

JL SHEPHERD & ASSOCIATES

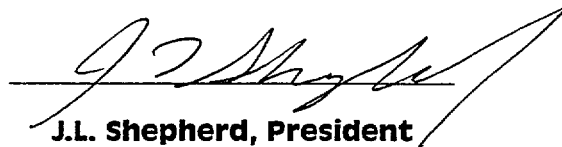
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QUALITY ASSURANCE PROGRAM PLAN

APPROVED BY:



J.L. Shepherd, President

October 5, 1995

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INTRODUCTION

J.L. Shepherd and Associates maintains a Quality Assurance Program, described in this manual, combining both Annex 1 *"Quality Assurance Programs Applicable to Design, Fabrication, Assembly, and Testing of Packaging Used in the Transport of Radioactive Material"* and Annex 2 *"Quality Assurance Programs Applicable to Procurement, Use, Maintenance, and Repair of Packaging Used in Transport of Radioactive Material"*, of USNRC Regulatory Guide 7.10 *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, Revision 1, June 1986, per Section 71.101 *"Quality Assurance Requirements"* of Subpart H of 10CFR Part 71. Additionally, in August 1989, the USDOE, Westinghouse Hanford, audited, evaluated and found JLS&A's Quality Assurance Program as meeting compliance criteria to ANSI/ASME NQA-1, 1986 Edition, Basic Requirements 1-18, which meets all quality requirements as called out in 10CFR21.

J.L. Shepherd & Associates manufactures shipping containers for radioactive materials in Type A, Type B and larger quantity categories, in both "Normal Form" and "Special Form", including but not limited to calibrators and irradiators which qualify as DOT Type 7A Containers, as called out in 10 CFR 71, Subpart H, for its own use and the use of others. J.L. Shepherd & Associates also uses its own and other manufacturer's approved containers and devices for the transportation of radioactive materials as described above. This Program pertains to quality assurance in design, testing, manufacture, procurement, use, maintenance and repair of the above referenced containers. Because of the specialized nature of its business, i.e., products involving radioactivity, J.L. Shepherd & Associates maintains all necessary equipment for calibration and radiological control of its products. Members of the Radiological staff of J.L. Shepherd & Associates personally perform all tests on equipment related to this aspect of operation, in addition to Quality Assurance/Control responsibilities.

Type A quantity shipping containers, including but not limited to irradiators and calibrators, and sources therein, appear in the *"Registry of Radioactive Sealed Sources and Devices, Safety Evaluation of Device"* of the U.S.N.R.C., when approval is applicable. All Type B shipping containers either have an U.S.N.R.C. issued *"Certificate of Compliance for Radioactive Materials Packages"* or are D.O.T. specification packages per 49CFR178 and, when applicable for international shipments a U.S.D.O.T. *"Competent Authority Certification for Type B Radioactive Materials Package Design"*. All certifications are in accordance with 10CFR71.

1.1 & 2.1 ORGANIZATION.

1. Statement of Responsibility.

J.L.Shepherd and Associates (hereinafter referred to as "JLS&A") implements the Quality Control/Quality Assurance Program, as follows, as normal operation procedures in the design, testing, manufacture, procurement, use, maintenance and repair of Type A, Type B and large quantity categories of both "Normal Form" and "Special Form" shipping containers for radioactive materials, for its own use and the use of others, as well as for containers made by other manufacturers. It is the policy of JLS&A to perform all important-to-safety work in accordance with the quality assurance requirements specified in 10 CFR 71, Subpart H, and as described in the QA Program plan and related implementing procedures.

The management of JLS&A is responsible for the continued implementation of this program on future projects.

2. Structure and Authority.

JLS&A has an established organizational structure with procedures which ensures that:

- (1) In all areas of quality assurance, the assignment and responsibility for each area, is achieved and maintained by appropriately qualified and trained personnel.
- (2) That conformance thereof is verified by either individuals or groups not directly responsible for work performed or in the case of multiple functions, conformance is later verified by other individuals or groups in evaluations or inspections.
- (3) That quality verification and reporting to management hierarchy precludes conflict of interest, i.e. interdependent from costing and scheduling, in management areas of responsibility. All personnel involved with Quality Assurance/Control have the authority and responsibility, in writing, to stop at any time, the further process of any nonconforming material, work, shipment, delivery or installation with direct recourse to upper management. QA/QC Management personnel have the further authority and responsibility, in writing, to supervise further processing after corrections, for any procedural reason, have been made.

JLS&A has established an Organization Chart, which identifies positions and functional infrastructure within the company which also describes these functions.

1.1 & 2.1 ORGANIZATION, continued.

3. Minimum Job Qualifications.

Accounting Staff:

High School Diploma or Equivalency Test
A Trade School or College or BA College Preferred
or 5-10 years work experience, or experience within JLS&A

Engineering Staff:

High School Diploma or Equivalency Test
4 Year College Degree in Engineering, additional science background preferred
4 years work experience, or experience within JLS&A

Electronics Staff:

High School Diploma or Equivalency Test
AA trade School or College Degree or BA College Degree preferred
or 4-10 years work experience, or experience with JLS&A except for entry level positions.

Manufacturing Staff, Welders, Machinists, Fabricators, Assemblers

High School Diploma or Equivalency Test
AA Trade School or College Degree and/or Certificates, Journeyman Level,
Blue Print Reading Ability
2-4 years work experience related to position offered, or experience within JLS&A
Pass competency test administrated by JLS&A
Note: entry level or starting positions only require High School Diploma or Equivalency Tests; i.e. shop helpers, delivery persons, etc.

Office/Sales/Administrative Staff:

High School Diploma or Equivalency Test
2-4 years related work experience to position offered,
except for starting, clerical or temporary positions.

Operations/Production Staff:

High School Diploma or Equivalency Test
AA Trade School or College or BA College Degree and/or workplace experience
2-4 years work experience, or experience within JLS&A

Purchasing Staff:

High School Diploma or Equivalency Test
2-4 years work experience, or experience within JLS&A

QA/QC Staff:

High School Diploma or Equivalency Test
AA Trade school or College or BA College Degree and/or workplace experience
Blueprint reading ability
2-4 years workplace experience or experience within JLS&A

QA/QC Lead Auditor Staff:

Qualifications will meet ANSI/ASME NQA-1-1979, Supplement 2S-3
or JLS&A qualifications if the numbers of audits in 2S-3 are not achieved.

1.1 & 2.1 ORGANIZATION, continued.

3. Minimum Job Qualifications - continued.

Radiological Staff:

Cognizant Radiological Personnel:

High School Diploma or Equivalency Test, some college or Health Physics classes or experience preferred

Passed JLS&A 40 hour Radiological Class and Test and State of California Radioactive Materials License training qualifications

Supervisory personnel:

the above plus meeting State of California's evaluation to become a Named User on JLS&A's Radioactive Materials License.

Some college science or chemistry background preferred or 5-10 years related work experience.

Shipping/Receiving Staff:

High School Diploma or Equivalency Test

some college or 2-5 years work experience preferred, or experience within JLS&A.

1.2 & 2.2 QUALITY ASSURANCE PROGRAM.

1. Documentation - Master Index of QA Procedures and Implementation.

| Implementing Document* | Title | 10CFR71 Subpart H Criteria | Description |
|------------------------|--------------------------------|----------------------------|--|
| QAM, QP 1.0 | Organization Chart | 1 | Identifies JLS&A internal organizational structure & relationships in performance of activities affecting quality. Status: complete. |
| QAM, QP 1.1 | Job Descriptions | 1. | Identifies individual QA/QC job functions within organization structure, responsibilities, authority and duties. Status: complete. |
| QAM, QP 2.0 | Quality Assurance Program Plan | 2. | Describes established procedures for JLS&A's documented QA/QC program, originally implemented in 1979, under 10CFR71, Appendix E, currently Subpart H. Status: complete. |
| QAM, QP 3.0 | Design Control | 3. | Describes established procedures for control of design process, input and verification directly related to NRC issued <i>"Certificate of Compliance for Radioactive Materials Package Design"</i> , and USDOT <i>"Certificate of Competent Authority for Type B Qualities"</i> , and USNRC issued <i>"Registry of Radioactive Sealed Sources & Devices"</i> for Type A Quantity shipping containers, including but not limited to irradiators, calibrators and sources contained therein, in addition to 10CFR71, Subpart H. Status: complete. |
| QAM, QP 4.0 | Procurement Document Control | 4. | Describes established procedures for control of procurement control of procurement document (purchase order) preparation, reviews, concurrences, and approvals, including but not limited to technical requirements, documentation, access to suppliers for audits, certifications and changes. Cross reference to QAM, QP 6.1. Status: complete. |
| QAM, QP 5.0 | Manufacturing Control | 5. | Describes established procedures for documented instructions, procedures, drawings, and acceptance criteria, with a clear sequence of action, for important to safety activities. Status: complete. |
| QAM, QP 6.0 | Document Control | 6. | Describes established procedures for document generation, document generation, issuance and changes, including but not limited to drawings and specifications, design changes, procurement documents, QA/QC manuals, inspection & test procedures, nonconformance reports, & corrective action reports, with a clear sequence of action. Status: complete. |

