Amersham Corporation
Quality Assurance Program
For Type B Radioactive Material
Transport Packages

July 30, 1982

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Introduction

Purpose

This Amersham Corporation Quality Assurance Program is promulgated to comply with the requirements of Section 71.51 and Appendix E of 10 CFR Part 71 "Packaging of Radioactive Material for Transport and Transporation of Radioactive Material Under Certain Conditions" of the United States Nuclear Regulatory Commission.

Scope

This Amersham Corporation Quality Assurance Program, as required by 10 CFR Part 71, applies to all activities affecting the components of the packaging which are significant to safety. Those activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing and modifying.

I. Organization

A. The overall responsibility for the Quality Assurance Program is retained and exercised by Amersham Corporation.

B. The responsibility for the Amersham Corporation Quality Assurance Program is shared by a number of departments within the company. The responsible departments, by function, include:

1. Engineering
The responsibility for design control; instructions, procedures and drawings in support of the design; assuring that all parts and components are manufactured to specifications; evaluation of the capability of a supplier to provide an acceptable service; all testing requirements; receiving inspections and the control of measuring and test equipment rests with the Engineering Department.

2. Purchasing
The responsibility for communicating to the manufacturers, via procurement documents, all applicable 10 CFR Part 71, Appendix E requirements rests with the Purchasing Department.

3. Health Physics & Safety
The responsiblity for overall coordination and monitoring of the handling, storage and shipping of these containers related to the containment of activity and operator safety rests with the Health Physics Department. Health Physics and Safety also has responsibility for advising other departments on regulatory requirements and reviewing the program to see that the requirements are being met.

4. Manufacturing
The responsibility for proper handling, loading and unloading of containers rests with the Manufacturing Department.

5. Operational Services
The responsibility for proper usage of containers during preparation for shipping and after receipt, routine inspection, handling and maintenance rests with the Operational Services Department.

6. Quality Assurance
The responsibility for auditing the Type B container quality assurance program to ensure that it has been properly established and implemented rests with the Quality Assurance Department.

C. A current organizational chart is included with this document as Attachment #1.

D. The key positions within Amersham Corporation that are involved in the administration of the Quality Assurance Program, and included in the departments outlined in I-B, are listed below with a brief description of the responsibilities of each.

1. Transport Container Officer (who is presently the Manager of Engineering and Technical Support and the Radiation Safety Officer) has overall responsibility and authority for the Quality Asssurance Program. This position reports to the Director, Operations who reports to the President.

2. Project Engineer is responsible for the successful coordination and implementation of all engineering aspects of the Q.A. Program for each project under which Type B containers are manufactured, assuring that specifications are met and regulatory requirements are satisfied.

3. Manager, Purchasing is responsible for directing purchasing activities and communicating to participating organizations the Q.A. requirements which must be met (as advised by the Project Engineer and the Health Physics and Safety Officer).

4. Health Physics and Safety Officer is responsible for reviewing the activities of the other departments with regard to operator safety and the containment of radioactive material and for ensuring that all departments are advised of regulatory requirements which must be met in the design, manufacture and use of Type B containers.

5. Manager, Manufacturing is responsible for handling, loading, and unloading of containers.

6. Manager, Operational Services is responsible for the shipping, receipt, routine inspection, handling and maintenance of Type B containers.

7. Director, Operations is responsible for the overall operation of Manufacturing, Engineering, Operational Services, Technical Support and Purchasing.

8. Director, Quality Assurance is responsible for advising on the establishment and implementation of the Quality Assurance Program and for periodic audits of the program to ensure that all requirements are being met.

E. The duties of the Transport Container Officer, who maintains overall responsibility and authority for the Type B Container Quality Assurance Program, include reviewing and approving procurement documents, and ensuring that any deficiencies found in the program are noted and corrected.

The Transport Container Officer is a technically-degreed, senior member of management who has had sufficient professional experience to judge that the safety-related issues involved in the manufacture and use of a Type B container are addressed in the Quality Assurance Program.

F. It is the responsibility of all individuals listed in I-D to ensure that quality products are produced. Therefore, each person listed has been delegated the necessary authority to stop unsatisfactory work and control further processing, delivery or installation of nonconforming material until proper disposition of the material is made.

II. Quality Assurance Program

A. The Transport Container Officer regularly assesses the scope, status, implementation, and effectiveness of the overall corporate Q.A. Program to assure that the program is adequate and complies with 10 CFR Part 71 Appendix E.

B. Provisions are established to control the distribution of Type B container quality assurance manuals and revisions thereto.

C. The Transport Container Officer communicates to all responsible organizations and individuals that quality policies and procedures are mandatory requirements which must be implemented and enforced.

D. Amersham Corporation Engineering will ensure that all safety-related systems, structures and components are identified and reviewed. These systems will be subject to the Q.A. fabrication and inspection programs.

E. The Transport Container Officer has the responsibility and authority to resolve disputes involving quality arising from a difference of opinion between personnel having Q.A. responsibilities and personnel from other departments.

