QUALITY ASSURANCE POLICY FOR COMPLIANCE WITH 10 CFR PART 71	Procedure No: QA 2000 1.0
	Revision: B : 2/7/94
	Date Issued: 11 - 7 - 79

1.0 ORGANIZATION

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

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 Director of Regulatory Affairs. 10(e)

All package design and fabrication shall be conducted under this Q.A. Program.

The Director of Regulatory Affairs is responsible for overall administration of the program, training and certification, document control and auditing.

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

2.0 QUALITY ASSURANCE PROGRAM

2.1 The Management of AMS establishes and implements this Q.A. Program. 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 Procedures 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.

2.2 The AMS Isotope Committee reviews the status and adequacy of the Q.A. Program at 12 month intervals.

2.3 A copy of the Q.A. manual is distributed to Regulatory Affairs, to the Engineering Manager, Radiation Safety Officer, Purchasing and Quality Assurance. 10(e)

Prepared by	Approval	Revisions
Edward Svigel	SJ Stern	1.0, 2.3, 2.4.4, 2.4.5, 2.7, 7.1.1, 10.4

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

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

2.4.1 REVISION: When it becomes necessary to revise the manual, the proposed changes will be reviewed by the Isotope Committee, to incorporate revisions, the following steps will be followed:

2.4.2 For historical purposes, the copy of the obsolete procedure will be marked obsolete, dated and placed into the appropriate history file.

2.4.3 The master procedure will be revised to reflect the changes approved by the Isotope Committee. In the revision block of the bottom of Page 1, the change will be noted. For each page in the procedure, the revision block will be changed to reflect the current revision.

2.4.4 The revised procedure will be returned to the Isotope Committee for review. If in agreement with the content, the Committee Chairman will sign the approval block. 1 (B)

2.4.5 DISTRIBUTION: Each approved procedure will be distributed as follows:

a) Director of Regulatory Affairs
b) Radiation Safety Officer
c) Purchasing Department
d) Engineering Department
e) Quality Assurance 1 (B)

2.4.6 REVIEW: The manual will be reviewed every twelve (12) months to verify that all procedures are correct and current. Results of the review will be indicated on the manual review form following the table of contents. The results of the review will also be discussed during the appropriate Isotope Committee meeting and a notation made in the minutes of the meeting.

2.5 The Director of Regulatory Affairs will communicate to all departments and individuals that quality policies, Q.A. manuals, and procedures are mandatory requirements which must be implemented and enforced.

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Edward Svigel	S J Stein	1.0, 2.3, 2.4.4, 2.4.5, 2.7, 7.1.1, 10.4

2.6 All items purchased, manufactured, or used by AMS in the manufacturing or service of its package are subject to Q.A. Control.

2.7 Any disputes involving quality between Q.A. personnel and other department personnel, will be resolved by the Director of Regulatory Affairs. (B)

2.8 An indoctrination and training program is established such that:

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

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

2.8.1 PERSONNEL REQUIREMENTS: Employees involved with this program will be given on the job training as necessary to perform the job assigned. Training will be documented and these records placed in the employee's Q.A. training files kept at the Geneva facility.

2.8.2 10 CFR Part 71 training will be conducted by the Director of Regulatory Affairs or designate. Training will be documented and kept in the employees Q.A. training files.

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

3.0 PACKAGE DESIGN CONTROL

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

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

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

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

3.5 Proper selection and accomplishment of design verification or checking processes such as by design reviews, alternate calculations or qualification test of a prototype or sample unit under design conditions be used.

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

3.7 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.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Section 4.1.1 delineates the sequence of actions to be accomplished in the preparation, review, approval and control of procurement documents.

4.1.1 Procurement Procedure: Procurement documents (purchase orders) will be initiated by either a written or verbal request for a component or service/repair.

Purchase orders will be accompanied by a current blueprint. Purchase orders will be logged in a purchase order record book; records will be kept of Purchase Order number, date, requested by, vendor, description, due date and cost.

The purchase orders for package components will contain a statement that the item or service being purchased must be supplied in compliance with 10 CFR Part 71. Special instructions, if any, will be indicated on the purchase order form.

4.2 Procurement documents identify the applicable 10 CFR Part 71 requirements, which must be complied with by the supplier's Q.A. Program.

4.3 Procurement documents contain or reference, if necessary, 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.

4.4 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.

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

4.6 Procurement documents contain AMS' right of access to supplier's facilities and records for source inspection and audit.

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

4.8 Procurement documents will be reviewed by the Engineering Manager and signed prior to being issued to suppliers of package components.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

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

5.2 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.

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

6.0 DOCUMENT CONTROL

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

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

6.2.1 CHANGES: All changes, revisions, and new package drawings must be reviewed by the Isotope Committee and approved by the Chairman. The Isotope Committee will record the results of their review in the Isotope Committee minutes.

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

6.4 Documents are available at the location where the activity will be performed.

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

6.5.1 MASTER LIST: In addition to the master list, all traveling requisition forms will be tagged to indicate that the package component must comply to 10 CFR 71. This information will also be entered into the inventory control computer.