1. Documentation - Master Index of QA Procedures & Implementation, continued.

| Implementing Document* | Title | 10CFR71 Subpart H Criteria | Description |
|------------------------|---|----------------------------|--|
| QAM, QP 7.0 | Control of Purchased Material, Equipment & Services | 7. | Describes procedures for procurement document planning, selection of procurement sources, bid evaluation & award, supplier conformance control, verification activities, controlling nonconformances and records, with an established clear sequence of action contained therein. Status: complete. |
| QAM, QP 8.0 | ID & Control of Materials, Parts & Components | 8. | Describes procedures for the identification, control & conditional releases of materials, parts & components, with materials, parts and components, with an established clear sequence of action contained therein. Status: complete. |
| QAM, QP 9.0 | Special Processes | 9. | Describes procedures for the control of special processes, special processes, including qualifications of procedures, equipment, personnel, operations and records, with an established clear sequence of action contained therein. Status: complete. |
| QAM, QP 10.0 | Inspection Control | 10. | Describes procedures for Inspection planning, inspections & their qualifications, with an established clear sequence of action contained therein. Status: complete. |
| QAM, QP 11.0 | Test Control | 11. | Describes requirements, procedures & result documentation & evaluation of test control, with an established clear sequence of action contained therein. Status: complete. |
| QAM, QP 12.0 | Calibration Equipment | 12. | Describes procedures for calibration equipment, with an established clear sequence of action contained therein. Status: complete. |
| QAM, QP 13.0 | Handling, Storage & Shipping | 13. | Describes procedures for handling, storage & shipping including preservation, release & delivery, with an established clear sequence of action contained therein, in accordance with regulatory guidelines, licenses, approvals & Certificates of Competent Authorities. Status: complete. |
| QAM, QP 14.0 | Inspection, Test & Operating Status | 14. | Describes established measures that ensure identification of test & operating status is known to QA/QC personnel, & that personnel, and that status indicators are procedurally controlled, with a clear sequence of action. Status: complete. |

1. Documentation - Master Index of QA Procedures & Implementation, continued.

| Implementing Document* | Title | 10CRF71 Subpart H Criteria | Description |
|------------------------|--|----------------------------|---|
| QAM, QP 15.0 | Control of Nonconforming Material, Parts or Components | 15. | Describes established procedures for control of nonconforming materials, parts or components, including identification, segregation, disposition & evaluation thereof, with a clear sequence of action therefore. Status: complete. |
| QAM, QP 16.0 | Corrective Action | 16. | Describes established procedures for corrective action, including reporting, monitoring and closeout, with a clear sequence of action therefore. Status: complete. |
| QAM, QP 17.0 | QA Records | 17. | Describes established procedures concerning all aspects of QA records, including, design, procurement, manufacturing, installation, evaluations, nonconformance reports, inspection results, tests, audits, analysis, as-built drawings & specifications, personnel qualifications, procedures, equipment, calibration procedures, training records, & corrective action reports, including records generation, indexing and classification, receipt, retrieval, disposition, storage, preservation & safekeeping thereof. Status: complete. |
| QAM, QP 18.0 | Audits | 18. | Describes established procedures for a comprehensive audit program, including scheduling, team selection, audit documents, pre and post audit conferences, reporting and response and follow up action, with a clear sequence of action. Status: complete. |

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS.

Applicability

1. Statement of Verification of Assessment of Quality Assurance Program.

The Officers of the Quality Assurance Program (hereinafter referred to as QAP), in addition to daily communications, hold scheduled conferences with appropriate departments, to review the status of each job in regard to design, purchasing, work process releases, work-in-progress, corrective actions (if necessary) and shipment on whatever phase of operation is currently pertinent to that job as well as overall views of work-in-progress. Annual audits to determine compliance, as well as for accounting and inventory purposes, are performed and reviewed by officers of the QAP.

2. Distribution of Quality Assurance Program Manuals.

Each officer of the QAP retains a copy of the QA/QC Program Manual. A master copy is kept and a copy is made available to any employee or auditor of JLS&A, upon request. (Each new employee is made familiar with the manual as a part of the Training Program.) QA records personnel are responsible for distributing approved revisions to all internal copies of the manual and advising the holders thereof of such revisions.

3. Statement of Verification that Quality Assurance Program Requirements are Applicable to Outside Vendors.

JLS&A retains the right to supervise and inspect products at a vendor's and/or contractor's facilities and to reject nonconforming materials. JLS&A has agreements with vendors and subcontractors stating this requirement in order to maintain mandatory QA/QC requirements.

4. Safety-related Systems, Structures and Components Controlled by Quality Assurance Program.

All mechanical, electrical and electronic components as well as components and completed systems are controlled and covered by the QAP by specification, drawing and/or operating manual, where applicable.

5. Statement of Verification of Resolution of Disputes.

If and when disputes arise concerning the quality of a product between the different departments, a review of the product's functions, specifications and compatibility with the QA/QC Program as well as NRC and DOT criteria is made by the QA officers and the appropriate departments. Reviews are made at scheduled conferences or as needed when all pertinent data is gathered. Agreements are subject to review by President/General Manager for final approval. In the event of unreachable absence of the President/General Manager, a review board has been established, with final resolution dispute to be arbitrated by Acting President.

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Applicability, continued.

6. Statement of Verification that Training Program is Implemented.

JLS&A maintains a training program for all new employees and employees assuming additional responsibilities. This program provides an examination of the QA/QC Program and the purpose of maintaining this program. Each QA officer's authority is delineated and the effect of that authority is demonstrated as well as an explanation of how the employee functions within the QA/QC Program. Complete documentation of this program is on file at JLS&A.

In as much as JLS&A is a small business, each employee is not only responsible to the QA officers, but is directly responsible for his/her own work within the company. Hence, in the training program, each individual is trained (and continuously monitored in the system of checks and balances maintained in review by the QA officers to whom the employee is responsible) to be effective in the continuous effect functioning of the QAP.

All personnel are adequately licensed or certified, i.e, Named Individual User, Cognizant Radiological Personnel, welders, machinists, when applicable. All licenses and certifications are kept current. If an employee is not performing to the specifications maintained by JLS&A, he/she is subject to a retraining program before continuing with his/her responsibilities and duties. If this is not successful, employment is terminated after the appropriate notice has been given and legal responsibilities fulfilled.

7. Statement of Verification that Quality-related Activities are Performed According to Predetermined Measures.

JLS&A performs all quality-related procedures, i.e., inspections and testing, in accordance with predetermined procedures which specify the equipment to be used and environmental conditions, if necessary. Inspectors are required to determine and document that all prerequisites have been satisfied before inspection and/or testing.

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Scope.

For each job undertaken by JLS&A, prior to the time purchase orders are issued to sub-contractors or vendors, a work plan is drawn up for that contract.

The work plan includes:

1. A complete work schedule including the purchase of long and short lead-time items.
2. A work order sheet which includes special instructions, job details and a drawing list.
3. A complete schedule for outside purchases (Bill of Materials) and stock withdrawals (cutting list).
4. A complete quality assurance program including, but not limited to, contracted parts, in-house manufactured components in process, with specific inspection points, final assembly and final check-out subsequent to source loading, as well as maintenance, handling, storage & cleaning for reusable shipping containers, as required.

This Quality Assurance Program takes into consideration the quality control procedures that will be necessary for satisfactory performance of the contract and outlines detailed specifications for raw materials, subcontracted parts and in-house manufactured components. This program also specifically calls out quality assurance inspection check points, time of inspection, inspection instructions and disposition of conforming or non-conforming parts, as well as equipment to be used by vendors, subcontractors and manufacturing personnel of JLS&A.

1. Procedures, Documentation and Records.

Intermediate and final inspection forms and records are permanently maintained at JLS&A, along with all necessary radiological data such as leak test certificates and any other records that pertain to the radiological aspect of the equipment as required by law, regulatory authorities and good quality assurance practices.

Included in the Quality Assurance records, which become a permanent file for each job, are the following forms:

1. Quotation/Customer Purchase Order/Customer Licensing
2. Work Order
3. Complete Drawing List
4. Bill of Materials
5. Purchase Orders with Certifications
6. Engineering Change Orders
7. Materials Rejection Form
8. Mechanical Components: Quality Control Certification
9. Electrical Systems Check List
10. Assembly Check List - Prior to Loading
11. QA/QC Operation Check List
12. Health Physics Check List - Subsequent to Loading
13. Installation/Operation Manual and appropriate Certifications, i.e. Leak Test, Calibration, External Radiation Levels
14. Shipping Check List
15. Container/Overpack Inspection Check List
16. Shipping Document and Bill of Lading

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Scope, continued.

