December 28, 2004

J. L. Shepherd, President
J. L. Shepherd & Associates
1010 Arroyo Ave.
San Fernando, California 91340-1822

SUBJECT: NRC INSPECTION REPORT NO. 71-0122/2004201 AND NOTICE OF VIOLATION

Dear Mr. Shepherd:

On November 16-18, 2004, the Nuclear Regulatory Commission (NRC) conducted an inspection of the J. L. Shepherd & Associates (JLS&A) facility at San Fernando, California. The inspection was conducted to evaluate the current implementation of JLS&A's quality assurance program (QAP) and to assess the adequacy of corrective actions in regard to findings identified during the previous NRC inspection in April 2003.

The team identified one violation comprising multiple examples where activities affecting quality were not prescribed in documented instructions and procedures, or where procedures and instructions prescribing quality activities were not followed. The team identified several weaknesses including: 1) the level of detail found in JLS&A procedures, which in turn affected the application of the procedures, and the accuracy and completeness of resulting associated documents and quality records, 2) the availability of completed external audit records and the fact that most of JLS&A's external supplier triennial audits had yet to be performed despite the near term procedural deadline for their completion by the end of December 2004, and 3) the fact that findings identified in the continuing independent auditor reports, required under NRC Confirmatory Order EA-01-164, were similar in nature and number to those found by the NRC during this inspection, which indicates that corrective actions taken by JLS&A have not been adequate in addressing concerns expressed in the cover letter of the previous NRC inspection report (71-0122/2003201) regarding procedure adherence and configuration control.

The NRC is concerned about this apparent lack of progress by JLS&A in addressing issues related to QAP implementation, particularly procedure adherence. This has been a recurrent theme identified in the previous four NRC inspections conducted since 1999 as well as those in the independent auditor reports. Its recurrence is particularly troubling and merits increased attention by JLS&A management.

Based on the results of this inspection, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because JLS&A failed to identify it.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room).

Sincerely,

/RA/

Robert J. Lewis, Section Chief
Transportation and Storage Safety and
Inspection Section
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards

Docket Nos.: 71-6280
71-0122

Enclosures:
1. NRC Inspection Report 71-0122/2004201
2. Notice of Violation

cc: Rick Boyle, Department of Transportation
Ed Bailey, State of California
Registered Users

REGISTERED USERS

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Advanced Medical Systems, Inc.
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Docket Nos.: 71-6280
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Ed Bailey, State of California
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U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Spent Fuel Project Office

Inspection Report

Docket No.:	71-0122
Report No.:	71-0122/2004201
Certificate Holder:	J. L. Shepherd & Associates
Dates:	November 16-18, 2004
Inspection Location:	J. L. Shepherd & Associates 1010 Arroyo Ave. San Fernando, California 91340-1822
Inspection Team:	Jim Pearson, Team Leader/SFPO Robert Temps, Senior Inspector/SFPO Frank Gee, Inspector/SFPO
Approved by:	Robert Lewis, Chief, Transportation and Storage Safety and Inspection Section Spent Fuel Project Office, NMSS

Enclosure 1

EXECUTIVE SUMMARY

J. L. Shepherd & Associates
NRC Inspection Repot No. 71-0122/2004201

The NRC conducted an inspection on November 16-18, 2004, at the J. L. Shepherd and Associates (JLS&A) facility at San Fernando, California. The inspection was conducted to evaluate JLS&A's current implementation of their quality assurance program (QAP) and to assess the adequacy of corrective actions in regard to findings identified during the previous U. S. Nuclear Regulatory Commission (NRC) inspection in April 2003. As a result of this inspection, then team identified the following:

- One violation comprising multiple examples where activities affecting quality were not prescribed in documented instructions and procedures, or where procedures and instructions prescribing quality activities were not followed.

- That JLS&A had not maintained adequate configuration control of quality documents. Improper document configuration control was cited in the April 2003 NRC inspection and its recurrence during this inspection indicated inadequate corrective action by JLS&A in addressing this continuing issue.

