

71-0122

JLS SHEPHERD *and Associates*

740 Salem Street, Glendale, California 91203

213/245-0187

Irradiation & Calibration Equipment

• Lead Shielding •

Nuclear Applications

QUALITY ASSURANCE PROCEDURES
FOR DESIGN, FABRICATION AND USE OF
SHIPPING CONTAINERS AND OVERPACKS
USED FOR THE TRANSPORTATION
OF RADIOACTIVE MATERIALS

DOCUMENT TITLE: Number QA-RM-001-A

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REVISION SHEET

Revision Number	Date	Summary	Initials
QA-RM-001-A	11/16/79	Total revision per receipt of 10CFR 71, Appendix E Acceptance Criteria - Transportation Packages for Normal Form Radioactive Material, from the U. S. N. R. C.	MFS <i>MJS</i>

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INTRODUCTION

J. L. Shepherd and Associates manufactures shipping containers for radioactive materials in Type A, Type B and large quantity categories, in both "Normal Form" and "Special Form", for its own and other's use. J. L. Shepherd and Associates also uses its own and other manufacturer's containers for the transportation of radioactive materials as described above. The Q. A. Program, described in this manual, pertains to quality assurance in design, manufacture and use of the above containers as called out in 10CFR71, Appendix E. Because of the specialized nature of its business, i. e. products involving radioactivity, J. L. Shepherd and Associates maintains all necessary equipment for calibration and radiological control of its products. Members of its staff personally perform all test on equipment related to this aspect of operation.

I. ORGANIZATION

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1. Statement of Responsibility

J. L. Shepherd and Associates implements the Quality Control/Quality Assurance Program, as follows, as normal operational procedure in the design, manufacture and use of Type A, Type B and large quantity categories of both "Normal Form" and "Special Form" shipping containers for radioactive materials, for its own and other's use and the use of these containers made by other manufacturers.

J. L. Shepherd and Associates is responsible for the continued implementation of this program on future projects.

J. L. SHEPHERD

C. H. PREHODA

R. N. DONELSON

M. F. SHEPHERD

M. IRISH

J. L. Shepherd
Clark H. Prehoda
R. N. Donelson
Mary F. Shepherd
Mal Irish

QUALITY PLANNING

For each job undertaken by J. L. Shepherd & Associates, prior to the time purchase orders are issued to subcontractors or to vendors for raw materials, a work plan is drawn up for the contract. This work plan includes:

1. A complete work schedule, including all outside purchases;
2. A complete cost schedule;
3. A complete quality assurance program for both the raw materials and the subcontracting to be undertaken as part of the job.

This quality assurance program takes into consideration the quality control procedures that will be necessary for satisfactory performance of the contract and outlines detailed specifications for materials and subcontracting, as well as quality assurance check points, time of inspection instructions to vendors, related to manufacturing as well as equipment to be used in undertaking quality assurance programs.

Costs. As part of the cost records of all jobs, all direct costs as attributed to quality assurance are included in a separate category and are available for purposes of evaluation and future planning. These costs include information to identify the correction of non-conforming materials and correction of defective work.

Records. Forms are prepared and forwarded to subcontractors covering the various areas of quality control to be checked by these people, as outlined above, and these are returned to J. L. Shepherd & Associates.

In addition, intermediate and final inspection forms and records are permanently maintained at J. L. Shepherd & Associates, along with all necessary radiological data, such as leak test certificates, calibration certificates, external radiation levels, and other records that pertain to the radiological aspect of the equipment, as required by law and good quality assurance practices.

Corrective procedures. A program for corrective procedures is maintained, which includes the following:

1. Monitoring and review of corrective actions, to assure their effectiveness;
2. Introduction of required improvements;
3. Analysis of scrapped products to determine reasons for non-conformity;
4. Analysis of methods and processes of work performance.

FACILITIES & STANDARDS

Drawings and Specifications. Engineering is to maintain the central current drawing and specification file.

Prior to release for fabrication, all drawings and specifications are to be reviewed for adequacy in regard to standard design practices and end-product use. Approval by engineering and quality assurance is required prior to release.

Changes are to be documented through the use of Design Change Orders and Specification Change Orders. Changes require the approval of Engineering and Quality Assurance.

Engineering is responsible for obtaining Government approval for changes as required and for transmitting change information to the Government as required.

Engineering is to be responsible for removing obsolete drawings and specifications from all issue points and for recording effectivity points.

The following section of the Quality Assurance Program may be broken into three categories: (1) those shipping containers/overpacks made in conformance with specific DOT fabrication specifications as called out in DOT regulations such as, but not limited to, Paragraphs 178.104 and 178.194; (2) shipping containers and overpacks made in conformance with DOT general packaging performance criteria such as, but not limited to, Paragraph 178.350; and (3) shipping containers and overpacks designed to ship large quantities of radioactivity for which NRC Certificate of Compliance and licenses are required.

(1) All drawings and design specifications must be checked for conformance with fabrication specifications as called out in the pertinent DOT specification and approved by the cognizant Quality Assurance Manager or General Manager before release for fabrication.

(2) All drawings and fabrication specifications, and all outside purchase specifications for units out purchased, must be checked and approved by the cognizant Quality Assurance Manager or General Manager prior to release for fabrication and/or purchasing. For this equipment, a prototype test of each class of containers which is the most likely to fail under the pertinent conditions of transport will either be tested or calculations will be made and approved by the cognizant Quality Assurance Manager or General Manager which show that the containers will meet the pertinent transport conditions.

