

July 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):
April-June 2005 Quarterly Report of Independent Auditor

Dear Mr. Baggett:

Pursuant to Condition 2 of the NRC's June 30, 2003 Confirmatory Order Rescinding Order (Effective Immediately), I enclose JLS&A Quality Assurance Program Independent Audit 05-002, by Donald R. Neely Associates, dated July 20, 2005 and covering the quarter of April through June 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 05-002

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

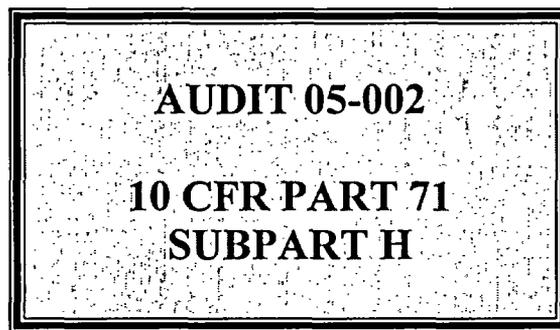
- Mitzi Young, Esq. (OGC)
- J. L. Shepherd/Mary Shepherd/Bill Brown
- Donald P. Irwin, Esq.

NMSS01

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

April - June 2005

Conducted By: Donald R. Neely Associates

Report Prepared By: Donald R. Neely Dated: 07/20/05
Donald R. Neely - Independent Auditor

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ASSURANCE PROGRAM PLAN, REVISION NO. 7
AUDIT REPORT 05-002**

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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the "Company"), thereby preventing it from engaging in any activities within the scope of 10 CFR Part 71 until the NRC rescinded or relaxed its prohibition.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). On May 30, 2005, the NRC issued a Confirmatory Order extending the May, 30, 2003 Confirmatory Order through June 30, 2005. On June 30, 2005, the NRC issued an Order (Ref. A.2.5) rescinding the Order of July 3, 2001 and restoring JLS&A to full scope of operations under 10 CFR Part 71, subject to quarterly audits for a period of one year and certain other conditions. This Audit is submitted pursuant to the May 30 Order.

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.

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A.2.5 NRC, Confirmatory Order Rescinding Order (Effective Immediately), June
30,2005

B. Regulatory Basis for Independent Audit

The May 30, 2005 Confirmatory Order continues in effect certain requirements stated in the Confirmatory Order of May 30, 2003. It requires that JLS&A fully implement and comply with Revision No. 7 of JLS&A's conditionally approved QA 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.

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C. Summary of Findings

The sixth quarterly independent audit under the May 30, 2003 Order was conducted during the period June 27-30, 2005. The independent audit focused on determining if the JLS&A QA Program was being fully and completely implemented as required by the May 30 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 procedures. Areas reviewed and evaluated during the course of the independent audit included package shipping and receipt operations, repair/maintenance, design controls, organization and staffing, the measuring and testing equipment, special processes, nonconformance reporting, document control, corrective action, test control, and the surveillance program. Based upon the review of these quality areas the Independent Auditor determined that effective implementation of quality assurance was taking place.

As a result of the audit process one (1) finding and six (6) observations were identified.

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.

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1.3 Audit Conferences

1.3.1 Pre-Audit Conference

A pre-audit conference was held at the beginning of the audit on June 27, 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.

1.3.2 Post-Audit Conference

A post-audit conference was held by telephone on July 6, 2005 with the Quality Assurance Manager following the conclusion of the on-site audit activities to discuss audit findings. The Independent Auditor's preliminary audit findings were presented and discussed during this conference call.

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

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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 March 15, 2005 through June 27, 2005 were reviewed for compliance with federal 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 some instances where a complete serial number had not been documented for the specific radiation monitoring instrument used for the inspection of the package. A review of the M&TE Master Inventory List indicated that these particular instruments were within their applicable calibration frequencies. Also, it was identified that one (1) Type B package checklist had an incorrect instrument calibration due date listed on the inspection form. A follow up review of the instrument calibration records revealed that the instrument was listed as being within the acceptable calibration time frame. Additionally, it was concluded that the individual performing the inspection activity had mistakenly listed the date when the instrument was calibrated on the checklist rather than the instrument calibration due date.

The Independent Auditor discussed these items with members of JLS&A management and expressed the need for management to place more diligence on proper documentation of quality data and oversight of these activities to ensure full and effective compliance is achieved.

Observation No. 05-002-01: Some checklists were completed using incorrect calibration data and partial serial numbers for M&TE utilized during Type B package inspections.

1.6.2.2 Package Maintenance and Repair

During tours of the operations and production areas the Independent Auditor did not identify any Type B packages undergoing maintenance or repair.

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However, records for Type B packages that had been recently repaired were reviewed and found to be in compliance with QA procedures and work instructions.

