71-0122

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September 6, 2006

James Pearson
Transportation and Storage Safety and Inspection Section
Spent Fuel Office
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Reference: Docket 71-0122
10 CFR 71 Quality Assurance Program Approval Renewal Application.

Dear Mr. Pearson:

This letter is to request the renewal of the J.L. Shepherd & Associates Quality Assurance Program, which expires on November 30, 2006.

We have enclosed two (2) copies of our Quality Assurance Program Plan, QAPP-001, Revision 4, dated September 5, 2006, Control # 0025-1, for the review of this renewal application.

Please let us know if we can provide any additional information or answer any questions.

Sincerely yours,

Mary F. Shepherd

Mary F. Shepherd
Vice President, Special Projects

For William H. Brown
Quality Assurance Administrator

NMSS01

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QAPP-001
REVISION 4
September 5, 2006

QUALITY ASSURANCE PROGRAM PLAN

PREPARED BY:
WILLIAM H. BROWN
QUALITY ASSURANCE ADMINISTRATOR
September 5, 2006

APPROVED BY:

J.L. SHEPHERD
PRESIDENT
September 5, 2006

CONTROL #: 00225-1

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1.0 QUALITY ASSURANCE ORGANIZATION.

1.1 Regulatory Reference.

71.103 Quality Assurance Organization.

The J.L. Shepherd & Associates (hereinafter referred to as JLS&A) quality assurance organization is formulated in accordance with the requirements found in paragraphs (a) through (f) of 10CFR71, Subpart H. JLS&A is a small business and the functional quality assurance elements (persons or organizations) of the quality program are structured in accordance with the provisions of 10CFR71.103(e), which provides for variables in program implementation, provided that these persons or organizations are assigned and have the required authority, responsibility and organizational freedom, irrespective of organizational structure, with direct access to management. The authority, responsibilities and duties of those persons or organizations that perform important to safety related activities, including but not limited to either performing activities associated with accomplishing quality missions or performance of quality assurance functions, are clearly established and depicted in appropriate work instructions. JLS&A's quality assurance organization, in conjunction with management staff, is responsible for the execution, effective implementation and verification of this quality assurance program. JLS&A's quality organization, including management members, has been provided with the appropriate training, authority and freedom to identify problems, to initiate, suggest or provide solutions, and to verify the implementation of solutions.

JLS&A's QAPP implementing procedures establish criteria to specify that adequate, continued and verifiable quality control is maintained over the quality missions contained in this program.

1.2 Statement of Responsibility

JLS&A implements a graded approach to the applicable important to safety quality control aspects of this Quality Assurance Program, for the design, testing, manufacture, procurement, use maintenance and repair of Type B quantity radioactive materials packages, for its own use, the use of other 10CFRPart 71 Program Licensees, and for licensed packages owned by others.

It is the corporate policy of JLS&A that the company perform any applicable important to safety activities on Type B packages in accordance with applicable requirements of 10CFR71, Subpart H, as described in this Quality Assurance Program Plan (QAPP), the Quality Assurance Manual (QAM) and related implementing procedures (QP's). A written policy statement signed by the President has been established and is contained in the top level series of administrative procedures of the QAPP. The Quality Assurance Policy Statement addresses major program elements such as authorities, responsibilities, commitment to resources, equipment, training and qualifications of quality personnel.

1.0 Quality Assurance Organization, continued.

1.2 Statement of Responsibility, continued.

The management of JLS&A not only endorses the Quality Assurance Program, but also maintains oversight, performs specific assigned QA/QC responsibilities, as they also have the required authority, responsibility and organizational freedom, irrespective of organizational structure, with direct access to other management members, and are responsible for the continued commitment to and implementation of this Quality Assurance Program.

1.3 Structure and Authority

JLS&A maintains a formally established functional organizational arrangement, depicted in Section 1.6 of this QAPP, which ensures that:

> The assignment and responsibility for the execution of specified QA/QC areas are performed by appropriately qualified and trained personnel, who have sufficient and written authority, responsibility and organizational freedom to identify problems, stop work, suggest or provide corrections, and to verify corrections, by various procedures such as inspections, checks or audits.
>
> The assignment of the overall authority and responsibility for the QA/QC Program is delegated to the QA/QC Manager/Administrator, who is appropriately qualified and trained, and has sufficient, written authority, responsibility and organizational freedom to verify conformance in the execution of the QAPP.
>
> QA/QC personnel have direct access to the QA/QC Manager/Administrator and to JLS&A upper management.
>
> Conformance or verification to requirements is verified by individuals not directly performing the work.
>
> QA/QC functions relative to verifying that quality requirements are being implemented and maintained are controlled using established procedures and instructions by only those individuals who have been authorized by the Quality Assurance Department.
>
> All personnel involved with QA/QC have the authority and responsibility, in writing, to stop at any time the further processing of any nonconforming material, work, shipment or delivery, with direct recourse to upper management. This authority and responsibility is internally documented through written procedures, and extends to effectivity of corrective actions and implementation of corrective action processes.

The JLS&A Organizational Chart, found within this plan, clearly defines Quality Assurance function.

1. Quality Assurance Organization, continued.

1.3 Structure and Authority, continued.

Abridged management responsibilities and authorities are as follows:

President and Chief Executive Officer. Chief Executive Officer, having ultimate responsibility for the success or failure of the organization. Has responsibility for the supervision of QA/QC department management, and overall responsibility for implementation of the Quality Assurance Program. Supervision and final decision maker (in case of impasse) for the final approval for resuming or correcting any item or procedure which has been stopped by QA/QC personnel. Determination of and reporting of 10CFR21 and 71 defects or nonconformances. Serves as a member of the Engineering Committee.

QA/QC Program Manager/Administrator. Reports to President. Provides overall responsibility and authority for the oversight, continued implementation and verification for all eighteen areas of the quality assurance program, including reviews and evaluations of QA/QC document control and record keeping as performed by various departments, as applicable. Is an observer of the Engineering Committee.

Vice President & General Manager. (Provisional – May be filled at discretion of management). Reports to the President on areas of operational importance. General Manager is responsible for overall management activities of the organization to include, research and development, engineering, finance, operations, sales and service. Has the direct supervision of Vice President Business Development and Vice President Operations, with the responsibility and authority to act on the President's behalf, either when delegated or during absence or unavailability. If unfilled, then responsibilities are assumed by the President and/or Vice President(s). Is a member of the Engineering Committee.

Vice President, Special Projects & Business Development. Has the responsibility for supervision of sales and serviced activities as well as Radiological Safety Program for the organization. Works with the Vice President Operations in providing senior management personnel with recommendations for compliance with regulatory issues. Maintains responsibility for implementation of Quality Assurance Program Plan within areas of operation, as directed by the President and/or General Manager. Is a member of the Engineering Committee.

Vice President, Electronics & Operations. Has responsibility for supervision of Engineering and Shop Operations activities. Works with Vice President, Business Development and senior management personnel on matters of regulatory compliance. Maintains responsibility for implementation of Quality Assurance Program Plan within areas of responsibility, as directed by the President, and/or General Manager. Chairs Engineering Committee in absence of staff engineer.

Engineer. Reports to Vice President, Operations. Responsible for the supervision of all engineering functions, from initial calculations and prototype testing for package approvals, approval of engineering drawing and procurement packages prior to release for fabrication, including but not limited to vendor selection and qualification, vendor QA/QC programs, drawing or procurement document revisions and/or change control and instructions or procedures and engineering document control and record

1.0 Quality Assurance Organization, continued.

1.3 Structure and Authority, continued.

keeping as applicable. Functions may be performed by an Engineering Committee and designated members, when position is unfilled.

Production/Operations Manager. Reports to Vice President, Operations, responsible for the supervision of all phases of product manufacturing and submittals to QA/QC for inspection processes, procurement of outside materials, stock withdrawals, instructions, procedures and drawing distribution and allocation, review of bills of materials, job package preparation, production scheduling and material rejection determination and segregation. Supervision of the maintenance, handling, storage, repair and preparation of packages for shipment in conjunction with radiological department, production and purchasing document control, and record keeping as applicable.

Procurement Specialist. Responsible for writing and placing purchase orders to qualified vendors in conformance with specifications as called out in the procurement documents, contacting vendors regarding rejected items and their return, checking that proper certifications accompany the shipment and follow-up on late deliveries as needed. In concert with production/operations, maintains procurement documents as applicable.

Radiological Safety Control / Radiation Safety Officer. Responsible for the supervision of health physics aspects of final inspections, involving verification and release of transportation packages relative to DOT and NRC shipment compliance with contamination control for packages as required by 10CFR71.87, the applicable DOT and Agreement State requirements and industry practice. Responsibilities include oversight of radiological QA/QC implementing documents such as package shipment, required radiological documentation and record keeping, as applicable. Is a member of the Engineering Committee.

The following are JLS&A QA/QC implementing documents concerning JLS&A's quality organization:

The organizational chart, which identifies QA/QC departments, personnel, positions, and functional infrastructure within the company.

Job Descriptions which detail QA/QC personnel functions and responsibilities.

Training and qualification criteria for each QA/QC position are identified to demonstrate competence.

1.0 Quality Assurance Organization, continued.

1.4 QA/QC Position Qualifications.

JLS&A maintains a formally established in-house training program for all new employees and employees assuming additional responsibilities.

> All employees receive an overview of the administration of the QA/QC Program. A more in-depth QA/QC orientation is provided to those personnel assigned to quality assurance/quality control overview activities, commensurate with their levels of responsibility.
>
> QA/QC employee training includes specific instructions, training and review of pertinent sections of the QA/QC Program and how the employee functions under the manager within the QA/QC program.

Audit personnel qualifications, including the QA/QC Program Administrator, principal QA/QC management positions, designated lead auditors and inspectors, are applied to and are commensurate with the applicable auditor qualification criteria of ANSI/ASME NQA-1-1989 "Quality Assurance Program Requirements for Nuclear Facilities". Basic Requirement 2 will be used as the primary qualification for audit personnel, with the incorporation of Supplement 2S-3. "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel", is used as a formulation guideline. Lead auditors and auditing personnel are qualified in accordance with formally established and approved procedures.

In addition to ANSI/ASME qualification, the QA/QC Program Manager/Administrator experience qualifications are to include five (5) years (minimum) working with ISO 9000, ISO 9001, ANSI, ASME, SAE, military or aerospace quality assurance programs in a management capacity.

Applicable qualification and training records are maintained as necessary. Training methodology, minimum experience requirements and certification protocols are established consistent with recognized industry guidance and standards for comparable positions. Proficiency re-evaluations are performed and documented, when applicable renewal of qualification measures are implemented.

JLS&A reserves the right to use appropriate QA/QC management discretion in determining the qualifications of audit personnel, using a combination of technical, educational, and experience factors specific to the type of audit to be performed, if and when situations arise where an auditor candidate may not definitively meet the qualification criteria specified in the applicable ANSI qualification criteria set forth in this section of the QAPP. Formally documented provisions will address these special circumstances, if a potential candidate does not specifically meet specification criteria, as written.

