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April 7, 2005

Mr. Frank J. Congel
 Director, Office of Enforcement
 United States Nuclear Regulatory Commission
 Washington, D.C., 20555-0001

Subject: Request to Rescind Order of July 3, 2001 Withdrawing Quality Assurance Program Approval (Docket 71-0122, Approval 0122, EA-01-164)

J.L. Shepherd & Associates ("JLS&A") hereby moves the NRC to rescind the Order Withdrawing Quality Assurance Program Approval (Effective Immediately), issued to JLS&A on July 3, 2001 (the "July 3 Order"), and to (1) restore NRC approval of JLS&A's Part 71, Subpart H Quality Assurance Program, and (2) authorize it to resume shipments of Type B quantities of radioactive materials in NRC-approved containers, subject to the conditions stated below. In support thereof, JLS&A states as follows:

1. Since January 17, 1980, JLS&A has been the holder of NRC Quality Assurance (QA) Program Approval for Radioactive Material Packages No. 0122 (Approval 71-0122), issued by NRC pursuant to 10 CFR Part 71, Subpart H and predecessor provisions.
2. JLS&A was also the holder of NRC Certificates of Compliance ("CoC") 5976 and 6280, governing specific transportation package designs for shipment of Type B quantities of radioactive materials.
3. The July 3 Order, issued through the NRC's Director of Enforcement, withdrew the NRC's approval of JLS&A's QA Program. That approval is necessary to conduct any activities under Part 71, which governs transportation of radioactive materials and related activities. The July 3 Order concluded a series of events involving two JLS&A-originated international shipments which were found to be not in compliance with 10 CFR Part 71, followed by inspections in which the NRC found further QA Program noncompliance.¹

¹July 3 Order, ¶¶ 3-6; Letter, E. William Brach to Joseph L. Shepherd, March 7 2002, with attachments 1&2 thereto. NRC Staff was concerned as to whether these non-compliances might have involved any deliberate violations of NRC regulations, and initiated an investigation by the Office of Investigations in the summer of 2001. That investigation concluded with a finding of no deliberate misconduct by JLS&A or by any officer or employee of the Company (Letter, Martin J. Virgilio (NRC) to Joseph L. Shepherd (JLS&A) June 11, 2002.

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4. The July 3 Order prohibited JLS&A from designing, procuring, fabricating, assembling, testing, modifying, maintaining, repairing or using transportation packages for which a 10 CFR Part 71, QA program approval is required. The effect was to shut down those aspects of JLS&A operations until further NRC approval.

5. JLS&A chose to seek to remedy the conditions listed in the July 3 Order rather than to contest the Order, and promptly undertook both immediate and long-term remedial measures. JLS&A also advised the Staff of the extreme hardship to its business occasioned by the July 3 Order and sought emergency relief to make limited shipments of Type B quantities in containers approved by DOT rather than the NRC.

6. The interim steps, set forth in a "Near-Term Corrective Action Program" ("NTCAP") filed August 17, 2001, and revised in interim QA Program Implementing Procedures ("QAPIP") filed September 4, 2001, built on the results of a QA Program audit conducted for JLS&A prior to the July 3 Order² as well as on subsequent efforts. These included physical repair and refurbishment of existing DOT-specification 20WC overpacks, procedure review and revision for interim use, training of all affected personnel on the revised procedures, and organizational revisions to insulate the Quality Assurance Manager from line responsibility. The Staff accepted these interim steps subject to certification under oath of their completion by JLS&A and by an Independent Auditor to be retained by JLS&A, and subject to inspection by the Staff, which was held November 13-15, 2001. JLS&A and the Independent Auditor so certified and JLS&A passed the inspection.

7. Under this and subsequent arrangement, memorialized in a series of Confirmatory Orders,³ the latest of which expires June 1, 2005, JLS&A has been able to make Type B shipments in both DOT-specification 20WC overpacks and NRC-approved Certificate of Compliance packages, subject to five conditions summarized as follows:

"(1) JLS&A must fully implement and comply with Revision 7 of the conditionally approved QA Program Approval No. 0122, dated September 13, 2001;

² Donald R. Neely Associates conducted an audit of JLS&A's Part 71 QA program from September 13 to October 10, 2000. JLS&A was in process of implementing Mr. Neely's audit recommendations as of July 3, 2001. Mr. Neely subsequently became the Independent Auditor, responsible for observing JLS&A compliance with NRC Confirmatory Orders in the matter.

³ September 19, 2001; November 20, 2001; December 13, 2001; March 29, 2002; April 26, 2002; June 6, 2002; and May 30, 2003.