7.0 CONTROL OF PURCHASED MATERIALS, PARTS AND COMPONENTS

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

7.1.1 The Director of Regulatory Affairs, assisted by the Engineering Manager, will evaluate suppliers. (E)

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

a. The supplier's capability to comply with the elements of 10 CFR Part 71 that are applicable to the type of material, equipment or service being procured.

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

c. 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.

7.3 The results of supplier evaluations are documented and filed.

7.3.1 SUPPLIER EVALUATION: The results of the supplier's evaluation will be maintained in a file located at the Geneva facility.

7.4 Surveillance, 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.

7.5 The supplier will furnish documentation to the purchaser that the material supplied or service performed meets the performance specification required by the Purchase Order.

7.6 Receiving inspection of the supplier-furnished material, equipment and services is performed to assure:

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

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

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

d. 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.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

8.1 Measures are established to identify and control materials, parts and components including partially fabricated subassemblies.

8.1.1 CONTROL: Parts will be kept in the stock area until needed. The stored parts will be tagged with their part number and inventoried.

8.2 The identification and control measures assure that identification is maintained either on the item or on records traceable to the item so as to preclude use of incorrect or defective items.

8.2.1 Items purchased in lot quantities will be kept together and marked with the part number and revision level as specified on the blueprint and also reference the Purchase Order number under which the lot was purchased. Items will be used from one lot only before proceeding to another. Inventory will be pulled on a "First In - First Out" basis.

8.3 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.

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

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

9.0 CONTROL OF SPECIAL PROCESSES

9.1 Special processes such as welding, heat treating, non-destructive testing and cleaning are procedurally controlled and accomplished by qualified personnel.

9.1.1 No special processes are performed by AMS personnel.

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

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

10.0 INSPECTIONS

10.1 An inspection program of activities affecting quality to verify conformity with requirements is established, documented and accomplished.

10.1.1 QA 1014 is to be followed to insure the package is acceptable.

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

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

10.4 Modifications, repairs and replacements are inspected in accordance with the original design and inspection requirements, or most current requirements. (E)

10.4.1 All inspections will be performed against the part drawings specified in the approval package.

11.0 TEST CONTROL

11.1 A test program to demonstrate that the package or components will perform satisfactorily in service is established, documented and accomplished in accordance with written procedures.

11.1.1 TEST PROGRAM: The results of the original drop test are on file and part of the package history. Unless there are major changes to the current design, no further drop tests will be performed. Any changes must be submitted and approved by the USNRC prior to being implemented.

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

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 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.

12.2 Measuring and test equipment is identified and traceable to the calibration test data, if applicable.

12.3 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.

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Edward Svigel	A J Stein	1.0, 2.3, 2.4.4, 2.4.5, 2.7, 7.1.1, 10.4

12.4 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.

13.0 HANDLING, STORAGE AND SHIPPING

13.1 Special handling, storage, cleaning and shipping requirements are established and accomplished by qualified individuals.

13.2 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.

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

14.0 INSPECTION TEST AND OPERATING STATUS

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

14.2 Non-conforming, inoperative or malfunctioning packages or components are clearly marked to prevent inadvertent use.

15.0 NON-CONFORMING MATERIAL, PARTS OR COMPONENTS

15.1 The identification, documentation, segregation, review disposition and notification to affected organizations of non-conforming materials, parts, components or services are procedurally controlled.

15.2 Documentation identifies the non-conforming item; describes the non-conformity, the disposition of the non-conformity, and the inspection requirements; and includes signature approval of the disposition.

15.3 Non-conforming items are segregated from acceptable items and identified as discrepant until properly dispositioned.

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

16.0 CORRECTIVE ACTION

16.1 Conditions adverse to quality (such as non-conformities, failures, malfunctions, deficiencies, deviations, and defective material and equipment) are promptly identified and the cause determined.

16.2 Corrective action is initiated to preclude repetition.

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

17.0 QUALITY ASSURANCE RECORDS

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

17.2 Q.A. records include design records, operating logs, results of reviews, inspections, tests, audits and material analysis; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; non-conformity reports; and corrective action reports.

17.3 Records are identifiable and retrievable.

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

17.5 Design related records (e.g., drawings, calculations, etc.) are maintained for the life of the package.

17.6 Inspection and test records contain the following, where applicable:

a. A description of the type of observation.
b. Evidence of completing and verifying a manufacturing, inspection or test operation.
c. The date and results of the inspection or test.
d. Information related to conditions adverse to quality.
e. Inspector or data recorder identification.
f. Evidence as to the acceptability of the results.

18.0 AUDITS - YEARLY

18.1 Audits of compliance with this procedure are conducted by personnel not having direct responsibilities in the areas being audited.

