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NRC BY-PRODUCT MATERIALS LICENSE NO. 37-00611-09

QUALITY ASSURANCE PROGRAM

COVERING

DESIGN, FABRICATION, TESTING, MAINTENANCE, AND USE OF SHIPPING PACKAGES---RADIOACTIVE MATERIAL

(10 CFR PART 71)

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QA Program (10-CFR-71)

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REV. #	COMMENTS	DATE	APPROVED

PREPARED BY: [signature] RSO & GEN'L MGR. (TITLE) 12-15-78 (DATE)

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INTRODUCTION

The Sperry Division of Automation Industries, Inc. operates a Hot-Cell located in Phoenixville, Pennsylvania. This facility processes and distributes sealed sources of Iridium-192 and Cobalt-60 for use in industrial radiographic inspection. The group also designs, fabricates, and distributes radiographic exposure devices and shipping packages for transporting these radioactive sources.

All sealed sources which are distributed meet the requirements of Special-Form Material and/or Special-Form Encapsulation. All sealed sources are of Type "A" or Type "B" quantities, and are packed within shipping containers which are designed and tested to meet the requirements of Type "A" or Type "B" packaging. We also use (for domestic shipments only) DOT-55 Spec. containers which were manufactured prior to the March 1975 cut-off date.

The above packages are also received at our facility, containing decayed sources which customers consign to us for disposal.

The facility also receives and (re-ships empty) shipping packages which are not of our manufacture. These packages are supplied by the irradiating reactor who supply us with the Iridium-192 and Cobalt-60 source material.

The facility also ships low-level waste products in 55 gallon drums (Spec. DOT-17H). These drums are picked-up at our facility by a licensed waste disposal contractor who we retain for these services.

This Quality Assurance (QA) Manual specifies the program to be implemented by Sperry Division, Phoenixville, Pa. in order to comply with the requirements of 10-CFR-71 "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material under Certain Conditions."

Radioactive Materials referenced in the QA Manual are those Special-Form Materials for which we are licensed by the Nuclear Regulatory Commission to receive, possess, process, and ship under NRC License No. 37-00611-09.

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INTRODUCTION (CON'T)

This QA Program is a mandatory requirement and shall be administered by the Management of The Sperry Division, Phoenixville, Pennsylvania.

This QA Manual supplements the requirements as defined in the companies':

By-Product Materials License No. 37-00611-09
Administrative Manual
Operating and Emergency Procedures Manual

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1.0 ORGANIZATION

1.1 GENERAL

The final responsibility for administering this QA Program rests with the Management of the Sperry Division, Phoenixville, Pa. The QA Program will be implemented using the Organization Chart in Appendix "A".

1.2 RESPONSIBILITIES

1.2.1 The Radiation Safety Officer (RSO). The RSO has the primary responsibility for implementing this program. He will assure that the procedures required by this Manual are prepared, distributed, and administered accordingly. He will monitor implementation of this Program as part of the Radiation Safety audits.

1.2.2 The responsible Management (General Manager, RSO, and the Manufacturing Manager) will have direct control of all engineering, design, fabrication, procurement, testing, use, receiving, storage, and transporting of all shipping packages.

1.2.3 The responsible Management will direct and delegate those duties which are incident to the day-to-day functions which sustain the continued operation of this facility. These functions will be accomplished only by individuals who have been trained in Radiation Safety and/or are radiation oriented. The responsible Management have the responsibility and authority to stop unsatisfactory work and control further processing, use, delivery, or marketing of nonconforming material.

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1.2.4 (History and Comments) This facility consists of a small, close-knit group consisting of six (6) individuals. Personnel breakdown consists of (2) Management, (2) Radiation Technicians, (1) Machinist, and (1) Secretarial & Office. The number of employees has remained constant for the past ten years. We experience minimal personnel turnover. Over 80% of our staff has been employed by the facility for more than 12 years. We have an excellent working team. We know our products, have excellent communications, and function as a very efficient group.

2.0 QUALITY ASSURANCE PROGRAM

2.1 The Management of Sperry Division, Phoenixville, Pa. shall be responsible for implementing this Program.

2.2 TRAINING

2.2.1 The two (2) Managers who will administer this Program are both graduate Engineers and both have been with this organization in Management capacity, directing all phases of Hot-Cell operations. They are both acquainted and versed with current requirements of NRC, DOT, and FAA regulations governing design, testing, shipping, use, and storage of radioactive shipping packages.

