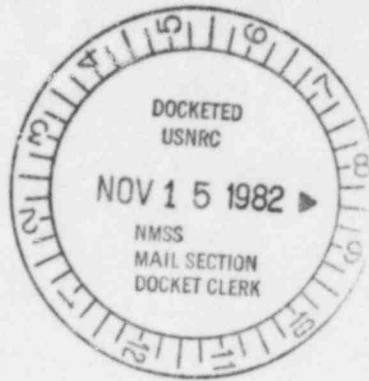


Amersham Corporation  
2636 South Clearbrook Drive  
Arlington Heights, Illinois 60005  
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**Amersham**

October 29, 1982

Mr. Charles MacDonald, Chief  
Transportation Certification Branch  
Division of Fuel Cycle and Material Safety, NMSS  
Nuclear Regulatory Commission  
Washington, D.C. 20555



Reference Docket No. 71-0370

Dear Mr. MacDonald:

Enclosed is the additional information that was requested in your August 30 letter concerning Amersham Corporation's Quality Assurance Program for Type B Radioactive Material Transport Packages.

I hope you will find the material adequate for its intended purpose. Should you have any questions, please do not hesitate to contact me.

Sincerely,

*Linda A. Bagby*

Linda A. Bagby  
Health Physics and  
Safety Officer

jl  
Enclosures

**FEE EXEMPT**

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Response to Request for Additional Information  
Amersham Corporation Docket No. 71-0370

The following is in response to the questions that were raised in the attachments to Charles MacDonald's August 30, 1982 letter. Where pages in the Quality Assurance Program were changed, replacement pages are provided.

Quality Assurance Program  
(Section II)

1. To properly perform his duties, the Transport Container Officer must regularly assess the scope, status and implementation of the Quality Assurance Program. However, during his audits, the Director of Quality Assurance also assesses the scope, status and implementation of the Quality Assurance Program in addition to assessing its effectiveness in complying with 10 CFR Part 71 Appendix E.
2. Preparing, distributing and making revisions to the Quality Assurance Manual for Type B Containers is the responsibility of the Health Physics and Safety Officer.

Design Control  
(Section III)

1. Paragraph D.2 is expanded to read as follows: "Inspection and testing criteria have been identified and requirements for handling, storage, cleaning and maintenance are addressed".

Instructions, Procedures, and Drawings  
(Section V)

1. A matrix is enclosed that identifies the procedures that will be followed in implementing each of the criterion of Appendix E to Part 71. Many of the Standard Operating Procedures noted there have not yet been assigned numbers but the title and a description of what the procedure will cover has been included. Procedures that have not been written yet or that must be put into the format of a Standard Operating Procedure will be completed by January 1, 1983.

Audits  
(Section XVIII)

1. The statement required concerning the contents of the audit plan has been included in the replacement pages.
2. A person performing an audit on another participating organization (outside Amersham Corporation) must be a technically-trained person who is familiar with the requirements of 10 CFR Part 71 Appendix E, Amersham Corporation's Quality Assurance Program for Type B Containers and the package design and construction so as to assess that all requirements are being met by the supplier.

A person performing an audit on departments within Amersham Corporation must be a technically-trained person who has at least 3 years of experience in Quality Control/Assurance and who is familiar with the requirements of 10 CFR Part 71 Appendix E and Amersham Corporation's Quality Assurance Program for Type B Containers.

Matrix of Implementing Procedures for  
Amersham Corporation's Quality Assurance Program for Type B Containers  
Docket No. 71-0370