(3) All pertinent data and calculations, including drawings, as called out in 10 CFR part 71 related to license applications and Certificate of Compliance applications for Type B and large quantity containers will be checked and approved by the cognizant Quality Assurance Manager or General Manager prior to submission of the package containing data to the NRC. After the Certificate of Compliance and license have been issued and prior to the fabrication of the approved unit, all drawings and purchase specifications for material must be checked and approved by the cognizant Quality Assurance Manager or General Manager.

PURCHASING

As noted in previous sections, J. L. Shepherd & Associates prepares a schedule of materials to be purchased, as well as all subcontracting for each job prior to initiation of work on the contract. Purchase orders which are let include all pertinent data, including a description, requirements for manufacturing, testing and packaging, and inspection, as well as any qualifications and approvals which must be met on Government contracts.

All pertinent drawings and manufacturing procedures are included as part of purchase orders. J. L. Shepherd & Associates purchase orders also require that all suppliers or subcontractors are to notify J. L. Shepherd & Associates and obtain approval before any changes in design, ie: drawing changes, inspection changes, etc., are undertaken.

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

J. L. Shepherd & Associates maintains a qualified vendors list, from which vendors are selected, based upon past performance as related to the greater than ten years' experience of Messrs. Shepherd, Donelson, and Doonan in dealing with vendors in this area.

All raw materials which are purchased directly by J. L. Shepherd & Associates are inspected by J. L. Shepherd & Associates at time of arrival, either at J. L. Shepherd & Associates' facilities or at the plant of the vendor who will be using these materials.

In cases where the subcontractor provides the materials on subcontracts let by J. L. Shepherd & Associates, these vendors are required to establish quality assurance procedures and records for raw materials received, including performance of fabricated parts purchased.

In case of subcontracts for manufacturing, J. L. Shepherd & Associates performs vendors surveys and evaluation prior to the letting of the subcontracts.

In cases where materials of a radiological nature are subcontracted, J. L. Shepherd & Associates requires control and quality assurance for these materials from vendors, who must submit to J. L. Shepherd & Associates detailed information for permanent records relative to the quality of these products, ie: leak test information on sealed sources.

The following terms and conditions related to quality control will apply to all purchase orders for any type of radioactive sources purchased by J. L. Shepherd

and Associates:

No source shall have greater than 1000 dpm removable contamination at time of shipment;

Each source shall have undergone a seven-day leak test in accordance with NRC and agreement state requirements prior to shipment;

A signed leak test certificate which calls out the following:

- (1) Source description
- (2) Source number
- (3) Date of leak test
- (4) Results of leak test
- (5) Method of leak test

will be included with each shipment, attached to the packing list. A second copy will be sent via mail at time of shipment.

Shields. All shipping containers will have the following maximum levels of removable contamination:

- (1) Beta-gamma 200 dpm/100 cm²
- (2) Alpha 100 dpm/100 cm²

Attached to each packing list prior to shipment will be a signed report form showing that the container has been checked both for contamination and for external radiation levels and giving actual values of these tests.

All shipments will be made in accordance with applicable ICC regulations, and all shipments will be properly labeled with the necessary data, including Bureau of Explosives number, where required.

Failure to comply with any of the above quality control requirements will result in rejection of the shipment and its immediate return.

MANUFACTURING CONTROL

Materials Control. Quality Assurance will insure that all incoming material is inspected, tagged, and segregated as received.

Non-conforming Materials and Parts. A Material Review Board is to be established for determining disposition of non-conforming items. The MRB will include representatives of Engineering and Quality Assurance and the Government representative.

Laboratory testing is to be employed as necessary and records of such tests maintained by Quality Assurance.

Processing Control. Engineering is responsible for establishing and maintaining detailed work instructions for processing operations.

Engineering and Quality Assurance is responsible for establishing in-process inspection points. Such points are to be designated by Engineering and approved by Engineering and Quality Assurance prior to release for fabrication.

Quality Assurance is responsible for determining that these inspections are performed and that parts are properly identified and segregated. This applies also to sub-contractors and vendors.

INSPECTION STATUS

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

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SOURCE TEST PROCEDURES

Quality Control. Pre-inspection--material certification, helium leak test, dye penetrant.

Pre-weld test specimens--one liner, one capsule sectioned and checked for weld penetration; minimum penetration 75% of wall thickness.

Post-weld test specimens--one liner, one capsule sectioned and checked for weld penetration; minimum penetration 75% of wall thickness.

Leak test, liner--Ethylene glycol to 10^{-4} cc/sec.

Leak test, capsule--Ethylene glycol to 10^{-4} cc/sec.

Heat cycle test, source--2 hours at 200° C., repeated after heat cycle.

Contamination test, source--0.01 uc/100 cm² by wipe test; maximum per source less than .005 uc.

Storage test, source--7 days leak test and contamination test repeated after storage test.

Special Form Tests. Free drop -- A free drop through distance of 30 feet onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage.

Percussion -- Impact of the flat circular end of a 1" diameter steel rod weighing three pounds, dropped through a distance of 40". The capsule or material is placed on a sheet of lead, of hardness number 3.5 or 4.5 on the Vickers scale, and not more than one inch thick, supported by a smooth, essentially unyielding surface.

Heating -- Heating in air to a temperature of 1,475^o F. and remaining at that temperature for a period of 10 minutes.

Immersion -- Immersion for 24 hours in water at room temperature. The water shall be at pH6 - pH8, with a maximum conductivity of 10 micro-ohms/cm.

Final Inspection. Final inspection requirements are to be established by Engineering and Quality Assurance.

Quality Assurance is responsible for assuring inspections are made and records of same maintained. Quality Assurance is also responsible for obtaining Government approvals as required.