Areas of assigned responsibilities and authority are delineated and are agreed upon and understood at the completion of the training and qualification program.

Training is kept current, with additional training classes performed as required and appropriately documented.

1.0 Quality Assurance Organization, continued.

1.4 QA/QC Position Qualifications, continued.

In the situations where an employee is not performing adequately, they are subject to re-training and re-qualification. If this is not successful, the employee will be removed from the function or process. Employment may be terminated after the appropriate notices and legal responsibilities are fulfilled.

1.5 Statement of Verification of Resolution of Disputes.

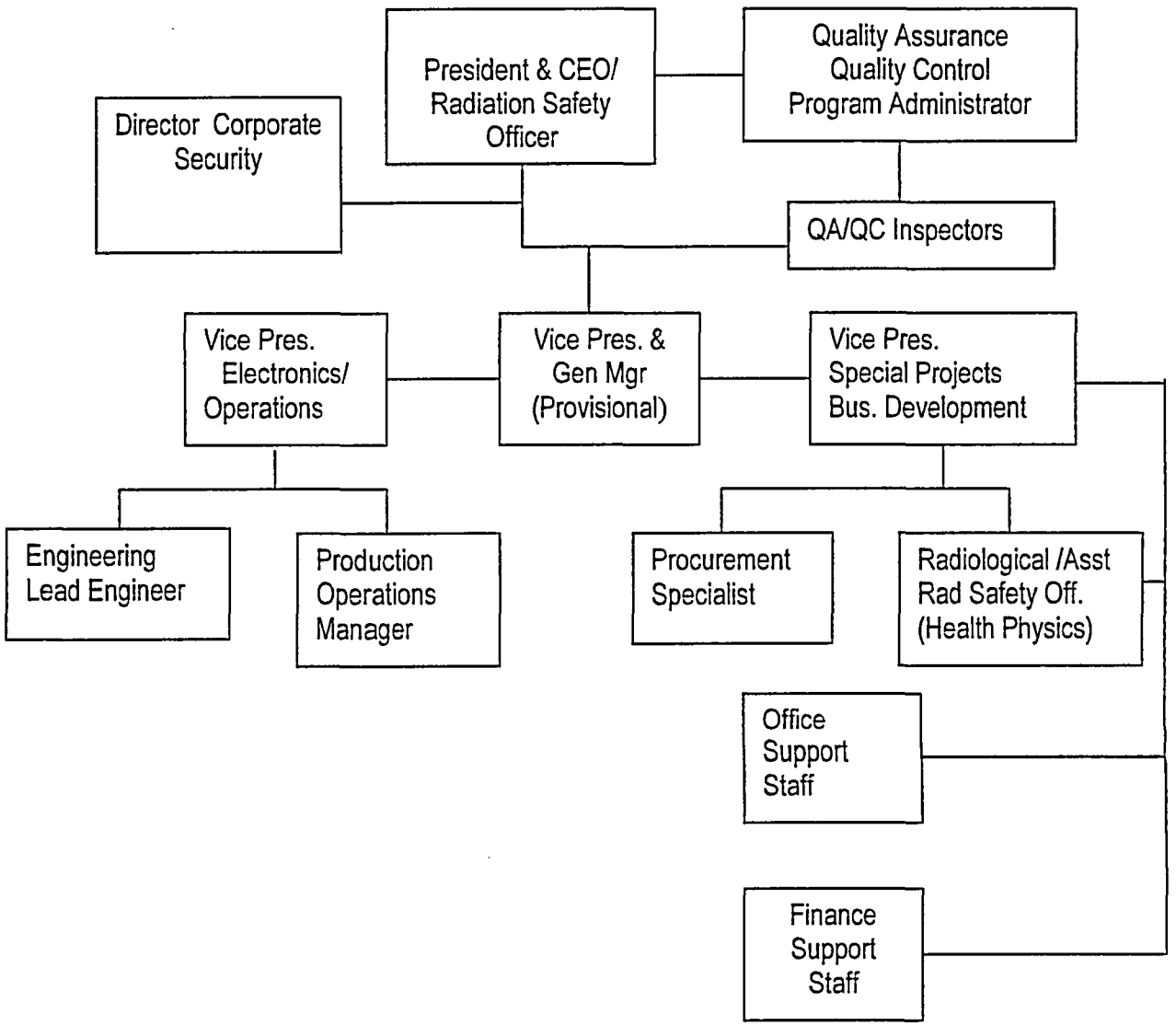
If disputes arise, either internally or by an outside entity, a review of the dispute and any applicable regulatory criteria is performed by JLS&A. Resolutions are subject to review by upper JLS&A management for final approval.

1.0 QUALITY ASSURANCE ORGANIZATION, continued.

1.6 JLS&A QA/QC Organizational Chart, representational showing functional organizational arrangement

CONDUCT OF OPERATIONS

Representational Functional Arrangement



2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM

2.1 Regulatory References for Quality Assurance Program Plan

This JLS&A Quality Assurance Program Plan (QAPP) is formulated in a graded approach in accordance with the requirements found in 10CFR71 – Packaging and Transportation of Radioactive Material, Subparts A, B, C, D, E, F, G and H, which are applicable to JLS&A Type B package quality, safety and transportation related activities.

2.2 10CFR Subpart A – General Provisions

71.0 Purpose and Scope

This Subpart establishes the requirements for the packaging, shipment preparation and transportation of Type B quantity radioactive materials and the procedures and standards for US Nuclear Regulatory Commission (NRC) approval of packaging and shipping procedures. Packaging and transport are also subject to the regulations of the U.S. Department of Transportation (DOT), U.S. Postal Service (USPS), and U.S. Coast Guard in addition to 71.0.

Provisions in Subpart A apply for JLS&A. An NRC general license is required. JLS&A is a Type B quantity radioactive materials packaging approval holder. JLS&A applications for NRC certificates of compliance for packages are to be prepared in accordance with Subpart D, which includes having an NRC approved Quality Assurance Program, to demonstrate that the package design satisfies standards found in Subpart E and test criteria found in Subpart F. For the transport or delivery to a carrier for transport, operating controls and procedure requirements are found in Subpart G, quality assurance requirements in Subpart H, general provisions of Subpart A; and DOT regulations referenced in 71.5.

JLS&A is a small business operating primarily as a discrete, made to order, manufacturer of irradiation and calibration facilities (devices) and the sealed radioactive sources contained therein. JLS&A procures or uses Type B packages manufactured by others and/or manufactures and uses Type B packages to facilitate the safe shipment of Type B quantity sealed sources in devices or for transfer into devices, which is the primary scope and focus of this Quality Assurance Program. JLS&A does not design, manufacture or contract for Type B packaging for the shipment of radioactive waste, radioactive liquids or nuclear fuel.

JLS&A was founded on January 9, 1967. Since its inception, the company mission has been to provide and ship the safest, most reliable possible gamma, beta and neutron irradiation and calibration sources and devices, and to provide the associated cradle to grave services and activities required for their safe use, relocation, or decommissioning. Concern for the radiological safety of staff, clients, and public is the fundamental basis of JLS&A's corporate policy and management's commitments and convictions.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.3 10 CFR Subpart B – Exemptions

71.12 Specific Exemptions

JLS&A may request specific transportation exemptions from the NRC.

71.13 Exemption of Physicians – not applicable for JLS&A.

71.14 Exemption for Low Level Material.

JLS&A is exempt from the requirements of this part if shipping packages of radioactive materials does not exceed 10 times the values specified in Appendix A, Table A-2 (activity concentration) for natural materials and ores, materials for which the activity concentration is not greater than the activity concentration or consignment values as found in Appendix A, Table A-2, Type A quantity radioactive materials, or special form americium or plutonium sources with an aggregate activity not exceeding 20 Curies with no fissile material or exemption standards thereof are met, in accordance with 71.5 and 71.88.

71.15 Exemption from Classification as Fissile Material.

Fissile material meeting the requirements of at least one of the paragraphs (a) through (f) of this section are exempt from classification as fissile material and from the fissile material package standards of §§ 71.55 and 71.59, but are subject to all other requirements of this part, except as noted.

(a) Individual package containing 2 grams or less fissile material.

(b) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid non-fissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid non-fissile material.

(c)(1) Low concentrations of solid fissile material commingled with solid non-fissile material, provided that:

(i) There is at least 2000 grams of solid non-fissile material for every gram of fissile material, and

(ii) There is no more than 180 grams of fissile material distributed within 360 kg of contiguous non-fissile material.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.3 10 CFR Subpart B – Exemptions (continued)

(2) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid non-fissile material.

(d) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass.

(e) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2 percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package.

(f) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

2.4 10CFR Subpart C – General Licenses

71.17 General Licenses: NRC approved package.

This subchapter is applicable to JLS&A activities for either transporting or delivering to a carrier for transport, licensed materials in NRC certificate of compliance packages, or for other approvals issued by the NRC.

- This general license is applicable for JLS&A, which maintains an NRC-approved quality assurance program, satisfying a graded approach to 10CFR71, Subpart H criteria.

- This general license is only applicable when JLS&A has the following:

  (1) Has a copy of the CoC, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

  (2) Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of this part; and

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.4 10CFR Subpart C – General Licenses, continued.

(3) Before the licensee's first use of the package, submits in writing to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

(4) This general license applies only when the package approval authorizes use of the package under this general license.

(5) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of § 71.19.

71.19 Previously Approved Type B Package.

JLS&A can use previously NRC approved Type B packages without a B(U) or B(M) designation with limitations as follows, until October 1, 2008:

Per paragraph a). Fabrication must have been completed before August 31, 1986, as demonstrated by application of its model number in accordance with 71.85.

A serial number that uniquely identifies each package which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each package.

Per paragraph b). For packages not designated as "-85", fabrication must have been completed by April 1, 1999, as demonstrated by application of its model number in accordance with 71.85.

A serial number that uniquely identifies each package which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each package.

The package cannot be used outside the US without obtaining a DOT multilateral approval as defined in 49CFR173.403.

Per paragraph c). For packages bearing the designation "-85" fabrication must have been completed by December 31, 2006, as demonstrated by application of its model number in accordance with 71.85.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.4 10CFR Subpart C – General Licenses, continued.

A serial number that uniquely identifies each package which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each package.

The package cannot be used outside the US without obtaining a DOT multilateral approval as defined in 49CFR173.403.

JLS&A must submit modification plans for these packages to the NRC for approval and identification number revision or changes must not be significant to the design, operation, or safety when the package is tested per 71.71 and 71.73.

71.20 General License: DOT Specification Container.

JLS&A either transports, or delivers to a carrier for transport, licensed material for Type B quantity radioactive material packages as specified by the DOT in 49 CFR173 and 178.

This general license is applicable for JLS&A which maintains an NRC approved quality assurance program, satisfying a graded approach to 10CFR71, Subpart H criteria.

This general license is only applicable when JLS&A has the following:

Has a copy of the specification;

complies with the terms and conditions of the specification;

complies with the applicable requirements of 10CFR71, Subparts A, G, and H;

the package cannot be used outside the US without obtaining a DOT special arrangement per 49CFR173.471 or 49CFR173.403, as appropriate.

