

QUALITY ASSURANCE PROGRAM  
for  
Shipping Packages of Radioactive Material  
Pursuant to  
10 CFR 71 - Appendix E

Source Production and Equipment Company, Inc.  
625 Oxley Street  
Kenner, Louisiana 70062

Louisiana Radioactive Material License LA-2966-L01

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## 1.0 ORGANIZATION

- 1.1 Source Production and Equipment Company, Inc. is solely responsible for the planning and implementation of the quality assurance criteria for radioactive material shipping packages.
- 1.2 No quality assurance functions are delegated to outside entities.
- 1.3 The Radiation Safety Officer (RSO) is responsible for administration of the quality assurance program. This individual is required to have adequate training and experience in all aspects of the design, manufacture and use of the radioactive material shipping packages, including the quality assurance functions. Qualifications are evaluated by the President who is responsible for staffing the position with a qualified individual and who may be the RSO himself because of the exceedingly small number of positions. Radiation Safety qualifications of the RSO are also evaluated by the radiation control agency which issues the radioactive material license under which the radioactive material shipping packages are manufactured, and which evaluates and approves the usage of the shipping package.
- 1.4 Individuals having specific quality control functions are empowered in a procedural manual to exercise final control over all processes, materials and packages under their authority, including curtailment.

## 2.0 QUALITY ASSURANCE PROGRAM

- 2.1 The President and Vice-President are individually associated with various aspects of the quality assurance program and they are responsible for its adequacy, including periodic audits by management and external evaluations where warranted.
- 2.2 Distribution of the quality assurance program, procedures, requirements, directives and related documents is administratively managed by the RSO using numbered copies and signed acknowledgments to assure proper distribution.

- 2.3 This quality assurance program encompasses the design, fabrication, assembly, testing, use and maintenance of each radioactive material shipping package, including but not limited to:
  - 2.3.1 Procedures for the design, testing and manufacture of SPEC packages.
  - 2.3.2 Procedures for establishing that other packages have been designed and manufactured in accordance with applicable regulatory requirements.
  - 2.3.3 Procedures for proper use and maintenance of all packages.
- 2.4 The President exercises final authority over any decisions concerning any aspects of the quality assurance program.
- 2.5 Training
  - 2.5.1 Personnel are qualified and/or trained in accordance with the SPEC radioactive material license. Instruction of employees directly associated with shipments of radioactive packages and/or quality assurance procedures will be performed by the RSO or their supervisor, and records of such training will be maintained.
  - 2.5.2 Periodic training and/or additional training will be performed as indicated by periodic audits or evaluations.
- 2.6 The fabrication, assembly, testing and maintenance of shipping packages are conducted in accordance with the provisions of the radioactive material license using specified equipment, procedures and processes.
- 2.7 Completeness of the design and manufacturing requirements are controlled by check-lists prior to final inspections and tests preceding use.
- 2.8 Employees are instructed during training that quality assurance requirements are mandatory. Also, quality assurance requirements are specified to be mandatory in contracts and orders issued to outside entities.

### 3.0 DESIGN CONTROL

- 3.1 Procedures are established by the RSO to a) specify appropriate standard and requirements; b) monitor adherence to specified standards and requirements; c) review designs; d) specify adequate testing; e) control revisions; and f) document the design review, verification and approval.
- 3.2 The RSO will review all designs to verify the inclusion of all applicable regulatory requirements in the documentation.
- 3.3 Applicable standards will be included in the design documentation and any revisions require the written approval of the RSO.
- 3.4 Written procedures are established for the adherence to specified standards, requirements and specifications within established limits throughout the manufacturing process by appropriate inspections, measurements and testing.
- 3.5 Verification of designs are checked by independent review, alternate calculations or by testing a prototype when necessary to substantiate radiation, mechanical, thermal or process parameters.
- 3.6 Original design and verification are normally performed by the President and Vice-President except that an outside consultant may be utilized when necessary.
- 3.7 Design and specification changes, including field changes, are subject to original criteria and such revisions require the written approval of the RSO.
- 3.8 Design review and/or verifications are conducted internally by the President and/or Vice-President, and they may be conducted externally by a consultant. Regulatory reviews are performed by the NRC and/or DOT to meet licensing and/or certification requirements.