2.2.2 Radiation Technicians and other employees who may have direct involvement with functions relating to shipping packages, will receive indoctrination in the Manual and its Procedures. The indoctrination shall be provided by the responsible Manager, and documented. Each employee will receive a copy of this Manual, complete with a copy of 10-CFR-71 and Appendix "E".

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2.3 Revisions to this Program require the approval of the Radiation Safety Officer.

2.4 The key elements of this Program is to govern the design, fabrication, testing, storage, and use of radioactive shipping packages. These elements are:---

2.4.1 The assurance by the Radiation Safety Officer that all shipping Packages of our own manufacture are designed, fabricated, and tested in accordance to the requirements of this QA Program. The RSO must also assure that shipping packages which are not of our manufacture, were also designed and fabricated under a QA Program approved by The Nuclear Regulatory Commission. This assurance must be satisfied for all shipping packages designed and/or fabricated after July 1, 1978.

2.4.2 That all defined Quality Control (QC) procedures, engineering procedures, and specific provisions of the package design and approval are satisfied.

2.4.3 That the characteristics of the package critical to safety are controlled.

2.4.4 That required tests have been performed to qualify the package for its intended use.

2.4.5 That all quality-related inspections and tests are performed with desingated fixtures, tools, and instruments under suitable enviromental conditions; and that all design and manufacturing prerequisites have been satisfied prior to inspection and testing.

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2.4.6 That all shipments of Radioactive Packages satisfy the requirements for:

(a) Adequate labeling of shipments
(b) Proper preparation of shipping documents
(c) Inspection, testing, and surveying of shipments for permissible levels of radiation

3.0 DESIGN CONTROL

3.1 The RSO will establish measures and standards to insure that all design activities are performed in a planned, controlled, and orderly manner.

3.2 All designs will be verified by design reviews, alternate calculation, qualification testing, or other appropriate means to substantiate validity of the design perimeters.

3.3 All designs originated by the General Manager will be reviewed and verified by the Production Manager and that this review will assure that:

(a) All design characteristics can be controlled, inspected, and tested
(b) All inspection and test criteria are identified

The design verification authority and responsibilities of the Production Manager are identified and documented within his job classification.

3.4 The RSO will establish measures to assure that all regulatory requirements are satisfied within the design of a shipping package. These requirements must be clearly included as part of the engineering drawings, design Specifications, and fabrication and assembly procedures.

3.5 The RSO will insure that suitable controls and engineering effort is utilized to such activities as radiation shielding, structural strength, accident conditions, compatibility of materials, maintenance, and repair.

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3.6 When mechanical or enviromental tests are required to verify design adequacy, these tests will be performed on a prototype unit under design. All test results must be documented and retained.

3.7 Revisions and changes to design and specifications are subject to same design controls and approvals tha were applicable to the original design.

3.8 Prior to release for productions, the RSO will submit all engineering drawings, specifications, operating instructions, and prototype test results to the NRC and/or DOT for approval, comments, and/or certification.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 The responsible Management will insure that all procurement documents are prepared, reviewed, approved by signature; and these documents are retained and filed in an orderly and systematic manner.

4.2 When applicable, procurement documents will identify and make reference to specific 10-CFR Part 71, Appendix "E" requirements which become part of the procurements document.

4.3 Procurement documents will identify all drawings, specifications, fabrication procedures, inspections, test results which when required become part of the procurement, and are to be prepared, maintained, and submitted to Automation Industries for review and approval.

4.4 When applicable, procurement documents will reference applicable regulatory requirements or specifications; or standard industrial codes which constitute the technical design basis for the purchased item.

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4.5 When applicable, procurement documents will include Automation Industries right of access to suppliers facility and records for purpose of inspection and audit.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 The responsible Management will prescribe and document by procedures or drawings all design and manufacturing activities affecting quality of the product.

5.2 Instructions, procedures, and drawings will be prepared, reviewed, and approved by the responsible Management prior to distribution. These preparations will be accomplished using generally accepted engineering practices. Any changes to these instructions, procedures, or drawings will be documented and approved by the responsible Management.