This provision expires October 1, 2008, unless a DOT exemption or special permit is granted for continued use.

71.21 General License: Use of Foreign-Approved Package.

JLS&A either transports or delivers to carriers for transport licensed material in packages approved by certificate by foreign national competent authorities with DOT re-validation.

JLS&A uses these packages solely for transport made to or from locations outside the US.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.4 10CFR Subpart C – General Licenses, continued.

This general license is applicable for JLS&A when:

A copy of the specific license, certificate of compliance and revalidation or other package approval, with the drawings and other documents referenced in these documents relating to maintenance and use and actions to be taken prior to shipment compliance with the terms and conditions of these documents, and with the applicable requirements of 10CFR71 Subparts A, G, and H, with quality assurance program exemptions from design, construction and fabrication considerations.

71.22 General license: Fissile material.

A general license is issued to any licensee of the Commission to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package and contains no more than a Type A quantity of radioactive material. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a). At present, JLS&A does not package, ship, or receive fissile materials in excess of those quantities identified in Table 71-2, Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per § 71.22(e).

71.23 General license: Plutonium-beryllium special form material.

A general license is issued to any licensee of the Commission to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package, contains no more than a Type A quantity of radioactive material and contains less than 1000 g of plutonium, provided that Pu-239, Pu-241 or and combination of these radionuclides constitutes less than 240 g of the total quantity of plutonium on the package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a). For shipment of multiple packages, the sum of CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 CSIs (for shipment on an exclusive use conveyance). JLS&A is a shipper of Pu-Be in licensed quantities permitted by this section.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.5 10CFR Subpart D – Application for Package Approval.

71.31 Contents of Application

JLS&A's quality assurance program description per 10CFR71.37 must be submitted as part of the application; and design, planning, and execution of such packages will fall under Subpart D criteria.

71.33 Package description.

The application must include a description of the proposed package in sufficient detail to identify the package accurately and provide a sufficient basis for evaluation of the package. At a minimum package description must include all information as called out in (1) through (8) of this paragraph. JLS&A's Quality Assurance Program and related Quality Assurance Procedures provide detailed instructions for package description requirements.

71.35 Package evaluation.

JLS&A's Quality Assurance Program and related Quality Assurance Procedures provide adequate instructions for inclusion of package evaluation criteria in any package certificate application. Specifically, instructions include the following:

(a) A demonstration that the package satisfies the standards specified in subparts E and F of this part;

(b) For a fissile material package, the allowable number of packages that may be transported in the same vehicle in accordance with § 71.59; and

(c) For a fissile material shipment, any proposed special controls and precautions for transport, loading, unloading, and handling and any proposed special controls in case of an accident or delay.

Note: JLS&A does not package, load, unload or handle fissile materials as part of normal business operations.

71.37 Quality Assurance.

JLS&A's quality assurance program, per 10CFR71, Subpart H, will describe the design, fabrication, assembly, testing, maintenance and use of proposed packages, including identification of applicable standards and codes or specific quality assurance provisions.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.5 10CFR Subpart D – Application for Package Approval, continued.

Applicable standards for packages may be found in 10CFR71, Subpart E, and prototype testing criteria are found in 10CFR71, Subpart F.

71.38 Renewal of a certificate of compliance or quality assurance program approval.

(a) JLS&A shall apply for renewal of any Certificate of Compliance or Quality Assurance Program in accordance with this paragraph. Each Certificate of Compliance or Quality Assurance Program Approval expires at the end of the day, in the month and year stated in the approval.

(b) In any case in which a person, not less than 30 days before the expiration of an existing Certificate of Compliance or Quality Assurance Program Approval issued pursuant to the part, has filed an application in proper form for renewal of either of those approvals, the existing Certificate of Compliance or Quality Assurance Program Approval for which the renewal application was filed shall not be deemed to have expired until final action on the application for renewal has been taken by the Commission.

(c) In applying for renewal of an existing Certificate of Compliance or Quality Assurance Program Approval, an applicant may be required to submit a consolidated application that incorporates all changes to its program that, are incorporated by reference in the existing approval or certificate, into as few referenced documents as reasonably achievable.

71.39 Requirement for additional information.

The Commission may at any time require additional information in order to enable it to determine whether a license, certificate of compliance, or other approval should be granted, renewed, denied, modified, suspended, or revoked. Such requests will be formally addressed by the JLS&A Quality Assurance Program with appropriate document controls applied.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.6 Subpart G – Operating Controls and Procedures.

71.81 Applicability of Operating Controls and Procedures.

JLS&A is bound by this Sub-Chapter as a general licensee, by either transporting or delivering to a carrier for transport, licensed materials in NRC certificate of compliance packages and is required to comply with the quality assurance requirements of 10CFR71, Subpart H, and general provisions of Subpart A.

71.83 Assumptions As To Unknown Properties.

Not applicable. JLS&A does not ship fissile materials.

71.85 Preliminary Determinations.

As part of the Subpart H Quality Assurance Program, JLS&A shall determine prior to the first use of any package that there are no defects which could significantly reduce the effectiveness of the package, the maximum normal operating pressure requirements (if applicable), that the package has been manufactured in conformance with the design approved by the NRC before appropriately marking the package in a conspicuous and durable manner; i.e., model number, serial number, gross weight, and package identification number.

71.87 Routine Determinations.

As part of the Subpart H Quality Assurance Program, JLS&A determines prior to each Type B radioactive materials package shipment that the following applicable criteria are satisfied:

The package is correct for the contents being shipped;

The package is in good physical condition, except for uncritical marks or dents;

The package closure, including any gaskets, is properly installed secured and free of defects (as applicable);

Any system for containing liquids is adequately sealed with provision for expansion. Normally, JLS&A does not ship liquids;

Any pressure relief valve (if installed) is operable and set in accordance with written procedures;

The package has been loaded and closed in accordance with written procedures;

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.6 Subpart G – Operating Controls, continued.

Determinations for fissile materials are not applicable for JLS&A;

Package lifting fixtures or tie downs are made inoperable for shipment unless part of package approval, unless it meets the design requirements of 71.45;

The level of removable contamination is as low as achievable and within DOT permissible levels per 49CFR173.443; and,

The package surface temperature will not exceed permissible levels per 10CFR71.43(g).

71.88 Air Transportation of Plutonium.

JLS&A will not ship plutonium by air in any form, either domestically or, import/export, unless the criteria found in paragraphs (1) through (4) is applicable.

71.89 Opening Instructions.

JLS&A will make available to the consignee, prior to transport, any special instructions needed to safely open the package, for consignees use per 10CFR20.1906(e).

71.91 Records.

JLS&A shall maintain the applicable records called out in this section for each shipment for a period of three years after the shipment.

71.93 Inspection and Tests.

JLS&A shall notify the commission 45 days in advance of beginning fabrication of the first packaging under a Certificate of Compliance in accordance with paragraph (c) of this part. Additionally, JLS&A shall permit the NRC to inspect JLS&A facilities and activities in accordance with this paragraph. Further, JLS&A shall perform, and permit the commission to perform any inspections and/or tests the commission deems necessary or appropriate for the administration of this section.

71.95 Reports.

(a) JLS&A, after requesting the certificate holder's input, shall submit a written report to the Commission of--

(1) Instances in which there is a significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use; or

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM. continued.

2.6 Subpart G – Operating Controls, continued.

(2) Details of any defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.

(3) Instances in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.

(b) JLS&A shall submit a written report to the Commission of instances in which the conditions in the certificate of compliance were not followed during a shipment.

(c) JLS&A shall submit, in accordance with § 71.1, a written report required by paragraph (a) or (b) of this section within 60 days of the event or discovery of the event. JLS&A shall also provide a copy of each report submitted to the NRC to the applicable certificate holder. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. Using an appropriate method listed in § 71.1(a), JLS&A shall report to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards. The reports will include the following:

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2) A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description will include the following specific information as appropriate for the particular event.

(i) Status of components or systems that were inoperable at the start of the event and that contributed to the event;

(ii) Dates and approximate times of occurrences;

(iii) The cause of each component or system failure or personnel error, if known;

(iv) The failure mode, mechanism, and effect of each failed component, if known;

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.6 Subpart G – Operating Controls, continued.

(v) A list of systems or secondary functions that were also affected for failures of components with multiple functions;

(vi) The method of discovery of each component or system failure or procedural error;

(vii) For each human performance-related root cause, a discussion of the cause(s) and circumstances;

(viii) The manufacturer and model number (or other identification) of each component that failed during the event; and

(ix) For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

(3) An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

(4) A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

(6) The name and telephone number of a person within JLS&A's organization who is knowledgeable about the event and can provide additional information.

(7) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(d) Report legibility. JLS&A shall provide reports of sufficient clarity and content so as to facilitate reproduction and/or microfilming.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.7 Subpart H – Quality Assurance

71.97 Advance Notification of Shipment of Nuclear Waste.

For purposes of this paragraph, JLS&A does not ship nuclear waste, as defined. In the event of a future need to ship nuclear waste, the requirements of this paragraph will be fulfilled.

71.101 Quality Assurance Requirements

This JLS&A Quality Assurance Program Plan, with implementing documents (i.e., written procedures, contained in quality assurance/quality control manuals, as approved by appropriate levels of JLS&A management), describes JLS&A's commitments to a graded approach (i.e., to an extent consistent with important to safety) quality assurance program in order to provide quality control over all important to safety activities, as applicable to the design, purchase, fabrication, handling, shipping, storage, cleaning, assembly, inspection, testing, operation, maintenance, repair and modifications of Type B radioactive materials packages.

JLS&A utilizes existing package designs and packages owned by others, per (d) and (e) of this paragraph.

JLS&A has established criterion with management reviews for distinguishing, identifying and controlling the important to safety components, structures and systems to be incorporated into the quality assurance program, and for verifying that any applicable components, structures and systems meet the design parameters. These criterion include pertinent documentation that important to safety activities are accomplished under controlled conditions using specified and applicable M&TE equipment, environmental conditions, special processes, codes standards and work instructions, and that these activities are performed by trained, qualified and knowledgeable personnel.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.8 Implementing Procedures, 71.101 – 71.137.