1. Procedures, Documentation and Records continued.

When necessary, forms are also prepared and forwarded to subcontractors covering the various areas of quality control to be checked by the, as outlined in Quality Planning, and then returned to JLS&A to be maintained in the permanent file.

Prior to assembly, mechanical components and fabricated parts are checked for material and dimensions by the operator or Production/Operations Manager and the QA Engineer. Also prior to assembly, all electrical system components are checked for operation and/or function by the assembler. An operational check is performed by the assembler in conformity with the QA Manager and/or Engineer with specific operation being determined by the Operation Manual for each unit. Criteria for these inspections is determined by individual drawings, per individual unit, as called out by Engineering and the QA/QC department.

Prior to radioactive materials loading, assembled parts are inspected by the assembler or Production/Operations Manager and by the QA Engineer, with criteria being determined by the individual drawings and specifications for the individual unit.

The above-mentioned Quality Assurance Forms are accompanied by Material Rejection Forms to be used if required. These forms become a part of the permanent file. See Corrective Procedures for details.

Subsequent to radioactive materials loading, QA performs a complete operational and safety check on the unit (in accordance with the Operating Manual for that unit) a minimum of 25 times. After the unit has been loaded, Radiological performs another complete operational and safety check (minimum of 25 times), instrument calibration, unit calibration, leak test and external radiation level measurement are performed. Radiological also prepares radiological shipping information in the form of a "Shipping Document", inspects the shipment and certifies the Bill of Lading for that shipment.

As part of the costing records for all jobs, all direct costs as attributed to quality assurance, are included in a separate category and are available for purposes of evaluation and future planning. These costing records include all pertinent information needed to identify the correction of nonconforming materials and/or correction of defective workmanship.

2. Corrective Procedures.

A program for corrective procedures is maintained. This include the following:

1. A separate inventory location for non-conforming parts or cessation of nonconforming procedures.
2. Re-inspections of corrected parts or procedures in the normal course of procedures of the corrected deficiencies and records thereof.
3. Analysis of scrapped products to determine reasons of nonconformity.
4. Analysis of methods and processes of work performed.
5. Introduction of required improvements.
6. Monitoring and review of corrective procedures to assure their effectiveness.

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Scope, continued.

3. Facilities and Standards.

Drawings and Specifications - Engineering maintains the central, current drawings and specification files, as well as permanent files containing archival drawings and specifications. Individual job files are permanently maintained, including but not limited to all pertinent drawings, correspondence, copies of contracts and/or customer's purchase order, copy of customer's license (if applicable), copies of all purchasing records and copies of all Quality Assurance/Radiological records and forms which are maintained by QA Records maintenance personnel.

Prior to release for fabrication, all drawings and specifications are to be reviewed for adequacy in regard to standard design practices and end-product use. Approval by Engineering, QA and Radiological, when applicable, is required prior to release.

Changes are to be documented on the drawings incorporating the current design and/or specifications. Changes require the approval of Engineering, QA and Radiological, when applicable.

Sales, Engineering or Radiological is responsible for transmitting change information to the customer, if required. Production Control and Engineering are also responsible for transmitting this information to the appropriate departments.

Engineering is to be responsible for the removal of obsolete drawings and specifications from all issue points.

The following sections of the Quality Assurance Program may be broken into three categories:

1. Those shipping containers/overpacks made in conformance with specific DOT fabrication regulations as called out in Department of Transportation regulations such as, but not limited to, Paragraphs 179.104 and 178.194;
2. Shipping containers and overpacks made in conformance with DOT general packing performance criteria such as, but not limited to Paragraph 178.350;
3. Shipping containers and overpacks designed to ship large quantities of radioactivity for which USNRC Certificate of Compliance are required.

4. Drawing Control.

Because of the nature of the products (products involving radioactivity and packages used to transport radioactive materials) products are approved by the proper licensing authorities. The initial design of a product entails providing licensing authorities with all pertinent drawings, and information pertinent to approval criteria, i.e. prototype testing, design review, calculations, etc.

All drawings and design specifications must be checked for conformance with fabrication specifications as called out in the pertinent NRC or DOT specifications and approved by the cognizant Quality Assurance Manager, Senior Engineer, General Manager or Radiation Safety Officer, when applicable, before release for fabrication.

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Scope, continued.

4. Drawing Control, continued.

All drawings and fabrication specifications and all outside purchase specifications for units out-purchased, must be checked and approved by the Quality Assurance Manager, General Manager, Senior Engineer or Radiation Safety Officer, when applicable, prior to release for fabrication and/or purchasing. For this equipment, a prototype of each class of container will either be tested or calculations will be made and approved by the cognizant Quality Assurance Manager, General Manager, Senior Engineer or Radiation Safety Officer, when applicable. A Work Order (release for fabrication) will not be released until it can be shown that the containers will meet pertinent transportation requirements.

All pertinent data and calculations, including drawings, as called out in 10 CFR Part 71, related to license applications and Certification of Compliance applications for Type B and large quantity containers, will be checked and approved by the cognizant Quality Assurance Manager, General Manager, Senior Engineer or Radiation Safety Office, when applicable, prior to the submission of approval data to the USNRC. After the Certificate of Compliance and license have been issued and prior to the fabrication of the approved unit, all drawings and purchase specifications for material must be checked and approved by the Quality Assurance Manager, General Manager, Senior Engineer or Radiation Safety Officer, when applicable.

5. Purchasing.

As noted in previous sections, JLS&A prepares a schedule of materials to be purchased, as well as subcontracted, for each job prior to initiation of work on the contract. Purchase orders which are issued include a complete description of the item to be purchased, as well as any qualifications which must be met on Government or customer contracts and any certifications which may be required.

All pertinent drawings and manufacturing procedures are included as part of the purchase orders. JLS&A purchase orders also require that all suppliers or subcontractors to notify JLS&A and obtain approval before any changes in design, materials and/or dimensions are undertaken.

In cases where shipment is made directly to the customer, all instructions regarding shipment are included.

JLS&A maintains a qualified vendor's list for which vendors are selected, based upon past performance, as evaluated by the JLS&A, by past performance, in surveys and/or audits, performed by the appropriate departments.

In cases of subcontracts for manufacturing, JLS&A reserves the right to evaluate the vendor prior to the letting of subcontracts.

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Scope, continued.

5. Purchasing, continued.

Where the subcontractor provides the materials, these vendors are required to have or establish quality assurance procedures and records for raw materials received with material certification, if required, including performance of fabricated parts purchased. MSDS sheets required, when applicable.

In cases where materials of a radiological nature are subcontracted, JLS&A requires that these vendors submit information for permanent record relative to the quality of these products, i.e. leak test information on sealed sources, source certification, etc.

The following terms and conditions related to quality control will apply to all purchase orders for any type of radioactive sources purchased by JLS&A:

1. A signed leak test certificate which calls out the following:
Source descriptions, Source Serial Number, Date of Leak Test, Results of Leak Test
2. Source certification including chemical form of nuclide, assay date and "Special" or "Normal" form certification.
3. Shields: All shipping containers will have the following maximum levels of removable contamination:
Beta-gamma: 200dpm/100cm²
Alpha: 100dpm/100cm²

Attached to each packing list for incoming shipments, a signed report form (Shipping Document) is required, showing that the container has been checked both for contamination and for external radiation levels and giving actual values of these tests.

All shipments will be made to JLS&A in accordance with applicable DOT, NRC and IAEA regulations and all shipments will be properly labeled with the necessary data. Failure to comply with any of the above quality control requirements will result in rejection of the shipment, if immediately apparent, its immediate return, if return meets applicable shipping regulations, and immediate notification to the proper regulatory agencies, per 10CFR21.

6. Manufacturing Control.

Materials Control - Quality Assurance, working with Inventory Control Personnel, will insure that all non-radiological incoming materials are inspected and tagged as received and segregated on job shelves or placed into inventory locations, as applicable. Radiological insures that all radiological incoming shipments are inspected, tagged and segregated as applicable, per JLS&A's Radiological Safety Control Manual and State of California License.

Nonconforming Materials and Parts - Representatives from Engineering, Quality Assurance, Inventory Control and/or Radiological, as required, determine the continuing disposition of non-conforming parts.

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Scope, continued.

6. Manufacturing Control, continued.

Laboratory testing is to be employed as necessary and permanent records of such tests is maintained by Quality Assurance, and/or in job files or other files, as applicable.

Processing Control - Engineering, Production Control/Operations and Radiological, as applicable will be responsible for establishing and maintaining detailed work instructions for processing operations.

Engineering and Radiological, working in conjunction with QA, are responsible for establishing in-process inspection points. Such points are to be designated by Quality Assurance and Radiological.

QA and Radiological are responsible for determining that these inspections are performed and that parts are properly identified and segregated. This also applies to subcontractors and vendors.