MEASURING AND TEST EQUIPMENT

Quality Assurance is responsible for maintaining equipment in first class condition and establishing calibration requirements and frequency. Records of all calibrations are to be maintained.

Quality Assurance is to monitor all vendors to assure that vendor's test equipment is properly maintained and calibrated.

STORAGE, PACKAGING, DELIVERY

Engineering is responsible for establishing requirements for storage, packaging and delivery, including any special requirements for radioactive materials. Attention is to be given to Government regulations, such as NRC and ICC regulations, in addition to the contractual specifications.

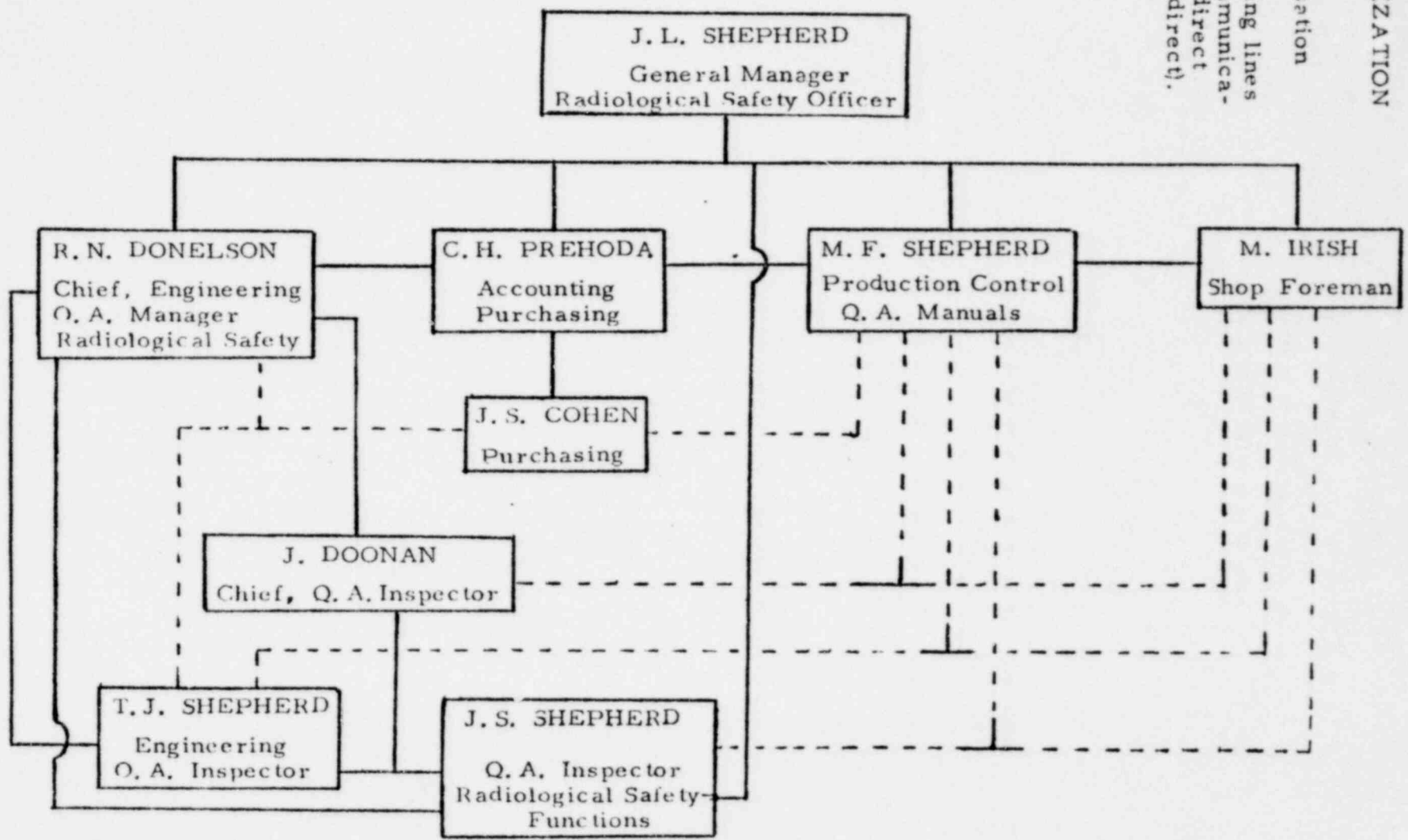
Quality Assurance is responsible for assuring that these requirements are met and that records of such inspections are maintained.

An individual log sheet (sample enclosed) will be maintained for all Type B, Certificate of Compliance shipping containers/overpacks routinely used by J. L. Shepherd & Associates in conjunction with transportation of radioactive materials.

AUDITS

On an annual basis, all log sheets covering containers routinely used by J. L. Shepherd & Associates as well as all pertinent data sheets covering shipping containers manufactured by J. L. Shepherd & Associates will be audited by our Accounting Department.

3. Organization
Chart
(including lines
of communication, direct
and indirect).



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I. ORGANIZATION

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4. Job Description - C. H. Prehoda

Clara H. Prehoda, Secretary-Treasurer, Accounting, Purchasing. Under the direction of J. L. Shepherd, Mrs. Prehoda is responsible for accounting and purchasing procedures and job cost records. The company books are set up to maintain complete records of costs, both direct and indirect, on a job by job basis. She is also responsible for maintaining all pertinent correspondence, records and contracts, including customer's licenses.

The "Voice" of J. L. Shepherd and Associates, Mrs. Prehoda attended Columbia Union College, Washington, D. C. and has twenty-three years' experience in customer relations in the nuclear field. She specializes in handling customer requests, inquiries and problems promptly, efficiently and cheerfully, aided by her excellent command of technical information.