Implementing Document	Subject Matter	10CFR71 Subpart H Criteria 18 Pts	Description
QAM/QP 1.0	Quality Assurance Program Plan	1	Describes established procedures for JLS&A's documented QA/QC program, originally implemented in 1979, under 10CFR71, Appendix E, currently Subpart H. Status: Complete 5/9/2003
	Job Descriptions	1	Identifies individual QA/QC job functions within organization structure, responsibilities, authority and duties. Status: Complete, 5/9/2003.
QAM/QP 2.0	Organization and Staffing	2	Identifies JLS&A internal organizational structure& relationships in performance of activities affecting quality. Defines training requirements, auditor qualifications, and inspection qualification. Other organizational functions described in sub procedures. Status: Complete 5/9/2003
QAM/QP 3.0	Design Control	3	Describes established procedures for control of design process, input and verification, directly related to NRC issued "Certificate of Compliance for Radioactive Materials Package Design", and USDOT "Certificate of Competent Authority" for Type B Quantity (Specification) Packages or DOT re-validated foreign Type B packages, including standards and prototype test criteria. Other relevant design functions described in sub procedures as necessary. Status: Completed 5/9/2003.
QAM/QP 4.0	Procurement Document Control	4	Describes established procedures for control of procurement document (purchase order) preparation, reviews, concurrences, and approvals, including but not limited to technical requirements, documentation, access to supplier facilities for audits, certifications and change orders. Other relevant functions described in sub procedures as necessary. Status: Complete 5/9/2003.
QAM/QP 5.0	Instructions, Procedures and Drawings	5	Describes established procedures for documented instructions, procedures, drawings, and acceptance criteria for important to safety activities. Also provides writing and style guide, definition of terms used within procedures. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003.
QAM/QP 6.0	Document Control	6	Describes established procedures for document generation, issuance and changes, to include drawings and specifications, design changes, procurement documents, QA/QC manuals, inspection & test procedures, nonconformance reports, corrective action reports, and others. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003.

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM. continued.

2.8 Implementing Procedures, 71.101 – 71.137, continued.

Implementing Document	Subject Matter	10CFR71 Subpart H Criteria 18 Pts	Description
QAM/QP 7.0	Control of Purchased Materials, Parts, Components, Equipment and Services	7	Describes procedures for procurement document planning, selection of procurement sources, supplier conformance control, verification activities, controlling nonconformances, deviations, and corrective action. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003
QAM/QP 8.0	Identification of Materials, Parts, and Components	8	Describes procedures for the identification, control & conditional releases of materials, parts & components including limited shelf-life items. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003.
QAM/QP 9.0	Control of Special Processes	9	Describes procedures for the control of special processes, including qualifications of procedures, equipment, personnel, operations and records. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003.
QAM/QP 10.0	Inspection	10	Describes procedures for inspections, inspection records and qualification of inspection personnel. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003.
QAM/QP 11.0	Test Control	11	Describes requirements, defines procedures for establishment and evaluation of test criteria, result documentation and evaluation of test activities. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003.
QAM/QP 12.0	Control of Measuring and Test Equipment	12	Describes procedures for M&TE selection, calibration requirements and records. Further defines process of recall in event of significant out of tolerance condition. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003.
QAM/QP 13.0	Handling, Storage, and Shipping	13	Describes procedures for handling, storage & shipping, including preservation, release and delivery in accordance with regulatory guidelines, licenses, approvals & Certificates of Competent Authorities. Other relevant functions described in sub procedures as necessary. Status: Complete 5/9/2003.
QAM/QP 14.0	Inspection, Test and Operating Status	14	Describes procedures for inspection, test and operating status. Further defines inspection process. Other relevant functions described in sub procedures as necessary. Status: Complete 5/9/2003

2.0 PURPOSE AND SCOPE OF QUALITY ASSURANCE PROGRAM, continued.

2.8 Implementing Procedures, 71.101 – 71.137, continued.

Implementing Document	Subject Matter	10CFR71 Subpart H Criteria 18 Pts	Description
QAM/QP 15.0	Control of Nonconforming Items	15	Describes established procedures for control of nonconforming materials, parts, components and services, including identification, segregation, disposition and evaluation thereof. Other relevant functions described in sub procedures as necessary. Status: Completed 5/9/2003.
QAM/QP 16.0	Corrective Action	16	Describes established procedures for implementing corrective action, including root cause analysis, inspection, monitoring and closeout. Further defines process of 10CFR21 reporting of significant safety related nonconforming items. Other relevant functions described in sub procedures as necessary Status: Completed 5/9/2003.
QAM/QP 17.0	Quality Records	17	Describes established procedure for maintenance of QA records, including design, procurement, manufacturing, installation, process evaluations, employee evaluations, nonconformance reports, inspection records, test reports, audits, analysis, as-built drawings and specifications, personnel qualifications procedures, equipment calibration procedures, training records, corrective action reports; includes record generation, indexing and classification, receipt, retrieval, disposition, storage, preservation and safekeeping thereof. Other relevant functions described in sub procedures as necessary Status: Completed 5/9/2003.
QAM/QP 18.0	Audits	18	Establishes an audit program designed to fairly evaluate effectiveness of implementation of QA/QC program and program controls. Includes guidance on scheduling, audit team structure, documentation, pre and post audit conferencing, reporting and corrective action. Other relevant functions described in sub procedures as necessary Status: Completed 5/9/2003.

3.0 DESIGN CONTROL

3.1 Regulatory Reference.

71.107 Package Design Control

JLS&A shall use applicable regulatory requirements for design control per 10CFR71, including this paragraph, Subpart D – Application for Package Approval, 71.31 through 71.39, Subpart E – Package Approval Standards, 71.41 through 71.51, Subpart F – Package and Special Form Tests, 71.21 through 71.77, and Subpart G – Operating Controls and Procedures, in a graded, important to safety approach for package designs.

JLS&A's engineering organization, in conjunction with management, quality assurance and production, is responsible for the oversight and implementation of this part of the quality assurance program. JLS&A's implementing documents establish criterion to assure that:

Applicable regulatory requirements pertinent to a package design are established, interpreted, and translated into specifications, drawings, procedures and instructions;

Measures are established regarding selection and review of the applicability and suitability for safety related functions of materials, parts, and components;

Measures are established for the identification and control of design interfaces and for coordination among design organizations, including written procedures for review, release, distribution and revision to interfaces;

Measures are established for verification or checking of design adequacy, by review, calculations, or prototype test programs which may employ use of outside agencies meeting vendor approval criteria;

Design control measures are established for other applicable safety related areas such as radiation shielding, stress, thermal limitations or considerations, accident analysis, compatibility of materials, accessibility for in-use inspections, maintenance, repair, decontamination and acceptance criteria for inspections and tests;

Design control measures are established for design changes, which are subject to the original design criteria, including those changes requiring re-application to the NRC for review and package approval amendments, in a graded approach to safety, consistent with each element's important to safety.

3.0 DESIGN CONTROL, continued.

3.2 Statement of Verification of Package Design Process Control

JLS&A has drafting/drawing standards, with provisions for drawing checks, review and approval protocols, issuance and distribution. Protocols are established for the development of a graded approach to the classification of important to safety package characteristics, with reviews to determine compliance with prototype test and inspection criteria.

JLS&A's revisions to drawings are controlled in the same manner as the originals. Any package drawing changes are documented, incorporating the current design and/or specifications. Package drawing changes require certificate of conformance review and approval, and transmittal of this information to the appropriate departments or licensing authorities, as appropriate, prior to release for production.

JLS&A's original, obsolete drawings or specifications are so marked and copies are removed from production points, as necessary.

JLS&A's central drawing list is maintained according to Quality Assurance Procedures.

JLS&A's specification (regulatory) references, codes and standards, are maintained in various locations at JLS&A facilities and are utilized as necessary by respective JLS&A organizations.

3.3 Statement of Verification of Responsible Package Design Input and Compliance with Regulatory Certificates and Requirements.

JLS&A's design procedures for packages require that designs are approved by the appropriate licensing/regulatory authority after prototype testing or calculation analysis.

JLS&A's prototype designs for certificate packages shall have any required regulatory approvals pending. The initial design of a package requires providing licensing authorities with all pertinent information as required by the approval criteria; i.e., prototype testing or calculations, design review, drawings, instructions or procedures as applicable. New designs will be formulated in accordance with package design and use criteria, with any applicable standards or regulatory guides, or sections thereof, and references used as required.

New certificate package designs and implementing documents or changes requiring approval to existing certificate package designs, will use a graded approach to safety or quality classification of systems, reflecting the applicable parts of the NRC's Classification of Transportation Packaging and Dry Spent Fuel Storage Systems Components, NUREG/CR6407.

3.0 DESIGN CONTROL,

3.3 Statement of Verification of Responsible Package Design Input and Compliance with Regulatory Certificates and Requirements, continued.

After licensing authority approval is granted to JLS&A and prior to release for production of new packages, drawings are to be reviewed for conformance to the approval specifications.
The standards used by JLS&A in this graded safety and quality approach QA/QC Program are contained within the provisions of 10CFR71, Subpart H, and pertain to applicable criteria consistent with each style or type of package design, manufacture, and use.

3.4 Statement of Verification of Adequacy of Package Design and, That Quality Standards Are Maintained.

JLS&A ensures the verification of adequate design for packages by means of prototype testing, modeling or calculation, which are allowed in licensing applications and approvals. Actual prototypes may be tested and inspected in the appropriate stages to verify that they meet all licensing authority criteria and design specifications. Inspection and test criteria are documented. 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 can be achieved.

JLS&A's design verification is performed in accordance with approved procedures that define responsibilities, methods, and documentation requirements. Design verification is performed by qualified independent personnel, other than the original designer.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Regulatory Reference.

71.109 Procurement Document Control.

JLS&A has procedures to ensure that quality control of procured safety-related material, equipment, and services for Type B quantity radioactive material packages, vendors who maintain quality assurance programs, as applicable, and specifies the rights of access, inspection and document retention on purchasing documents issued.

JLS&A's quality assurance organization, in conjunction with management, engineering and production, is responsible for the oversight and implementation of this part of the quality assurance program.

JLS&A's QAPP implementing documents establish criterion to assure adequate quality control is maintained over purchasing documents and processes.

4.2 Statement of Verification of Purchasing Department Procedure for Packages.

JLS&A has established procedures which control the preparation, review concurrence and/or approval for the preparation of bills of materials which are the guidance documents for the purchasing department. These procedures define a sequence of actions for the conduct of purchasing operations.

4.3 Statement of Verification That the Scope of Work is included on Purchase Orders for Packages.

JLS&A's purchase requisition documents provide the purchasing department with purchase order information and instructions pertinent to the scope of work to be performed by the vendor.

4.4. Statement of Verification That Appropriate Reference of Specifications Appear on Purchase Orders.

JLS&A's purchase requisition documents provide purchasing activities with the appropriate package references regarding 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, to be included on purchase orders when applicable.

4.0 PROCUREMENT DOCUMENT CONTROL, continued

4.5 Statement of Verification That Subpart H Criteria and Appropriate Reference of Documentation Appear on Purchase Orders.

JLS&A's purchasing activity in coordination with licensing and engineering identifies 10CFR71 Subpart H criteria, when applicable, as provided by bill of materials instruction, per 4.2 above, for packages. The following items will also be required, as applicable: certification of model and serial number; NRC approved QA/QC Program for manufacturing, use and maintenance instructions, and verification procedures; Certificates of Compliance; use and maintenance manuals; drawings and photographs, or sketches.

4.6 Statement of Verification That Package Purchase Orders Contain a "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 inspections or audits, when applicable.

4.7 Statement of Verification That Appropriate Documents Are Retained by Vendor and/or Delivered to Purchaser for Packages.