F. Indoctrination and training programs are established, such that personnel responsible for performing quality-related activities are instructed as to the purpose, scope and implementation of the QA instructions and procedures. They are trained and qualified in the principles and techniques of the activity being performed, and their proficiency is maintained by retraining, reexamining and recertifying. The scope, the objective, and the method of implementing the above program is formally documented.

G. All quality-related activities are to be performed with proper equipment under suitable environmental conditions and all prerequisites will have been satisfied prior to inspection and testing.

III. Design Control

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

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

C. Quality standards are specified in the design documents and deviations or changes from the quality standards are controlled.

D. Designs are reviewed to ensure that:

1. The design characteristics can be controlled, inspected and tested and

2. Inspection and testing criteria have been identified.

E. Proper selection and accomplishment of design verification or checking processes such as design reviews, alternate calculations, or qualification testing are performed. When a test program is used to verify the adequacy of a design, the prototype is subjected to the most adverse design conditions.

F. Design verification will be conducted by a person other than the original designer.

G. All design and specification changes are subject to the same design controls and approvals as the original design.

H. The authority and responsibility of persons performing design reviews and other design verification activities are identified and controlled by written procedures.

IV. Procurement Document Control

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

B. Procurement documents identify the applicable 10 CFR Part 71 requirements which must be addressed and complied with during fabrication of the container.

C. The procurement documents contain or reference the design technical requirements including the applicable regulatory requirements, and any applicable material and component identifications, drawings, specifications, codes and industrial standards, test and inspection requirements and special process instructions.

D. The procurement documents identify the documentation to be prepared, maintained, and submitted to the purchaser for review and approval.

E. The procurement documentation identifies those supporting records to be retained, controlled, and maintained by the supplier, and those delivered to the purchaser prior to use of the hardware.

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

G. All changes and revisions to the procurement documents are subject to the same review as the original document.

V. Instructions, Procedures and Drawings

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

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

C. The Q.A. organization outlined in I.B. reviews, and concurs with the inspection plans; test, calibration and special process procedures; drawings and specifications; and changes thereto or acceptable alternatives.

VI. Document Control

A. The review, approval and issuance of documents and changes thereto, prior to release, are procedurally controlled to assure that they are adequate and that quality requirements are stated.

B. Changes to documents, including instructions, procedures, and drawings are reviewed by the same organization that performed the original review and approval or by other qualified, responsible organizations as delegated by Amersham Corporation.

C. Approved changes are included in instructions, procedures, drawings and other documents simultaneously with the implementation of the change.

D. Current issues of applicable documents will be available at the location where an activity is being performed. This will preclude the use of obsolete or superseded documentation.

E. 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

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

B. The evaluation of a supplier will be based on one or more of the following:

1. The supplier's capability to comply with the elements of Appendix E of 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 the supplier on similar articles of the type being procured.

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

C. The results of the supplier evaluations are documented and filed.

D. 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.

E. The supplier will furnish the following records to Amersham Corporation when the container is delivered.

1. Documentation showing which of the purchased material or equipment meets the requirements in the procurement document.

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".

F. A receiving 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. Materials, components, equipment and acceptance records are inspected and judged acceptable in accordance with predetermined inspection procedures, 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 for use are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further work.

VIII. Identification & Control of Materials, Parts & Components

A. Procedures are established to identify and control materials, parts and components, including partially fabricated sub-assemblies.

B. Procedures are established to ensure that identification of an item is maintained by part number, serial number, or other appropriate means, either on the item or on records traceable to the item to preclude use of incorrect or defective items.

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

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

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

IX. Control of Special Processes

A. All special processes, such as welding, are procedurally controlled.

B. All procedures, equipment, and personnel connected with special processes are qualified in acordance with applicable codes, standards and specifications.

C. The qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

X. Inspection

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

B. The inspection personnel are independent from the individuals performing the activity being inspected.

C. The inspectors are qualified in accordance with applicable standards and company training programs. Their qualifications are kept current through continued retraining on revised procedures.

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

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

XI. Test Control

A. 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.

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

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

XII. Control of Measuring & Test Equipment

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

B. Test equipment is identified and traceable to the calibration test data.

C. 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.

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

XIII. Handling, Storage and Shipping

A. Any special handling, preservation, storage, cleaning, packaging and shipping requirements for Type B containers are established and accomplished by qualified individuals in accordance with predetermined instructions.

B. All conditions of the NRC package approval and U.S. Department of Transportation shipping requirements are satisfied prior to shipment.

C. All necessary shipping papers will be prepared as required.

D. The departure, arrival time and destination of any Type B containers will be established and monitored to a degree consistent with the safe transportation of the package.

XIV. Inspection, Test and Operating Status

A. The appropriate identification of packages as to the status of inspections and testing and therefore the overall operating status of the unit, is known by affected organizations.

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

C. The bypassing of required inspections, tests and other critical operations is procedurally controlled.

D. The status of nonconforming, inoperative, or malfunctioning packages or components is clearly indicated in such a manner to prevent their unauthorized use.

XV. Nonconforming Material, Parts or Components

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

B. Documentation identifies a nonconforming item; describes the nonconformance, the disposition of the nonconformance and the inspection requirements; and includes the appropriate approval signature related to the disposition.