### 4.0 PROCUREMENT DOCUMENT CONTROL

- 4.1 Procurement documents pertaining to materials and services which have been identified to be administratively controlled will be reviewed and approved by signature by the RSO. Copies of these documents will be retained for a prescribed period for audit and/or inspection.

- 4.2 Procurement documents will specify compliance with specific 10 CFR 71 Appendix E identified sections when applicable.
- 4.3 Procurement documents will refer to appropriate regulations material specifications and recognized codes when applicable.
- 4.4 Procurement documents will specify all documentation pertaining to specification, process and tests which must be prepared by the vendor and submitted to SPEC for review and approval or maintained by the vendor.
- 4.5 SPEC will reserve the right on applicable procurement documents to inspect materials, review required records and audit applicable procedures at the vendor's facility.
- 4.6 Revisions to procurement documents are subject to original review and approval criteria.

#### 5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

- 5.1 All functions performed during manufacturing, use and maintenance which affect radiation safety will be specified by procedures and/or drawings.
- 5.2 Instructions, procedures and drawings will be reviewed and approved by the RSO based on accepted practices and industry standards.
- 5.3 The President and/or Vice-President will review and approve all inspection plans, testing procedures, processes, documentation and/or revisions affecting radiation safety of the package.

#### 6.0 DOCUMENT CONTROL

- 6.1 Documents pertaining to the design, manufacture, testing. Use and maintenance of radioactive material packages will be reviewed, approved and issued by the RSO.
- 6.2 Revisions to documents are based on original criteria and approval.
- 6.3 The RSO is responsible for issuing approved revisions prior to implementation.
- 6.4 Required quality assurance documents will be available for reference at each work location where a referenced function is performed.

- 6.5 Distribution of required documentation is controlled by numbered copies and signed acknowledgements.

#### 7.0 CONTROL OF PURCHASED MATERIALS, PARTS AND COMPONENTS

- 7.1 Appropriate employees will evaluate a vendor's capability to provide materials, components and materials which meet specified acceptance criteria.
- 7.2 Vendors are evaluated on their ability to meet applicable 10 CFR 71 Appendix E criteria; and/or their previous performance on supplying similar materials; and/or a site survey of their facilities and quality control program.
- 7.3 Summaries of vendor evaluations will be maintained for review and inspection.
- 7.4 Site inspections of a vendor during preparation of critical materials and components will be conducted when specified in accordance with established design procedures.
- 7.5 SPEC will require that all vendors submit documentation that adequately identifies the item(s) and certifies the specific procurement requirements which have been met or not met.
- 7.6 Incoming materials and components will be inspected at receipt to determine their proper identification and to establish that they meet prior specified criteria.
- 7.7 Receipt inspection records and required documentation must be present prior to release of materials and components for use.
- 7.8 Released materials and components will be tagged to identify individual items available for use.

#### 8.0 IDENTIFICATION AND CONTROL OF MATERIALS PARTS AND COMPONENTS

- 8.1 All material, parts and components will be identified by part and/or drawing number which will be located either on the individual item or on records directly associated with the item.

- 8.2 Items critical to radiation safety functions will be uniquely identified with their individual procurement documents, acceptance tests and manufacturing batch.
- 8.3 Identification of items will not adversely affect their function, and verification is documented by check list that appropriately identifies items used during each manufacturing process.

## 9.0 CONTROL OF SPECIAL PROCESSES

- 9.1 Welding, cleaning and leak testing are performed in accordance with established written procedures and the SPEC radioactive material license.
- 9.2 Industry standard and/or radioactive material license requirements apply to welding, cleaning and leak testing processes and personnel qualifications.
- 9.3 Welding parameters, instrument calibrations, written procedures and specified personnel qualifications and/or training are maintained on a current status.
- 9.4 Casting of depleted uranium shields is performed by an outside contractor and this process is controlled by the methods specified in Item 7.0 of this quality assurance program.

## 10.0 INSPECTION

- 10.1 The RSO maintains a documented inspection program which addresses the criteria in this quality assurance program.
- 10.2 The President, Vice-President and/or RSO may have inspections functions, and an outside consultant will be used if warranted. Inspection functions may be delegated to appropriate employees, who did not perform the work being inspected, as permitted by the limited staff and multiplicity of duties performed by each employee.
- 10.3 The above personnel are well qualified by training and extensive experience to perform all design, manufacturing, testing maintenance and usage of all shipping packages at SPEC, and their qualifications are a matter of record under the Louisiana radioactive material license issued to SPEC. Qualification records of other designated employees are maintained.