- That while internal audits were being performed adequately, the completion of external audits was progressing too slowly to be a timely representation of JLS&A's supplier performance. The team expressed concern regarding JLS&A's ability to adequately perform the remaining large number of Part 71 supplier evaluations by the end of 2004 to meet their triennial audit cycle as required by JLS&A procedures. The team also noted that an external audit schedule had not been prepared as required by procedure.

- That temporary changes were made to quality procedures in an unapproved manner and that some quality records had improperly recorded information, indicating a lack of attention to detail. The team also concluded that if JLS&A personnel had implemented package handling procedures as written, then at several points in the procedures, personnel would have had to stop and obtain procedure guidance as the procedures could not be implemented as written. The team noted that this failure stop quality activities when not controlled by applicable procedures is a recurrent theme in previous NRC inspections and provides further indication that JLS&A personnel are either not reading, or using, approved QAPs for activities affecting quality. This recurrence also indicates a lack of adequate corrective actions by JLS&A management in addressing such issues.

- That JLS&A training procedures had improved from the last review in that they addressed weaknesses identified in the April 2003 NRC inspection.

- A purchase order for torque wrench calibration did not specify appropriate tolerance and range information as required by JLS&A procedures. The measuring and test equipment (M&TE) database log does not have appropriate categories/headings for entry of applicable information for M&TE controls, and the basis for existing entries could not be substantiated.

PERSONS CONTACTED

The inspection team held an entrance meeting on November 16, 2004, with William Brown (Quality Manager), Mary Shepherd (Vice President) and Diana Shepherd (Vice President), to present the scope and objective of the NRC inspection. On November 18, 2004, the NRC held an exit meeting to present the preliminary findings of the inspection with J. L. Shepherd, Mary Shepherd, Diana Shepherd, William Brown, Donald Neely (Consultant to JLS&A) and Donald Irwin (Counsel to JLS&A).

REPORT DETAILS

Background

An April 22-24, 2003, NRC team inspection addressed the readiness of JLS&A to operate under their NRC-approved Quality Assurance Program (QAP) and associated implementing procedures. The use of the QAP had been limited by the NRC Confirmatory Order (EA-01-164). The team also performed a review of the recent shipment and maintenance history of JLS&A's Department of Transportation 20WC packaging conducted under an earlier version of the QAP. In 2003, the team identified one violation, one weakness, and three concerns that the team assessed could present challenges to JLS&A as it proceeded, when allowed, to implement its QAP. The violation involved a failure to follow procedures and the use of non-approved forms to document quality inspection activities. The weakness involved a failure to maintain proper configuration control on an electronically distributed version of the QAP such that the text differed from the controlled hard-copy version of the QAP.

While operating under the NTCAP (near term corrective action plan) that was developed in response to NRC Confirmatory Order EA-01-164, JLS&A had been limited to shipment of 20WC packages. In may 2003, NRC issued a new Confirmatory Order to extend JLS&A's ability to use these packages, and to conduct 10 CFR Part 71 activities, through June 1, 2005, using the newest NRC approved QAP. This action was intended to allow JLS&A the opportunity to develop and implement the necessary processes and procedures to support the QAP implementation. The purpose of the current inspection performed in November 2004 was to determine the current status of the QAP implementation and to assess whether JLS&A had corrected program weaknesses identified during the last NRC inspection performed in April 2003, and had implemented their current QAP at a level to acceptably control future activities under 10 CFR Part 71.

1. Configuration Controls

a. Inspection Scope

Using NRC Inspection Procedure 86001, the inspection team performed a review to determine if JLS&A had implemented adequate configuration controls by review of current program processes and procedures.

b. Observations and Findings

In the inspection performed in April 2003, the NRC team identified one violation in regard to procedure noncompliance, and also noted improper configuration controls of quality-related documents associated with the JLS&A QAP. In view of these past weaknesses, the team reviewed the controlled copy of the Quality Assurance Manual (QAM), used in the QA manager's office. The team identified that the revision level of one quality procedure (QP), QP 3.0, "Design Control," was not in accordance with the current revision indicated in the Table of Contents to the QAM. After the identification to the QA manager, the QA manager found two additional QPs in the QAM that also contained non-current revisions. The team then randomly reviewed three additional controlled copies of the QAM located in other areas and determined that they were properly configured with the current revisions of QPs as listed in the table of contents.

