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VALIDATION

ATOMIC ENERGY OF CANADA LIMITED - COMMERCIAL PRODUCTS
QUALITY ASSURANCE PROGRAM
FOR DELIVERY OF A RADIOACTIVE MATERIAL PACKAGE
TO A CARRIER FOR TRANSPORT

Prepared by: _____ May 25, 1981
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_____ 25 May, 1981.
Manager, Regulatory Affairs — Date

Approved by: _____ 25 May, 1981
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Executive Vice-President — Date

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1. INTRODUCTION

1.1 Purpose

The purpose of this plan is to define Atomic Energy of Canada Limited - Commercial Products' (AECL-CP) quality assurance program for radioactive material packages used to deliver radioactive material to a carrier for transport as required by 10 CFR71.12. The program is limited to the company-operational dependent activities in the shipment of packages containing radioactive materials; therefore, the package dependent elements of the quality assurance program as defined in 10 CFR71 - Appendix E are not addressed.

1.2 Scope

1.2.1 The scope of this program is limited to the operational elements for packages intended for use to ship Type B quantities of radioactive material.

1.2.2 As a general guideline, packages normally used by AECL-CP which are under this quality program include, but are not limited to, those described in the following USNRC and Agreement State Licences:

54-00300-04
54-00300-09
54-00300-12
54-00300-13
12-18482-01
37-19318-01
5-2623 (Texas)
G.A. 695-1 (Georgia)

Also specific package design models as follows:

F-121	F-154
F-127	F-158
F-127X	F-168
F-131	F-168X
F-143	F-245
F-144	F-247
F-146	F-251
F-147	F-254

1.2.3 This program applies to the integrity of the package as achieved by loading, closure, monitoring, and labelling prior to delivery to a carrier for transport.

2. ORGANIZATION

AECL-CP organization is shown in Figure 1. The structure of the Quality Assurance Division is illustrated in Figure 2. Specific responsibilities as they relate to the program's activities are summarized below.

2.1 Executive Vice-President

The Executive Vice-President is responsible for establishing the company's Quality Assurance Policy and ensuring that all company operations are carried out in full compliance with that policy; this responsibility includes the quality assurance program described herein.

2.2 General Manager, Quality Assurance

The General Manager, Quality Assurance, reports directly to the Executive Vice-President and is responsible for providing quality assurance program management for shipment of radioactive material packages. He is the final authority and represents AECL-CP on all quality matters. His specific duties with respect to packages include:

(a) The responsibility for the promulgation and execution of instructions, policies and procedures.

(b) The administration of the quality assurance program.

(c) The authority to stop activities when the seriousness of a condition may adversely affect quality or safety.

(d) The overall activities related to licensing of packages.

(e) The performance of quality assurance audits of operations and the reporting of non-conformances to established quality assurance practices and procedures.

(f) Conducting audit follow-up and monitoring corrective action.

2.3 Manager, Regulatory Affairs

The Manager, Regulatory Affairs reports to the General Manager, Quality Assurance, and is responsible for the required activities for the licensing and provision of quality assurance documents of packages. He is a licensed source handler and also serves as the Radiation Safety Officer for all field operations, and as such, assures that packages used have been approved by the Competent Authority of Canada and re-validated by the U.S. Department of Transportation for use in transporting radioactive by-product material.

2.4 General Manager, Industrial Products

The General Manager, Industrial Products reports to the Executive Vice-President. He is responsible for the activities and facilities related to the use of packages incident to transport of radioactive materials for use in products under his responsibility. He is responsible for ensuring that these activities are carried out in compliance with the quality assurance program and procedures.

2.5 General Manager, Medical Products

The General Manager, Medical Products reports to the Executive Vice-President. He is responsible for the activities and facilities related to the use of packages used for transport of radioactive materials to be installed in medical products. He administers, through the Manager, Medical Installation and Service, and the Area Service Managers, the operations of the Area Offices. He ensures that these activities are carried out in compliance with the quality assurance program and procedures.

2.6 Manager, Product Integrity

The Manager, Product Integrity reports to the General Manager, Quality Assurance. He is responsible for performing audits of those activities related to the program and reporting non-conformances to the responsible managers. He also follows up audits, and requests and monitors corrective actions.

3. QUALITY ASSURANCE PROGRAM FOR OPERATIONS

3.1 The quality assurance program for shipping packages is implemented through the use of written procedures, instructions and training. Also, it includes the documentation of work done, checks, inspections, personnel and procedure qualifications and audits. To comply with the quality assurance program requirements, procedures and instructions are available and controlled for the following areas: training of authorized personnel, loading, closure, monitoring and labelling of packages and licensing.

