

71-0122

April 20, 2005

Mr. Steven L. Baggett
U. S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Md. 20852

In the Matter of J. L. Shepherd & Associates
(NRC Docket No. 71-0122, EA-01-164):
January-March 2005 Quarterly Report of Independent Auditor

Dear Mr. Baggett:

The NRC's May 30, 2003 Confirmatory Order Relaxing Order authorized J. L. Shepherd & Associates (JLS&A) to continue making shipments of radioactive materials under specified conditions, including the conduct of quarterly audits by an Independent Auditor. Pursuant to Condition 3 thereof, I enclose JLS&A Quality Assurance Program Independent Audit 05-001, by Donald R. Neely Associates, dated April 20, 2005 and covering the quarter of January through March 2005.

Please do not hesitate to call me if you have any questions about the enclosed report.

Respectfully submitted,


Donald R. Neely
Independent Auditor

Enclosure: Independent Audit 05-001

cc w/encl (by fax, hand or overnight courier):

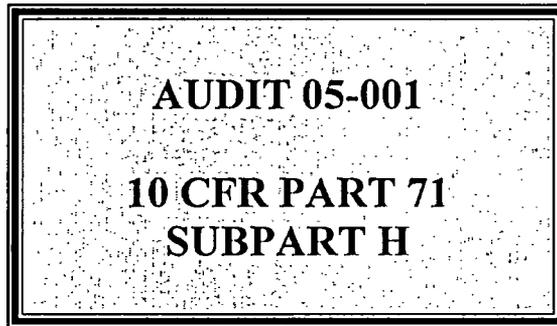
- Mitzi Young, Esq. (OGC)
- J. L. Shepherd/Mary Shepherd/Bill Brown
- Donald P. Irwin, Esq.

NM5501

J. L. SHEPHERD & ASSOCIATES

Docket No: 71-0122

**QUALITY ASSURANCE DEPARTMENT
INDEPENDENT AUDIT**



SCOPE:

**Quarterly Independent Review of the Subpart H
Program Implementation**

Audit Period

January -March 2005

Conducted By: Donald R. Neely Associates

**Report Prepared By: Donald R. Neely Dated: 04/20/05
Donald R. Neely - Independent Auditor**

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ASSURANCE PROGRAM PLAN, REVISION NO. 7
AUDIT REPORT 05-001**

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EXECUTIVE SUMMARY

A. Background

A.1 History

In an Order dated July 3, 2001 (Ref. A.2.1), the NRC withdrew its approval of the Part 71 Quality Assurance program of J. L. Shepherd & Associates (“JLS&A” or the “Company”), thereby preventing it from engaging in any activities within the scope of 10 CFR Part 71 until the NRC rescinded or relaxed its prohibition. In response, JLS&A developed a Near-Term Corrective Action Plan (the “NTCAP”), and obtained limited interim relief from the NRC in a series of Confirmatory Orders, which permitted it to conduct 10 CFR Part 71 Quality Assurance Program activities related to the procurement, use, maintenance and repair of Department of Transportation (DOT) Type B quantities of radioactive materials as defined within DOT regulations at 49 CFR Parts 173 and 178, using DOT Type 20WC transportation packages. The last of these Orders expired May 31, 2003. On December 6, 2001, the NRC conditionally approved JLS&A’s Revision 6 to its Quality Assurance Program Plan (“QAPP”) and implementing procedures; JLS&A amended them further on February 28, 2002 (Revision 7). On February 7, 2003, JLS&A requested the NRC to rescind the July 3, 2001 Order (Ref. A.2.2). On May 30, 2003, following an inspection (Ref. A.2.3), the NRC issued a letter and a new Confirmatory Order which did not grant the full relief requested by JLS&A, but extended JLS&A’s ability to effect shipments and conduct other Part 71 activities through June 1, 2005 in accordance with to QAPP Revision 7, pursuant to certain conditions recited in Part B, immediately below (Ref. A.2.4).