JLS&A's bill of materials provides the appropriate references of records, certification or test reports to be retained, controlled and maintained by the supplier and for those which are to accompany delivery to JLS&A, to be included with the purchase order when applicable. When possible, these items are specified in supplemental instructions to vendors.

4.8 Statement of Verification That NonConformances are Reported and Dispositioned.

JLS&A implements and maintains procedures which are used to identify, report and disposition nonconforming information, features, processes, or specification deviation from purchase documents.

4.9 Statement of Verification That Package Purchase Order Revision is Subject to Review and Approval.

JLS&A's purchasing department has instructions that require revisions or changes to purchase requisition documents, or specifications contained therein, made by purchasing, the vendor or subcontractor, are to be subjected to the same review and approval by the issuing department as were the original documents.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS.

5.1 Regulatory Reference.

71.111 Instructions, Procedures, and Drawings.

JLS&A has procedures to ensure that control of package quality and important to safety affected activities are documented. Documentation is administered through the use of instructions, procedures or drawings as appropriate to the activity, and includes quantitative or qualitative acceptance criteria.

JLS&A's quality assurance organization, in conjunction with management, engineering and production is responsible for the oversight and implementation of this part of the quality assurance program.

5.2 Statement of Verification that Package Important-to-Safety Activities Are Accomplished In Accordance With Specifications.

Important to safety activities affecting the quality of packages, are accomplished by JLS&A according to documented instructions, procedures, and/or drawings.

5.3 Statement of Verification of Compliance per 10CFR71, Subpart H Criteria.

JLS&A's QAPP administrative and implementing procedures contain adequate instructions, procedures and drawings, to demonstrate compliance with applicable sections of 10CFR71, Subpart H, relative to package parts, materials, and components.

5.4 Statement of Verification that Package Safety-Related Activities are Satisfactorily Accomplished.

JLS&A's implementing procedures for packages include requirements for dimensions, tolerances, operating limits and specifications, as applicable, for safety related activities to determine that inspection and acceptance criteria verify that these have been satisfactorily accomplished.

5.5 Statement of Verification of Quality Assurance Responsibility.

JLS&A's quality organization is arranged, such that particular departments are assigned authority and responsibility for implementing various elements of the quality related activities under the auspices of the QAPP. As described above, certain staff members have been trained, certified and authorized to perform verifications of safety related activities. In all cases these individuals are restricted from performing any type of direct work activity relative to the respective verification processes for which they are assigned. The QA/QC department reviews

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS, continued.

5.5 Statement of Verification of Quality Assurance Responsibility, continued.

these activities to ensure that procedures, instructions and applicable regulations of NRC and DOT are being implemented and followed.

5.6 Statement of Verification that Packages Are Prepared for Use.

JLS&A's QA/QC instructions and procedures are designed and established to meet the applicable routine determination requirements of 10CFR71.87, for placing packages in use and/or for inspection before re-use as part of the QA/QC program.

5.7 Statement of Verification that Package Repair, Rework and Maintenance Instructions are Established.

JLS&A's procedures ensure that routine or major repair, rework, and/or maintenance instructions for packages are prescribed before that work begins. Important to safety activities are required to be reviewed by the quality assurance staff and are included in instructions and procedures as applicable. These activities have prescribed QA/QC hold points for QA/QC inspections and are coordinated with the Quality Assurance Department.

5.8 Statement of Verification of Package Storage, Packaging and Delivery Instructions.

JLS&A has procedures and/or instructions for package storage, packaging and delivery. DOT and/or NRC shipping regulations are documented and implemented in accordance with the formally approved procedures for all packages.

5.9 Statement of Verification of Package Loading/Unloading Procedures.

JLS&A's receiving procedures ensure that loading/unloading of radioactive materials packages meets regulatory requirements, including but not limited to radiation surveys, contamination wipe surveys, and rigging, for packages, as applicable.

5.10 Statement of Verification of Proper DOT Transport of Package.

JLS&A's outgoing shipments of packages are controlled using procedures that ensure the packages are in compliance, in good operating condition, meet external contamination levels and are properly identified and labeled in accordance with all pertinent DOT and NRC regulations.

6.0 DOCUMENT CONTROL

6.1 Regulatory Reference

71.113 Document Control

JLS&A has procedures to ensure that issuance of quality and important to safety related documents for Type B radioactive materials packages, such as instructions, procedures and/or drawings, and the changes thereto, are controlled and maintained. These procedures also ensure that this documentation and any changes thereto are reviewed for adequacy, approved for release by authorized personnel and that they are used and maintained in the locations where the activity is performed.

JLS&A's quality assurance organization, in conjunction with management, engineering and production, is responsible for the oversight and implementation of this part of the quality assurance program.

6.2 Statement of Verification of Controlled Documents for Packages

JLS&A's QA/QC procedures, implementing documents, and revisions thereto are controlled, utilizing methods such as computer password, by distribution or in controlled QA/QC files, as applicable. These documents may include, but are not limited to drawings, specifications, purchase orders, QA/QC manuals, change order reports, inspection reports, test reports, conformance reports, nonconformance reports, operating and maintenance procedures, loading and unloading procedures, repair and maintenance procedures, packaging for transport procedures, design change requests and corrective action reports.

6.3 Statement of Verification That the Issuance of Package Documents is Procedurally Controlled.

JLS&A has procedural controls to check, review, approve and/or change documents and/or procedures prior to issuance.

Each JLS&A department head retains a controlled copy of the QA/QC Manual and is provided changes and updates as applicable. The master copy of the QA program procedure documents is kept by the QA/QC Department under the control of the Document Coordinator, who is responsible for distributing approved revisions to all controlled copies of the QA/QC Manual and associated implementing procedures. Employees, customers, and/or outside auditors may receive uncontrolled copies of procedures or documents for specific programs, but do not receive changes or updates unless specifically requested.

6.0 DOCUMENT CONTROL, continued.

6.4 Statement of Verification That Changes to Package Documents Are Made By the Original Department That Prepared The Initial Document.

Any JLS&A department initiating QA/QC documents, when notified of the need for change or modification, approves revisions to the original documents. Major changes are reviewed and approved using the same process as the original document. Minor changes such as inconsequential editorial corrections, do not require the same level of review as the original document. Formally approved procedures define the types of changes considered minor and the process for requesting changes.

6.5 Statement of Verification that All Pertinent Package Documents Are Available At the Site Where They Are to Be Implemented.

Pertinent JLS&A procedural documents are available at the site where they are to be implemented, prior to starting work, whether at JLS&A's facility or temporary job sites. JLS&A has established formal procedures to control document distribution and to ensure that the most current documents are distributed.

6.6 Statement of Verification that Master Lists, Including Revisions, Are Current and Appear on Appropriate Package Documents.

JLS&A keeps a master index of QA/QC instructions and procedures which reflects the overall current status of the QP/QAM, with revisions. Revisions are identifiable, appear on the current appropriate documents and are distributed.

7.0 CONTROL OF PURCHASED MATERIALS, PARTS, COMPONENTS, EQUIPMENT AND SERVICES.

7.1 Regulatory Reference.

71.115 Control of Purchased Material, Equipment and Services.

JLS&A has inspection procedures to ensure that purchased materials, parts, components, equipment and/or services, important to safety/quality for Type B radioactive materials packages, comply with the purchase documents and the provisions contained therein.

JLS&A has established procedures for vendor evaluation and selection, including quality program evaluation as applicable and appropriate for the purchase of materials, parts, components, equipment and/or services.

JLS&A has established controls so that documentary evidence of receiving inspections and records showing conformance to the purchase orders is maintained for the life of the package.

JLS&A's quality assurance organization, in conjunction with management, engineering and production, is responsible for the oversight and implementation of this part of the quality assurance program.

7.2 Statement of Verification of Evaluation of Package Vendors (Selection of Procurement Sources).

JLS&A's QA/QC procedures provide necessary control over the selection of quality vendors, using a graded approach to evaluate the safety significance assigned to the item or vendor.

JLS&A's personnel responsible for determining bill of materials and/or purchase requisition documents (purchase order planning), vendor selection or for qualifying vendors' QA/QC programs, are trained and possess sufficient experience to establish vendor acceptability to meet specifications applicable for the purchase order.

JLS&A's vendor selection for materials, parts, components, equipment and/or services for packages is discretionary, is used in those situations as a function of the relative importance, complexity and quality of the item or service procured, along with vendor performance history and may be made by using all or part of the following criteria, as applicable:

7.0 CONTROL OF PURCHASED MATERIALS, PARTS, COMPONENTS, EQUIPMENT AND SERVICES, continued.

7.2 Statement of Verification of Evaluation of Package Vendors (Selection of Procurement Sources) continued.

The vendor's capability to comply with the appropriate elements of 10CFR71, Subpart H, or 10CFR21 and/or NRC approved QA/QC program (or equivalent), which are applicable to the type of material, part, component, equipment or service for the package being procured.

Continuous satisfactory performance of current vendors.

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

A survey or audit of the vendor's facility and QA/QC program is performed, 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, or a copy of the QA/QC Manual and/or NRC or DOE approval, are acceptable in lieu of a formal JLS&A survey or audit, or on a case by case basis as determined by the QA/QC Program Administrator.

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

Currently not applicable. JLS&A does not use the bid evaluation and awards process due to the nature of the materials or services provided, although they may be required by outside contractual obligations. JLS&A implements and maintains established procedures that ensure the appropriate departments evaluate prospective bidders, when required.

7.4 Statement of Verification that Inspection and/or Supervision of a Package Vendor is Performed. (Vendor Performance Control).

JLS&A performs receipt inspections, utilizing established inspection criteria to determine that items are properly identified and correspond to the specifications contained within purchasing documents.

JLS&A does not currently use items that are contingent on tests after installation on packages, but has procedures to establish inspection and conformance criteria for such activities.

If required, and as applicable, a JLS&A QA/QC Inspector will be present at the vendor's site during fabrication, testing and/or shipment of a package to assure conformance with purchase order specifications. Inspection and/or supervision requirements are transmitted to the purchasing staff using a bill of materials for inclusion in the purchase order.

7.0 CONTROL OF PURCHASED MATERIALS, PARTS, COMPONENTS, EQUIPMENT AND SERVICES, continued.

7.5 Statement of Verification of Minimum Records to be Supplied by Purchaser for Packages. (Verification Activities).

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

Documentation that identifies the purchased materials, parts, components, equipment or service and documented evidence that specific procurement requirements (e.g., codes standards and specifications) are met by the item;

Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances. Contingent on acceptance by JLS&A, all nonconforming items must be repaired or replaced and certification thereof provided by the vendor;

QA/QC inspection reports and documentation from vendor's facility, when applicable by contract terms or specifically requested by JLS&A management.

7.6 Statement of Verification of QA/QC Inspector Acceptability Criteria and Responsibility for Package Inspections (Controlling Nonconformances).

JLS&A's inspectors are responsible for and will not accept packages or package components that do not meet the following criteria:

The material, component or equipment is properly identified and corresponds with the requirement or specifications contained in receiving documentation, including verification of any documentation required by the purchase document.