3.2 Training

Personnel performing activities affecting quality and safety are formally trained in proper handling techniques for the packages and also receive indoctrination in

(a) Principles and practices of radiation protection.

(b) Radioactivity measurement standardization, monitoring techniques and instruments.

(c) Mathematics and calculations basic to the use and measurement of radioactivity, and

(d) Biological effects of radiation.

3.3 Personnel Qualifications

Personnel handling or preparing shipping packages for delivery to a carrier for transport are competent and duly licensed source handlers, and are also appropriately trained and qualified.

3.4 Management Review

Review of the scope, status, implementation and effectiveness of the quality assurance program is conducted by management on that portion of the program for which they have designated responsibility. The reviews are conducted and documented at least once every two years.

3.5 Revision

The General Manager, Quality Assurance is responsible for maintaining the currency of quality assurance program documents. New or revised quality assurance program requirements are implemented within 90 days following issue or as determined by the General Manager, Quality Assurance.

Temporary deviations or additions to this document may be made with the approval of the General Manager, Quality Assurance and authorized by the Executive Vice-President and accepted by the responsible managers. It is the responsibility of the Manager, Regulatory Affairs to ensure that the revisions to these documents are approved by the same signatories as the original document and that, where necessary, it is lodged with the appropriate international competent authorities.

3.6 Package Configuration

The Radiation Safety Officer assures that modifications to packages are approved by the competent authority in Canada and are submitted to the U.S. Department of Transportation for re-validation.

4. DOCUMENT CONTROL

All documents related to shipping packages are controlled through the use of written procedures. All changes to documents are performed according to written procedures approved by management. The Radiation Safety Officer ensures that all relevant quality assurance program procedures and revisions are provided to each Area Office and that line responsibilities are conducted in accordance with those procedures. Each of the Service Managers shall assure that the source handlers are aware of the latest procedures and are required to satisfy the RSO of same.

5. CONTROL OF MEASURING AND TEST EQUIPMENT

For package operations a portable radiation survey instrument is used to establish the radiation level of the shipping package and to determine if the

package is contaminated with radioactive material. The procedures used to control the standard of the measuring instrument provide for:

5.1 Identification of the instrument.

5.2 Calibration of sources used for calibrating the instruments in accordance with standards established by the National Research Council of Canada.

5.3 Establishment of frequency of calibration of the instrument.

5.4 Maintenance of calibration records.

5.5 The removal from service and repair of damaged or inaccurate instrumentation.

6. HANDLING, STORAGE AND SHIPPING

For package operations, written procedures provide for:

6.1 Work instructions for handling, preservation, storage, cleaning, packaging, labelling, monitoring and shipping requirements to be completed by duly licensed source handlers.

6.2 Verification by the source handler that the activities in Item 6.1 have been completed and that the USNRC and U.S. Department of Transportation shipping requirements are properly satisfied prior to consignment to a carrier for transport.

6.3 All shipping documentation (certification, acceptances, etc.) to be prepared prior to shipment by AECL-CP at the Ottawa Head Office of AECL-CP.

6.4 The assurance that a duly licensed source handler performs all the critical handling, monitoring, storage and preparation for transport operations.

6.5 Emergency procedures by both AECL-CP (the consignor) and the commercial carrier.

7. INSPECTION, TEST AND OPERATING STATUS

7.1 Inspection, test and operating status of the package are indicated and controlled by written procedures in conjunction with the handling, storage, monitoring, labelling and shipping operations.

7.2 A check list is prepared and signed by the source handler and maintained both at the U.S. Office and at AECL-CP, Ottawa, for each shipment. The check list identifies the regulatory required inspections and tests as in the written procedures.

7.3 Each Area Service Manager ensures that these functions are performed. The Radiation Safety Officer, by verification of documentation, and periodic inspection, assures that these functions have been performed.

7.4 If the package is not suitable for shipment because of damage or non-conformance the status and disposition of the package is maintained by written procedure.

8. QUALITY ASSURANCE RECORDS

8.1 Sufficient records are prepared and maintained in accordance with the written procedures of the quality assurance program to furnish objective evidence of the integrity and safety of the shipping package. These records are identifiable to written procedures and traceable to the package and its movements.

8.2 Records attesting to the personnel training and qualifications are maintained at each Area Office and at AECL-CP.

8.3 Records are stored at AECL-CP Central Records and at the applicable Area Office for use as working records. Record retention times are based on established procedures consistent with commitments to the competent authority.

9. AUDITS

9.1 Planned Quality Assurance audits are performed by personnel who are appropriately trained and have no direct responsibilities in the areas

audited. The audits are performed in accordance with written procedures and established quality audit techniques.

9.2 The audits determine the degree of conformance to approved procedures and quality assurance documents and provide objective evidence to evaluate the effectiveness of the program.