A.2 References

- A.2.1 NRC Order Withdrawing Quality Assurance Program Approval, dated July 3, 2001.
- A.2.2 JLS&A letter (Irwin to Congel), dated February 7, 2003, Re: Request for rescission of NRC Order of July 3, 2001.
- A.2.3 NRC Inspection Report No. 71-0122/2003-201, dated May 20, 2003.
- A.2.4 NRC letter (Luehman to Irwin), dated May 30, 2003, Re: Issuance of Confirmatory Order Relaxing Order to J. L. Shepherd & Associates, (hereafter, “Confirmatory Order”) granting interim relief from reference A.2.1, above.

B. Regulatory Basis for Independent Audit

The current Confirmatory Order (Reference A.2.4) issued to JLS&A requires that JLS&A fully implement and comply with Revision No. 7 of JLS&A’s conditionally approved QA

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Program approval No. 0122, and that periodic independent audits be conducted by an NRC approved Independent Auditor to ensure that the QA Program Plan is being fully and completely implemented. Certain conditions of the May 30, 2003 Order applicable to the verification of QAPP implementation and compliance therewith are listed as follows:

1. JLS&A shall fully implement and comply with Revision No. 7 of the conditionally approved QA Program Approval No. 0122;
2. JLS&A shall fully train JLS&A's staff, contractors and sub-contractors on Revision No. 7 of the conditionally approved QA program plan and implementing procedures, prior to any shipments or design, procurement, fabrication, assembly, testing, modification, maintenance, repair or use of packaging covered by Revision No. 7;
3. JLS&A shall use an Independent Auditor, approved by the Commission, to ensure that Revision No. 7 of the conditionally approved QA program plan is fully and completely implemented. Additionally, the Independent Auditor shall conduct monthly QA program audits and provide NRC with a report by the 20th of each month. These monthly audits shall continue for a period of seven (7) months from the date of the Order. After the seven (7) month period, audits shall be performed on a quarterly basis, with a report provided to the NRC by the 20th of the month following the quarter. The Independent Auditor shall verify the compliance of the conduct of shipping operations with Revision No. 7 of the conditionally approved QA program plan and implementing procedures;
4. JLS&A will stop all shipping operations if the audit conducted by the Independent Auditor identifies safety concerns associated with the JLS&A conduct of shipping operations. In such event, JLS&A shall inform the NRC of the audit findings and JLS&A's proposed corrective actions within three (3) business days of the identification of the audit findings to JLS&A by the Independent Auditor. JLS&A will suspend all shipping operation until the safety concerns are corrected and the Independent Auditor has found the corrective action acceptable. The Independent Auditor will inform NRC of the audit findings, JLS&A corrective actions, and the results of the Independent Auditor's review of the corrective actions in its audits.

C. Summary of Findings

The 5th quarterly independent audit under the May 30, 2003 NRC Confirmatory Order was conducted during the period March 14-16, 2005. The independent audit focused on determining if the JLS&A QA Program was being fully and completely implemented as required by the Confirmatory Order. In addition, the independent audit was focused on verification that the conduct of shipping operations was being carried out in compliance with Revision No. 7 of the conditionally approved QA program and implementing

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procedures. Areas reviewed and evaluated during the course of the independent audit included package shipping and receipt operations, repair/maintenance, design controls, training and qualifications, the measuring and testing equipment, special processes, nonconformance reporting, corrective action, test control, and the audit program. Based upon the review of these quality areas the Independent Auditor identified three (3) observations needing attention.

1 INDEPENDENT AUDIT REPORT DETAILS

1.1 Objective

The objective of the quarterly independent audit was to determine if JLS&A operations, shipments, repair and maintenance of packages, inspection processes, records control and identification of nonconformance and associated corrective actions appropriate to the conduct of quality-related activities are being fully implemented and are in compliance with JLS&A's QAPP and NRC requirements.

The methodology for performing the audit consisted of performance-based and in-depth evaluation techniques. Specifically, the inspection guidance contained in Chapter 4 of NUREG/CR-6314 was used as the primary basis, along with other guidance deemed appropriate by the Independent Auditor for evaluating the compliance and effectiveness of the quality assurance program areas.

1.2 Scope

The scope of the quarterly independent audit consisted of a review and evaluation of those principal quality assurance activities associated with the preparation, use, repair, and transportation of Type B packages authorized under 10 CFR Part 71.12 and applicable provisions of DOT regulations at 49 CFR Parts 173 and 178. The independent audit consisted of reviewing packaging operations in progress, independent confirmatory compliance inspections, review of records and interviews with the JLS&A staff members appropriate to the program area being audited/inspected, and physical walk downs of the JLS&A main production and operations facility areas.