- 10.4 Modifications, repairs and replacements are inspected in accordance with original criteria or approved documented alternatives.
- 10.5 Incorporated in written procedures are specified points during the manufacturing, maintenance or shipping processes which must be inspected by a designated individual prior to proceeding.

#### 11.0 TEST CONTROL

- 11.1 A documented test program will be established for each package and/or component which adequately demonstrates that it will perform satisfactorily in service. Records of test results will be maintained for inspection and review.
- 11.2 Modifications or repairs are tested in accordance with original criteria or approved documented alternatives.
- 11.3 Test results are analyzed by the RSO to determine acceptability.

#### 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

- 12.1 Instrumentation used to measure or evaluate critical parameters related to the radiation safety of a shipping package will be calibrated at specified intervals as required by regulations, standards, codes and/or all factors required to provide a known accuracy of measurement.
- 12.2 Calibration data will be uniquely identified with an individual instrument.
- 12.3 Whenever an instrument is determined to be out of calibration an evaluation of the consequences will be documented and appropriate corrective action taken, if any.
- 12.4 Calibrations will be based on national or industry standards and/or procedures, where applicable.

#### 13.0 HANDLING, STORAGE AND SHIPPING

- 13.1 Receipt, preparation and shipment of radioactive material packages are performed by individuals qualified under the SPEC radioactive material license in accordance with documented procedures.



- 13.2 Check lists are used where possible to insure that applicable requirements of the NRC certificate of compliance and/or DOT regulations are met prior to each shipment.
- 13.3 Shipping papers will be completed as required by DOT.
- 13.4 Scheduling and routing of all radioactive material shipments will be coordinated with the recipient to facilitate its safe and expeditious transport.

#### 14.0 INSPECTION, TEST AND OPERATING STATUS

- 14.1 Each package being manufactured will be accompanied by a check-list which shows the satisfactorily completed processes. Each completed or reused package will be tagged to indicate its operational status.
- 14.2 Administrative procedures are established which specify how each package or component is identified and traceable to the initiator at each manufacturing stage or during processing for shipment.
- 14.3 Flow charts are established which provide for the approved sequential processes during manufacture and shipment preparation. Alternatives must be individually approved and documented by the RSO.
- 14.4 Packages not meeting established criteria are tagged to prevent unauthorized use.

#### 15.0 NONCONFORMING MATERIALS, PARTS OR COMPONENTS

- 15.1 Items not meeting established criteria will be identified and subject to established procedures for repair, acceptance or disposal. Manufacturing areas or operating stations where the fault originated will be informed.
- 15.2 Documentation on rejected items will include identification of the items, description of the fault, required inspection after repair and signature authorization for repair or destructive disposal.
- 15.3 Rejected items are segregated and tagged to prevent unauthorized use.
- 15.4 Acceptability of repaired or reworked items will be based on original criteria or an equivalent inspection and/or testing method specifically documented and approved by the RSO.