In those instances of nonconforming items, the issuance of the following type documents is procedurally controlled:

Material Rejection Forms and/or tags for nonconforming parts, assemblies, etc.
In-House nonconformance report for nonconforming procedures etc.
NRC Part 21 or Part 71 nonconformance reporting, as appropriate.

When a commercial grade item identified in a design document is substituted with an alternate commercial grade item or If an item is recommended/considered to be "use as is" or "repaired", the supplier's design organization verifies that the substitute or "use as is" or "repaired" item will perform to the intended function satisfactorily, when appropriate justification documentation provided to JLS&A.

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

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

8.1 Regulatory Reference

71.117 Identification and control of material, parts, and components.

JLS&A has procedures to ensure that the identification and control of materials, parts and components relating to quality or important to safety items for Type B radioactive materials packages is achieved in order to prevent the use of the wrong or defective item.

JLS&A has procedures for identifying items in an appropriate and nondestructive manner, or by traceable documentary records during fabrication, installation or use phases.

JLS&A's quality assurance organization, in conjunction with management, engineering, and production is responsible for the oversight and implementation of this part of the quality assurance program.

8.2 Statement of Verification that Established Procedures are Used for Identifying and Controlling Materials, Parts, or Components for Packages.

JLS&A has procedures for identification of package materials, parts, and/or components received or fabricated as part of the QA/QC program.

8.3 Statement of Verification that Package Materials, Parts, or Components are Identified Properly.

As part of JLS&A's receiving procedures, all incoming quality or safety related materials, parts and /or components are inspected for conformance to the purchase order. They are then identified and marked to be directly traceable to specific jobs, or alternately placed into general inventory by the appropriate department. Non-inspected parts or components are held in separate inventory locations as applicable for the item. Non-conforming materials, parts, or components are placed in separate locations as applicable for those items.

8.4 Statement of Verification that the Location and Method of Identifying Package Materials, Parts, and/or Components is not Harmful to Them.

JLS&A's receiving areas and methods of identification (several methods are used as appropriate to the item) do not in any way interfere with the fit, function or quality of the package.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS, continued.

8.5 Statement of Verification that Identification Numbers for Packages are Verified Before Release.

Any item taken from JLS&A's general or dedicated inventory is verified to be the proper item for the job before release for fabrication, assembly or installation. Completed packages have discrete serial numbers which are verified before release for shipment.

8.6 Statement of Verification that Limited Life Items are Controlled.

Currently not applicable for the type of packages utilized by JLS&A. JLS&A implements and maintains established procedures that ensure the appropriate implementing controls are in place for the replacement of limited life items, whose shelf life has expired or the prescribed operation time has expired, as applicable.

8.7 Statement of Verification that Conditional Releases for Packages, Materials, Parts and Components are Controlled.

In those instances where required inspections and/or tests of package materials, parts, or components have not been completed, JLS&A has established controls to facilitate the continued processing activity. Identification by an appropriate tagging type method and control by segregation or by status indicators as appropriate of such items is procedurally maintained at all times. Conditional release of completed NRC or DOT approved Type B packages is not permitted under any circumstances. JLS&A has established provisions for identification, control and surveillance for prototype Type B packages slated for destructive testing before such testing occurs.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 Regulatory Reference

71.119 Control of Special Processes.

JLS&A has established procedures to assure that applicable special processes, including but not limited to, welding and non-destructive testing activities relating to quality or important to safety items for Type B radioactive materials packages are controlled and accomplished by qualified personnel using procedures which include applicable or appropriate codes, standards, specifications, criteria or other special requirements.

JLS&A's quality assurance organization, in conjunction with management, engineering and production is responsible for the oversight and implementation of this part of the quality assurance program.

9.2 Statement of Verification that Special Processes for Packages are Procedurally Controlled.

JLS&A has established procedural controls for packages which may be determined to require special processes, such as certified welding. Procedures for establishing controls for other special processes such as heat treating, non-destructive testing and/or cleaning are developed and controlled by work instructions as required for the package. Special processes are defined by JLS&A as those processes requiring specific standards outside the normal scope of operations.

9.3 Statement of Verification that Package Procedures, Equipment and Personnel Meet Applicable Specifications, Codes and Standards.

JLS&A has procedures and equipment, personnel training and qualifications programs which allow for the application of codes, standards, and/or specifications, required documentation and records as appropriate, for special processes. JLS&A has in place provisions for establishing additional qualified procedures, equipment and personnel training and qualifications for future applications.

9.4 Statement of Verification that Qualification Records Concerning Special Processes for Packages are Established and Current.

JLS&A has procedures that govern the conduct of special process operations and the retention requirements for qualification records associated with the special process. The qualification records for current processes and qualifications of personnel are kept current, with administrative controls to ensure that personnel and equipment qualifications are retained and current.

10.0 INSPECTION CONTROL.

10.1 Regulatory Reference

71.121 Internal Inspection

JLS&A has established measures for planning and accomplishing quality or important to safety inspections and/or for verifying conformance with documented instructions, procedures, and drawings for those activities. Receiving, in-process and/or final inspections are performed by individuals not performing the activity being inspected or, in cases where this is not practical or possible, by indirect control and conformance review. Specific hold points, when applicable, are incorporated into the appropriate documents. These inspections and reviews are designed to ensure that each activity affecting quality or safety is adequately identified, evaluated and documented in accordance with established procedures.

JLS&A's quality assurance organization, in conjunction with management, engineering and production, is responsible for the oversight and implementation of this part of the quality assurance program.

10.2 Statement of Verification that the Package Inspection Program Verifies Conformity of Items in Accordance with Established Procedures.

JLS&A's conformance inspections on packages are performed in accordance with established procedures, instructions, and/or checklists and are documented.

10.3 Statement of Verification that Package Receiving Inspections Verify the Integrity of Important to Safety Items.

JLS&A's receiving inspections for important to safety items are designed to verify integrity of such items. In the cases of re-usable packages, an inspection is performed, identifying maintenance and/or repair items, as required to assure package integrity and/or to prevent or mitigate the release of the radioactive materials or contamination. Receiving inspections also have provisions for purchase order conformance inspections, when applicable, and for physical control and disposition of accepted or rejected items.

10.4 Statement of Verification that Package In-Process Inspections are Established.

When appropriate and applicable to important to safety items, JLS&A has established procedures to ensure that in-process inspections are performed on packages, with the appropriate documentation maintained. JLS&A has provisions for establishing additional in-process inspection procedures, as required for future applications.

10.0 INSPECTION CONTROL, continued.

10.5 Statement of Verification that Package Final Inspections Verify Item Integrity.

JLS&A's final inspection verifies the package integrity. As a minimum, items are inspected for completeness, markings, calibration, adjustments, and protection from damage. The acceptance of the item will be documented and approved by authorized personnel. Modification, repair or replacement requires re-inspection or re-testing, as appropriate to verify acceptability.

10.6 Statement of Verification of Package Inspection Activity.

JLS&A's receiving inspections of materials, components, parts, equipment and services, as applicable, are performed by qualified QA/QC inspectors, not performing the activity being inspected. For in-house outgoing, loaded package inspections, QA/QC inspection personnel may have performed the activity being inspected and quality assurance or management personnel either supervise or perform final conformance verification of the activity, depending upon the safety aspects of the activity. For those situations involving remote site inspections for shipment activities, package preparation and inspections activities are performed by authorized and trained QA/QC personnel and quality assurance or management personnel either supervise or perform final conformance verification of the activity, depending upon the safety aspects of the activity.

The QA/QC Department audits these types of activities to ensure that the quality program is being implemented and maintained in accordance with established procedures and that the program is effective.

10.7 Statement of Verification that Package Inspectors are Qualified per A Training Program and that Qualifications Are Current.

JLS&A maintains in-house qualified QA/QC inspectors and their certifications and qualifications are on file. QA/QC personnel who verify conformance of work or activities for acceptance are qualified to perform QA/QC inspections in accordance with established procedures. These qualifications reference applicable standards or codes related to the safety aspects of the inspections to be performed. Personnel at temporary job sites require certification, training is provided and those records are also kept on file.

Training and qualification of inspectors is implemented and maintained in accordance with the criterion and processes defined in the appropriate procedures and specifications.

The QA/QC Manager/Administrator reviews these training activities to ensure that the quality program training is being implemented and maintained in accordance with established procedures and to verify the program is effective.

11.0 TEST CONTROL

11.1 Regulatory Reference.

71.123 Test Control.

JLS&A currently uses packages manufactured before August 31, 1986, and DOT specification packages or foreign approved packages with DOT revalidation. JLS&A implements and maintains formally established procedure protocols for initiating a formal prototype test or calculation review program in accordance with 10CFR71, Subpart G criteria; or, production tests, proof tests, operational tests, structural integrity, leak-tightness (if applicable), shielding integrity and thermal integrity testing is performed to current standards when either modifications requiring NRC review and approval or packages are tested to meet new standards. These protocols call out the determination of any applicable test to pre-determined standard and suitable environmental conditions; and, then documentation reviews, and evaluations assure that the test requirements have been met. The current types of packages used by JLS&A do not require production, proof or operational tests; however, procedure protocols are formally established if and when these tests are required.

JLS&A's quality assurance organization, in conjunction with management, engineering, and production, is responsible for the oversight and implementation of this part of the quality assurance program.

11.2 Statement of Verification that Package Test Programs and Procedures Are Established, Documented and Performed Accordingly.

JLS&A has protocols to establish a prototype test program and procedures pursuant to 10CFR71 Subpart G criteria, or to other current standards for packages when needed, i.e., when either modifications requiring NRC review and approval or packages are tested to meet new standards.

11.3 Statement of Verification that Packages Meet Test Acceptance Criteria Prior to Shipment

JLS&A has procedure protocols for package test programs which provide for the evaluation and verification of acceptance criteria prior to shipment and are implemented when required, which are package specific. Packages are identified both by serial number and DOT or NRC Certificate identification. Newly manufactured packages must pass a complete physical design and fabrication compliance inspection, including inspection of purchased parts and/or components, along with a review of conformance with the package's individual type of certificate and procedures, with a conformance verification before release for initial shipment. The compliance inspection for JLS&A packages includes structural integrity and shielding integrity (for the applicable package component). Repaired packages must pass a physical inspection including review of purchased parts and/or components.

11.0 TEST CONTROL, continued.

11.3 Statement of Verification that Packages Meet Test Acceptance Criteria Prior to Shipment, continued

Leak tightness, component performance and thermal integrity testing are not applicable for the types of packages used by JLS&A to ship sealed sources. Acceptance protocols are implemented prior to shipment, as described under Section 13, Handling, Shipping and Storage, to this QAPP, by implementing procedures, including instructions and inspections which contain acceptance or nonconformance criteria.

12.0 CONTORL OF MEASURING AND TEST EQUIPMENT (M&TE).

12.1 Regulatory Reference

71.125 Control of Measuring and Test Equipment.

JLS&A has procedures to assure that the applicable tools, gauges, instruments or other measuring and testing equipment related to quality or important to safety activities are properly controlled and calibrated.