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

1.6.3 Organization and Staffing

This program area was reviewed specific to the addition of the newly assigned Quality Assurance Assistant in March of 2005. The review was limited to discussions regarding implementation of the JLS&A QA Program. Based upon these discussions and reviews of Surveillance Audits performed by this individual it appears that the level of diligence over certain areas of the QA Program has been increased to a satisfactory level. This individual has not yet been authorized to perform independent audits of Type B packages.

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

1.6.4 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 March 7, 2005 - May 18, 2005 were reviewed and found to contain several reviews with regard to authorized use of certain DOT Type 7A containers. Also, one Committee meeting had to deal with the planned use of a vendor supplied NRC approved Type B package.

During the course of the Independent Audit the engineering design program area was discussed with JLS&A management. JLS&A management indicated that they were planning to initiate the design for a new Type B package for eventual submittal to the NRC for review and approval. JLS&A management indicated that they were actively recruiting senior engineering personnel to support the new package design effort. Based upon discussions with management it appears that JLS&A is doing adequate diligence in seeking out qualified candidates for the engineering positions.

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

1.6.5 Document Control

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The quality area of Document Control was reviewed for compliance with QAPP implementing procedure QAM/QP No. 6.0, "Document Control". This effort consisted of randomly selecting four (4) assigned controlled copies of the QAM/QP implementing procedure manuals. This review revealed that all required changes had been appropriately inserted into the respective manuals. However, based upon a thorough review of each manual it was determined that one (1) revision to the manuals had a typographical error, in that, not all of the affected pages contained consistent revision dates. This was brought to the attention of the Quality Assurance Assistant, who indicated that this typographical error had been previously identified by JLS&A and that corrective action to issue the correct revision date was in progress. The Independent Auditor considered this matter to be classified as licensee identified and had no further questions.

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

1.6.6 Surveillance

This quality program area was reviewed against the applicable conditions of the JLS&A QAPP and QAM/QP 10.1, "Surveillance". The review of this area consisted of reviewing records of surveillances conducted and discussions held with the Quality Assurance Assistant regarding the conduct of surveillances.

During the period of March 29, 2005 -April 20, 2005, a total of twenty-one (21) formally controlled quality assurance surveillances were performed as required by QAM/QP 10.1. The quality areas inspected included procurement, M&TE, instructions and procedures, package shipping and handling records, control of nonconforming items, corrective action, quality records, document control, inspection and test, control of special processes, engineering, identification and control of material and receiving inspections. The Independent Auditor verified that as required by QAM/QP 10.1 appropriate Surveillance Checklists had been prepared and approved for conduct of the surveillances. Also, it was determined that Surveillance Reports required by QAM/QP 10.1 had been filled out and submitted for review and approval. However, based upon further review of the Surveillance Reports the Independent Auditor identified one (1) Surveillance Report (No. SR007) that had not been signed off by the Quality Assurance Manager as being reviewed. All other Surveillance Reports submitted for review and approval had been signed as required. The review of this quality area also indicated that surveillances conducted were entered into the Surveillance Report Log and issued appropriate identifying numbers as required.

As part of the review of this area the distribution and nonconformance reporting aspects of the Surveillance Program were reviewed. This review identified that the completed Surveillance Reports did not contain the required report distribution lists

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as specified in sub-section 5.3.1 of QAM/QP 10.1. Based upon discussions with the Quality Assurance Assistant it was determined that those Surveillance Reports applicable to departments other than Quality Assurance were not distributed as required by procedure. It appeared that required Nonconformance Reports (NCRs) were issued and filed properly. In some cases NCRs were issued when nonconforming conditions did not exist, but JLS&A management elected to request formal corrective action based on the important nature of the findings and observations identified.

Observation No. 05-002-02: Surveillance Report had not been signed off as required for report closure.

Observation No. 05-002-03: Surveillance Reports did not contain distribution lists as required.

1.6.7 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 Quality Assurance Manager and inspection of operations areas and work in progress. Based on these discussions it was stated to the Independent Auditor that there had not been a need by JLS&A management to implement special administrative controls, other than standard operating procedures currently in place, for conducting special processes.

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

1.6.8 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 Quality Assurance Manager regarding the need to implement this area of the quality program during this audit reporting period. Based on these discussions it was stated to the Independent Auditor that JLS&A personnel and management did not have the need to control quality activities using formal test procedures and controls as required by applicable QAM/QP implementing procedures.

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

1.6.9 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". A review of the Master Inventory List for Category 1 M&TE devices was reviewed and found to be current with no M&TE reflecting an overdue status. However, two (2) items of M&TE had calibration expiration due dates of June 29, 2005. Appropriately, M&TE calibration due notices had been issued as required on or about June 1, 2005. Past due calibration notices were in the process of being issued for the two (2) items of M&TE. A further review of the operating status of these two (2) items of M&TE revealed that one of the items was in transit from a recently completed project at a customer facility while the other item of M&TE was located on June 30, 2005 in the JLS&A source loading area at their San Fernando facility. The instruments were to have been returned for re-calibration by June 29, 2005. The Independent Auditor noted that the instrument located in the source loading area had not been labeled with a "Reject" tag indicating the calibration period had expired. Based upon a review of shipping inspection checklists the Independent Auditor determined that neither instrument had been utilized for performing shipping inspections while in past due calibration status.