JLS&A procedure QAM/QP 6.0, "Document Control," provides specific instructions on the issuance of procedures and their distribution to those requiring controlled distribution. Contrary to these requirements, the NRC identified that out-of-date revisions of procedures were contained in a QAM. This failure to follow procedure QAM/QP 6.0 is an example of the Violation cited in Enclosure 2 for failure to follow procedures or to have adequate procedures for activities affecting quality.

c. Conclusions

The team concluded that JLS&A had not maintained adequate configuration control of quality documents. Improper document configuration control was cited in the April 2003 NRC inspection and its recurrence during this inspection indicated inadequate corrective action by JLS&A in addressing this continuing issue.

2. Audit Controls

a. Inspection Scope

Using NRC Inspection Procedure 86001, the inspection team performed a review to determine whether acceptable auditing procedures and practices are in place and reflected in the review of recently performed audits.

b. Observations and Findings

The team reviewed multiple samples of JLS&A audit reports as noted below. Audit documents overall were acceptable, but the more recently developed audit document had been simplified for use as a checklist format. The team noted from their review that much of the detail documented in an earlier JLS&A audit was now absent, leaving the audit comprehensiveness in question. The detail typically documented in audit reports provides the planner of the next audit in this same area(s) a tool for determining the depth of previous results not found typically in checklist type audit report documents. The documented detail also often tells the reader the extent of acceptability for audit findings. Marginal areas may be revisited sooner rather than later, and acceptably strong areas may not need to be revisited during the next audit. The JLS&A audits did not provide this type of insight due to the low level of documented detail.

The team noted that QAM/QP 18.0, "Audits," step 5.6, requires that audit reports include, as applicable, purpose and scope statements and statements regarding the effectiveness of QA program implementation. Contrary to this requirement, the team noted that neither type of statement was included in audits 04-01, 04-02, 04-03, 04-04, 04-05, 04-06, 04-14, and 04-15. This failure to follow procedure QAM/QP 18.0 is an example of the Violation cited in Enclosure 2 for failure to follow procedures or to have adequate procedures for activities affecting quality.

The team reviewed portions of QAM/QP 7.1, "Vendor Selection & Audit," which in turn refers to procedure QAM/QP18.0, "Audits." Step 5.2 of QAM/QP 18.0 requires the QA manager prepare an annual internal and external audit schedule. Contrary to this procedural requirement, no external audit schedule was available for review during the inspection. This failure to follow procedure QAM/QP 18.0 is an example of the Violation cited in Enclosure 2 for failure to follow procedures or to have adequate procedures for activities affecting quality.

During the inspection, JLS&A was asked to provide recently completed external audits performed for Part 71 suppliers; however, only one older audit could be produced immediately, and only two additional, more recent audits, were provided near the end of the inspection. While these three external audits had been performed acceptably, the team was concerned that JLS&A may have difficulty in adequately performing the remaining required evaluations of their eighteen Part 71 suppliers by the end of 2004, especially since JLS&A had only completed three such audits in the previous two years and ten months. JLS&A procedure QAM/QP 7.1 states that these supplier audits are to be performed triennially; however, it does not address actions to be taken should the triennial audit date be missed. The team notes this lack of guidance is acceptable provided that audits are scheduled and conducted so as not to miss the triennial date.

c. Conclusions

The team concluded that while internal audits were being performed adequately, the completion of external audits was progressing too slowly to be a timely representation of JLS&A's supplier performance. The team expressed concern regarding JLS&A's ability to adequately perform the remaining large number of Part 71 supplier evaluations by the end of 2004 to meet their triennial audit cycle as required by JLS&A procedures. The team also noted that an external audit schedule had not been prepared as required by procedure.

