QUALITY ASSURANCE PROCEDURES

FOR

PACKAGING FOR RADIOACTIVE MATERIALS

Ref. No.: 001

Amersham Corporation
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Arlington Hts., IL 60005

Author: D. P. Belgrair
Date Issued: 14 July 1980

Approved by:

Date: 14 July 80

10 CFR 71 APPENDIX E

I. Organization

1. The Q.A. program will be retained and exercised by:

   Amersham Corporation

2. Prior to shipment to the U.S. each transportation package will be checked by Q.A. personnel at TRC, using the attached audit checklist. Prior to use within the U.S., Amersham Corporation personnel will inspect those items applicable to trans-shipment of the package to insure compliance with Appendix E of 10 CFR 71. In the case of a shipment originating in the U.S., Amersham Corporation will be responsible for all Q.A. performed on each type B container it uses.

3. Please refer to attachments B and C for complete organization charts for TRC and Amersham Corporation.

4. The Responsibilities of Each Job Function:

   A. Radiation Safety Officer will regularly audit the Q.A. Plan and report to Regulatory Affairs Manager his findings.

   B. Director, Q.A., shall retain responsibility for Q.A. plan to be executed by Q.A. personnel.

   C. Supervisor, Q.A. is to insure that line personnel (Q.A. inspectors) shall carry out the plan. Q.A. Supervisor reports to Q.A. Manager.

   D. Q.A. Inspectors are to report inspection findings to Q.A. Supervisor.

   E. Q.A. Supervisor will release to the Shipping Supervisor each type B container that has been approved by Q.A. line personnel.

   F. Shipping Supervisor will be responsible for proper labeling and surveying of each type B container being transported.

5. Q.A. program responsibility rests in Q.A. Director. This individual has overall responsibility for Q.A. and is appropriately trained and experienced.

6. Packages that do not meet the requirements set forth in 10 CFR 71 shall not be released by the Q.A. Department to Shipping. Any of the following individuals have the authority to withhold release:

   Q.A. Director
   Q.A. Manager
   Q.A. Supervisor
   Radiation Safety Officer
   Manager, Regulatory Affairs
   Safety Officer

   Non-conforming material may be stopped by any one of the aforementioned individuals, with or without the presence or consultation of any of the others.

II. Quality Assurance Program

1. Regulatory Affairs Department, consisting of Manager of Regulatory Affairs, Radiation Safety Officer and Safety Officer, shall routinely assess the Q.A. program for compliance with 10 CFR 71. These individuals report to Q.A. Director, and will inspect and issue formal reports to him.

2. Q.A. manuals and revisions shall be controlled and distributed by Q.A. Supervisor, following review by a member of the Regulatory Affairs staff, who may also request revisions to the plan.

3. Each of the individuals listed in the organizational chart shall be made aware that the Q.A. program is mandatory and will be enforced; and compliance audited regularly by a member of the Regulatory Affairs staff.

4. The Following components shall be controlled by the Q.A. program:

   A. For Type B quantities of radioactive materials that will not be repackaged, the following components shall be inspected:

      a) Outer packaging

b) Material and integrity

c) Lifting attachments

d) Permanent labels

e) Sealing gaskets

f) Bolts, closures, fasteners, both inside and outside

B) For Type B quantities, shipments originating within the United States:

a) Inner packaging

b) Intermediate packaging, including shielding material and integrity

c) Outer packaging

d) Lifting attachments

e) Permanent labels

f) Sealing gaskets

g) Bolts, closures and fasteners, both inside and out

5. In the event of a dispute involving quality, a meeting shall be arranged in order to present opposing viewpoints and reach a resolution of the conflict consistent with the intent of 10 CFR 71.

6. An indoctrination and training program for Q.A. personnel, as well as examination of proficiency will be established and administered by the RSO, or the Safety Officer.

7. All quality-related activities will be performed under normal conditions of use incident to transport and handling of each package covered by 10 CFR 71.

III. Design Control

All package designs originate in, and design specifications are set by the Engineering Group of the parent company, The Radiochemical

Centre (TRC). Designs must be approved by United Kingdom Competent Authority prior to transport and re-use within the U.S. All aspects of design control are executed by TRC personnel. Those design aspects that may be inspectable without unpacking the container (i.e., those features listed in 4A of Part II of this document) will be re-inspected by Amersham Corporation personnel.

For those shipments of Type B quantities originating in the U.S., each container will be completely inspected at Amersham Corporation before use, in a manner consistent with the intent of 10 CFR 71.

IV. Procurement Document Control

All necessary requirements are carried out by properly trained individuals at TRC. Procurement documents are maintained at TRC and are available for inspection. As an integral part of Amersham Corporation's Q.A. program, these documents will be regularly reviewed by a designated member of the Regulatory Affairs staff.

Each supplier of components for use in TRC packages is to be notified that his facilities must be open for inspection and audit by TRC personnel. All revisions to procurement documents are to be subject to the same review and approval as original documents.