<u>Implementing Document</u>	<u>Title</u>	<u>10 CFR Part 71 Appendix E Criteria</u>	<u>Description</u>
Quality Assurance Manual (QAM)	-	1	Identifies organizations and their responsibilities in performing activities affecting quality.
Individual Operating Procedures	-		Identifies specific personnel who are responsible for activities affecting quality.
QAM, Standard Operating Procedures (S.O.P.) #	Control of Type B Container Q.A. Manual	2	Identifies how Type B Container Q.A. Manuals will be controlled.
QAM, S.O.P. #	Training Procedure for Personnel Performing Quality-Related Activities on Type B Containers	2	Describes training program and requirements for personnel performing quality-related activities on Type B Containers.
QAM, S.O.P. #	Control of Type B Container Designs	3	Describes requirements which must be addressed when a container design is being developed.
QAM, S.O.P. #	Type B Container Procurement Document Control Procedure	4	Establishes sequence of actions to be accomplished in preparation, review, approval and control of procurement documents in order to be certain that all applicable regulatory and technical requirements are addressed.
QAM, S.O.P. # 106	Preparation, Approval Distribution, Control and Change of a Standard Operating Procedure	5, 6	Establishes sequence of actions to be accomplished in preparation, review, approval and control of a Standard Operating Procedure.

<u>Implementing Document</u>	<u>Title</u>	<u>10 CFR Part 71 Appendix E Criteria</u>	<u>Description</u>
QAM, S.O.P. #	Preparation, Approval Distribution, Control and Change of Instructions and Drawings for Type B Containers	5, 6	Establishes sequence of actions to be accomplished in preparation, review, approval and control of instructions or drawings.
QAM, S.O.P. #	Evaluating Potential Suppliers for Type B Container Materials	7	Establishes criteria by which a potential supplier is evaluated and delineates documentation to be prepared.
QAM, S.O.P. #	Receiving Inspection Procedure for Type B Containers	7, 10, 15, 17	Establishes how specific containers should be inspected, how status should be indicated, how nonconforming containers should be handled and documentation required.
QAM, S.O.P. #	Audits of Type B Container Manufacturer	8, 9, 10, 12, 14, 15, 16, 17, 18	Establishes requirements of what must be reviewed when an audit is performed. Examples: <ol style="list-style-type: none"> <li>1. That procedures have been established to identify and control parts used to fabricate containers.</li> <li>2. That special processes such as welding are properly controlled.</li> <li>3. That procedures are established for performing in-process inspections properly.</li> <li>4. That measuring and test equipment are calibrated appropriately.</li> <li>5. That procedures are established to properly handle nonconforming materials and to correct cause of nonconformance.</li> </ol>

Implementing  
Document

Title

10 CFR Part 71  
Appendix E Criteria

Description

<u>Implementing Document</u>	<u>Title</u>	10 CFR Part 71 <u>Appendix E Criteria</u>	<u>Description</u>
			6. That appropriate records are generated.
QAM, Quality Control Procedure (QCP) 015	Transport Containers - Testing and Inspection Prior to Use of Type B Containers in Excess of 100 Kg	11	Establishes procedure for assessing if an individual container meets design criteria and therefore will perform satisfactorily in service.
QAM, S.O.P. #	Calibration of Instruments Used to Inspect Type B Containers	12	Establishes calibration requirements for instruments used to inspect Type B containers.
QAM, Specified in Design Control Section	-	13	Establishes requirements for any special handling, storage, cleaning or packaging.
QAM, S.O.P. #	Non-conforming Material, Parts and Components for Type B Containers	15, 16	Establishes procedure for how non-conforming material, parts and components will be handled and describes how evaluation should be done to determine whether corrective action is needed.
QAM, S.O.P. #	Audits of Q.A. Program for Type B Containers	18	Describes how audits should be performed, reviewed, and corrective actions made.

Replacement pages for:

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

10/29/82

Instructions:

Remove undated page 3 and replace with page 3 dated 10/29/82.

Remove undated page 4 and replace with page 4 dated 10/29/82.

Remove undated page 11 and replace with page 11 dated 10/29/82.

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 Director, Quality Assurance 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. This will be the responsibility of the Health Physics and Safety Officer.
- 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 and requirements for handling, storage, cleaning and maintenance are addressed.
- 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.

- 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.
- F. The audit plan includes:
  - a. purpose or objective of audit;
  - b. scope;
  - c. specific organizations to be audited;
  - d. names of team members and team leader;
  - e. approximate schedule;
  - f. written notification to audited organization;
  - g. pre-audit conferences;
  - h. post audit conferences (exit interview); and
  - i. method of reporting and evaluating findings.