3. Nonconformance Controls

a. Inspection Scope

Using NRC Inspection Procedure 86001, the inspection team performed a review to determine the acceptability of the JLS&A nonconformance process in identifying issues in regard to program implementation or transportation package use.

b. Observations and Findings

The team reviewed JLS&A procedure QAM/QP 15.0, "Control of Nonconforming Items," to determine how JLS&A documents, tracks, and resolves nonconformances. Overall procedure guidance was assessed to be adequate; however, several instances were identified where JLS&A did not implement QAM/QP 15.0 procedure requirements properly. Specifically, step 5.2 states the following: "Validated Nonconformance Reports (NCRs) shall be entered into the NCR Log or database and assigned a unique sequential tracking number. A current file copy shall be kept by QA until NCR closure. The NCR Log or databases shall contain, as a minimum, the following information: NCR number, issue date, disposition, name, and organization responsible for action, schedule completion date, and NCR closed date." Step 6.0 also states, in part, that all records generated by this procedure are considered Quality Records and shall be maintained by the department/activity involved and QA.

Contrary to these requirements, a review of the NCR Log indicated that the NCR numbering scheme was not being implemented consistently and that none of the NCR Log entries contained all of the information required by QAM/QP 15.0, step 5.2. Further, JLS&A QA was unable to produce a complete file of all NCRs (completed and/or pending) and the team noted several instances where the QA file that was produced contained hard copies of NCRs that were not entered into the NCR Log. These failures to follow procedure QAM/QP 15.0 are an example of the Violation cited in Enclosure 2 for failure to follow procedures or to have adequate procedures for activities affecting quality.

c. Conclusions

The team concluded JLS&A was not following their procedure for NCR controls. Given the incomplete and inconsistent logging of NCRs, the team questioned how JLS&A could be performing adequate trend analysis of NCRs as required by Step 4.4, which refers one to QAM/QP 15.3, "Trend Analysis."

4. Inspection Controls

a. Inspection Scope

To determine that JLS&A has prepared and implemented adequate inspection checklists for inspection of quality related activities through review of shipment documentation packages and physical inspection and dimensional checks where applicable. Also verify that JLS&A has current documentation supporting all applicable CoCs.

b. Observations and Findings

Use of DOT Specification 20WC and Other NRC CoC Packages:

The team reviewed JLS&A's use of Specification 20WC packages as well as two other NRC CoC packages, the RWE Nukem 10-142B (CoC 9208) and 3-82B (CoC 6574). The team reviewed their use against the requirements of QAM/QP 13.0, "Handling, Shipping, and Storage," and QAM/QP 13.1, "Inspection of Packages Used in Shipping."

The team reviewed the records for four different Specification 20WC packages for their use over the last calendar year. The packages reviewed were serial numbers 22422, 22027, 22280, and 22238. Each package's file appeared to be complete and contained the inspection records required by QAM/QP 13.1.

In reviewing the data inspection sheet, with QA Approval dated 11/3/04, for package 22238, the team noted the following handwritten change had been added to the bottom of the data sheet: "REV 2: 10/22/04 (TEMPORARY) per new DOT regulations." When questioned about this by the team, JLS&A stated that because of new DOT regulations that went into effect on October 1, 2004, the labeling instructions on the form also needed to be changed to conform. Due to expediency, the change was handwritten on affected forms as they were used, pending formal revision of all affected QAMs/QPs. However, the team reviewed JLS&A procedure QAM/QP 5.0, "Instructions, Procedures and Drawings," and concluded that the procedure does not provide for any method of temporary procedure changes as noted on the inspection data sheets. Therefore, the handwritten changes were assessed by the team to be unauthorized changes to quality records and therefore in violation of QAM/QP 5.0. This failure to follow procedure QAM/QP 5.0 is an example of the Violation cited in Enclosure 2 for failure to follow procedures or to have adequate procedures for activities affecting quality.