V. Instructions, Procedures and Drawings

All activities affecting quality shall be specified formally in writing. This includes package design information and engineering drawings. Q.A. will be in accordance with Amersham Corporation and TRC official Q.A. Procedures.

VI. All documents relating to components and designs, including Q.A. inspection findings and design changes shall be available for inspection at TRC. Additionally, copies of Q.A. reports for inspections performed at Amersham Corporation will be on file there as well.

VII. Control of Purchased Materials, Parts and Components

This will be carried out by properly trained individuals in the Engineering staff of TRC. Whenever deemed necessary, staff members are to inspect and audit suppliers of package components, as indicated in Section IV of this document.

VIII. Identification and Control of Materials, Parts and Components

All package designs must be clearly and permanently labeled with appropriate identifying information. Components will be identified, with information accompanying each container that is used by Amersham Corporation within the U.S.

IX. Control of Special Processes

These will be carried out according to formal written procedures at TRC. Records will be available for inspection at TRC.

X. Inspection

The inspection program is carried out in accordance with formal written procedures, including checklists accompanied by formal instruction. The individuals carrying out the inspection shall be separate from those involved with design of the package.

XI. Test Control

All testing will be performed at TRC or at locations in the U.K. designated by TRC. Written records of test results will be maintained at TRC.

XII. Control of Measuring and Test Equipment

Whenever necessary, calibrations of test equipment will be performed using appropriate methods, by personnel designated responsible at TRC.

XIII. Handling, Storage and Shipping

All conditions of NRC and U.S. DOT shall be met prior to re-use of TRC packages within the U.S. The appropriate certifications and instructions to carriers and consignees will accompany each package shipped.

XIV. Inspection, Test and Operating Status

All test results, including inspections of markings, labels and tags will be communicated formally to the appropriate individuals at Amersham Corporation, TRC, carriers and consignees. Whenever a package fails inspection, its status shall be clearly indicated on the package and it is to be stored in such manner to prevent its unauthorized use.

XV. Non-conforming Materials, Parts or Components

As specified in Section XIV, these are to be segregated to prevent their use and await formal proceedings to scrap or return to TRC for further inspection and repair. The ultimate disposition of non-conforming components will be formally recorded and available for inspection at TRC, or Amersham Corporation whenever warranted.

XVI. Corrective Action

Corrective action will be initiated whenever deemed necessary by TRC, with complete reports furnished to TRC and Amersham Corporation.

XVII. Quality Assurance Records

All records relating to safety characteristics of packages, including design criteria, engineering drawings and specifications and prototypes testing will be documented by TRC personnel. Records will be maintained at TRC and available for inspection there. All TRC inspections prior to use of packages will be filed at TRC, and appropriate documents provided with each package shipped to Amersham Corporation. Amersham Corporation will maintain these on file in addition to:

1. U.S. DOT revalidations
2. NRC approvals
3. Q.A. inspections performed at Amersham Corporation
4. Inspections of TRC procedures performed by Amersham Corporation personnel.

All records will be dated, signed and approved by a level of management consistent with its significance to health and safety, as required by 10 CFR 71, Appendix E.

XVIII. Audits

Audits will be conducted annually: Results of all audits will be maintained wherever the work was performed. Corrective action will be documented. This will be reviewed by a level of management responsible for corporate compliance with U.S. NRC and DOT regulations.

Attachment A

THE RADIOCHEMICAL CENTRE

QUALITY CONTROL DEPARTMENT

QUALITY CONTROL PROCEDURE

1. Title: Turn-around inspection and maintenance of transport containers

2. Procedure prepared by: R A Vaughan ..... date: 24.10.78

3. Procedure approved by: APPROVED ..... date: .....
Quality Controller

4. Turn-around inspection is to be carried out by the user in accordance with the following check-list before use at every turn-around:

4.1 Monitor the container to ensure that it is empty.

4.2 Test for external and internal contamination. Maximum permissible levels for non-fixed contamination are 10^{-4} $\mu Ci/cm^2$ for beta/gamma, and $10^{-5}\mu Ci/cm^2$ for alpha, when averaged over any area of 300 cm^2.

4.3 Check the assembly visually for damage or defects:

(a) Check the condition and fit of plug and other shielding component

(b) Check that sealing gaskets are undamaged and seating correctly.

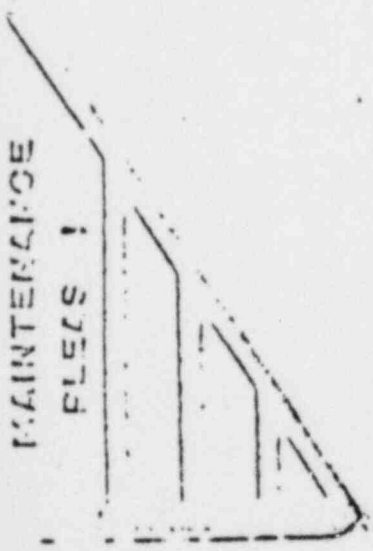
(c) Check the condition of bolts, all closures, and fasteners, internal and external.