## 16.0 CORRECTIVE ACTION

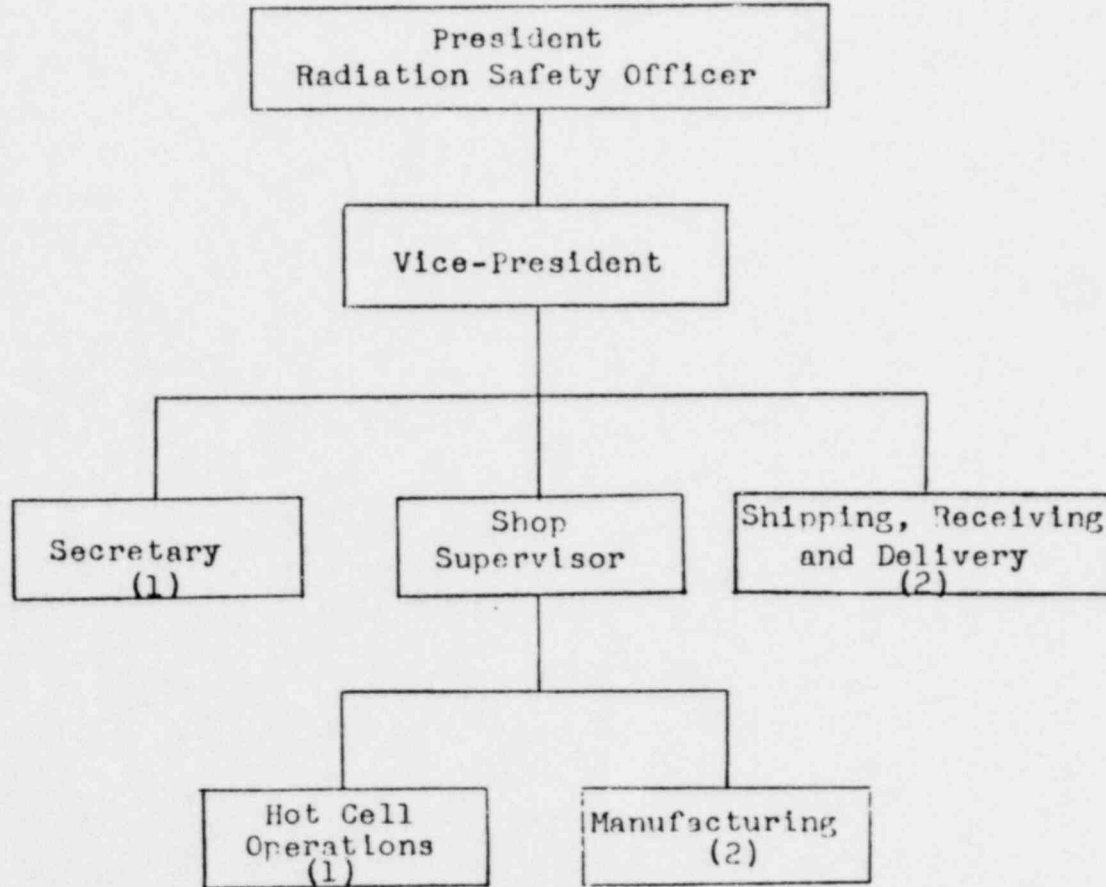
- 16.1 All items which do not meet established quality control criteria are reviewed and evaluated by the RSO to determine if corrective action is warranted.
- 16.2 Whenever quality control anomalies are symptomatic then corrective action will be implemented to prevent recurrence.
- 16.3 Corrective action is documented and subsequent reviews are conducted to verify proper implementation and its effectiveness so that the corrective action can be incorporated into revised procedures and its documentation terminated.

## 17.0 QUALITY ASSURANCE RECORDS

- 17.1 Required regulatory records including quality assurance records required and identified under this program are maintained in accordance with retention requirements.
- 17.2 Quality assurance records required and identified under this program include records such as design documentation, operational logs, review summaries, inspections, tests, audits, personnel qualifications and material specifications.
- 17.3 Quality assurance records are identified and retrievable.
- 17.4 Quality assurance records are listed by category and storage location.
- 17.5 Records pertaining to the design of a package will be maintained for the life of the package; and all other records will be retained as specified by applicable regulations, or if not specified for a period of two years.
- 17.6 Inspection and test results will normally contain:
  - 17.6.1 Individual and equipment identification
  - 17.6.2 Purpose of inspection and/or test
  - 17.6.3 Description or reference to the inspection or test method.
  - 17.6.4 Date and results of test or inspection
  - 17.6.5 Evaluation of results
  - 17.6.6 Quality assurance anomalies

## 18.0 AUDITS

- 18.1 Audits will be performed by the President, Vice President and/or RSO. When warranted, an outside consultant may be used.
- 18.2 Audits are performed pursuant to documented procedures and/or check lists.
- 18.3 Audit results are recorded and reviewed with individuals performing the functions audited.
- 18.4 Deficiencies revealed by an audit will be re-audited at a time specified in the initial audit report to ascertain that the deficiency has been corrected and recurrence minimized.
- 18.5 The President, Vice President and/or RSO will prescribe corrective actions for deficiencies revealed during an audit.
- 18.6 Audits of specific quality assurance functions are performed whenever a procedural deficiency has been revealed by an inspection or test. All quality assurance functions will be audited at least annually and the total quality assurance program evaluated to determine its effectiveness.



Organization Chart

Source Production and Equipment Company, Inc.