5.3 Prior to release, all inspection plans; test, calibration, and special process procedures; drawings and specifications; and changes thereto will be independently reviewed by either the General Manager or the Production Manager.

6.0 DOCUMENT CONTROL

6.1 The RSO will maintain direct control of reviewing, approving, and issuance of all documents pertaining to the design, engineering, specifications, procurement of components, fabrication, assembly, testing, use, storage, and transporting of radioactive shipping packages.

6.2 All documents will be available at the location where the quality-related activity will be performed prior to commencing the work.

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6.3 Changes to any of these documents will require authorized approval by the RSO, and records of these changes will be retained.

6.4 Obsolete drawings or discontinued specifications will be segregated to prevent inadvertent use.

6.5 Originals or copies of all documents relating to design, testing, fabrication, and use of shipping packages shall be controlled and retained at the Sperry Division's, Phoenixville, Pa. facility.

7.0 CONTROL OF PURCHASED MATERIALS, PARTS, AND COMPONENTS

7.1 The responsible Management will evaluate all vendors capabilities to provide acceptable quality services and products.

7.2 All vendors will be evaluated with regards to ability to comply with requirements of Appendix "E" of 10 CFR Part 71 when applicable; or evaluated against past performance records of acceptability and quality for similar articles provided on previous contracts. When necessary, a survey of the suppliers facility and quality program will be evaluated to insure his capability to provide the desired end product.

7.3 Results of suppliers grading or evaluations will be documented and retained.

7.4 When required, surveillance of suppliers progress during manufacturing, inspection and testing of materials or components, will be monitored in accordiance with designed procedures to assure complete procurement requirements.

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7.5 As a minimum, all suppliers will furnish documents that identifies the purchased material or equipment by part of drawing number, and Purchase Order number, and incorporate any specific codes or standards which were included as part of the procurement requirements.

7.6 Receiving inspection of vendor furnished material will be performed to assure that purchased items are properly identified; inspected, and judged acceptable prior to storage or release for further processing.

7.7 All inspection records or certificates of conformance attesting to the acceptability of the material and components will be on file and available prior to installation or use of the material or components.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.1 All materials, parts and components will be identified by part number or drawing number, which will allow traceability to design drawing, design specifications, procurement documents, and manufacturing and inspection procedures.

8.2 Identification of all materials, parts, and components will be verified and documented prior to release for storage as finished goods, or prior to release for further processing, fabrication, and/or further assembly or installation.

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

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9.0 CONTROL OF SPECIAL PROCESSES

9.1 All special or critical processes such as welding, heat treating, mechanical testing, cleaning, decontamination will be procedurally controlled.

9.2 All procedures, equipment, and personnel connected with special or critical processes are trained and/or qualified in accordance with applicable standards or requirements of our operating NRC License.

9.3 Qualification records of procedures, equipment, and personnel associated with special for critical processes are established, filed, and kept current.

10.0 INSPECTION

10.1 The responsible Management personnel will implement an inspection program to assure conformance with specific requirements of design, specifications, and drawings for all shipping packages.

10.2 Particular inspection emphasis shall be placed on radiation shielding, and locking and sealing, devices which are used in securing the packages.

10.3 Radiation shields (Depleted Uranium or poured lead type) will be inspected for shielding integrity, both prior to, and after final assembly. Survey results will be documented by shield serial number.

10.4 All Shielding surveys shall be performed by using a properly operating, and recently calibrated instrument.

10.5 The responsible Manager will provide a check list which will designate acceptance and rejection criteria based on permissible levels of radiation.

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10.6 Provisions will be established that identify mandatory inspection hold points for witness and review by an inspector and responsible Management.

10.7 Final approval of radiation survey data rests with the responsible Manager.

10.8 All non-acceptable components shall be segregated, and returned to manufacturing for rework, replacement, or disposal.

10.9 All mechanical components will be inspected for dimensional tolerance and fits using standard machinist's gauges. Acceptance and rejection criteria will be in accordance to tolerances specified on engineering drawings.

11.0 TEST CONTROL

11.1 The responsible Management will establish a test program to demonstrate that items or components will perform satisfactorily in service. These test programs will be documented, and accomplished in accordance with regulatory or written controlled procedures.

11.2 When repairs or modifications are incorporated into an existing component or assembly, these repaired or modified items will be tested to the original design requirements.