1.3 Audit Conferences

1.3.1 Pre-Audit Conference

A pre-audit conference was held at the beginning of the audit on March 14, 2005 with the JLS&A Quality Assurance Manager. During the meeting the Independent Auditor explained the purpose of the independent audit and the areas of the program that were expected to be reviewed.

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1.3.2 Post-Audit Conference

A post-audit conference was held on March 16, 2005 following the conclusion of the on-site audit activities to discuss audit findings. The Quality Assurance Manager was briefed in the post-audit conference. The Independent Auditor's preliminary audit findings were presented and discussed during this conference.

1.4 Persons Contacted

A listing of those JLS&A staff members contacted and/or interviewed is contained in Attachment A to this audit report.

1.5 Applicable Regulatory Basis Documents

A listing of regulatory documents, regulatory guides and license documents referenced and/or utilized during the performance of the audit effort is contained in Attachment B to this audit report.

1.6 Audit Details

1.6.1 JLS&A Facility Tours

During the course of the Independent Audit, walkdowns of the production and operating facilities were conducted by the Independent Auditor on several occasions for purposes of determining program compliance. The Independent Auditor focused primarily on the quality activities related to implementation of management controls applicable to (a) the proper segregation of parts, materials and components for those designated as 10 CFR Part 71 quality related items and (b) ongoing repair and maintenance of Type B overpacks. These facility walkdowns and assessments revealed that Type B packages were being properly stored, tagged and labeled as required by JLS&A Quality Assurance implementing procedures and current DOT marking requirements.

The Independent Auditor found this area of the quality program to be adequate and did not identify any items of noncompliance as a result of touring and inspecting these areas.

1.6.2 Packaging and Shipping/Transportation Activities

1.6.2.1 DOT Type B Shipments

During the course of the independent audit, records for Type B packages shipped and received by JLS&A during the period of December 3, 2004 through March 8, 2005 were reviewed for compliance with federal

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regulations and Quality Assurance Manual/Quality Procedures (QAM/QP) implementing procedures. This review consisted of evaluating inspection check lists and required shipping documents for both loaded and unloaded Type B packages received at or shipped from the JLS&A operations facilities located in San Fernando, California, as well as incoming and outgoing shipments at off-site client facilities.

During the review of this quality area of the program the Independent Auditor identified two (2) instances where required signatures had not been applied acknowledging approval by quality assurance on DOT 7A checklists. The Independent Auditor noted that approval signatures were applied to the accompanying 20 WC-5 & 6 checklists for the particular shipping papers reviewed. In addition, it was identified that on three (3) occasions checklists utilized for the purpose of documenting "Package Information" including M&TE calibration data had the incorrect calibration due dates listed. The year 2004 was indicated rather than 2005. This incorrect data indicated that M&TE used for the measurements was over due for calibration. A review of calibration records revealed this not to be the case. The Independent Auditor brought these items to attention of JLS&A management and emphasized the need to carry out due diligence in completing quality forms. JLS&A management took immediate corrective action to sign the documents and correct the incorrect data and placed them in their appropriate quality files.

Observation No. 05-001-01: Several checklists were missing required approval signatures and incorrect calibration data was applied to checklists.

1.6.2.2 Package Maintenance and Repair

During tours of the operations and production areas the Independent Auditor observed that one (1) 20WC-6 metal overpack was undergoing repair for a new closure blot replacement. The Independent Auditor determined that the required repair work paperwork was properly issued and affixed to the overpack. Also a Type B package was appropriately labeled with the required reject tag.

The Independent Auditor did not identify any nonconformance associated with this area of the quality assurance program.

1.6.3 Design Control

The quality area of Design Control was reviewed for compliance with the QAPP and QAM/QC implementing procedures by review of several Engineering Committee meeting minutes. Minutes for meetings covering the period January 6,

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2005 - March 7, 2005 were reviewed and found to contain several reviews of planned projects using Type 7A containers and JLS&A 20 WC wooden overpacks for shipments of Type B quantities of radioactive materials.