7. Inspection Status.

Quality Assurance or Radiological provides the mechanism for identifying the inspection status of parts and assemblies. This may include tags, stamps or routing cards as appropriate.

8. Source Testing.

All sources are manufactured to JLS&A specifications, as approved by licensing authorities, meet "Special Form" prototype testing, per 10 CFR 173.496 Special Tests and ANSI Standard Testing, Classification and Performance Standard E35434, per Publication N542.

"Special Form" prototype testing, per 10 CFR 173.496 Special Tests:

1. Free drop - a free drop through a distance of 30' onto a flat essentially unyielding surface, striking the surface in such a position as to suffer maximum damage.
2. Percussion - Impact of the flat circular end of a 1" diameter steel rod weighing three pounds, dropped through a distance of 40" onto capsule. The capsule is placed on a sheet of lead, of a hardness number 3.5 or 4.5 on the Vickers scale and not more than one inch (1") thick, supported by a smooth, essentially unyielding surface.
3. Heating - Heating in air to a temperature of 1,475 degrees F., and remaining at that temperature for a period of 15 minutes, then allowed to cool.
4. Immersion - Immersion for 24 hours in water at room temperature. The water shall be pH6-pH8, with a maximum conductivity of 10 micro-ohms/cm.
5. Leak Test - Bubble test, capsule heated to 240 degrees F. in glycol, no bubbles should emerge. Alternately a vacuum test is used.

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Scope, continued.

8. Source Testing continued.

ANSI Standards Testing, Classification and Performance Standard E53434, per Publication N542, includes:

1. Temperature/Thermal Shock
2. External Pressure
3. Impact
4. Vibration
5. Puncture
6. Leak Test

Sources manufactured by others to JLS&A specifications are required to meet "Special Form" requirements for Type A₁ Quantities and ANSI Standard E53434, per Publication N542, with documentation.

Source capsules produced by JLS&A for encapsulation by others are required to meet "Special Form" prototype testing and ANSI Standard E35434, per Publication N542, with documentation. Nondestructive testing of liners and capsules also includes:

1. Preweld test specimen - capsule sectioned and checked for weld penetration, minimum penetration 75% of wall thickness.
2. Dimensional Check.
3. Helium Leak Test, prior to encapsulation.

Final Inspection - Final inspection requirements are to be established by Engineering, Radiological and Quality Assurance. Quality Assurance is responsible for assuring inspections are made and records of same maintained. Quality Assurance is also responsible for obtaining Government approvals as required.

9. Measuring and Test Equipment.

QA and/or Radiological, where applicable, is responsible for maintaining calibration equipment in first class condition, and establishing and maintaining calibration requirements and frequency. Records of all calibrations are maintained. QA and/or Radiological will monitor all vendors to assure that vendor's test equipment is properly maintained and calibrated.

10. Storage, Packaging, Delivery.

Engineering and Radiological, working in conjunction with QA, are responsible for establishing requirements for storage, packaging and delivery, including any special requirements for radioactive materials. Attention is given to government regulations, such as the USNRC and DOT regulations, in addition to contractual specifications.

QA and/or Radiological, where applicable, is responsible for assuring that these requirements are met and that records of such inspections are maintained.

1.2 & 2.2 SCOPE & APPLICABILITY OF QA PROGRAM, INCLUDING PERSONNEL & CONTROLLED CONDITIONS, continued.

Scope, continued.

10. Storage, Packaging, Delivery, continued.

An individual log sheet will be maintained for all Type B Certificate of Compliance shipping containers/overpacks routinely used by JLS&A in conjunction with transportation of radioactive materials.

11. Audits.

On an annual basis, JLS&A conducts internal audits, covering all aspects of the QA/QC Program, with emphasis on important to safety activities. Radiological audits are performed on a quarterly basis, due to JLS&A's State of California License requirements.

1.3 & 2.3 DESIGN CONTROL.

1. Statement of Verification of Responsible Design Procedures.

JLS&A has an established design procedure for its products. Because of the nature of our business and products (products involving radioactivity and packages used to transport radioactive materials), products are approved by the proper licensing authority and all new products have approvals pending. Therefore, in the initial design of a product, the first step is to provide licensing authorities with all pertinent drawings and information pertinent to approval criteria, i.e. prototype testing, design review and calculations.

After licensing authority approval and prior to release for fabrication, all drawings and specifications are to be reviewed for adequacy in regard to standard design practice and end-product use. Approval by Engineering, QA and Radiological, when applicable, is required prior to release.

Changes are to be documented through the use of revised drawings incorporating Specification Changes, if required. Changes require the approval of Engineering and Quality Assurance and Radiological, when applicable.

Licensing, Engineering and/or Radiological, when applicable, is responsible for obtaining licensing agency approval for changes as required and for transmitting change information to that agency, as required, i.e. additional prototype testing, drawings, design review and/or calculations.

Engineering is responsible for permanent vellum archives, as-built or in-process drawings, issuing current drawings and specifications and removing obsolete drawings and specifications from all issue points and placing them into permanent archives.

2. Statement of Verification of Compliance with Regulatory Requirements in Drawings.

Engineering, QA, Licensing, Sales and Radiological Departments, as applicable, review all product drawings, specifications for materials, procedures and instructions and design parameters with a final review by General Manager, Radiological and/or Senior Engineer on each job to verify that they meet all regulatory and licensing criteria, including codes, standards, maintenance, repair, inspection, handling, storage and cleaning requirements, as applicable, as incorporated into the product approval.

3. Statement of Verification that Quality Standards are Maintained.

Engineering maintains a complete list of specifications for each non-radiological product. Radiological maintains a complete list of specifications for radiological products. They issue a Bill of Materials to Purchasing with these specifications. Any change from these specifications by the vendor or subcontractor is subject for review by Engineering, QA or Radiological, as applicable, before purchase is made. Any change or deviation on a particular product is noted on the specification documents of that particular product. All purchases are individually checked on delivery to verify that they meet specifications before they are accepted. Any material from vendor or subcontractor found not to be in conformance, is immediately returned and further purchase of that item from that source is immediately put on suspension, until review and audit, if required, and either rein-

1.3 & 2.3 DESIGN CONTROL, continued.

3. Statement of Verification that Quality Standards are Maintained, continued.

statement or termination is determined by QA, Engineering and/or Radiological and forwarded to Purchasing. The Shop Foreman is directly responsible for routing of production to QA for inspection at various designated stages of completion. If, at any time, a critical to safety related item, which has been called out in product approval by a regulatory or licensing agency, is no longer available, an amendment to the product approval will be applied for and item will not be used until amendment has been issued.

4. Statement of Verification of Design Control.

Engineering, QA and Radiological Departments, review each approved product design and all approved revisions before release for manufacture. Any deviation from this is subject to a review by QA for initial approval or rejection. Inspection and test criteria are identified and made available to QA before release.

5. Statement of Verification of Adequacy of Design.

QA, Engineering and Radiological Departments insure the proper selection of components and design verification of each package, by means of prototypes, testing of which is provided for licensing applications and approvals. The prototypes are thoroughly tested and inspected in all stages to verify that they meet all licensing authority criteria and design specifications. All inspection and test criteria are documented and made available to the QA Department and Radiological, which documents acceptance or rejection and all pertinent data thereof. Additionally, each package design is reviewed to assure that the design characteristics are such that components can be readily inspected and tested, and that maintenance, handling, storage and cleaning requirements, as required, are specified.

6. Statement of Verification of Design Department Controls.

The President/General Manager and Senior Engineer is responsible for the final design verification review, prototype tests review and calculations review after reviews by the Engineering, QA and Radiological Departments.

7. Statement of Verification of Design Change Control.

JLS&A maintains design specification change controls on the same basis as the original designs, See 1, 2, 3, 4, 5 & 6 above.

8. Statement of Verification of Engineering and QA Responsibility and Authority.

JLS&A maintains written procedures delineating the areas of responsibilities and authority of the Engineering and QA Departments, which are agreed upon and understood at the completion of the Training Program. Radiological personnel are trained in accordance with licensing agency approval programs in addition to QA Program. Hazmat personnel are trained in accordance with 40CFR172.

1.4 & 2.4 PROCUREMENT DOCUMENT CONTROL.

1. Statement of Verification of Purchasing Department Procedure.

The Purchasing Department maintains a definite sequence of action in any purchasing operation, including but not limited to reviews, concurrences and/or approvals when designated and defined by other appropriate departments. A list of procedures is posted in the Purchasing Office and is explained in the employee training program. As noted in 1.3 and 2.3 Design Control, Engineering and Radiological provide to Purchasing, via Bills of Materials, all specifications, drawings, etc., pertinent to the scope of work to be performed by the supplier.