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I. ORGANIZATION

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4. Job Descriptions -- R. N. Donelson

R. N. Donelson, Chief Engineer, and Quality Assurance Manager. Mr. Donelson is responsible for all engineering and for the quality assurance program of J. L. Shepherd & Associates (JLS&A). He has specific responsibility for vendor selection and qualification and vendor quality assurance programs, purchasing and control of raw materials, drawings and drawing change control. Mr. Donelson also has responsibility for quality assurance of radiological aspects of JLS&A products, including calibration, leak testing, and certification of radiological safety, both of units in which this work is performed at a vendor's facility, and those units on which work is performed in the field.

Radiation safety and engineering consultant, Mr. Donelson has a B.S. in Chemical Engineering from the University of Washington and is a Certified Health Physicist. His thirty-one (31) years of experience in the nuclear field include the design, engineering and installation of all types of irradiation facilities and plants for handling radioactive materials, as well as production management. Mr. Donelson also acts as an independent consultant in the radiation safety field.

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I. ORGANIZATION

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4. Job Descriptions -- Mary F. Shepherd

Mary F. Shepherd, Production Control and QA Manuals. Ms. Shepherd, working with R. N. Donelson (Engineering), Clara H. Prehoda (Purchasing) and Malford Irish (Shop), and under the direction of J. L. Shepherd, is responsible for correlating the progress in all departments on a daily job-by-job basis, expediting or delaying progress as warranted, and notification to the proper departments. She is also responsible for approximate scheduling of work in progress, and tests and inspections as necessary in weekly bi-departmental conferences.

Ms. Shepherd's QA responsibilities include the distribution and update of QA Manuals as necessary.

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I. ORGANIZATION

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4. Job Description -- Malford Irish

Malford Irish, Shop Foreman, working directly with J. L. Shepherd, R. N. Donelson, Clara H. Prehoda, and Mary F. Shepherd, has the responsibility of delegating proper materials to the respective jobs and supervising the work in progress at JLS&A.

I. ORGANIZATION

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4. Job Description -- Jerri S. Cohen

Jerri S. Cohen, Purchasing Officer. Under the direction of R. N. Donelson and the Engineering Department, as well as Clara H. Prehoda, Ms. Cohen is responsible for proper documentation on purchase orders and the placement of them to vendors, with all applicable specifications. She is also responsible for notification on all delivery dates to Mary F. Shepherd, Production Control, so that production, testing, and inspection procedures can be scheduled accordingly.

I. ORGANIZATION

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4. Job Description -- Joseph Doonan

Joseph Doonan, Chief Inspector. Under the direction of Mr. Donelson, Mr. Doonan has responsibility for inprocess inspection and sub-assembly inspection at various vendors' and contractors' facilities. Mr. Doonan also has responsibility for inspection of incoming materials, to assure that they meet specifications called out by purchase orders on which they are obtained, and for determining that these raw materials are properly tagged, either at time of receipt at the vendors' facilities or at time of shipment from JLS&A to vendors' facilities.

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I. ORGANIZATION

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4. Job Description -- Thomas J. Shepherd

Thomas J. Shepherd, Engineering and QA Inspector. Under the direction of R.N. Donelson (Engineering), Mr. T. Shepherd is responsible for the distribution of drawings and specifications to the appropriate departments after approval.

Working with Mr. J. Doonan (Chief, QA Inspector), Mr. T. Shepherd performs QA Inspections as required.

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I. ORGANIZATION

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4. Job Description -- Joseph S. Shepherd

Joseph S. Shepherd, QA Inspector and Radiological Safety Functions. Working with J. Doonan (Chief, QA Inspector), Mr. J. S. Shepherd performs all inspections as necessary. Under the direction of J. L. Shepherd and R. N. Donelson, Mr. J. S. Shepherd is responsible for the inspection of components related to radiological safety functions.

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I. ORGANIZATION

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5. Job Description and Qualifications - Head of Q. A. Program

J. L. Shepherd, President, General Manager and Head of Q. A. Program. Mr. J. L. Shepherd is responsible for the general management of the company, specifically related to sales, contract management products and quality assurance. Mr. Shepherd is personally responsible for the final inspection of all products after completion, including those related to radiological safety, before delivery to the customer.

Mr. J. L. Shepherd has a B. S. from Loyola University of Los Angeles. He did graduate work at Notre Dame and University of California at Los Angeles, and has had Twenty-six years experience in product development, applications, engineering, sales, marketing and general management in the nuclear field. He specializes in the evaluation and selection of the optimum radiation sources and/or tracers and related equipment for nuclear applications, based upon the customer's total requirements, including such parameters as licensing, radiation safety, cost and reliability and proper shipping containers as required.

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I. ORGANIZATION

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6. Statement of Responsibility.

J. L. Shepherd, C. H. Prehoda, M. F. Shepherd, M. Irish, J. Doonan, T. J. Shepherd and J. S. Shepherd have the responsibility and authority to reject unsatisfactory materials, stop unsatisfactory work and to supervise further processing after corrections have been made.

J. L. Shepherd	<i>J. L. Shepherd</i>	M. Irish	<i>Mal Irish</i>
C. H. Prehoda	<i>Clara H Prehoda</i>	J. Doonan	<i>Joseph J Doonan</i>
R. N. Donelson	<i>RN Donelson</i>	T. J. Shepherd	<i>T. J. Shepherd</i>
M. F. Shepherd	<i>MF Shepherd</i>	J. S. Shepherd	<i>J S Shepherd</i>

J. L. Shepherd, R. N. Donelson and C. H. Prehoda have the further responsibility and authority to stop the delivery and/or installation of nonconforming products or materials.