Based upon a review of this area of the quality assurance program the Independent Auditor did not identify any instances of noncompliance.

1.6.4 Training and Qualifications Program

During March 2005 JLS&A management authorized the hiring of an individual to fill the position of Assistant Quality Assurance Manager. This new employee appears to possess extensive experience in quality assurance related to the aerospace industry, both supervisory and technician level. Also, the individual has several years of experience as a production supervisor overseeing general production operations. The Independent Auditor reviewed training records for this individual and determined the required employee Training Matrix had been initiated and completed. Initial training had commenced for the new employee with the assignment of reading the QAPP and QAM implementing procedures.

Based upon a review of this area of the quality assurance program the Independent Auditor did not identify any items of noncompliance.

1.6.5 Control of Measuring and Test Equipment (M&TE)

The quality program area of M&TE was reviewed for compliance with QAPP implementing procedure QAM/QP No. 12.0, "Control of Measuring and Test Equipment". This effort consisted of discussions with the M&TE Calibration Coordinator regarding the status of M&TE devices and review of M&TE records including inventory lists and equipment status. In addition, a random selection of M&TE calibration records was reviewed for quality and accuracy. The review of these records indicated that M&TE devices were being properly calibrated and maintained and the Master Inventory List was being adequately administered. Also, the administration of the Master Inventory List was receiving appropriate JLS&A management oversight.

Based upon a review of this area of the quality assurance program the Independent Auditor did not identify any items of noncompliance.

1.6.6 Control of Special Processes

This quality program area was reviewed against the applicable conditions of the JLS&A QAPP and QAM/QP 9.0, "Control of Special Processes". The review of this area consisted of discussions with the Manager, Quality Assurance and inspection of operations areas and work in progress. Based upon the review of this

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area the Independent Auditor determined that during this audit reporting period JLS&A did not have the need to implement required administrative controls for controlling special processes.

Based upon a review of this area of the quality assurance program the Independent Auditor did not identify any items of noncompliance.

1.6.7 Control of Nonconforming Items

This quality program area was reviewed against the conditions of Section 15.0 of the JLS&A QAPP and QAM/QP No. 15.0, "Control of Nonconforming Items". The review consisted of reviewing Nonconformance Reports (NCR's) issued during this audit reporting period. Specific emphasis during the review process was focused on NCR No. 005005, dated February 23, 2005, involving excessive gouging to the interior of the wooden overpack. This particular Type B Overpack, designated as No. 22281, utilizing an inner DOT 7A shielded container and containing approximately 852 Ci of radioactive material was packaged and shipped by an authorized JLS&A sub-contractor shipped from a client facility on or about February 18, 2005. During receipt inspection at the JLS&A San Fernando, California facility on February 23, 2005, it was identified that the inner package had not been secured properly for restricting movement during shipment over the highway. Specifically, appropriate cribbing had not been installed around the Type A inner container to stabilize and restrict its movement inside the wooden overpack during shipment. Based upon a review of photographs taken with the Type 7A container located inside the overpack it appeared that the inner container had at least twelve (12) to fifteen (15) inches of area for movement within the interior area of the wooden overpack. Consequently, failure to properly crib the inner Type 7A container resulted in the inner walls of the wooden overpack receiving multiple abraded surface areas twelve (12) to fifteen (15) inches long and approximately 3/8 of an inch deep at the deepest point caused by the unrestricted movement of the Type 7A container. JLS&A inspection personnel and management took action to reject the package for further use until the inner areas of the wooden overpack were repaired. Also, the individual who had loaded and released the package from the client's facility was immediately restricted from performing radioactive material shipping and inspection activities until re-training was received. In addition, the President of JLS&A issued a letter to the individual involved expressing concern about the incident and instructed the individual to exercise increased diligence during future similar shipping activities. The Independent Auditor expressed concern to JLS&A management regarding the lack of proper loading and shipping of this particular loaded wooden overpack and indicated that re-training activities for the individual involved would be reviewed. Based on a further review of NCR's the Independent Auditor noted the same individual involved in NCR No. 00505 had been issued two other NCR's related to Type B packaging activities during this audit

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reporting period, which JLS&A management was already investigating and processing.