(d) Check the soundness of lifting attachments.

(e) Check the condition of paintwork and the general standard of appearance.

(f) Check the security and legibility of permanent labelling. This should include a metal trefoil label and an orange-coloured oval identity label.

(g) Check that all temporary labels have been removed.

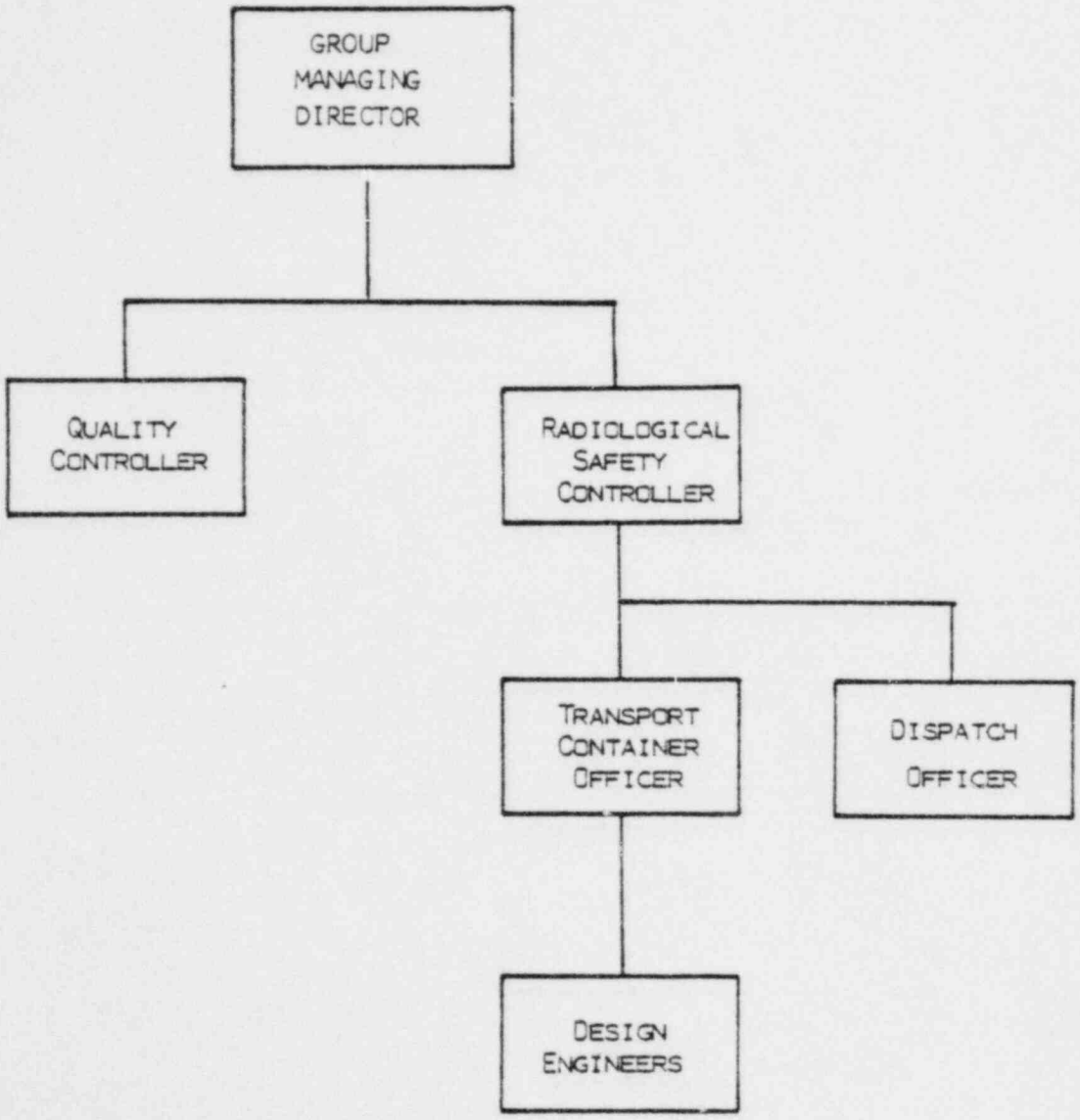


4.4 Where practicable rectify any defect. Where further work is required attach a 'Maintenance please' label, arrange for Health Physics clearance, and request the maintenance required using attached Maintenance Request form.

4.5 Maintain a record of each inspection and the result.

4.6 If the date shown on the "Maintenance due" label (for Scheduled Maintenance) is close to expiry, inform the Owner Section.

ORGANIZATION CHART: TRC



ORGANIZATION CHART: AMERSHAM CORPORATION