Observation No. 05-992-04: Two (2) items of M&TE, radiation monitoring instruments, had not been returned to Calibration Coordinator within the thirty day recall period as required by QAM/QP 12.0 and Reject Tags had not been applied.

1.7.0 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 NCRs and records related to the respective NCRs. The review covered the period of March 29, 2005 - June 24, 2005. There were approximately fifty-four (54) NCRs issued by JLS&A during that period. The NCRs reviewed addressed quality areas that had nonconforming conditions identified, as well as recommendations for program enhancements to certain quality areas. Some of the NCRs were elevated to corrective action reporting status by JLS&A management. Based upon a review of these NCRs the Independent Auditor identified one (1) nonconforming condition related to some NCR reports that been entered into the NCR Log book as being closed but had not been signed off as required. Specifically, four (4) of the NCRs had not been signed off by the Quality Assurance Manager for purposes of acknowledging final acceptance and closure. The NCRs identified were Nos. 00548, 00550, 00551 and 00552. Based upon further review of these specific NCRs the Independent Auditor noted that these particular NCRs had been signed off by the Quality Assurance Manager under the section titled "Disposition Approval" and therefore had received some degree of review and disposition approval. Immediate corrective action was initiated by the Quality Assurance Department to address this oversight. Corrective action to

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prevent recurrence will be reviewed by the Independent Auditor during the next independent audit.

A further review of the NCR's identified several instances where the sections of the NCR relative to disposition approvals had not been filled out and preventive actions to prevent recurrence had not been specified. The Independent Auditor noted that many of the NCRs missing the required information addressed administrative issues and program enhancements while others were documenting nonconforming conditions. The Independent Auditor indicated to JLS&A management that all of the sections of the NCR needed to be completed to properly execute and properly close the NCR. Subsequently, JLS&A management initiated corrective action to revise the NCR forms to better allow for utilization of the forms for all types of items needing corrective action or enhancements.

Another area of concern identified by the Independent Auditor had to do with the assignment of NCR disposition and corrective action responsibility to the respective department manager for whom the nonconforming condition should have been assigned. Many of the NCRs issued were clearly the responsibility of the Quality Assurance Department for disposition since they were written against the Quality Assurance organization. It was also clear that other NCRs should have been properly addressed by other JLS&A department managers. In these instances the NCR disposition approval blank was left unsigned and subsequently accepted and closed out by the Quality Assurance Department. Specific NCRs identified under this observation were Nos. 00525, 00529 and 00544 which had been issued to the Production and Health Physics Departments.

The area of NCR trending was reviewed for effectiveness during the course of the Independent Audit. As discussed above, many NCRs had been issued during the last calendar quarter. Trend codes were being utilized as specified in QAM/15.2. The Independent Auditor noted that the problem codes included as Enclosure 1 to QAM/QP 15.2 needed to be expanded to adequately identify casual factors for effective analysis of program trends for all types of NCRs issued. JLS&A management concurred and during the course of the audit proceeded to enhance and expand the problem codes. JLS&A management indicated that the NCR implementing procedures are to be revised to reflect the enhancement changes.

Based on the overall review of the NCRs issued the Independent Auditor determined that the Quality Assurance Department has since late March of 2005 undertaken an aggressive approach in conducting an increased level of diligence in reviewing the implementation of the quality assurance program. This has been carried out utilizing the quality area of surveillance as the key program to ascertain whether or not quality implementing procedures are being properly administered by JLS&A personnel. The addition of the newly hired Quality Assurance Assistant to

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initiate this increased level of diligence has been of major benefit to JLS&A management.

Finding No. 05-002-01: Failure to complete the review and acceptance sign-off sections of the NCR's.

Observation No. 05-002-05: Certain NCR's did not have all the appropriate sections of the form completed.

Observation No. 05-002-06: The section of the NCR requiring disposition approval was not in all cases signed off by the responsible manager for the department to which the NCR was issued.

1.7.1 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 of this quality area the Independent Auditor determined that several Corrective Action Reports had been issued during this audit reporting period and that all of them had been completed and closed out as required, including the identification of root cause.

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

2 CONCLUSIONS

Audit Results

The Quarterly Independent Audit identified one (1) item of noncompliance in the area of nonconformance identification and reporting. Also, six (6) observations were noted in the quality areas of package checklists, surveillance reports, M&TE and nonconformance reporting.

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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
M. Shepherd	Vice-President, Business Development And Licensing	JLS&A
W. Brown	Quality Assurance Manager	JLS&A
C. Harper	Quality Assurance Assistant	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. Surveillance Reports
10. Corrective Action Reports
11. DOT Package Repair Records