11.3 The responsible Management will evaluate all test results to determine acceptability criteria. Test results will be documented and retained.

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12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Measuring and test instruments are calibrated as required based on the required accuracy, use and purpose, degree of usage, age of instrument, inherent stability of measuring elements, and other conditions affecting accuracy.

12.2 Measures will be established and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.

12.3 When required, measuring and test equipment is identified and traceable to calibration test data.

12.4 Where applicable, reference and transfer standards and traceable to nationally recognized standards, or to documented basis of calibration procedures.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 Only qualified radiation technicians shall perform the critical handling, storage, and shipping functions as required in the normal operation and the facility.

13.2 Shipping packages shall be handled, stored, and shipped in accordance to our operating and emergency procedures and/or the specific operating and instruction manual for the particular package.

13.3 All incoming shipping packages shall be surveyed for radiation levels at time of delivery. The shipper's name, package model and serial number, and results of surveys shall be documented and recorded in the daily receiving log.

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13.4 All out-going shipping packages shall be checked to insure proper operation of mechanical components and locking devices. Packages will be closed and decontaminated to within permissible levels.

13.5 All out-going shipping packages shall satisfy the requirements for:

(a) Adequate markings and labeling
(b) Proper preparation of shipping documents
(c) Surface radiation levels and transport index
(d) Certificates of Conformance and/or Compliance
(e) Shipper's Certificate for radioactive materials
(f) Peligro labels for air shipment

13.6 All safety-related conditions (operations, tests, inspections, and specifications) of the NRC package apprival and the U.S. Department of Transportation shipping requirement are satisfied prior to shipment.

13.7 For all radioactive shipments, the departure, routing, arrival time, and destination of the package will be established and monitored to a degree consistent with the safe transportation of the package.

13.8 When a package is found to be defective and not conforming to all requirements regulating its use, the nature of the defect shall be reported to the responsible Manager. The Manager will verify the item of non-conformance; tag the package as defective; segregate the package from normal inventory to prevent inadvertant use; and arrange for repair of the defect, or disposal of the package.

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14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 Each shipping package shall be metal engraved or stamped with model and serial number. Work order tags shall be attached to each package as a means of controlling the package as it progresses through the various phases of production.

14.2 Non-conforming shipping packages are defined as those which fail any of the inspection tests which are safety-related to transporting of radioactive materials.

14.3 Defective of non-conforming packages shall not be processed beyond the point of defect detection. Defective packages shall be tagged accordingly, segregated, and not be used until final disposition of the package is determined by Management.

14.4 By-passing of any required inspections, tests, and other critical operations will be procedurally controlled and documented. These deviations must have the direct written approval of the responsible Management.

15.0 NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

15.1 Nonconforming items will be identified and tagged, documented, segregated, reviewed for rework or disposition, and all affected organizations shall be notified of the nature of nonconformance.

15.2 Reject documentation will identify each nonconforming item; describe the nonconformance, the disposition of the nonconformance, and the subsequent inspection requirements; and shall include signature approval of the final disposition.

15.3 All nonconforming items shall be segregated from acceptable inventory and will be tagged as discrepant until properly reworked or disposed of.

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15.4 All nonconforming items which are reworked or repaired will be subjected to the same acceptability and inspection tests by retesting to original equipment inspection requirements.

16.0 CORRECTIVE ACTION

16.1 The responsible Management will evaluate all nonconformances adversary affecting quality and implement corrective action in accordance with established procedures.

16.2 For all nonconformances affecting quality, the responsible Management will initiate corrective action to preclude recurrence.

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

17.0 QUALITY ASSURANCE RECORDS

17.1 Records as required by NRC and DOT regulations and all complimentary documents generated by the QA Program shall be retained at the Phoenixville, Pa. facility.

17.2 All QA records are identified and retrievable.

17.3 A chronological log listing all QA records will be maintained.

17.4 All design related records such as drawings, calculations, test results, etc., will be maintained for the life of the shipping package and all other records will be maintained for a minimum period of two years.

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17.5 Where applicable inspection and test records will document the fo[illegible]ng:

(a) A description of the type of observation

(b) Evidence of completing and varifying

(c) The date and results of the Inspection or test

(d) Any information related to conditions adverse to quality of the component or assembly

(e) Identification of the inspector or person recording test data

(f) Written evidence as to the acceptability of the results

18.0 AUDITS

18.1 Due to the small size of the organization, it becomes rather difficult to implement a pre-established comprehensive auditing procedure. In reality, the two responsible Managers who work in close harmony, are auditing each other's responsibilities on a daily and informal basis.

