Inspection and Enforcement.

(3) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(4) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(c) Individuals subject to paragraph (b) of this section may be required by the Commission to supply additional information related to the defect or failure to comply.

PROCUREMENT DOCUMENTS

§ 21.31 Procurement documents.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall assure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978 specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

INSPECTIONS, RECORDS

§ 21.41 Inspections.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall permit duly authorized representatives of the Commission, to inspect its records, premises, activities, and basic components as necessary to effectuate the purposes of this part.

§ 21.51 Maintenance of records.

[42 FR 28891]

(a) Each licensee of a facility or activity subject to the regulations in this part shall maintain such records in connection with the licensed facility or activity as may be required to assure compliance with the regulations in this part.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part shall prepare records in connection with the designs, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of any facility, basic component supplied for any licensed facility or to be used in any licensed activity sufficient to assure compliance with the regulations in this part. After delivery of the facility or component and prior to the destruction of the records relating to evaluations (see § 21.3(g)) or notifications to the Commission (see § 21.21), such records shall be offered to the purchaser of the facility or component. If such purchaser determines any such records:

(1) Are not related to the creation of a substantial safety hazard, he may authorize such records to be destroyed, or

(2) Are related to the creation of a substantial safety hazard, he shall cause such records to be offered to the organization to which he supplies basic components or for which he constructs a facility or activity.

If such purchaser is unable to make the determination as required above

then the responsibility for making the determination shall be transferred to the individual, corporation, partnership, or other entity subject to the regulations in this part that issued the procurement document to the purchaser. In the event that the determination cannot be made at that level then the responsibility shall be transferred in a similar manner to another individual, corporation, partnership, or other entity subject to the regulations in this part, until, if necessary, the licensee shall make the determination.

(c) Records that are prepared only for the purpose of assuring compliance with the regulations in this part and are not related to evaluations or notifications to the Commission may be destroyed after delivery of the facility or component.

(d) The effective date of the section has been deferred until January 6, 1978.

[42 FR 28091]

ENFORCEMENT

§ 21.61 Failure to notify.

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

[49 FR 19623]

➤ [Note removed 49 FR 19623]