

71-0122

January 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):
October-December 2004 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 04-004, by Donald R. Neely Associates, dated January 20, 2005 and covering the quarter of October through December 2004.

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 04-004

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

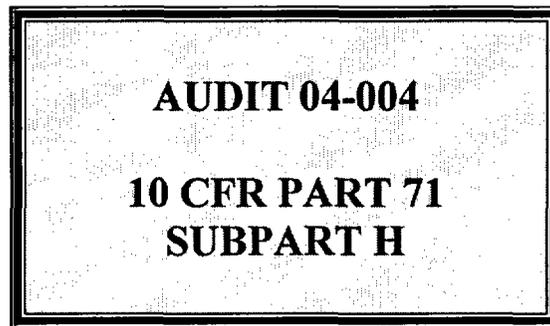
- Mitzi Young, Esq. (OGC)
- J. L. Shepherd/Mary Shepherd/Bill Brown
- Donald P. Irwin, Esq.

N1M5501

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

October -December 2004

Conducted By: Donald R. Neely Associates

**Report Prepared By: Donald R. Neely Dated: 01/20/05
Donald R. Neely - Independent Auditor**

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ASSURANCE PROGRAM PLAN, REVISION NO. 7
AUDIT REPORT 04-004**

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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the “Company”), thereby preventing it from engaging in any activities within the scope of 10 CFR Part 71 until the NRC rescinded or relaxed its prohibition.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 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 4th quarterly independent audit under the May 30, 2003, NRC Confirmatory Order was conducted during the period December 6-8, 2004. 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, design controls, instructions and procedures, test control, special processes, nonconformance reporting, repair/maintenance, the measuring and testing equipment program, and surveillance. Based upon the review of these quality areas the Independent Auditor identified four (4) nonconforming conditions and four (4) 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 December 6, 2004 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 December 8, 2004 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 October 20, 2004 through November 29, 2004 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.

The Independent Auditor identified that inspection check lists (forms) being utilized by JLS&A personnel had not been procedurally/formally changed to incorporate the newly implemented Department of Transportation regulation changes for Type B packages. This item is being identified as an observation and is further discussed in sub-section 1.6.5 below.

Based upon a review of shipment records evaluated the Independent Auditor determined that this area of the quality assurance program was being implemented and maintained in accordance with the applicable requirements of 10 CFR Part 71 and applicable QAPP implementing procedures.

1.6.2.2 Package Maintenance and Repair

Based upon a review of this area the Independent Auditor did not identify any Type B wooden packages staged or identified in repair/maintenance status.

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 and was limited to the review of Engineering Committee meeting minutes. Minutes for meetings dated October 14; November 1, 9, 11 & 18; and December 2, 2004, respectively, were reviewed as part of the audit evaluation of this quality area. Based upon a review of this area it was determined that several of the meeting minutes documented specific technical types of discussions associated with the use of specific vendor supplied NRC approved Type B Certificate of Conformance (COC) packages for use on planned projects requiring shipment of Type B quantities of radioactive material.

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 Control of Measuring and Test Equipment (M&TE)

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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 and notification letters to M&TE Holders.

Based upon a review of calibration records associated with this area of the quality program it was determined that one M&TE item listed on the M&TE Master Inventory List had passed the listed deadline for re-calibration. Specifically, M&TE Number QA 71 (Serial No. 1461) "Eberline Radiation Survey Meter" had an expiration date of November 23, 2004 and the required Past Due Notice had not been sent out to the M&TE Holder. The Independent Auditor determined that the required Calibration Due Notice had been issued on or about November 4, 2004. The instrument was eventually returned to the JLS&A facility for the required re-calibration on December 6, 2004.

Based upon a further review of the M&TE Master Inventory List the Independent Auditor identified several data inconsistencies, which are as follows:

- The M&TE Master Inventory List, dated December 1, 2004, had not been revised to correct in accurate tolerance specification identified by the NRC during their mid-November inspection
- A new torque wrench recently procured and received by JLS&A had not been entered into the M&TE Master Inventory List as of December 6, 2004
- M&TE Number QA 69 (Torque Wrench) was entered on the Master Inventory List as being still in service on December 6, 2004. The torque wrench was actually removed from service on October 25, 2004 and sent out for calibration. The torque wrench was returned to JLS&A by the calibration vendor on or about December 6, 2004 in a non-operable status due to unavailability of replacement parts. Upon receiving the inoperable torque wrench JLS&A personnel removed the device from active service, applied the required Rejection Tag and issued the required Nonconformance Report.