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

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

XVI. Corrective Action

A. The evaluation of conditions detrimental to quality (such as non-conformances, deficiences, failures, malfunctions, deviations and defective material and equipment) is conducted to determine the need for corrective action in accordance with established procedures.

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

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

XVII. Quality Assurance Record

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

B. The QA records maintained for Type B containers include qualification of of personnel, procedures and equipment; list of nonconformances; corrective action reports for nonconformances; results of reviews, inspections, tests, audits and material analysis; other documentation such as drawings, specifications, procurement documents and calibration procedures.

C. Records are identifiable and retrievable.

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

E. All design related records (e.g., drawings, calculations, etc.) are maintained for the life of the shipping package and all other records are maintained for a minimum of two years.

F. The 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

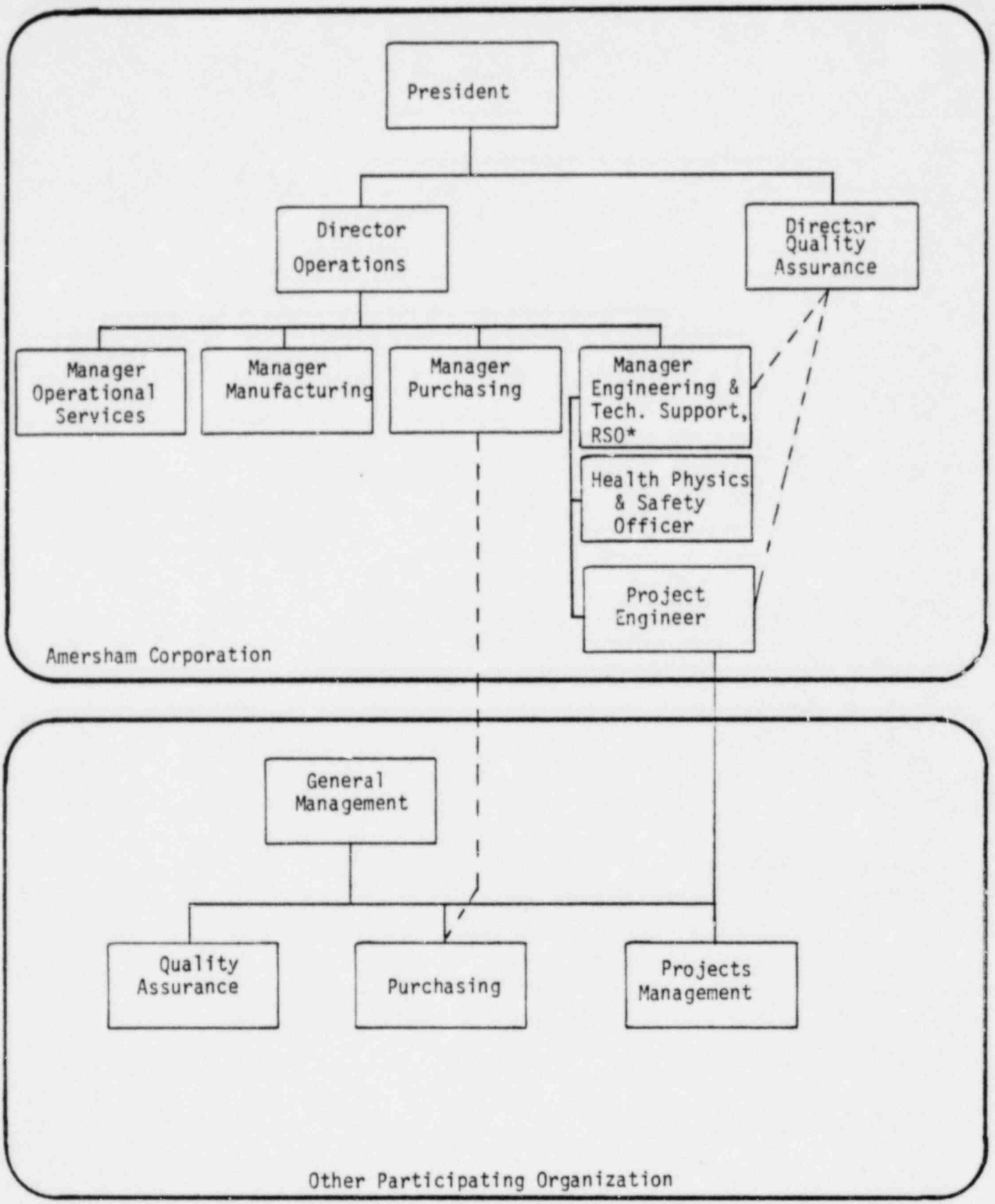
A. Audits are performed in accordance with pre-established written procedures or check lists and conducted by personnel not having direct responsibilities in the area being audited.

B. The results of audits are documented and reviewed with responsible management of areas audited.

C. The responsible management takes the necessary action to correct deficiencies revealed by the audit on a timely basis.

D. Deficient areas will be reaudited on a timely basis to verify implementation of corrective actions to minimize recurrence of deficiencies.

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



*Transport Container Officer

OVERALL ORGANIZATION CHART

ATTACHMENT 1