The team also reviewed the records made for shipments utilizing NRC CoC 6574 and 9208 packages. Each of the packages was supplied with an instruction manual by RWE Nukem. The manuals were verified to contain the latest CoC revisions and drawings as well as operating and maintenance instructions. In reviewing JLS&A's records for package CoC 9208, the team noted multiple examples where information for quality records was recorded inaccurately. For example, a torque wrench used for verifying lid bolt tightness was recorded with at least five different variations of its serial number, although in all cases, the same wrench was used. Inaccuracies in the calibration dates for the same pieces of other equipment (pressure gauge and leak test device) were also noted. When these inaccuracies were brought to the attention of the QA department, the team was informed that the discrepancies were known but had not yet been corrected. Issues related to the use of M&TE that were identified during this review are discussed further in Section 6 of this report.

The team assessed that while JLS&A's use of CoC packages 6574 and 9208 was apparently performed safely, the use of these CoCs was not recognized by procedures QAM/QP 13.0 and 13.1. While both procedures provided instructions on use of CoC packages, they were written assuming the packages were JLS&A CoC packages, specifically, CoC 6280 overpacks. The procedures did not provide guidance on what JLS&A's controls should be when using non-JLS&A CoC packages. This failure of QAM/QP 13.0 and 13.1 to provide adequate controls on the use of non-JLS&A CoC packages is an example of the Violation cited in Attachment 2 for failure to follow procedures or to have adequate procedures for activities affecting quality.

c. Conclusions

The team identified that temporary changes were made to quality procedures in an unapproved manner and that some quality records had improperly recorded information, indicating a lack of attention to detail. The team also concluded that if JLS&A personnel

had implemented QAM/QP 13.0 and 13.1 as written, then at several points in both procedures, personnel would have had to stop and obtain procedure guidance as the procedures could not be implemented as written. The team noted that this failure stop quality activities when not controlled by applicable procedures is a recurrent theme in previous NRC inspections and provides further indication that JLS&A personnel are either not reading, or using, approved QAPs for activities affecting quality. This recurrence also indicates a lack of adequate corrective actions by JLS&A management in addressing such issues.

5. Employee Training

a. Inspection Scope

Verify that JLS&A has provided adequate training for all personnel performing quality-related functions through the use of an approved training procedure/program. Also verify that the training program for employees is acceptably prepared and shows that JLS&A personnel are trained and qualified on the appropriate procedures for quality-affecting activities.

b. Observations and Findings

The team reviewed the procedure, QAM/QP 2.3, "Employee Training," that governs employee training requirements. The team noted that the QA manager was also functioning as the overall training coordinator. Adequate training was identified as being tailored to the specific job and provided to all levels of employees, which had been a previously identified weakness. The team reviewed the training records of two new employees and also reviewed the training records of the calibration coordinator. The team concluded that the reviewed employees had formal records of training to document the required practical factors and readings of the QAM and the assigned QPs. Appropriate signatures and dates of completion were provided on the training records and the certificate of training. The team reviewed the JLS&A training procedure and determined that it adequately addressed the previously NRC identified weakness, in April 2003 inspection, where training at JLS&A had only been provided to the higher level employees in the company.

c. Conclusions

The team found the JLS&A training procedure to be improved from the last review in that it addressed weaknesses that existed in the April 22-24, 2003 inspection. The team found training records and associated documentation acceptable.

6. Measuring and Test Equipment Calibration Program

a. Inspection Scope

Using NRC Inspection Procedure 86001, the inspection team performed a review to determine that JLS&A had adequate procedures for the control of measuring and test equipment (M&TE) used in JLS&A quality related activities.

