

71-0370

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A Macdonald
396-55

AUG 30 1982

FCTC:LLG
71-0370

Amersham Corporation
ATTN: Ms. Linda A. Bagby
2636 South Clearbrook Drive
Arlington Heights, IL 60005

Gentlemen:

This refers to your application dated July 30, 1982 requesting approval for your QA program plan applicable to the design, fabrication, and use of Type B radioactive material transport packages.

We reviewed your application and find the need for the additional information identified in the enclosure to this letter.

If you have any questions regarding this request, please contact Len Gordon of my staff at 301/427-4122.

Sincerely,
Original Signed by
CHARLES E. MACDONALD

Charles E. MacDonald, Chief
Transportation Certification Branch
Division of Fuel Cycle and
Material Safety, NMSS

Enclosure: As stated

Distribution: w/encl
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8209140076 820830
PDR ADOCK 07100370
C PDR

OFFICE	FCTC <i>Len Gordon</i>	FCTC <i>CEM</i>				
SURNAME	Gordon:alm	CEMacDonald				
DATE	08/25/82	08/30/82				

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

Encl to ltr dtd: AUG 30 1982

The following questions are arranged so as to facilitate cross referencing with the applicable section of the QA program submittal dated July 30, 1982.

QA Program
(Section 2)

1. Paragraph A. states that the Transport Container Officer assesses the scope, status, implementation, and effectiveness of the corporate QA program. The duties of the Transport Carrier Officer, as stated in Paragraph 1.E., includes the overall responsibility for the QA program including performing certain activities such as review of approval of procurement documentation. In consideration of the statements above, describe how the Transport Container Officer meets the principal that verification of conformance to established requirements must be independent from those assigned responsibility for performing work.
2. Expand Paragraph B to identify the position(s) or organizations having responsibility for (a) preparation of QA manuals, and (b) distribution and revision thereto.

Design Control
(Section 3)

1. Expand Paragraph D.2. to add the activities of handling, storage, cleaning, and maintenance.

Instructions, Procedures, Drawings
(Section 5)

1. Provide a matrix identifying those procedures/instructions that implement each of the applicable criterion of Appendix E to Part 71. With respect to those activities not yet initiated but anticipated, identify by indicating proposed title and give a brief description of the content and estimated date of completion.

(To assist you, attached is an illustration of a format we have found useful to applicants in presenting such information.)

OFFICE ▶							
SURNAME ▶							
DATE ▶							

Audits
(Section 18)

The following refers to audit plans, procedures, composition, and qualification of auditing personnel.

1. Provide a statement that the content of the audit plan includes:
 - a. purpose or objective of the 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. preaudit conferences;
 - h. post audit conferences (exit interview); and
 - i. method of reporting and evaluating findings.
2. Identify the qualification requirements imposed for audit team members and the lead auditor.

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DATE ▶							

Table 1

FORMAT FOR LISTING OF IMPLEMENTING PROCEDURES*

Implementing Document	Title	10 CFR Part 71 Appendix E Criteria	Description
Quality Assurance Manual (QAM), Quality Procedure (QP) 1	Organization	1	Identifies organizations and their relationships in performance of activities affecting quality.
QAM, QP 2	QA Program	2	Describes basic methods for establishing a documented QA program that implements requirements of Appendix E to Part 71.
QAM, QP 3	Design Control	3	Describes design control measures established for structures, systems, and components.
QAM, QP 4	Procurement Document Control	4	Describes procedure for ensuring that applicable regulatory requirements, design bases, and other requirements necessary to ensure adequate quality are suitably included or referenced in documents for procurement of material, equipment, and services.
* * * * *	* * * * *	* * * * *	* * * * *
QAM, QP 18	Audits	18	Describes internal and external audit programs applicable to both in-house and major suppliers.

* The information requested for all 18 criteria would be listed; examples for only criteria 1, 2, 3, 4, and 18 are shown.