9.3 Corrective action for non-conformance is requested from the responsible manager and completion of the corrective action is verified. Uncorrected non-conformances are carried as Open Audit Items until corrected.

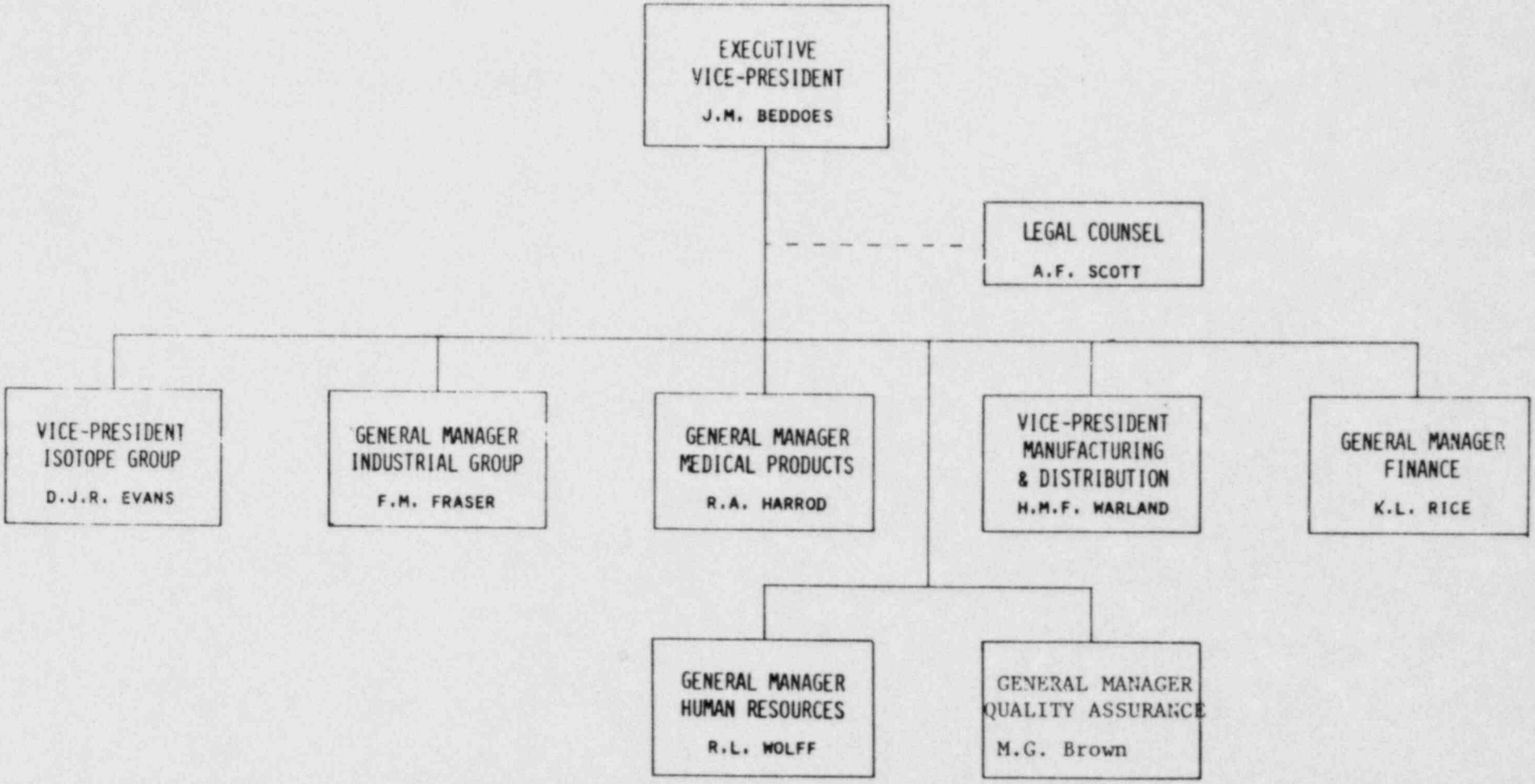
9.4 Audit frequency is based on the status, safety, importance or problems. At least one activity is audited each year.

9.5 Copies of audit reports are provided to responsible managers and senior management. Audit reports and related corrective action are maintained in Central Records at the Ottawa Head Office of AECL-CP.

FIGURE 1

ATOMIC ENERGY OF CANADA LIMITED - COMMERCIAL PRODUCTS

EXECUTIVE ORGANIZATION



J.M. BEDDOES
1981 APRIL

FIGURE 2

ATOMIC ENERGY OF CANADA LTD.
COMMERCIAL PRODUCTS

QUALITY ASSURANCE DIVISION ORGANIZATION