2. Statement of Verification that Appropriate Reference of Specifications Appear on Purchase Orders.

Engineering and/or Radiological Departments, when applicable, provide appropriate reference to technical requirements, i.e, regulatory requirements, material and component identification requirements, drawings, specifications, codes and/or industrial standards, test and inspection requirements and special process instructions, on the Bill of Materials which is submitted to Purchasing to be included on purchase orders when applicable. MSDS sheets also required when applicable.

3. Statement of Verification that Subpart H Criteria Appears on Purchase Orders.

Purchasing identifies 10CFR71 Subpart H or 10CFR21.31 criteria, when applicable, as provided by the appropriate departments, via Bills of Materials, etc., per 2. above, for package components or complete packages. The following item will be required, when applicable, certification of model and serial number, NRC approved QA/QC program manufacturing practice certificate, use and maintenance verification programs, and certificates compliance, use and maintenance manuals, drawings, photographs or sketches. Replacement parts for important to safety package components are subject to the same requirements as called out in this program.

4. Statement of Verification of Purchase Order Containing Right of Access Clause.

JLS&A's purchase orders contain an agreement clause covering JLS&A's right of access to the supplier's facilities and records for an inspection/audit when applicable.

5. Statement of Verification that Appropriate Reference of Documentation Appears on Purchase Orders.

Engineering and/or Radiological Departments, when applicable, provide appropriate references and/or documentation, i.e., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, procedures qualifications, chemical, MSDS sheets and test results of material, on the Bill of Materials which is submitted to

Purchasing to be included on purchase orders and provided to vendor.

1.4 & 2.4 PROCUREMENT DOCUMENT CONTROL, continued.

6. Statement of Verification of Appropriate Documents Retained by Vendor and Delivered to Purchaser.

Engineering and/or Radiological Departments, when applicable, provide the appropriate references of records, certification or test reports to be retained, controlled and maintained by the supplier and those which are to accompany delivery to JLS&A, on the Bill of Materials which is submitted to Purchasing to be included with the purchase order.

7. Statement of Verification that Purchase Order Revision is Subject to Approval.

As stated in 1.3 and 2.3, "Any change from these specifications by the vendor or subcontractor is subjected to review by the Engineering, QA or Radiological Departments, as applicable, before purchase is made. Any change or deviation on a particular product is noted on the specification documents of that particular product. All purchases are individually checked on delivery to verify that they do meet specifications before they are accepted. Any material from vendor or subcontractor found not be in conformance, is immediately returned and further purchase of that item from that source is immediately put on suspension, until review and audit, if required, and either reinstatement or termination is determined, by QA, Engineering and/or Radiological and forwarded to Purchasing. The Shop Foreman is directly responsible to the QA Officers for routing production to QA for inspection at various designated states of completion.

1.5 INSTRUCTIONS, PROCEDURES AND DRAWINGS, MANUFACTURING.

1. Statement of Verification that Activities Affecting Quality are Accomplished in Accordance with Specifications.

JLS&A has established with the implementation of the QA/QC program that activities affecting the quality of a product and activities important to safety are adhered to in all phases of manufacture and operation according to prescribed documented instructions, procedures, inspections and/or drawings.

2. Statement of Verification of Clear Sequence of Actions Concerning Instructions, Procedures and Drawings, per 10CFR71, Subpart H Criteria.

JLS&A has established with the implementation of the QA/QC Program, a clear sequence of procedure in the preparation, review, approval and control of instructions, procedures and drawings, including all those applicable sections of the 18 point criteria of 10CFR71, Subpart H.

3. Statement of Verification that Activities Important to Safety are Satisfactorily Accomplished.

JLS&A has established QA/QC procedures which direct that instructions, procedures drawings and acceptance criteria of important to safety activities include dimensions, tolerances, operating limits, and workmanship be called out and that the inspection and acceptance criteria verify that these have been satisfactorily accomplished.

4. Statement of Verification of Quality Assurance Department Responsibility.

QA and Radiological Departments have the authority and responsibility, under the provisions of the QA/QC program, to review inspection plans, test calibration and special process procedures, drawings and specifications, and all changes and/or acceptable alternatives thereto; and that the these departments fulfill this responsibility. Prior to release for fabrication, the QC/QC program provides for inspection check points and inspection instructions, with times determined at scheduled conferences or as needed.

2.5 INSTRUCTIONS, PROCEDURES AND DRAWINGS, PACKAGES

1. Statement of Verification that Packages are Prepared for Use.

JLS&A has established procedures, which meet requirements of 10CFR71, 71.87, for placing packaging used in the transport of radioactive materials into use. These procedures are incorporated into the initial regulatory approval applications and are subject to the same QA/QC implementation program, including permanent current and archival files.

2. Statement of Verification that Repair, Rework and Maintenance Procedures are Established.

JLS&A has established provisions to ensure that repair, rework and maintenance procedures for packages is prescribed before that work begins. These provisions are subject to the established procedures for individual jobs undertaken by JLS&A, which are covered under this QA/QC Program.

3. Statement of Verification of Loading/Unloading Procedures.

JLS&A has an established program, found in the State of California approved Radiological Safety Control Manual and JLS&A's Radioactive Materials License criteria, to ensure that loading/unloading of radioactive materials packaging meets all regulatory requirements, including but not limited to radiation surveys, contamination wipe tests, measurements of temperature and pressure, adequate package venting, rigging and movement.

4. Statement of Verification of Proper DOT Transport of Package.

JLS&A has established measures, per Item 3 above, which ensure that the packages are in good condition (per Item 1 above), adequately secured in the transport vehicle (included in Item 3 above), identified per all pertinent DOT regulations, and properly identified (including model and serial number).

1.6 & 2.6 DOCUMENT CONTROL.

1. Statement of Verification of Controlled Documents.

JLS&A has established procedures so that all documents and revisions thereto under the control of the QA/QC Program are subject to review and concurrences by the appropriate departments. Documents which fall under these procedures include, but are not limited to all design documents and specifications, procurement documents, QA/QC Manuals, operating and maintenance manuals, change order reports, inspection and test procedures, nonconformance reports, design change requests, and corrective action reports.

2. Statement of Verification that the Issuance of Documents and Procedures thereof are Procedurally Controlled.

Engineering, working with the QA, Radiological, Licensing and Purchasing Departments, have adequate procedural controls to check, review, approve and/or change documents and/or procedures prior to release.

3. Statement of Verification that Changes to Documentation are Made by the Original Organization that Prepared Initial Document.

Engineering and/or Radiological Departments, when notified of the need for changes or modification by itself or other departments, in cooperation with QA and/or Radiological, when applicable, reviews and approves or rejects revisions to the original documents, as needed. Whenever any change or modification in any department is initiated, the department which initiated the change or modification has the responsibility and authority to supervise further processing, in conjunction with QA, Radiological and/or Licensing as appropriate.

4. Statement of Verification that Revisions are Made on Appropriate Documents.

Engineering Department is responsible for making all necessary revisions on all related documents of a project, after approval thereof, prior to the implementation of these changes, or non-radiological items. Radiological is responsible for making all necessary revisions on all related documents of a project for radiological items.

1.6 & 2.6 DOCUMENT CONTROL, continued.

5. Statement of Verification that all Pertinent Documents are Available at Site Where They are to be Implemented.

Engineering and/or Radiological Department, when applicable, is responsible for all pertinent documents related to a job to be available at the site where they are to be implemented, prior to starting work. The Engineering and/or Radiological Department, when applicable, is also responsible for providing Purchasing with all pertinent documents to accompany the purchase order (if applicable) to the supplier or subcontractor before work begins on the project.

6. Statement of Verification that Master Lists of Revisions are Current and Appear on Appropriate Documents.

JLS&A's established procedures provide that the appropriate department has the responsibility and authority to keep a current listing of revisions on specified documents, so that revisions are identifiable, that appropriate revisions appear on current documents and that revisions are distributed appropriately.

1.7 & 2.7 CONTROL OF PURCHASED MATERIALS, PARTS, COMPONENTS, EQUIPMENT AND SERVICES

1. Statement of Verification of Procurement Document Planning, that Qualified Personnel Evaluate Suppliers for Acceptability. (Procurement Document Planning.)

The Senior Engineer, Radiological Manager, and/or QA Manager, as applicable, are qualified and responsible procurement planning for vendor selection, qualifying vendors' QA/QC Programs, and to establish that materials, parts, components, equipment and/or services to be provided meet specifications for the procurement item.

2. Statement of Verification of Evaluation of Suppliers (Selection of Procurement Sources).

The Senior Engineer, Radiological Manager, and/or QA Manager are responsible for supplier selection and use the following criteria for approving a vendor:

The supplier's capability to comply with the elements of 10CFR71, Subpart H or 10CFR21 and/or NRC approved QA/QC Program, which are applicable to the type of material, part, component, equipment or service being procured.

A review of previous records and performances of suppliers who have provided similar articles of the type being procured.