Observation No.04-004-01: The M&TE Master Inventory List is not being updated in a timely manner in order to reflect the current status and technical data for M&TE utilization.

Finding No.04-004-01: The required Past Due Notification correspondence was not issued to M&TE Holders as required by QAM/QP 12.0.

1.6.5 Instructions, Procedures and Drawings

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This quality program area of the QAPP was reviewed against the specifications contained in QAM/QP 5.0, "Instructions, Procedures and Drawings". This review consisted of reviewing the implementing procedures contained within the QAM/QPs and discussions with the QA Manager.

The review was specific to evaluating the contents of QAM/QP 5.0 regarding the ability of JLS&A management to implement controlled temporary changes to implementing procedures, on an as needed basis, while the more permanent procedure change/revision process is carried out. This review was acted upon based upon the fact that hand written changes to some technical forms (inspection check lists) had been initiated by JLS&A management and personnel due to recent changes in Department of Transportation (DOT) regulations applicable to Type B package labeling and classification designations. Specifically in October 2004 JLS&A began making hand written changes to the shipping inspection forms based on DOT regulation changes. As of December 6, 2004 this methodology was still being implemented at JLS&A without the inspection forms being formally revised to reflect the required technical changes.

A provision in QAM/QP 5.0 allows for JLS&A to make changes to forms if it is considered an enhancement as long as essential elements remain the same. The hand written changes to the forms appear to be covered by this provision, however, the practice should be considered temporary in nature with the forms being revised as necessary in a timely manner to ensure the document control process is effectively administered and controlled. A temporary change policy within the implementing procedures may be a resolution for this matter.

Observation 04-004-02: A formal practice of authorizing and controlling temporary procedure changes/revisions should be considered for effective control of the procedure change process and the inspection forms need to be finalized to eliminate further marking up of the forms .

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 consisted of evaluating the formal implementing procedure associated with managing the administrative and technical aspects for the application of special processes in the development, production and maintenance of Type B packages. The review also consisted of discussions with the Quality Assurance Manager. Based upon these reviews and information provided during these discussions the Independent Auditor determined that during this audit period JLS&A personnel did

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not have the need to implement special processes controlled by implementing procedure QAM/QP 9.0.

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 Surveillance

The quality program area of product testing was reviewed for compliance with QAPP implementing procedure QAM/QP No.10.1, "Surveillance". The review of this area consisted of reviewing records, evaluating the specifications set forth in the controlling implementing procedure and discussions with the Quality Assurance Manager.

Sub-section 4.0 specifies the responsibilities for administration of QAM/QP 10.1, Specifically; procedural step 4.1 assigns certain administrative responsibilities to Quality Assurance regarding the identification of surveillance activities, and the assignment, preparation, performance and documentation of surveillance plans. One specific provision contained within specification 4.1 requires that a Surveillance Plan be developed utilizing Enclosure 1 to the implementing procedure for documentation purposes. The Independent Auditor reviewed the Surveillance Plan contained within QAM/QP 10.1 and determined that this particular aspect of the implementing had been carried out. Based upon a review of records of similar origin provided to the Independent Auditor by the Quality Assurance Manager it was determined that the Surveillance Plan had been developed utilizing several different controlled forms, but in all cases contained the same information. This is an observation relative to proper document control. Also, two Surveillance Plans had been approved by the Quality Assurance Manager on April 14, 2003 and September 1, 2004, respectively.

Based upon a review of surveillance records provided to the Independent Auditor it appears that only one surveillance activity had been carried out during the period April 14, 2004 through the time of this Independent Audit. That surveillance had been carried out by the Quality Assurance Manager on or about April 1, 2004 and covered Shop Operations. Documentation of this surveillance consisted of the required surveillance check lists and report. However, the specific information to be included in the Surveillance Report documentation was not complete as required specifically by sub-section 5.3.1 of QAM/QP 10.1. With regard to surveillance report distribution it could not be determined if the required distributions were made as required by the implementing procedure.

The Surveillance Plans approved and signed off by the Quality Assurance Manager addresses seventeen areas of the quality program that are to be carried out under the

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surveillance activities. These consist of clearly de-fined quarterly, semi-annual and annual surveillances frequencies.