J. L. Shepherd	<i>J L Shepherd</i>
C. H. Prehoda	<i>Clara H Prehoda</i>
R. N. Donelson	<i>RN Donelson</i>

A statement of this responsibility is signed by each individual and posted in a visible location.

II. QUALITY ASSURANCE PROGRAM

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1. Statement of Verification of Assessment of Quality Assurance Program

The officers of the Quality Assurance Program (QAP), in addition to daily communication, hold weekly conferences in conjunction with appropriate departments, to review the status of each job in regard to design, purchasing, work release, work in progress, corrective procedures, inspections, testing, safety, storage or shipment, proper documentation, corrective action (if applicable) and shipment, on whichever phase of operation is pertinent to that job as well as overall views of all work in progress. Annual audits to determine compliance, as well as for accounting and inventory purposes, are performed and reviewed by the officers of the QAP.

2. Distribution of Quality Assurance Program Manuals

Each officer of the QAP retains a QA/QC Program Manual. A master copy is kept and a copy is also made available for any employee to refer to. (Each new employee is made familiar with the manual as part of the Training Program.) M. F. Shepherd is responsible for distributing approved revisions to all copies of the manual and advising the holders thereof of the revisions.

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

J. L. Shepherd & Associates retains the right to supervise and inspect products at vendor's and contractor's facilities and/or to reject nonconforming materials; and has agreements with vendors and contractors stating such to maintain our Quality Control mandatory requirements.

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

All mechanical, electrical, and electronic components, as well as all complete systems, are controlled and covered by the QAP.

5. Statement of Verification of Resolution of Disputes

If, and when, disputes arise concerning the quality of a product between the different departments, a review of the product's functions, specifications, and compatibility with the QA/QC Program, as well as NRC and DOT Criteria is made by the QA officers and appropriate offices. Reviews are made at the weekly conferences or as needed when all pertinent data is gathered. Agreements are subject to review by J. L. Shepherd for final approval.

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II. QUALITY ASSURANCE PROGRAM

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6. Statement of Verification that Training Program is Implemented

J. L. Shepherd & Associates maintains a training program for all new employees and employees assuming additional responsibilities. This program provides a thorough examination of the QA/QC Program, the purpose of maintaining this program, each QA officer's authority delineated and how it is effective, as well as how the employee functions within the program.

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

All personnel are adequately licensed or certified, ie: Health Physicists, welders, machinists, for example, when applicable. All licenses and certifications are kept current. If an employee is not performing to the specifications maintained by Shepherd & Associates, they are subject to a retraining program before continuing with their responsibilities or their employment is terminated.

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

J. L. Shepherd & Associates performs all quality-related procedures, ie: inspections and testing, in accordance with pre-determined procedures which specify the equipment to be used, if necessary, and environmental conditions. Inspectors are required to determine and document that all prerequisites have been satisfied before inspection and/or testing.

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III. DESIGN CONTROL

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1. Statement of Verification of Responsible Design Procedures

J. L. Shepherd & Associates has an established design procedure for its products. Because of the nature of our business and products, ie: products involving radioactivity, all products are licensed by the proper licensing authority and all new products have licenses pending. Therefore, in the initial design of a product, the first step is to provide licensing authorities with all pertinent drawings.

Sales drawings, if applicable, are made per customer requirements and licensing criteria.

Engineering is to maintain the central current drawing and specification file.

Prior to release for fabrication, all drawings and specifications are to be reviewed for adequacy in regard to standard design practices and end-product use. Approval by engineering and quality assurance is required prior to release.

Changes are to be documented through the use of Design Change Orders and Specification Change Orders. Changes require the approval of Engineering and Quality Assurance (QA).

Engineering is responsible for obtaining Government approval for changes as required and for transmitting change information to the Government as required.

Engineering is to be responsible for removing obsolete drawings and specifications from all issue points and for recording effectivity points.

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

J. L. Shepherd & Associates Engineering Department and QA Department reviews all product drawings, specifications for materials, procedures and instructions, with a final review by J. L. Shepherd or R. N. Donelson on each job to verify that they meet all regulatory requirements and licensing criteria.

3. Statement of Verification that Quality Standards are Maintained.

J. L. Shepherd & Associates' Engineering Department maintains a complete list of specifications for each product. It issues a Bill of Materials to the Purchasing Department with these specifications. Any changes from these specifications by the vendor or sub-contractor is subjected to review by the

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III. DESIGN CONTROL

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Engineering Department and QA Department before purchase is made. Any change or deviation on a particular product is noted on the specification documents for that particular product. All purchases are individually checked on delivery to verify that they do meet specifications before they are accepted. The Shop Foreman is directly responsible to the QA Officers for production which is inspected at various stages of completion.

4. Statement of Verification of Design Control

J. L. Shepherd & Associates Engineering Department and QA Department reviews each product design with all revisions approved before release for manufacture. Any deviation from this is subject to a review by the QA Department before approval or rejection. Inspection and test criteria are identified and made available to the QA Department before release.

5. Statement of Verification of Adequacy of Design

J. L. Shepherd & Associates QA Department and Engineering Department insures the proper selection of components and design verification of each unit by means of prototypes from which licensing is applied. The prototypes are thoroughly tested and inspected in all stages to verify that they meet all licensing authority criteria and design specifications. All inspection and test criteria are documented and made available to the QA Department, which documents acceptance or rejection and all pertinent data thereof.

6. Statement of Verification of Design Department Controls

J. L. Shepherd or R. N. Donelson of Shepherd & Associates are responsible for the final design verification review after reviews by the Engineering Department and by the QA Department.