(2) JLS&A fully train JLS&A's staff, contractors, and sub-contractors in Revision No. 7 of the conditionally approved QAPP and implementing procedures, prior to any shipments, design, procurement, fabrication, assembly, testing, modification, maintenance, repair or use of packaging covered by Revision No. 7:

(3) JLS&A must use an Independent Auditor, approved by the Commission, to ensure that Revision No 7 of conditionally approved QA program plan is fully and completely implemented. The Independent Auditor shall conduct and report to the NRC the results of, periodic QA program audits, which will verify the compliance of the conduct of shipping operations with Revision No.7 of the QAPP and implementing procedures:

(4) JLS&A shall suspend all shipping operations and notify the NRC if the audit conducted by the Independent Auditor identifies safety concerns associated with the JLS&A conduct of shipping operations, and shall not resume shipping operations until the safety concerns are corrected and the Independent Auditor so informs 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: and;

(5) During the interim relief period, the NRC will conduct an inspection of JLS&A operations and implementation of the JLS&A QA Program, Revision No 7. Implementation of QA Program Approval No. 0122, Revision No. 7, without restrictions, may be permitted after NRC has verified JLS&A performance through an NRC inspection program in which no violations or only minor non-conformances are identified. The Director, Office of Enforcement, or the Director, Office of Nuclear Material Safety and Safeguards, may in writing, relax or rescind this Order upon demonstration of good cause by JLS&A."

8. JLS&A has at all times attempted to cooperate fully with NRC Staff in the enforcement action and investigation associated with the July 3 Order. The Company has also undertaken a re-design of its Quality Assurance Program in order to respond affirmatively to NRC's criticisms and those of the Independent Auditor.

9. During each of the most recent past two inspections (April 2003 and November 2004) JLS&A was notified of one severity level four violation (one for each inspection held in April 2003 and November 2004) which contained statements of concern by the Staff that JLS&A continued to experience issues of managerial oversight consistent with those associated with conditions leading to the July 3 Order.

10. JLS&A believes that, at this time, it has implemented effective corrective actions, which are in the process of eliminating those issues and will preclude those issues from recurring. In the re-design of the Quality Assurance Program, JLS&A moved the responsibility for Quality Assurance from a single departmental manager to all personnel within all aspects of JLS&A operations, with middle managers accounting for QA activities to senior management. This approach has reduced, appreciably, the number and severity of errors associated with implementation of QA Program activities.

11. Since beginning operations under the NTCAP, JLS&A has made some 300 shipments of Type B quantities of radioactive materials without incident, made complete renovation of its Quality Assurance Procedures in order to bring them in line with QAPP, Revision 7, and conducted training on a routine basis for all employees relative to their respective areas of influence of 10 CFR Part 71 QA Operations. In addition, .

- JLS&A has retired Certificates of Conformance numbers 6280 and 5796. (The COC 6280 packages were the packages involved in both import/export violations).
- JLS&A has obtained the services of an experienced Quality Assurance professional and now has employed, an experienced and certified QA Assistant.

For the foregoing reasons, JLS&A requests the Commission rescind the July 3, 2001 Order Withdrawing Approval of its Part 71 Quality Assurance Program under the following conditions:

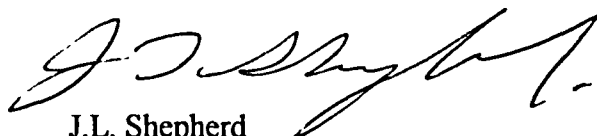
1. JLS&A shall continue implementing its new QA Procedures such that reviews are conducted to ensure that all activities under the scope of Part 71 are governed by procedures defining the activity, documenting the activity, and providing audit trail of the activity performed.
2. The Independent Auditor shall continue to perform quarterly audits verifying the implementation of the conditionally approved JLS&A Quality Assurance Program Plan and Implementing Procedures. Reports shall be provided quarterly by the 20th day of the month following completion of the audit. Any areas of non-conformance, not self-identified by JLS&A, to be reported to NRC.
3. JLS&A shall keep monthly statistics regarding QA Program implementation and procedure adherence. Such statistics shall include the number of nonconformances, nature of the nonconformances, and those referred to corrective action processes. Such information shall be provided the Independent Auditor who will report any areas of concern to NRC during scheduled reports.

4. JLS&A shall immediately stop work or cause to be stopped any work which would result in a potential hazard to public health and safety.

5. Conditions 1 through 4 shall remain effective for one year from date of rescission of the July 3 Order, or until the Independent Auditor shall issue four successive quarterly reports that show no violations of NRC regulations and effective implementation of the JLS&A Quality Assurance Program.

For the reasons stated above, and subject to the five conditions enumerated above, JLS&A respectfully requests restoration of its Quality Assurance Program, effective immediately.

Sincerely,

A handwritten signature in black ink, appearing to read "J.L. Shepherd". The signature is fluid and cursive, with a long horizontal stroke at the end.

J.L. Shepherd
President