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

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

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

18.5 Audits of the Q.A. Program are performed based on safety significance of the activity being audited.

MANUAL REVIEW

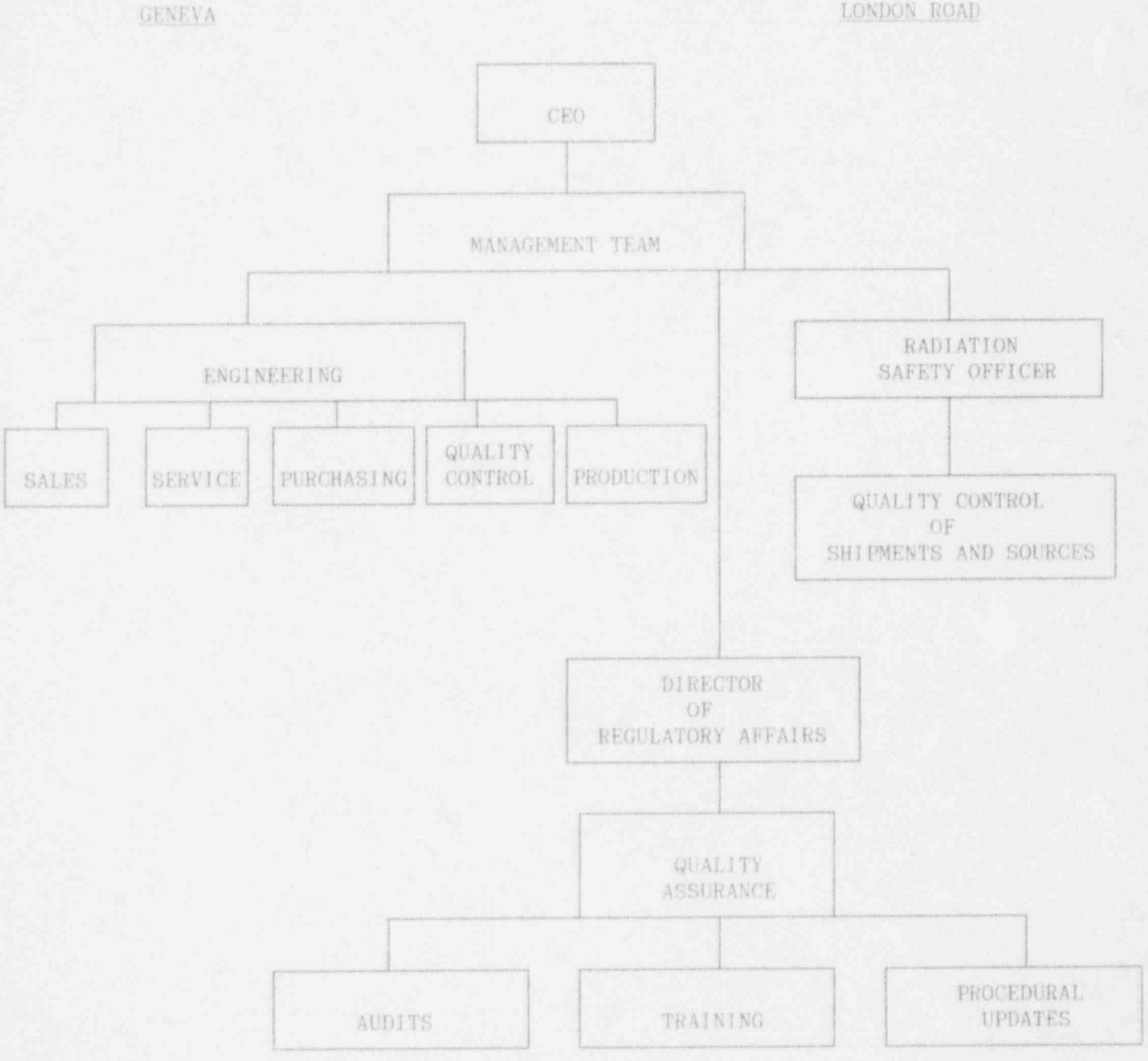
DATE OF REVIEW	REVIEWER	SUGGESTED CHANGES

REVISIONS

LETTER	DATE	PAGES AFFECTED	CHANGES
A	7/8/93	All	Procedure Revised in its Entirety
B	2/7/94	1, 2, 3, 6, 9	1.0 Change "responsible to Engineering Manager" to "responsible to Director of Regulatory Affairs." 2.3 Change "Quality Control" to "Quality Assurance". 2.4.4 Change "approvel" to "approval" 2.4.5 Change "Quality Control" to "Quality Assurance". 2.7 Change "resolved by the Engineering Manager" to "resolved by the Director of Regulatory Affairs". 7.1.1 Change "Directory" to "Director" 10.4 Change "acceptable alternatives" to "most current requirements."

AMS ORGANIZATIONAL CHART

FOR PURPOSES OF 10 CFR PART 71 CONTROLS



TRAINING DOCUMENTATION RECORD

AMS Quality Assurance Policy
for
Compliance with 10 CFR Part 71
Procedure 2000 1.0
Training Acknowledgement

I have reviewed both 10 CFR Part 71 and QA 2000 1.0 and am familiar with their contents. I have been instructed in the principles and techniques of AMS' quality assurance procedures as they affect my job.

_____ _____

Date Name