A survey or audit of the supplier's facility and NRC approved QA Program, when applicable, to determine capability to supply a product which meets the design, manufacturing and quality requirements. Note: audit results and approvals by other cognizant entities, along with a copy of the QA Manual and/or NRC or DOE approval, is acceptable in lieu of a formal JLS&A audit.

3. Statement of Verification of Contract Evaluation and Award Procedures. (Bid Evaluation and Award.)

JLS&A has established procedures that ensures that the appropriate departments evaluate prospective suppliers, for purchased material, equipment or services which are procured on the basis of bid solicitations. Criteria to be considered will include, when applicable, supplier's capability to comply with 10CFR71, Subpart H, conformance to QA requirements and survey results of supplier's facility and QA Program, per Item 3 above.

1.7 & 2.7 CONTROL OF PURCHASED MATERIALS, PARTS, COMPONENTS, EQUIPMENT AND SERVICES, continued.

4. Statement of Verification that Inspection and/or Supervision of Supplier is Performed. (Supplier Performance Control.)

At the scheduled meetings between the QA Department and other appropriate departments, it is determined if and when it is required that the QA Engineer or appropriate representative be present at supplier's site during fabrication, testing and/or shipment of a product, to assure accordance with purchase order specifications. Inspection and/or supervision requirements are transmitted to JLS&A Purchasing Department (via Bill of Material) for inclusion in Purchase Order.

5. Statement of Verification of Minimum Records Supplied to Purchaser. (Verification Activities.)

JLS&A requires as a minimum from all vendors the following documentation:

Documentation that identifies the purchased material, part, component, equipment or services and that specific procurement requirements (e.g., codes, standards and specifications) are met by the items.

Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances.

Note: Contingent on acceptance by JLS&A, all nonconforming items must be repaired or replaced and certification thereof provided.

QA/QC inspection reports and documentation from vendor's facility, when applicable, subject to the same requirements as called out for in-house QA/QC inspection procedures.

6. Statement of Verification of QA/QC Inspectors Acceptability Criteria and Responsibility. (Controlling Nonconformances.)

The QA or Radiological Department, when applicable, is responsible for and will not accept products that do not meet the following criteria:

The material, component or equipment is properly identified and corresponds with the identification on receiving documentation.

Records of certificates of conformance attesting to the acceptance of material and components, prior to disbursement, when applicable.

Any nonconforming item, categorized by the supplier, along with technical justification, conditional acceptance, until review and disposition has been ascertained by the appropriate departments, using established procedures, in appropriate circumstances.

Note: Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further work.

1.7 & 2.7 CONTROL OF PURCHASED MATERIALS, PARTS, COMPONENTS, EQUIPMENT AND SERVICES, continued.

7. Statement of Verification of Purchased Material, Parts, Components, Equipment or Services Records.

Permanent records are maintained in job files or other files as appropriate, which identifies the material, component, part, equipment or service, the specific requirements as called out on the purchase document, the certifications which accompany that item, identification of specifications which have not been and disposition of nonconformances.

JLS&A maintains files on the results of supplier evaluations made by the appropriate departments, as well as current specifications on products supplied.

1.8 & 2.8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

1. Statement of Verification of Established Procedures Used for Identifying and Controlling Materials.

The QA or Radiological Departments, when applicable, use a standard procedure for identifying all materials, parts and/or components received or fabricated as part of the QA/QC Program.

2. Statement of Verification that Products are Identified Properly.

As part of the standard receiving procedure of the QA or Radiological Departments, when applicable, all products are inspected, identified and marked. This identification and marking is directly traceable to all pertinent records and this system precludes the use of incorrect or defective items. Fabricated parts or components are inspected, identified and marked at applicable stages (before placements into inventory and again when taken from inventory or released into the assembly process. Non-conforming or non-inspected parts or components are identified and marked and held in a special inventory location separate from inventory for disposition.

3. Statement of Verification that Safety-Related Materials are Identified Properly.

As stated in VIII.2, all items purchased or fabricated are inspected, identified and marked directly traceable to all pertinent records, i.e., drawings, specification, purchase orders, test reports, including and specifically the safety-related items which are thoroughly inspected, either as received, placed into inventory, taken out of inventory or released into the assembly process.

4. Statement of Verification that the Location and Method of Identifying Products is Not Harmful to Them.

JLS&A maintains separate receiving, inspection, non-conforming and non-inspected areas where all products, purchased or fabricated, are identified and marked before allocation to proper inventory areas. The receiving area and method of identification (one of several methods appropriate to item) do not in any way interfere with the fit, function or quality of the product.

5. Statement of Verification that Product Identification Numbers are Verified Before Release.

JLS&A, as part of the QA/QC Program, requires that any item from inventory be verified that it is the proper item for the job before release for fabrication, assembly or installation.

6. Statement of Verification that Conditional Releases are Controlled.

In the instance of a nonconforming or not inspected or tested item, a conditional release of a partial sub-assembly or component will be released to facilitate continued processing, when required inspections or test have not been completed. Physical control and identity of such items will be maintained.

1.9 & 2.9 CONTROL OF SPECIAL PROCESSES

1. Statement of Verification that Special Processes are Procedurally Controlled.

The Shop Foreman is directly responsible, in conjunction with periodic QA inspections, for the procedural control on each job which requires special processes, such as welding, heat treating, nondestructive testing and cleaning of items. The QA Department is responsible for inspecting and controlling these processes at suppliers' installations, as applicable.

2. Statement of Verification that Procedures, Equipment and Personnel Related to Special Processes Meet Applicable Specifications, Codes and Standards.

The Engineering Department and Shop Foreman, in cooperation with the QA Department, are responsible for maintaining appropriate procedures, equipment and personnel connected with applicable codes, standards and specifications, such as ISO, SNT, ASME, AWS or ANSI standards, as appropriate for special processes or non destructive testing.

3. Statement of Verification that Qualification Records Concerning Special Processes are Established and Current.

The Engineering Department maintains current qualification records of all areas associated with special processes. In addition, copies of applicable records are maintained in each job file. Personnel records are maintained by the QA Department.

1.10 & 2.10 INSPECTION CONTROL

1. Statement of Verification that Inspection Program Verifies Conformity of Articles in Accordance with Established Procedures.

All inspections performed by JLS&A which check conformity with quality associated areas are performed in accordance with written and controlled procedures, instructions or checklists and are documented. The Shop Foreman is responsible for the supervision of work, including holding work progress until it has been inspected at the appropriate phases. The Shop Foreman holds work for inspection in accordance with predetermined inspection specifications and for informing the QA Department of the forthcoming inspections at scheduled meetings and time of inspection.

2. Statement of Verification that Receiving Inspections Verify Integrity of Important to Safety Items.

All receiving inspections performed by JLS&A on important to safety items, as previously discussed in Sections 1.4 & 2.4, 1-7 Procurement Document Control, 1.5, 2 Instructions, Procedures and Drawings, 2.5, 1-4 Instructions, Procedures and Drawings, Packages, 1.7 & 2.7, 1-7 Control of Purchased Materials, Parts and Components and 1.8 & 2.8, 1-5 Control of Materials, Parts and Components. JLS&A's State of California Radioactive Materials License and approved Radiological Control Manual, have established safe radioactive materials receiving procedures, including but not limited to CRP visual inspection on arrival, wipe test and survey of outer container, survey and wipe test of inner container, if applicable, appropriate log entries, and document evaluation.

In the cases of reusable shipping packages, an inspection is performed, identifying maintenance items. If replacement parts are required, a separate job for that program is instituted, with all the design, purchasing, inspections and acceptance criteria of the QA/QC program applicable, before that package is released for shipment.

Both radiological and important to safety items are placed in separate receiving areas before dispersal to inventory locations.

3. Statement of Verification that In-Process Inspections Are Established.

When applicable, JLS&A has established procedures to ensure that process specifications, with documentation, provides for indirect control by monitoring processing methods, equipment and personnel, if direct supervision is impractical.

1.10 & 2.10 INSPECTION CONTROL, continued.

4. Statement of Verification that Final Inspections Verify Item Integrity.

Final inspections are a cumulative result of Sections 1.1 & 2.1, 6 Purchasing and 11 Storage, Packaging and Delivery, 1.4 & 2.4, 1-7 Procurement Control, 1.5, 2 Inspections, Procedures and Drawings, 2.5, 1-4 Instructions, Procedures and Drawings, Packages, 1.7 & 2.7 Control of Purchased Materials, Parts and Components, and 1.8 & 2.8, 1-5 Control of Materials, Parts and Components. Final inspections include complete operational check out, supervisory reassessment of all identifiable and traceable records, documents and inspections, including nonconformance dispositions, and that completed items are protected from physical and environmental damage, prior to shipment.

Inspectors perform all inspections, including those on any modifications, repairs or replacements, in accordance with the original design specifications and procedures or acceptable alternatives; and all inspections are documented.