7. Statement of Verification of Design Change Control

J. L. Shepherd & Associates maintains design specification change controls on the same basis as the original designs. See III. 1, 2, 3, 4, 5, & 6.

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

J. L. Shepherd & Associates maintains written agreements delineating the areas of responsibilities and authority of each member of the Engineering Department and the QA Department, which are agreed upon and understood at the completion of the Training Program.

IV. PROCUREMENT DOCUMENT CONTROL

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1. Statement of Verification of Purchasing Department Procedure

J. L. Shepherd & Associates' Purchasing Department maintains a definite sequence of action in any purchasing operation. A list of procedures is posted in the Purchasing Department (PD) Office and is explained in the employee training program.

2. Statement of Purchase Orders--Appendix E Criteria Verification

J. L. Shepherd & Associates' Purchasing Department routinely identify 10CFR, Part 71, Appendix E criteria, as applicable and is described in the QA Program proper. Standard purchase order forms designate spaces for this information.

3. Statement of Appropriate Reference of Specifications on Purchase Orders

J. L. Shepherd & Associates' Engineering Department provides appropriate references to technical requirements, ie: regulatory requirements, material and component identification requirements, drawings, specifications, codes and/or industrial standards, test and inspection requirements and special process instructions, on the Bill of Materials which is submitted to the PD to be included on purchase orders, when applicable.

4. Statement of Appropriate Reference of Documentation on Purchase Orders

J. L. Shepherd & Associates' Engineering Department provides appropriate references of documentation, ie: drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedures qualifications and chemical and test results of material, on the Bill of Materials which is submitted to the PD to be included on purchase orders and provided to vendor, if applicable.

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

J. L. Shepherd & Associates' Engineering Department provides the appropriate references of records, certification or test reports to be retained, controlled and maintained by the supplier and those delivered to the purchaser prior to use of item, on the Bill of Materials which is submitted to the PD to be included on the purchase order if applicable.

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

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IV. PROCUREMENT DOCUMENT CONTROL

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J. L. Shepherd & Associates purchase orders contain an agreement clause covering the right to access to the supplier's facilities and records for a source inspection audit, when applicable.

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

As stated in III, #3, "Any changes from these specifications by the vendor or subcontractor is subjected to review by the Engineering Department and QA Department before purchase is made. Any change or deviation on a particular product is noted."

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V. INSTRUCTIONS, PROCEDURES & DRAWINGS

Page 23

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

J. L. Shepherd & Associates (JLS&A) has established with the implementation of the QA/QC program that activities affecting the quality of a product are adhered to in all phases of operation according to prescribed documentation of instructions, procedures and/or drawings.

2. Statement of Verification of Clear Sequence of Actions Concerning Instructions, Procedures, and Drawings

JLS&A has established with the implementation of the QA/QC Program that there is a clear sequence of procedure in the preparation of, review, approval, and control of instructions, procedures, and drawings.

3. Statement of Verification of Quality Assurance Department Responsibility

JLS&A QA Program Department has the authority and responsibility to review inspection plans; test calibration and special process procedures; drawings and specifications; and all changes thereto and/or acceptable alternatives, under the provisions of the QA Program, and does so.

VI. DOCUMENT CONTROL

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1. Statement of Verification that the Issue of Documents and Procedures thereof are Procedurally Controlled

JLS&A Engineering Department, working with the QA Department and Purchasing Department, have adequate procedural controls to check if review, approval and issue of documents and changes thereto, prior to release, on a product, are satisfactory to quality requirements.

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

JLS&A Engineering Department, when notified of the need for change or modification by itself or other departments, in conjunction with the QA Department, reviews and approves or rejects revisions to the original document, as needed.

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

JLS&A Engineering Department is responsible for making all necessary revisions on all related documents of a project, after approval thereof, prior to the implementation of these changes.

4. Statement of Verification that All Pertinent Documents are Available at Site where They are to be Implemented

JLS&A Engineering Department is responsible for all pertinent documents related to a job to be available at the site where they are to be implemented, prior to starting work. The Engineering Department is also responsible that the Purchasing Department has all pertinent documents to accompany the purchase order (if applicable) to the supplier before work begins on the project.

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

JLS&A Engineering Department keeps a current master listing of revisions on products so that revisions are identifiable and is responsible that the appropriate revisions are on documents and distributed thus.

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1. Statement of Verification that Qualified Personnel Evaluate Suppliers for Acceptability

R. N. Donelson, Chief Engineer and QA Manager of JLS&A, is qualified and responsible for vendor selection and qualification of vendor QA Program to provide materials that meet specifications.

2. Evaluation of Suppliers

R. N. Donelson, Chief Engineer and QA Manager of JLS&A, who is responsible for supplier selection uses the following criteria for approving a vendor:

The supplier's capability to comply with the elements of Appendix E to 10CFR Part 71 that are applicable to the type of material, equipment, or service being procured.

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

A survey of the supplier's facilities and QA Programs to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

3. Statement of Verification that Supplier Evaluations are on File

JLS&A maintains current files on the results of supplier evaluations made by R. N. Donelson, Chief Engineer and QA Manager, as well as current specifications on products supplied.

4. Statement of Verification that Inspection and/or Supervision of Suppliers is Performed

At the weekly meetings of the QA Department and appropriate departments, it is determined if and when it is required that the Chief Inspector or appropriate officer be present during fabrication, testing and shipment of a product, to assure accordance with purchase order specifications.

5. Statement of Verification of Minimum Records supplied to Purchaser

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

Documentation that identifies the purchased material or equipment and the specific procurement requirements (e. g., codes,

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VII. CONTROL of PURCHASED MATERIAL, PARTS & COMPONENTS

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standards, and specifications) met by the items.

Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances dispositioned "accept as is" or "repair."

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

6. Statement of Receiving Inspectors Acceptability Criteria and Responsibilities

The Chief Inspector for JLS&A is responsible for, and will not accept, products that do not meet the following criteria:

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

Material, components, equipments, and acceptance records are inspected and judged acceptable in accordance with predetermined inspection instructions, prior to installation or use.

Inspection records or certificates of conformance attesting to the acceptance of material and components are available prior to installation or use.

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

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VIII. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, &
COMPONENTS

Page 2

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

Chief Inspector of JLS&A uses a standard procedure for identifying all products received, as part of the QA/QC Program.

2. Statement of Verification that Products are Identified Properly

As part of the standard receiving procedures of the Chief Inspector of JLS&A, all products are identified and marked. This identification and marking is directly traceable to all pertinent records and this system precludes the use of incorrect or defective items.

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

As stated in VIII, #2, all items are identified and marked, directly traceable to all pertinent records, i.e., drawings, specifications, purchase orders, test reports, including and especially the safety related items, which are thoroughly inspected.

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

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

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

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

IX. CONTROL of SPECIAL PROCESSES

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1. Statement of Verification that Special Processes are Procedurally Controlled

The Shop Foreman at JLS&A is directly responsible, in conjunction with periodic QA officer inspections, on each job, for the procedural control of special processes such as welding, heat treating, non-destructive testing, and cleaning for items in-house. The Chief Inspector is responsible for inspecting and controlling these processes at supplier's installations, as applicable.

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

JLS&A Engineering Department and Shop Foreman, in conjunction with the QA Department, are responsible for maintaining appropriate procedures, equipment, and personnel connected with applicable codes, standards, and specifications.

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

As part of the implementation of the QA Program, the Engineering Department at JLS&A maintains current qualification records of all areas associated with special processes. In addition, copies of applicable records are filed in each job file.

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X. INSPECTION

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

All inspections performed by JLS&A, which check conformance with quality associated areas, are performed in accordance with written and controlled procedures and are documented.

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

Inspection personnel at JLS&A are independent from the personnel performing the activity being inspected, qualifications and independence determined by the QA Department.

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

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

4. Statement of Verification that Revisions are Inspected in Accordance with the Original Specifications

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

5. Statement of Verification that Inspection Points are Established and Observed

The Shop Foreman is responsible for the supervision of work, including holding work progress until it has been inspected, at the appropriate phases. The Shop Foreman holds work for inspection in accordance with predetermined inspection specifications and for informing the QA Department of forthcoming inspections at weekly meetings and time of inspection.

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XI. TEST CONTROL

Page 40

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

Test Programs to determine if an item will perform satisfactorily are performed by JLS&A Engineering and QA Departments and are performed in accordance with established documented specifications, and are fully documented.

2. Statement of Verification that Revisions in Design are Tested in Accordance with Specifications of the Original Design

JLS&A Engineering Department, in conjunction with the QA Department, tests all modifications, repairs or replacements to the original design in accordance with original specifications or acceptable alternatives.

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

All test program results are fully documented. They are then evaluated and determined acceptable by qualified Engineering and QA Department officers of JLS&A.

XII. CONTROL OF MEASURING & TEST EQUIPMENT

Page 41

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

JLS&A maintains properly calibrated measuring and test equipment, based upon required accuracy, purpose, degree of usage, stability characteristics, or other conditions affecting the measurement. Instruments used involving the measurement of radioactivity are calibrated at three (3) month intervals; all other instruments are calibrated yearly.

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

JLS&A requires and maintains serial numbers on all measuring and test equipment and requires all calibration test data to reference the instruments' serial number.

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

JLS&A performs new tests or measures (which are documented) to validate previous inspections in the event that an instrument is found to be out of calibration, and notifies appropriate parties, if applicable.

4. Statement of Verification that Calibration Meets Appropriate Standards

JLS&A maintains National Bureau of Standards traceable calibration records on all instruments which measure radioactivity, and these standards are referenced on all appropriate documentation. Other inspection instruments either meet nationally recognized standards or manufacturer's specifications which are documented and are on file at JLS&A.

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XIII. HANDLING, STORAGE, & SHIPPING

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

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

2. Statement of Verification that Conditions of the NRC and U. S. DOT Shipping Requirements are Satisfied before Shipment

JLS&A performs a final inspection, before shipment, on all items pertinent to NRC and U. S. DOT specifications and conditions. Items must pass all criteria before shipment is made.

3. Statement of Verification that Shipping Papers are Properly Prepared

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

- Date of shipment
- Customer
- License of Customer
- Source information
- Shipping container type and device
- Radiation level at surface of shipping container
- Radiation level three feet (3') from surface of container
- Surface contamination
- Instrument
- Leak Test
- DOT class label
- Transport Index
- Truck placard requirement
- Shipping weight
- Freight Classification

Also included with shipments are External Radiation Level Certificate, Leak Test Certificate, Calibration Certificate, Attenuator Certificate, if applicable.

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

JLS&A routinely uses motor freight for shipments because the weight inhibits fast delivery and our products' nature does not demand it. Departure occurs after a package has passed final inspection to meet NRC, DOT criteria and

XIII. HANDLING, STORAGE & SHIPPING

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the customer has necessary licensing (if applicable) and is ready to accept delivery. Shipments are monitored as applicable to the motor freight delivery schedule and customer notification of arrival.

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XIV. INSPECTION, TEST, & OPERATING STATUS

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

JLS&A QA Department, in conjunction with other appropriate departments (such as shipping, engineering, production, secretarial), is responsible that the appropriate documentation and identification of inspection, test, and operating status of packages is known and received by affected organizations, such as inter-departmental, shipping agents, and/or customers.