JLS&A's quality assurance organization, in conjunction with management, engineering, and production, is responsible for the oversight and implementation of this part of the quality assurance program.

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

JLS&A maintains calibrated measuring and test equipment, based upon required accuracy, purpose, and degree of usage, stability characteristics or other conditions affecting the measurement of salient characteristics of a particular item, calibration requirements and frequency. Measuring and test calibration frequencies/intervals are established and implemented consistent with industry guidance and recommendations as applicable. Records of calibration history are maintained. Vendors are required to submit standards used and certifications, as required.

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

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

12.4 Statement of Verification that Calibration of Measuring and Test Equipment Meets Appropriate Standards.

JLS&A maintains requirements and procedures to ensure that package M&TE is calibrated to National Institute of Standards and Technology (NIST, formerly NBS), or other appropriate nationally recognized standard used for calibration. The parameters for that calibration procedure will be documented.

12.0 CONTORL OF MEASURING AND TEST EQUIPMENT (M&TE), continued.

12.5 Statement of Verification that Measurements Are Taken, Documented, and Validated, Against Previous Measurements When an Instrument Is Found To Be Out of Conformance During Calibration.

JLS&A requires that new measurements be taken to validate previous inspections in the event that an instrument is found to be out of conformance during calibration. The appropriate parties are notified, as applicable. Any measuring equipment which is consistently out of tolerance will be removed from service, then repaired or replaced.

13.0 HANDLING, STORAGE AND SHIPPING

13.1 Regulatory Reference

71.127 Handling, Storage and Shipping Control

JLS&A has instructions and procedures to control the handling, shipping, storage, cleaning, and preservation of packages to prevent their damage and/or degradation. Special protective environments are not required for the packages currently used by JLS&A. However, procedural controls are formally established to apply this protective system when situations call for such control.

JLS&A's quality assurance organization, in conjunction with management, engineering, and production, is responsible for the oversight and implementation of this part of the quality assurance program.

13.2 Statement of Verification that Handling, Storage, Cleaning and Routing Preservation Requirements for Packages are Accomplished in Accordance with Work and Inspection Instructions.

JLS&A has procedures that ensure the unloading, handling, storage, cleaning and preservation activities are performed in accordance with work and/or inspection instructions in order to prevent damage or degradation.

13.3 Statement of Verification that Special Requirements for Package Environments are Accomplished by Qualified Individuals in Accordance with Work and Inspection Instructions.

Currently there are no special requirements for special preservation associated with packages utilized or operated by JLS&A. In the future, if the scope of package operations or requirements change criteria for special inspection instructions and qualification of employees exists in current Quality Assurance Procedures for performing work related to special handling , preservation, storage, cleaning, packaging and shipping requirements, in order to preclude physical or environmental damage, as required for that package.

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

JLS&A has established a shipment preparation program, which includes a clear sequence of actions for inspections covering package acceptance criteria and/or documentation, prior to shipment of radioactive materials. Acceptance criteria will be based upon: Certificates of Compliance and compliance certifications thereof; drawings, operating and maintenance instructions or manuals; physical inspections based upon package criteria for integrity, or other documentation that may become applicable.

13.0 HANDLING, STORAGE, AND SHIPPING, continued.

13.5 Statement of Verification that Conditions of the NRC and DOT Shipping Regulations are Satisfied Before Shipment.

JLS&A performs package inspections before shipment of radioactive materials and documents all items pertinent to NRC (10CFR71, Subpart G) and DOT shipping regulations applicable to the package, package certificate of compliance, and for the shipment itself. Items must pass all criteria, including cumulative results of previous sections contained therein, all of which is documented, before shipment is made. Empty packages are screened for surface contamination, proper closure and general condition prior to shipment as an exempted empty package.

13.6 Statement of Verification that Inspections and Procedures are Established, Documented and Performed Accordingly on Packages.

JLS&A's quality assurance organization in conjunction with the health physics radiological inspection program ensures that packages remain in conformance, usable and free of excessive radiation and contamination, through a series of inspections, documented wipe tests and radiation surveys, which are reviewed and approved in advance of shipments and in accordance with established procedures.

13.7 Statement of Verification that Package Shipping Papers Are Properly Prepared.

All necessary shipping papers are prepared by JLS&A for shipment of loaded packages in accordance with NRC, DOT and/or other regulatory agency requirements with validation and control implemented utilizing JLS&A approved procedures. Shipping papers for radioactive shipments are reviewed and approved by specifically trained and authorized personnel.

13.8 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. JLS&A implements periodic surveillance of the postings to ensure that the information depicted remains current and is conclusive.

JLS&A has procedures that contain specific instructions for reporting and handling of concerns required to be reported and dispositioned in accordance with the requirements of 10CFR Part 21. In addition to the actual posting of the 10CFR Part 21 document, JLS&A maintains in the same general area, and in clear sight, specific instructions to employees regarding the protocols for reporting any 10CFR or Part 21 type concerns.

14.0 INSPECTION, TEST AND OPERATING STATUS.

14.1 Regulatory Reference.

71.129 Inspection, Test, and Operating Status.

JLS&A has instructions and procedures to control the applicable inspection indicators for packages or individual items of packages, by using markings, such as stamps, tags, labels, or other suitable means of tracking to prevent inadvertent by-passing of required inspections and/or tests. Critical operating status parameters are required for the transport of the packaging shipped by JLS&A and include items such as structural and thermal criteria.

JLS&A's quality assurance organization, in conjunction with management, engineering, and production is responsible for the oversight and implementation of this part of the quality assurance program.

14.2 Statement of Verification that Package Inspection Results are Documented and Reviewed by Appropriate Departments.

JLS&A's package operation and maintenance inspection program results are documented by appropriately trained personnel working within responsible departments.

14.3 Statement of Verification that Status of Packages is Provided to Affected Departments or Organizations.

JLS&A's procedures contain provisions for determining the status of packages through the use of acceptance or rejection media, such as tags or other markings. Affected internal departments or outside organizations are notified as to package status changes as required.

14.4 Statement of Verification that Removal of Package Inspection Indicators are Procedurally Controlled.

JLS&A's mechanism for identifying a nonconforming package inspection status is achieved through a method of utilizing a rejection "tag" or other marking process. Rejection tag or marking application and removal procedures are established and controlled, with management oversight provided as necessary. The removal of any other inspection or other status indicator is performed by responsible QA/QC inspection personnel and is procedurally controlled.

14.5 Statement of Verification that By-Passing of Package Inspections or Tests is Controlled.

The by-passing of JLS&A's inspections or tests is procedurally controlled by means of JLS&A's documentation, work structure, procedures, inspection checklists and daily communications as applicable. The QA/QC Program Manager/Administrator has overall responsibility for the adequacy of effectiveness relative to the implementation of this important program.

15.0 Nonconformances.

15.1 Regulatory Reference.

71.131 Nonconforming materials, parts, or components

JLS&A has instructions and procedures to control adverse conditions applicable to quality and safety related procedures, processes, materials, parts, components or complete packages. These procedures include provisions for the identification, documentation, segregation, disposition, and notification to affected departments or organizations. Nonconforming items are rejected, segregated, evaluated, repaired, re-worked or reviewed and accepted, as applicable, and the disposition status is documented. Nonconformance implementing procedures also provide for management notification to the NRC when nonconforming conditions warrant regulatory notification.

JLS&A's quality assurance organization, in conjunction with management, engineering, and production is responsible for the oversight and implementation of this part of the quality assurance program.

15.2 Statement of Verification that Nonconforming Package Items or Procedures are Identified and Procedurally Controlled.

JLS&A implements and maintains material rejection procedures, and nonconformance reports for: 1) nonconforming parts, assemblies, etc.; 2) nonconforming Type B radioactive materials packages; 3) nonconforming procedures, etc.; and 4) NRC Part 21 or Part 71 Nonconformance Reporting, as appropriate.

These JLS&A procedures have provisions to assure that the identification, documentation segregation, review disposition of nonconforming items or procedures are implemented and that affected departments are appropriately notified.

15.3 Statement of Verification that Nonconforming Package Items are Segregated from Accepted Items.

JLS&A maintains separate locations for nonconforming items, as appropriate for the item, and those items are identified and controlled as nonconforming, until the necessary corrective actions are taken by designated department personnel.

15.4 Statement of Verification That Repaired or Re-worked Package Items are Subjected to Original Inspection or Testing Criteria.

Replaced, re-worked, or repaired items are subjected to the same documentation, original inspection, and/or test procedures, as applicable, by JLS&A.

15.0 Nonconformances (continued)

15.5 Statement of Verification That Package Nonconformance Reports are Evaluated.

JLS&A management and the QA/QC Program Manager/Administrator perform evaluations of nonconformance reports to determine quality trends, identify problem areas requiring further management review and assessment for regulatory reporting, as applicable.

15.6 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 areas of the JLS&A facility in the prescribed manner, in accordance with 10CFR21.6.

Formal administration of this facet of the program is carried out in accordance with established JLS&A implementing procedures. Also, auditing is performed by JLS&A management, as necessary, to ensure current and appropriate postings are maintained.

JLS&A has procedures that contain specific instructions for reporting and handling of concerns required to be reported and dispositioned in accordance with requirements of 10CFR21. In addition to the actual posting of the 10CFR Part 21 documents, JLS&A maintains in the same general area, in clear sight, specific instructions to employees regarding the protocols for reporting concerns to upper management, as well as directions on utilizing and formally reporting any 10CFR Part 21 type concerns.

16.0 CORRECTIVE ACTION.

16.1 Regulatory Reference.

71.133 Corrective Action

JLS&A has instructions and procedures to control and identify adverse conditions applicable to quality and safety related corrective actions regarding nonconforming procedures, materials, parts, components, or complete packages. These procedures contain provisions for the identification, documentation, segregation, disposition, and notification to affected departments or organizations of conditions adverse to quality. For conditions adverse to quality, corrective action procedures include determination of the cause of the nonconformance, and a corrective action sequence to prevent recurrence of the nonconforming condition. Corrective action procedures also provide for reporting to JLS&A management and management's response to NRC when nonconforming conditions warrant regulatory notification.

JLS&A's quality assurance organization, in conjunction with management, engineering, and production, is responsible for the oversight and implementation of this part of the quality assurance program.

JLS&A's QAPP implementing documents establish appropriate criterion to assure that adequate control and documentation is maintained over corrective actions related to nonconformances.

16.2 Statement of Verification That Package Corrective Actions are Implemented.

JLS&A's internal program for corrective action processing is implemented and documented.

Each JLS&A corrective action processed contains provisions for:

The reason for corrective action(s), including an analysis of methods and procedures, if required;

Statement of work for the corrective actions to be taken;

Re-inspection of the non-conforming condition, as corrected;

Implementation of improvements, if required;_and, monitoring and evaluation of corrective actions to assure effectiveness and NRC Part 21 and 71 reporting, as appropriate.

If an external or internal JLS&A inspection determines a nonconforming condition exists, resulting in an internal corrective action, it is documented and reported to the appropriate JLS&A department managers. The nonconformance is subsequently evaluated by the department manager(s) with the corrective action proposed and closeout protocols established.