18.2 We shall however, establish written procedures and/or check list for objectively evaluating or upgrading our QA Program. The entire QA assurance program will be ofjectively reviewed periodically and at least anually.

18.3 Deficient areas uncovered by these objective evaluations will be reviewed and re-evaluated on a timely basis to assure that corrective actions have been taken to minimize recurrence.

18.4 Results of these audits will be documented and retained as part of our Radiation Safety Committee records.

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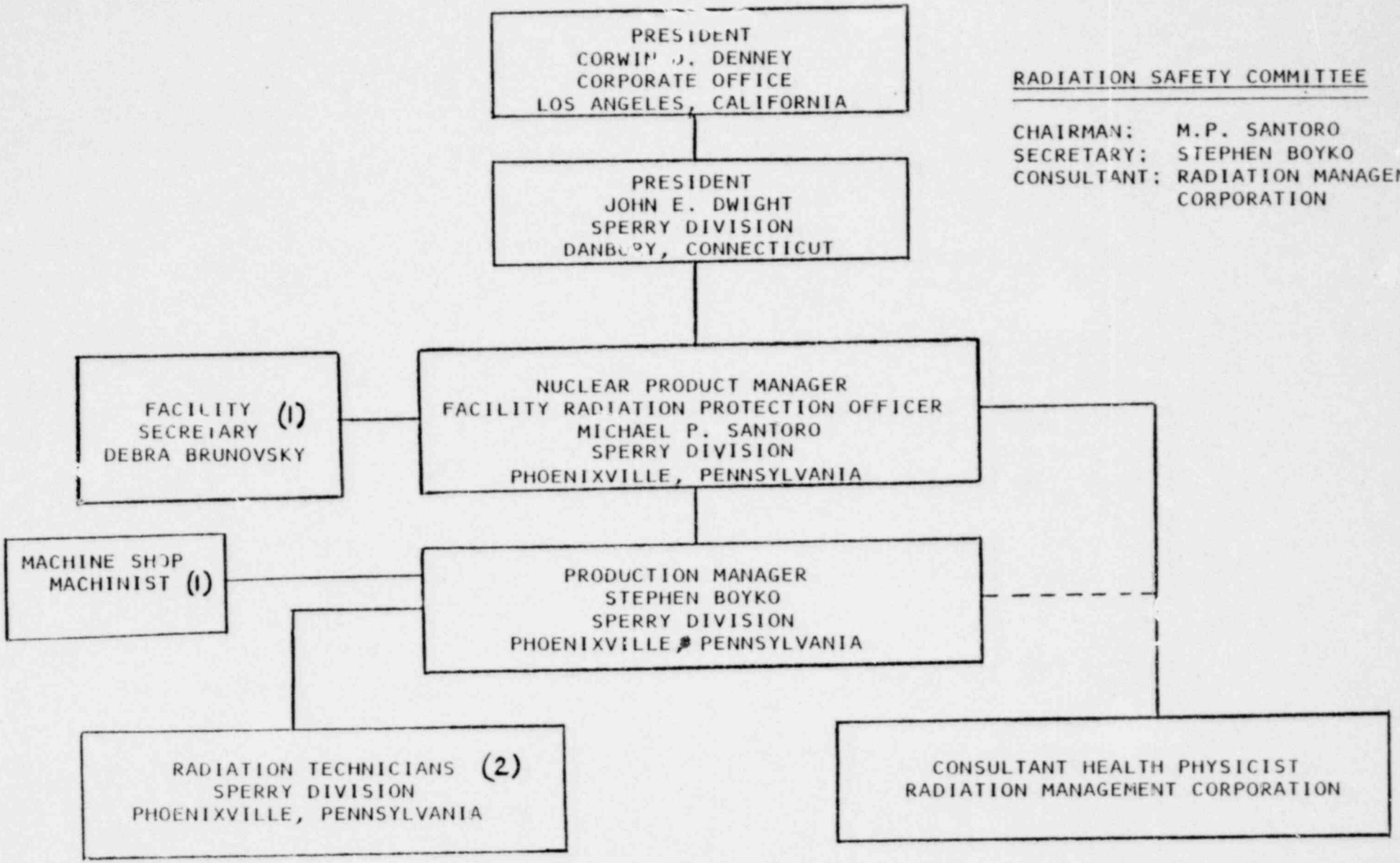
ORGANIZATION STRUCTURE
(REVISED JUNE 15, 1978)