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

JLS&A requires that all inspection and welding stamps and/or status indicators such as tags, markings, labels, or stamps, when removed from an item for fabrication, be checked with the Shop Foreman at the time of removal (for verification purposes) for records of "in-process" work. Any stamps or status indicators to be applied to an item are done so after the appropriate inspector has inspected and passed an item and is also documented accordingly.

3. Statement of Verification that Bypassing of Inspection Tests or Other Critical Operations is Controlled

The bypassing of inspections, tests, or other critical operations is procedurally controlled by documentation, work structure and procedure and daily communication, as well as weekly meetings, between all departments and the QA Department.

4. Statement of Verification that Nonconforming Items are Identified

The Chief Inspector at JLS&A is responsible for identifying and inspecting in-coming materials. Nonconforming items are so identified, not placed in inventory, but returned to vendor. If items are found to be defective or otherwise nonconforming during procedural inspections, these items are identified and either returned to vendor or placed in a special inventory for rework and retesting. These procedures are established to preclude the inadvertent use of nonconforming materials.

XV. NONCONFORMING MATERIALS

Page 45

1. Statement of Verification that Nonconforming Items are Procedurally Controlled

JLS&A has established and enforced procedures during receiving inspection and for subsequent inspections to assure that the identification, documentation, segregation, review disposition are implemented, affected organizations are notified and that replacement and repair are carried out.

2. Statement of Verification that Nonconforming Item Documentation is Complete

When a non-conforming item is found during inspection or testing, the inspection or test individual of JLS&A is required to document the reasons of nonconformance, identify the item, and signature the report; and subsequent appropriate action is taken.

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

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

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

JLS&A inspectors subject all replaced, reworked, or repaired items to the same documentation testing procedures per the original inspection, or by acceptable alternative testing procedures.

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XVI. CORRECTIVE ACTION

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1. Statement of Verification that Evaluations are Conducted to Determine the Need for Corrective Action, if Required

JLS&A does not accept or use nonconforming materials for use in a product, as established by procedural inspections at various phases of operation. In the event that an inspection determines there is a nonconformance, such as failures, malfunctions, deficiencies, or defectiveness, the Engineering and QA Departments jointly evaluate the need for corrective actions in accordance with established procedures.

2. Statement of Verification that Corrective Action is Initiated, if Required

In the event of nonconformance, the Engineering and QA Departments of JLS&A evaluate all aspects of the nonconformance and determine the kind of corrective action to be taken to preclude reoccurrence. This process is documented accordingly, before the corrective action is taken and reinspected according to prescribed procedures.

3. Statement of Verification that Reviews of Corrected Actions are Conducted

The Engineering and QA Departments of JLS&A conduct inspections and follow-up reviews of corrective actions to determine if they are acceptable, and either close out required documentation and/or implement these actions as part of standard operations, whichever is needed.

XVII. QUALITY ASSURANCE RECORDS

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1. Statement of Verification that Documentation is Maintained Concerning Evidence of Quality and Safety of Items and Activities

The Engineering Department of JLS&A maintains all documentation concerning the quality and safety of items and activities which affect quality and safety areas, with revisions and updates made annually, or as needed, or as required.

2. Statement of Verification that Safety and Quality Related Documents Contain Required Information

JLS&A QA records, maintained by the Engineering Department include operating logs; results of reviews, inspections, tests, audits, and material analyses; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports; and corrective action reports.

In addition, pertinent documentation is included with each job file.

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

JLS&A maintains a numerical and alphabetical system which cross references all QA documentation, as well as all associated documentation, throughout all filing systems in all departments. Through the implementation of this system, all records are identifiable and retrievable.

4. Statement of Verification that a List of Required Records and Storage Locations is Maintained

JLS&A maintains a master list of where required records may be located, which includes the use of the established numerical and alphabetical identification system.

5. Statement of Verification that Required Records are Kept on File

JLS&A maintains complete files, including design related records, inspection and related QA documents, since the company was established in 1967, and updates these files as required, i.e., repairs or replacement parts, correspondence, etc. These files are identifiable and retrievable per the master list discussed in XVII. 3 & 4.

6. Statement of Verification that Inspection and Test Records Contain

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XVII. QUALITY ASSURANCE RECORDS

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Appropriate Information

JLS&A Engineering Department has established and maintains inspection and test records which include the following criteria:

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

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XVIII. AUDITS

Page 47

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

JLS&A performs audits in accordance with prescribed procedures and checklists. All audits are performed by employees who do not have direct responsibilities for the area being audited. Audits are performed interdepartmentally if those departments contain individuals who are qualified to do so.

2. Statement of Verification that Audits are Reviewed by Management

JLS&A management personnel review all audits in their areas affected by the audit. Employees compile all audits and a complete report is made available to management for a comprehensive review.

3. Statement of Verification that Management Reviewing Audits have the Responsibility to Correct Deficiencies

The management personnel of JLS&A are responsible for correcting deficiencies as required after a review of the complete auditing reports.

4. Statement of Verification that Deficiencies Revealed by Audits are Re-audited Regularly

JLS&A, at the receipt of an order, makes total inventory and appropriate audits at that time, to determine the correct status of items. Special notations and attention is made on items found previously deficient, or items frequently used.

5. Statement of Verification that QA Program is Audited Annually

Qualified JLS&A management personnel, in conjunction with the QA Department, annually audits and review the entire QA Program and its implementation with special emphasis on the safety related features. Other audits and reviews are performed as necessary, if required.

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