16.0 Corrective Action, continued

16.2 Statement of Verification That Package Corrective Actions Are Implemented (continued).

External notifications of noncompliance or JLS&A internal noncompliance notification and corrective actions are reviewed by JLS&A management to determine it is also reportable to applicable regulatory authorities. In the event that a nonconformance or corrective action is reportable to a regulatory authority under Part 21, Part 71, or other regulation(s) the regulations call out a sequence of actions for JLS&A management reporting, and is implemented in accordance with formally established procedures.

16.3 Statement of Verification That Package Corrective Action Proceedings are Completed.

In the event of a non-regulatory reportable corrective action, the cognizant personnel of the applicable JLS&A department, in accordance with established procedures, will evaluate the nonconformance, determine the course of the corrective action to prevent recurrence and establish a completion date.

JLS&A's QA/QC Program Administrator is responsible for reviewing and monitoring this process, including closure.

In the event that an adverse condition requiring corrective action is reportable to a regulatory authority, JLS&A management will present a sequence of actions to be taken for completion and close-out.

17.0 QUALITY ASURANCE RECORDS.

17.1 Regulatory Reference.

71.135 Quality Assurance Records.

JLS&A has instructions and procedures for the management and administration of quality records relative to the area of safety related design, fabrication, assembly, procurement, modification, use, repair, maintenance, transportation and testing of Type B radioactive materials packaging manufactured and used by JLS&A. These quality records furnish documentary evidence related to requirements for classification, legibility, identification, receipt, indexing, filing, storage, transmittal, retention, retrieval and disposition.

JLS&A's quality records include, but are not limited to, applicable Type B package instructions and procedures, drawings, and specifications, procurement, inspection, test and audit results, non-conformance/corrective action reports, and qualifications of personnel, procedures and equipment, and personnel training and re-training records.

JLS&A's quality assurance organization, in conjunction with engineering, production and operations management team is responsible for maintaining oversight and administration of this part of the quality assurance program.

JLS&A's QA implementing documents establish criterion to assure adequate control and documentation is maintained over these instructions and procedures for record retention, changes and safekeeping.

17.2 Statement of Verification That Package Records Documentation Furnishes Evidence of Activities Affecting Quality or Safety.

JLS&A shall maintain sufficient written records describing the activities affecting quality. These records will include the instructions, procedures and drawings required by 10CFR71.111 to prescribe quality assurance activities and include closely related specifications such as required qualifications of personnel, procedures and equipment. These records include the instructions or procedures which establish the records retention program which is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. These records shall be retained for three years beyond the date when JLS&A last engages in the activity for which the QA/QC Program was developed along with other records as required by law, regulatory authority and good manufacturing practices. If any portion of the written procedures or instructions is superseded, JLS&A shall retain the superseded material for three years after it is superseded.

JLS&A'S QA/QC records are indexed and retained in appropriate locations and contain sufficient information for determining the identification between the record and item(s) or activities to which they are applicable.

17.0 QUALITY ASSURANCE RECORDS, continued.

17.2 Statement of Verification that Package Records Documentation Furnishes Evidence of Activities Affecting Quality or Safety, continued.

JLS&A's QA/QC inspection and prototype test records include the following criteria, as applicable:

A description of the activity;

Evidence of completion or verification of a manufacturing inspection or test operation;

Data and results of the inspection or tests;

Information related to conditions adverse to quality;

Inspector(s) identification;

Evidence as to the acceptability of the results.

17.3 Statement of Verification that Package Records are Legible and Completed.

All of the JLS&A quality departments that are required to implement quality measures commensurate with their functional responsibilities have authority and accountability for maintaining legible and completed quality records.

17.4 Statement of Verification that Package Records are Identifiable and Retrievable.

JLS&A maintains master listings of locations where quality records are maintained within the quality records system. Identification of records is implemented using control methods, such as, numerical, alphabetical and/or alpha-numerical means, with cross-referencing to other records as applicable.

JLS&A'S records are designated as "lifetime", "permanent", or "non-permanent/temporary", as applicable. Permanent records pertain to the package fabrication, storage, safe operation, repair, re-work, replacement, modification, instructions for use, inspections, nonconformances and corrective actions, and also include qualifications for packages, equipment and personnel. Temporary records which do not meet the protocols for permanent records shall be kept for a minimum of two years after the last shipment.

JLS&A implements and maintains formally established procedures that require prior review and approval of any record designated for destruction.

17.0 QUALITY ASSURANCE RECORDS, continued.

17.5 Statement of Verification that Package Records are Subject to Storage, Preservation and Safe Keeping.

JLS&A'S quality records, when not in use, are stored in approved areas to minimize risk of elemental, zoological or botanical damage. All current and completed records are retained for safe keeping and are kept in file cabinets when not in use or upon completion of a project. Measures are established for replacement, if at all possible, for lost or damaged records, including daily computer back-ups. Computer programs are password protected, with view and/or write access protected, as applicable. JLS&A office and storage area access is controlled to prevent unauthorized access by members of the public.

JLS&A has a program to duplicate some critical (pre-computer) QA/QC records, especially drawings, for storage in either multiple internal files or at other locations if they are not on the computer back-up. The latest computer back-up is removed from the JLS&A premises. Critical corporate records (as defined by JLS&A) are kept in fire-proof file cabinets, when not in use.

18.0 INTERNAL AUDITS.

18.1 Audits Program Administration.

71.137 Quality Assurance Records

JLS&A implements and maintains instructions and procedures for ensuring that a comprehensive system of periodic and planned QA/QC audits is implemented. These internal and external audits are designed to verify contract and/or specification compliance, procedure adherence and effectiveness of the overall Quality Assurance Program. This audit program includes provisions for internal program audits, as well as for external audits and surveillance of suppliers (as appropriate).

JLS&A's trained and qualified personnel perform audits using appropriate checklists or procedures. Audit results are documented and reviewed by JLS&A management personnel.

JLS&A's QA/QC Program Administrator, in conjunction with the quality organization, management, engineering, and production personnel is responsible for the oversight and implementation of this part of the quality assurance program.

18.2 Statement of Verification that Internal Audits are Conducted in a Prescribed Manner.

Internal JLS&A company audits are conducted on a three year cycle, or an "as needed" basis depending upon frequency and trending of nonconformances, using a graded approach for evaluating quality areas of the program, which are considered to be of major importance to safety. Emphasis is placed on package certification compliance and effectiveness of the program's implementation. Audits of the balance of the program criteria, not covered by frequency, will be conducted over cycle intervals not to exceed three years.

JLS&A's scheduled and planned audits are conducted using approved audit plans and formally established procedures and/or checklists. Audits of the general program are performed by qualified employees, who do not have direct responsibility for the area being audited, with provisions for timely access to documents and facilities. Individuals who have received appropriate training and who have been certified by management as being qualified, perform the required audits of certificate of compliance for Type B packages.

JLS&A's nonconformance follow-up actions, based on audit results, are subject to re-audit.

Alternatively, JLS&A management reserves the right to retain the services of qualified outside consultants to perform these audits.

18.0 INTERNAL AUDITS, continued.

18.3 Statement of Verification that Audits are Scheduled.

Internal audits and management assessments are scheduled and planned by the JLS&A QA/QC Program Administrator with approval of executive management. Management provides the necessary resources to ensure that the important to safety elements of the program are identified, receive priority and are evaluated in a timely and appropriate manner. Additional internal audits or re-audits may be performed more frequently if circumstances arise relative to nonconformances or negative audit finding trends.

JLS&A has provisions in place to control audit and surveillance activities for the approval of and contract oversight of package vendors and suppliers. Audits and surveillance are defined and implemented on an as needed basis, dependent upon the frequency of purchasing activities and based upon the safety significance applicable to the quality related service or activity needed. After initial JLS&A qualification, acceptance and approval of vendors or suppliers, continued audit and surveillance frequency will not exceed three year intervals, as applicable for high safety significant items. Some vendors or suppliers may receive more or less frequent surveillance and oversight due to the degree of safety significance applied to their activities and frequency of purchasing activities. JLS&A management provides oversight and reviews audits of applicable vendors or suppliers providing important to safety items or activities and these evaluations will be documented. Vendors who provide commercial grade parts, materials and components may require less stringent and frequent audits or oversight, as deemed appropriate by the Quality Assurance Manager/Administrator. JLS&A uses other entities audit results as justification for limiting the extent and scope of vendor audit surveillance.

18.4 Statement of Verification of Qualifications of Audit Personnel.

Audit personnel qualifications, including the QA/QC Program Administrator, principal QA/QC management positions, designated lead auditors and inspectors, are applied to and are commensurate with the applicable auditor qualification criteria of ANSI/ASME NQA-1-1989 "Quality Assurance Program Requirements for Nuclear Facilities". Basic requirement 2 is used as the primary qualification for audit personnel, with the incorporation of Supplement 2S-3, "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel", which is used as a formulation guideline. Lead auditors and auditing personnel are qualified in accordance with procedures and may serve at the discretion of the Quality Assurance Program Manager/Administrator with proper documentation.

Applicable qualification and training records are maintained as necessary. Training methodology, minimum experience requirements, and certification protocols are established and consistent with recognized industry guidance and standards for comparable positions. Proficiency re-evaluations are performed and documented when applicable renewal of qualification measures is warranted.

18.0 INTERNAL AUDITS, continued.

18.4 Statement of Verification of Qualifications of Audit Personnel (continued).

JLS&A may periodically utilize industry consultants for audits. Their individual qualifications will be reviewed and approved by JLS&A in accordance with formally established procedures.

18.5 Statement of Verification of Pre-Audit Conferences.

JLS&A's pre-audit conferences will be held either before, or at the beginning, of a scheduled audit. Completion dates for the conclusion of the audit will be established at this conference.

JLS&A's audits are implemented using a documented plan that includes the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, schedules, documents to be reviewed and applicable written check lists. Audit teams are formed prior to or at the beginning of a scheduled audit, utilizing personnel with no direct responsibility for the activity being evaluated.

18.6 Statement of Verification of Post-Audit Conferences.

JLS&A's post audit conferences are scheduled and conducted between management and audit team(s) to present and review audit results. During this conference the management of the organization audited is provided the opportunity to discuss the specific audit findings, in order to understand; clarify, provide additional records, etc.; resolve any audit findings disagreements, or misunderstandings prior to the issuance of the formal audit report.

18.7 Statement of Verification of Audit Reporting, Management Review, Response and Follow-up.

Upon completion of audit activities, JLS&A's audit team(s) formally compile and document audit results, including applicable follow-up corrective actions, with distribution to appropriate management. Management, in conjunction with audit team personnel, review the proposed corrective actions respective to the audit findings, to clarify and to resolve any and all concerns related to the corrective actions proposed by the organization being audited.

In the event a JLS&A corrective action can not be determined or implemented in a timely manner, a schedule for implementation and closure dates will be determined by management. Audit teams and management are responsible for the verification and accountability of timely responses and adequate audit reports, responses to findings, closure of corrective actions and the re-auditing of corrective activities taken and completed.