RADIATION SAFETY COMMITTEE

CHAIRMAN: M.P. SANTORO
SECRETARY: STEPHEN BOYKO
CONSULTANT: RADIATION MANAGEMENT CORPORATION

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APPENDIX E—QUALITY ASSURANCE CRITERIA FOR SHIPPING PACKAGES FOR RADIOACTIVE MATERIAL

Introduction.—In accordance with § 71.24, every applicant for an approval for use of a shipping package is required to describe his quality assurance program, and every licensee is required by § 71.31 to establish and maintain a quality assurance program for the design, fabrication, assembly, testing, use, and maintenance of each packaging, as defined in § 71.4(l).

This appendix establishes quality assurance requirements which apply to all activities affecting the components of the packaging which are significant to safety. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing, and modifying.

As used in this appendix, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

1. ORGANIZATION

The licensee[1] shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility therefor. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (a) assuring that an appropriate quality assurance program is established and effectively executed and (b) verifying, such as by checking, auditing, and inspection, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend or provide solutions; and to verify implementation of solutions. Such persons and organizations performing quality assurance functions shall report to a management level such that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any

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[1] While the term "licensee" is used in this appendix, the quality assurance requirements are applicable to whatever design, fabrication, assembly and testing of the package is accomplished with respect to a package prior to the time a package approval is issued.

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location where activities subject to this Appendix are being performed shall have direct access to such levels of management as may be necessary to perform this function.

2. QUALITY ASSURANCE PROGRAM

The licensee shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. The quality assurance program shall be documented by written procedures or instructions, and shall be carried out in accordance with those procedures throughout the period during which packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated function of these organizations. The quality assurance program shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools and skills to attain the required quality, and the need for verification of quality by inspection and test.

The licensee shall base the requirements and procedures of his quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The importance of malfunction or failure of the item to safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

3. DESIGN CONTROL

Measures shall be established to assure that applicable regulatory requirements and the package design, as specified in the license, for those materials and components to which this appendix applies, are correctly translated into specifications, drawings, procedures and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the materials, parts, and components of the packaging.

Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. Design control measures shall be applied to items such as the following: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.

Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the package approval require Commission approval.

4. PROCUREMENT DOCUMENT CONTROL

Measures shall be established to assure that applicable requirements of this part which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by his contractors or subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this part.

5. INSTRUCTIONS, PROCEDURES AND DRAWINGS

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. These shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

6. DOCUMENT CONTROL

Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another organization.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement specifications shall be available prior to installation or use of such material and equipment. This documentary evidence shall be retained by or be available to the licensee and shall be sufficient to identify the specific requirements met by the purchased material and equipment. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the licensee or designee at intervals consistent with the importance, complexity and quantity of the product or services.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

Measures shall be established for the identification and control of materials, parts, and components. These measures shall assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective materials, parts and components.

9. CONTROL OF SPECIAL PROCESSES

Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

10. INSPECTION

A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Such inspection shall be performed by individuals other than those who performed the activity being inspected. Examination, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work shall not proceed without the consent of its designated representative, are required, the specific hold points shall be indicated in appropriate documents.

11. TEST CONTROL

A test program shall be established to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

Measures shall be established to assure

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that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.

13. HANDLING, STORAGE AND SHIPPING

Measures shall be established to control the handling, storage, shipping, cleaning and preservation of materials and equipment to be used in packaging in accordance with instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels and temperature levels shall be specified and provided.

14. INSPECTION, TEST AND OPERATING STATUS

Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent by-passing of such inspections and tests.

Measures shall also be established for indicating the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

16. CORRECTIVE ACTION

Measures shall be established to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

17. QUALITY ASSURANCE RECORDS

Sufficient written records shall be maintained to furnish evidence of activities affecting quality. The records shall include the following: design records, records of use and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the licensee shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

18. AUDITS

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.

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