Another administrative condition relating to tracking of surveillance is contained in sub-section 5.2.2 of QAM/QP 10.1 which specifies that a Surveillance Report Log be maintained by the Quality Assurance Department using Enclosure 4 to QAM/QP 10.1. Based upon a review of surveillance records the Independent Auditor did not find evidence that the required surveillance log was implemented and being maintained.

Based upon discussions with the Quality Assurance Manager regarding the status of the Surveillance Program it was identified that it was the intent of the Quality Assurance Manager to move the required surveillance activities out to the operating departments of JLS&A for full implementation but that that had not yet occurred.

The Independent Auditor also identified several minor corrections that needed to be addressed by JLS&A regarding the enclosures to the implementing procedure. These were : 1) Surveillance Plan attached to the procedure bears both the designation "(Enclosure 1)" and the designation "(Enclosure 2)" ; and 2) the Surveillance Check List attached to the implementing procedure was not marked as an Enclosure.

Observation No. 04-004-03: Several versions of the Surveillance Plan are being utilized rather than the specific form version depicted in the Enclosure to QAM/QP 10.1

Observation No. 04-004-04: Enclosures 1 &2 to QAM/QP need to be edited to reflect accurate identification of the enclosures for proper use and control purposes.

Finding No. 04-004-02: Failure to adequately implement QAM/QP 10.1, having several examples, as follows: 1) Surveillance Plan activities have not been implemented as required for 2003 & 2004: 2) Surveillance Report does not contain all the information as required by sub-section 5.3.1 and 3) the Surveillance Log is not being maintained as required.

1.6.8 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 records of Nonconformance Reports (NCRs) issued and required log books and evaluation of procedural specifications. The following program elements were reviewed for adequacy and compliance:

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- NCR Log Books:

The Quality Assurance Manager has the overall responsibility for tracking all NCR's approved and issued. This has been historically implemented utilizing an NCR Log Book. The Log Book and NCR's were reviewed by the Independent Auditor and found to be deficient, in that, not all NCR's had been entered into the NCR Log, and some had been entered incompletely. Specifically, there was no entry found for NCR issued as No.O31020. Also, the pre-established numbering sequence was not being consistently implemented. Based on several discussions with the Assistant Quality Assurance Manager it was learned that a recent practice allowed for JLS&A staff members to make entries of NCR's into the NCR Log Book rather than have the Quality Assurance Manager assign specific sequential numbers and make the required log book entries. Additional procedure specifications require that certain information be contained in the NCR log or database. Specifically, the information required to be included consists of the NCR number, issue date, disposition, and name of individual or organization responsible, schedule for completion and NCR closure date. The NCR Log Book currently being utilized did not contain all the required information specified in the procedure specifications.

Prior to completion of the Independent Audit the Quality Assurance Manager had established a new NCR Log Book/Database containing the required information specified in QAM/QP 15.0, sub-section 5.2.

- Trend Analysis:

This quality area was reviewed for compliance with QAM/QP 15.2. The review consisted of a review of NCR trending information, as well as discussions with the Quality Assurance Manager. The review of records and discussions indicated that the required narrative reports required by sub-section 5.2 of QAM/QP 15.2 had not been prepared as required. QAM/QP 15.2 requires that narrative reports documenting both negative and positive trends be prepared on a semi-annual basis. The Quality Assurance Manager concurred that the required narrative reports had not been developed and that the trending effort was limited to the development of charts.

Finding No. 04-004-03: Failure to adequately implement the procedural provisions regarding the assignment of numbers and administrative tracking of NCR's.

Finding No. 04-004-04: Failure to properly implement QAM/QP15.2 regarding full implementation of procedural provisions relative to preparing narrative trend reports on a semi-annual basis.

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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". The review consisted of evaluating the implementing procedure developed for controlling the specific processes utilized for product acceptance and discussions with the Quality Assurance Manager. Based on the information provided during these discussions the Independent Auditor determined that during this audit reporting period JLS&A personnel did not carry out development, production or maintenance activities that required the use of test controls commensurate with QAM/QP 11.0.

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 identified four (4) items of nonconformance related to M&TE control, surveillance and nonconformance control areas of the JLS&A Quality Assurance Program. There were also four (4) observations noted, in the quality areas of instructions and procedures, M&TE controls and surveillance.

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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
Huyen Kay	Assistant Quality Assurance Manager (In Training)	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. Surveillance Reports & Plans
8. M&TE Records
9. Engineering Committee Minutes