JLS&A's State of California Radioactive Materials License and approved Radiological Control Manual, have established safe radioactive materials storage and shipping procedures, including but not limited to CRP visual inspection, wipe test and survey of source and container, survey and wipe test of outer container, if applicable, appropriate log entries, and document evaluation. Shipments include compliance with all applicable DOT or IAEA regulations and shipping checklists which verify that the package is properly maintained, assembled, conspicuously and durably marked, in accordance with DOT regulations. Established procedures ensure that only CRP's prepare radiological certifications and shipping documentation, with reviews by supervisory personnel.

5. Statement of Verification that Inspection Personnel are Independent from Individuals Performing Activity Being Inspected.

Inspection personnel at JLS&A are usually independent from the personnel performing the activity being inspected; if not, supervisory personnel perform verification. Qualifications and independence or verifications are determined by the QA or Radiological Departments, as applicable.

6. Statement of Verification that Inspectors are Qualified and Qualifications are Recorded.

The QA Department is responsible for maintaining qualified inspectors (in accordance with applicable codes, standards and training programs) and the certifications and qualifications thereof are on file and kept current.

1.11 TEST CONTROL

1. Statement of Verification that Test Programs are Established, Documented and Performed Accordingly.

All products are subject licensing authority approval which requires prototype testing, design review and calculation review. JLS&A test programs, including prototype, production, proof and/or operational tests, which determine if an item will perform satisfactorily are performed by JLS&A's Engineering, QA and/or Radiological, when applicable, in accordance with established documented specifications and are fully documented.

Engineering, in conjunction with the QA and Radiological Departments, when applicable, tests all modifications, repairs or replacements to the original design in accordance with original specifications or acceptable alternatives.

2. Statement of Verification that Test Procedures are Established.

All test programs have established procedures, which identify the appropriate test criteria, including instrument calibration and condition, monitoring, hold points, environmental conditions, methods of physical identification, records, documentation and acceptance criteria.

3. Statement of Verification that Test Results are Documented, Reviewed and Accepted by Appropriate Departments.

All test program results are fully documented. They are then evaluated and determined acceptable by the appropriate Engineering, QA and/or Radiological Departments, and when applicable, officers of JLS&A.

1.12 & 2.12 CONTROL OF MEASURE AND TEST EQUIPMENT

1. Statement of Verification that Measuring and Test Equipment are Properly Calibrated.

JLS&A maintains properly calibrated measuring and test equipment, based upon required accuracy, purpose, degree of usage, stability characteristics or other conditions affecting the measurement of the salient characteristics of a particular item. Survey instruments which measure radioactivity are calibrated at three (3) month intervals; all other instruments are calibrated yearly. Additional survey instrument calibration checks are called out in JLS&A's Radiological Safety Control Manual.

2. Statement of Verification that Measuring and Test Equipment are Identified and Traceable to Calibration Test Data.

JLS&A requires and maintains serial numbers on all measuring and test equipment and requires all calibration test data to reference the instrument's serial number(s). All measuring and test equipment is labeled or tagged to indicate date of next calibration.

3. Statement of Verification that Calibration Meets Appropriate Standards.

JLS&A maintains National Institute of Standards and Technology (NIST, formerly NBS) radiation source standards in-house. Additionally, radiation measurement equipment is either re-calibrated yearly to NIST traceable calibration or cross calibrated, with known valid relationships to NIST traceability. Radiation survey instruments are calibrated quarterly to known valid relationships to NIST traceability. Non-radiological measurement and test equipment is calibrated yearly to NIST or other nationally recognized standards. Other inspection instruments either meet nationally recognized standards or manufacturer's specifications which are documented and are on file at JLS&A. In the event that no known recognized standard is used for calibration, the parameters of that calibration procedure will be documented. Records on all instruments which measure radioactivity are kept in current files or permanent archives and these standards are referenced on all appropriate documentation.

4. Statement of Verification that Measurements are Taken, Documented, and Validated against Previous Measurements if Instrument is Found to be out of Calibration.

JLS&A performs new test or measurements (which are documented) to validate previous inspections in the event that an instrument is found to be out of calibration and notifies appropriate parties, if applicable. Any measuring equipment which is consistently out of calibration will be removed from service and repaired or replaced.

1.13 & 2.13 HANDLING, STORAGE AND SHIPPING

1. Statement of Verification that Special Requirements and Preservation are Accomplished by Qualified Individuals in Accordance with Work and Inspection Instructions.

In accordance with predetermined established procedural work and inspection instructions, qualified employees of JLS&A perform work related to special handling, preservation, storage, cleaning, packaging and shipping requirements, to preclude physical or environmental damage.

2. Statement of Verification that Conditions of the NRC and US DOT Shipping Requirements are Satisfied Before Shipment.

JLS&A performs a final inspection before shipment on all items pertinent to NRC and DOT shipping requirements for that shipment. Items must pass all criteria, cumulative results of previous section contained therein, which is documented, before shipment is made.

3. Statement of Verification that Shipping Papers are Properly Prepared.

JLS&A prepares and keeps on file all necessary shipping papers as required. Shipping papers on shipments containing radioactivity include the following documentation:

- Date of Shipment
- Customer
- License of Customer
- Source Information, Source Serial Number
- Shipping Container Type and Device and Serial Numbers
- Radiation Level at Surface of Shipping Container
- Radiation Level at three feet (3') from Surface of Device
- Surface Contamination
- Instrument
- Leak Test
- DOT Class Label
- Transport Index
- Truck Placard Requirements
- Shipping Weight
- Freight Classification
- Signature by radiologically cognizant personnel

Also included with shipments are External Radiation Level Certificate, Leak Test Certificate, Calibration Certificate, Attenuator Certificate and Operating and Maintenance Manual, as applicable.

2.11 TEST CONTROL, PACKAGES

1. Statement of Verification that Packages Meet Acceptance Criteria Prior to Shipment.

JLS&A has an established shipment preparation program, with a clear sequence of action, in which QA, Radiological, Engineering, Licensing, Production/Operations and Shipping Departments, when applicable, are responsible for package acceptance criteria and documentation, prior to shipment. Acceptance criteria is based upon applicable documentation (certificate of compliance and certification thereof, and operating and maintenance manuals) and physical inspections (structural integrity, leak tightness on containment vessels, as well as auxiliary equipment and shield tanks, component performance of valves, gasket and fluid transport devices, shield integrity and thermal integrity).

2. Statement of Verification that Maintenance Test Programs are Established.

JLS&A has an established maintenance test programs in accordance with JLS&A's State of California Radioactive Materials License and approved Radiological Control Manual, which ensure that packages remain usable and free of excessive radiation and contamination, through a controlled series of documented wipe tests.

1.13 & 2.13 HANDLING, STORAGE AND SHIPPING, continued.

4. Statement of Verification that Shipment Time is Consistent with Safe Transportation Time.

JLS&A routinely uses motor freight for most shipments. Weight, end use, transport and/or diamond label, inhibits fast delivery by air or express company and the nature of our products does not demand it. Departure occurs after a package has passed final inspection to meet NRC and DOT criteria and the customer has necessary licensing (if applicable) and is ready to accept delivery. Shipments are monitored covering the motor freight delivery schedule and customer notification of arrival and installation scheduling, if applicable.

5. Statement of Verification that 10CFR21.6 Posting Requirements Have Been Established.

"Notification to Comply or Existence of A Defect - Explanation of Notification Procedures and Proper Authorities", along with Section 206 of the Energy Reduction Act of 1974, Section 206, Noncompliance is posted in the prescribed manner according to 10CFR21.6.

1.14 & 2.14 INSPECTION, TEST AND OPERATING STATUS

1. Statement of Verification that Status of Packages is Acknowledged by Affected Organizations.

The QA and Radiological Departments, in conjunction with other appropriate departments such as Shipping, Engineering, Production/Operations, Licensing, or Administrative, is responsible for the appropriate documentation and identification of inspections, tests and operating status of packages, and that it is acknowledged and received by affected departments or organizations, such as shipping agents and/or customer.

2. Statement of Verification that Removal of Inspection and Status Indicators are Procedurally Controlled.

JLS&A requires that all inspection and welding stamps and/or other status from an item for fabrication, be checked with the Shop Foreman at the time of removal (for verification purposes) for records of "in-process" work. For inspection controlled items, any stamps or status indicators that apply to any item are removed and documented accordingly by the appropriate QA or Radiological inspector.

3. Statement of Verification that By-passing of Inspection Tests or Other Critical Operations is Controlled.

The by-passing of inspections, tests or other critical operations are procedurally controlled by documentation, work structure, procedure and daily communication. These procedures are discussed during the scheduled meetings of the QA Department and all appropriate departments, as required.

4. State of Verification that Nonconforming Items are Identified.

The QA Department is responsible for identifying and inspecting incoming materials. Nonconforming items are identified and return to vendor. On cases where return is delayed, items are identified and placed in a separate, special inventory location. If items are found to be defective or otherwise nonconforming during procedural inspections, these items are identified and either returned to vendor or placed in a special inventory in a separate location for rework and retesting. These procedures are established to preclude the inadvertent use of nonconforming materials.