The quality area of record retention for NCR's was reviewed by the Independent Auditor. Based upon this review it was determined that not all of the NCR's located in their required retention files contained all of the required review and approval signatures, causing some files to be incomplete. The Independent Auditor brought this to the attention of JLS&A management, who took immediate corrective action to ensure that all required record retention files contained the appropriate approval records.

Observation No. 05-001-02: Lack of due diligence during shipping operations resulted in damage to a Type B wooden overpack and loading procedures were not adequately followed. This is considered a licensee identified nonconformance having appropriate corrective action being implemented.

Observation No. 05-001-03: All required files for retention of NCR's issued need to properly reflect the status of open and closed NCR's. Required files did contain similar status of NCR's.

1.6.8 Corrective action Program

The quality area of corrective action was reviewed during the course of the Independent Audit. The status of corrective action reports previously issued, as well as the status of new corrective action reports, was reviewed. Based upon discussions with the Manager, Quality Assurance, it was determined that all previously issued corrective action reports had been closed and there had not been any new corrective action reports opened.

Based upon the review of this area of quality assurance the Independent Auditor did not identify any items of noncompliance.

1.6.9 Test Control

The quality program area of product testing was reviewed for compliance with QAPP implementing procedure QAM/QP No.11.0, "Test Control". This review consisted of discussions with the Manager, Quality Assurance regarding the need to implement this area of the quality program during this audit reporting period. Based upon these discussions the Independent Auditor determined that JLS&A personnel and management did not have the need to control quality activities using formal test controls as required by QAM/QP implementing procedures.

Based upon the review of this area of the quality assurance the Independent Auditor did not identify any items of noncompliance.

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1.7.0 Audits

The quality area of audits was reviewed for compliance with QAM/QP No. 18.0, "Audits". This review consisted of reviewing records of external audits completed recently. Some external audits consisted of performing formal written surveys of the vendor's quality assurance program. External audits reviewed indicated that they appeared to have been carried out and documented properly with required follow up for audit results implemented. The review also included assessing the status of the external annual audit schedule issued in December of 2004.

Based upon the review of this area of the quality assurance the Independent Auditor did not identify any items of noncompliance.

2 CONCLUSIONS

Audit Results

The Quarterly Independent Audit did not identify any items of noncompliance. However, three (3) observations were noted in the quality areas of Type B package shipping and receiving checklists, packaging and transportation operations and nonconformance reporting records retention.

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ATTACHMENT A

Persons Contacted

| <u>Name</u> | <u>Title</u> | <u>Company</u> |
|--------------------|---|-----------------------|
| J. L. Shepherd | Chief Executive Officer | JLS&A |
| D. Shepherd | Vice President, Operations/Electronics | JLS&A |
| M. Shepherd | Vice-President, Business Development And Licensing | JLS&A |
| W. Brown | Quality Assurance Manager | JLS&A |
| C. Harper | Assistant Quality Assurance Manager | JLS&A |
| D. Tran | Calibration Administrator | JLS&A |

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ATTACHMENT B

Applicable Regulatory Basis Documents

- 10 CFR Part 71 Specifications
 - Requirements for Type B Package use and transportation
 - Subpart H Quality Assurance Requirements
 - Regulatory Guide 7.10
- Subpart H Quality Assurance Program Plan (QAPP) Revision 3, dated September 13, 2001 & Procedures
 - Policy and administrative procedures
 - Technical and operational procedures
 - JLS&A Special QA Instructions and Memoranda
- NRC Confirmatory Order Relaxing Order, Dated May 30, 2003
- Department of Transportation Regulations, Title 49 CFR Parts 173, 178 (as applicable)
- NRC Quality Assurance Program Approval For Radioactive Material Packages No. 0122, Revision 7, dated February 28, 2002

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ATTACHMENT C

Documents Reviewed

1. JLS&A Quality Assurance Manual (QAM/QP) Revision 1, dated 5/9/03
2. 20WC Package Compliance Check Lists (Inbound and Outbound Shipments)
3. JLS&A DOT Shipping Records
4. Quality Assurance Program Plan Revision 3, dated 09/13/01 (Control No. 00218-1)
5. Nonconformance Reports
6. M&TE Master Inventory List
7. M&TE Records
8. Engineering Committee Minutes
9. Training and Qualification Records