1.15 & 2.15 NONCONFORMING MATERIALS.

1. Statement of Verification that Nonconforming Items are Procedurally Controlled.

JLS&A has established material rejection procedures for receiving and subsequent inspections to assure that the identification, documentation, segregation, review disposition of non-conforming items is implemented. Affected departments are notified so that replacement or repair procedures can be carried out. When a nonconforming item is found during inspection or testing, the QA or Radiological inspector, when applicable, is required to document the reasons for nonconformance, identify the item, place item into special inventory, sign the report and notify the appropriate departments for item disposition.

2. Statement of Verification that Nonconforming Items are Segregated from Acceptable Items.

JLS&A maintains a separate special inventory location for nonconforming items, which are identified as such, until appropriate actions are taken.

3. Statement of Verification that Repaired or Reworked Items are Subjected to Original Testing.

QA or Radiological inspectors, when applicable, subject all replaced, reworked or repaired items to the same documentation, original inspection procedures and testing procedures, or to acceptable alternate testing procedures.

4. Statement of Verification that Nonconformance Reports are Evaluated.

QA and Radiological Departments, when applicable, perform analysis of material rejection reports to determine quality trends and areas of problems for management review and assessment.

5. Statement of Verification that 10CFR21.6 Posting Requirements Have Been Established.

"Notification to Comply or Existence of a Defect - Explanation of Notification Procedures and Proper Authorities", along with Section 206 of the energy Reduction Act of 1974, Noncompliance, is posted in the prescribed manner according to 10CFR21.6.

1.16 & 2.16 CORRECTION ACTION.

1. Statement of Verification that Corrective Actions are Reported.

JLS&A does not unconditionally accept or use nonconforming materials for use in a product, as established by procedural inspections at various phases of operation. See Sections 1.4 & 2.4, 7 Procurement Document Control, 1.5, 4 Instructions, Procedures and Drawings, 1.7 & 2.7, 6 Control of Purchased Materials, etc., 1.8 & 2.8, 2,3,6 Identification and Control of Materials, etc., and 1.15 & 2.15, 1-4 Nonconforming Materials. In the event that an inspection determines there is such nonconformity, such as failure, malfunction, deficiency, or defectiveness, the QA Department documents and reports nonconformances to the appropriate departments. Engineering, QA and Radiological Departments, when applicable, jointly evaluate the problem and establish the need for corrective action in areas of vendor evaluation, engineering, purchasing, manufacturing or inspection and/or test procedures, etc. Corrective action procedures are in accordance with established procedures. The item in question is also dispositioned in accordance with established procedures.

2. Statement of Verification that Corrective Action Proceedings are Completed.

In the event of a corrective action, the cognizant personnel of the Engineering, QA and Radiological Departments, when applicable, evaluate all aspects of the discrepancy and determine the kind of correction action to be taken to avert reoccurrence. This process is documented accordingly before the corrective action is taken and reinspected according to prescribed procedures.

Engineering, QA and Radiological Departments, when applicable, conduct inspections and follow-up reviews of corrective actions to determine if they are acceptable and appropriate within the procedures of the established program and either close out required documentation or implement these actions as part of standard operations, whichever is needed.

1.17 & 2.17 QUALITY ASSURANCE RECORDS.

1. Statement of Verification that Documentation Furnishes Evidence of Activities Affecting Safety.

QA records, maintained by Engineering, QA, Radiological, Licensing, Purchasing, Accounting and Administrative Departments, contain documentation concerning the quality and safety of items and of activities which affect quality and safety areas; revises and updates them annually or as required. Included are drawings, specifications, purchasing documents, operating logs, results of reviews, inspections, tests, audits, materials analysis, qualifications of personnel, procedures and equipment, calibration procedures and reports, nonconformance reports and correction action reports. Additionally, pertinent documentation is included with each job file, which are maintained on a permanent basis.

Engineering, QA and Radiological Departments have established and maintain inspection and test records which include the following criteria:

1. A description of the type of observation.
2. Evidence of completion and verification of a manufacturing inspection or test operation.
3. The date and results of the inspection or test.
4. Information related to conditions adverse to quality.
5. Inspector or data recorder identification.
6. Evidence as to the acceptability of the results.

2. Statement of Verification that Records are Legible and Completed

QA, Radiological and all departments have the responsibility and authority for maintaining legible records, and to have records completed and processed to avoid unnecessary delays if a record is needed.

3. Statement of Verification that Required Records are Indexed and Classified.

JLS&A maintains master listings of where required records may be located, which includes the use of established numerical and alphabetical cross-reference identification systems.

JLS&A has maintained complete files, including design-related records, inspection and related QA documents, since the company was established in 1967 and regularly updates these files as required, i.e., repairs or replacement parts, correspondence, etc. These files are maintained on a lifetime basis and identifiable and retrievable per the master list discussed above. JLS&A maintains these files on a lifetime (permanent) basis because the devices we manufacture have a usable expectancy period of over 30 years. Files on reusable shipping containers (also used for shipping these devices when applicable) may also be maintained on a permanent basis, rather than the prescribed 2 years, on a discretionary basis.

Nonpermanent records, which show evidence that an activity has been performed but do not meet criteria for lifetime status, are maintained on a 5 year basis.

1.17 & 2.17 QUALITY ASSURANCE RECORDS, continued.

4. Statement of Verification that Quality Assurance Documents are Identifiable and Retrievable.

JLS&A has an established record receipt system which includes personnel routing of such records and the numerical and alphabetical systems which cross-reference all QA documentation as well as all associated documentation throughout all filing systems in all departments. Implementation of this system assures that all records are controlled, identifiable and retrievable.

5. Statement of Verification that Records are Subject to Storage, Preservation and Safekeeping.

JLS&A uses record storage facilities which minimize risk of elemental, zoological or botanical damage. All current, permanent or temporary records are securely fastened within folders or binders and are placed in steel file cabinets. Measures are established for replacement, if possible, for lost or damaged records. JLS&A has an on-going program to duplicate records for storage at another location(s) and to place critical records (as defined by JLS&A) into fire-proof file cabinets. Measures have been established to restrict entry of unauthorized personnel into storage areas.

1.18 & 2.18 AUDITS.

1. Statement of Verification that Audits are Conducted in Prescribed Manner.

JLS&A performs audits in accordance with prescribed procedures and/or check lists. All audits are performed by employees who do not have direct responsibility for the area being audited, with provision for access to facilities and documents.

Audit team(s) compile and report audit findings, to responsible management, including corrective action suggestions, if required. Management personnel review all audits in all areas covered by the audit. Management personnel, working with audit team(s), are responsible for correcting deficiencies as required after a comprehensive review of the complete audit reports.

Vendor audits are covered under Section 1.7 & 2.7, 3 Statement of Verification of Evaluation of Suppliers, with emphasis on NRC approved QA/QC Programs and conformance to 10CFR71, Subpart H.

2. Statement of Verification that Audits are Scheduled.

JLS&A schedules internal and external audits only, with direct management participation, with a complete QA Program audit, including implementation, emphasis on activities important to safety. Internal audits are scheduled on an annual basis (or as close to an annual basis as small company circumstances and priorities of audit personnel and management permit, such as production, shipments and installations, inventory, etc.) or more frequently if circumstances dictate an immediate audit, such as nonconformances. Radiological audits are performed on a quarterly basis, in accordance with JLS&A's State of California Radioactive Materials License. External surveys or audits of major contractor's or supplier's facilities are performed at time of initial contract/purchase, per Section 1.7 & 2.7, 3, and contractor's and suppliers will be re-evaluated if specifications change, in the case of non-conformances or corrective actions or after a license or approval is renewed.

3. Statement of Verification of Qualifications of Audit Personnel.

Qualifications for lead auditors and audit personnel have been established using ANSI/ASMI NQA-1-1979, Supplement 2S-3, "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel", or on the basis of work experience at JLS&A if ANSI requirement cannot be met.

4. Statement of Verification of Preaudit Conferences.

Preaudit conferences are held at the time an audit is scheduled. Lead auditors and/or team selection, management involvement, agenda, scope of audit, anticipated completion dates and avenues of communication are established at this conference.

1.18 & 2.18 AUDITS, continued.

5. Statement of Verification of Post Audit Conferences.

Post audit conferences are held between management and audit team(s) to present and review audit results, implementation of changes and/or to clarify misunderstandings, if any.

6. Statement of Verification of Audit Reporting and Response.

Audit and/or corrective action reports are subject to time constraints, as determined at audit scheduling, or interim meetings. In the event that a corrective action cannot be implemented immediately, a schedule for implementation and completion dates will be determined by management.

7. Statement of Verification of Audit Follow up Action.

Audit team leader(s) and management are responsible for verification of timely response and adequacy of audit reports, and that corrective actions have been accomplished.