b. Observations and Findings

QAM/QP 12.0, "Control of Measuring and Test Equipment," governs the M&TE calibration program at JLS&A. The program is controlled by the QA manager and maintained by the calibration coordinator. The procedure states the responsibilities, requirements, and instructions for the control and use of Category 1 M&TE. Paragraph 5.2.2 of QAM/QP 12.0 requires that calibration accuracy/tolerance requirements shall be set and documented for each Category 1 M&TE item and that this information shall be stated on the M&TE Master List (which is maintained as a database). Contrary to this requirement, the M&TE Master List database did not have the proper M&TE range, and accuracy/tolerance specifications for the instruments included on the list. Instead, the M&TE database had a heading for a standard accuracy/tolerance of +/- 20%, regardless of the type of M&TE referenced. Specific examples where this was an incorrect application was for calibrated torque wrenches QA 69 and QA 70. While the database stated their accuracy/tolerance as +/- 20% and range as various, the team determined that their tolerance, as stated in the vendor document, as +/- 4% clockwise. Further, the ranges for both instruments are from 200 ft-lb to 500 ft-lb and from 200 in-lb to 1,000 in-lb, respectively. This failure to follow procedure QAM/QP 12.0 is an example of the Violation cited in Enclosure 2 for failure to follow procedures or to have adequate procedures for activities affecting quality.

Paragraph 5.2.4 of QAM/QP 12.0 requires that Category 1 M&TE be calibrated by approved suppliers only. QA 69, with a calibration due date of February 12, 2005, was sent out to the vendor for calibration. The team verified that the vendor for calibrating QA69 was on the approved vendor list. The team also reviewed the purchase order for proper application of the provisions of 10 CFR Part 21.

Paragraph 5.2.6 of QAM/QP 12.0 requires that requisitions for calibration services for Category 1 M&TE shall be processed in accordance with procedure QAM/QP 7.0, "Control of Purchased Materials, Parts, Components and Services," and that purchase requisitions shall include the following as a minium:

- Unique M&TE number (Item serial number).
- A complete description of the (Make, Model, Serial No., Range, etc.)
- Required accuracy to be met.
- Special statements, necessary to define the calibration requirements such as manufacturer's instructions, specific checks, tests, ranges, measurement acceptance, and adjustment tolerances.

Contrary to these requirements, no instrument range, accuracy, or tolerance was specified in the purchase order for the calibration of QA 69. This failure to follow procedure QAM/QP 7.0 is an example of the Violation cited in Enclosure 2 for failure to follow procedures or to have adequate procedures for activities affecting quality.

c. Conclusions

A purchase order for torque wrench calibration did not specify appropriate tolerance and range information as required by JLS&A procedures. The M&TE database log does not have appropriate categories/headings for entry of applicable information for M&TE

controls, and the basis for existing entries could not be substantiated.

Exit Meeting

On November 18, 2004, at the conclusion of the inspection, the team held an exit meeting with JLS&A management and its consultant to present the preliminary inspection findings. JLS&A management acknowledged the inspection findings presented by the team. No proprietary information was discussed.

NOTICE OF VIOLATION

J. L. Shepherd & Associates
San Fernando, California

Docket No. 71-0122

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at J. L. Shepherd and Associates (JLS&A) in San Fernando, California, on November 16-18, 2004, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below.

10 CFR 71.111, “Instructions, procedures, and drawings,” requires in part that a certificate of compliance holder shall prescribe activities affecting quality by documented instructions or procedures of a type appropriate to the circumstances and shall require that these be followed.

Contrary to this requirement, the NRC identified the following examples where JLS&A Quality Assurance Manual/Quality Procedures (QAM/QPs) were inadequate or were not followed:

1. JLS&A procedure QAM/QP 6.0, “Document Control,” provides specific instructions on the issuance of procedures and their distribution to those requiring controlled distribution. Contrary to these requirements, the NRC identified that out-of-date revisions of procedures were contained in a QAM.

2. QAM/QP 18.0, “Audits,” step 5.6, requires that audit reports include, as applicable, purpose and scope statements and statements regarding the effectiveness of QA program implementation. Contrary to this requirement, the NRC noted that neither type of statement was included in JLS&A audits 04-01, 04-02, 04-03, 04-04, 04-05, 04-06, 04-14, and 04-15.

3. Step 5.2 of QAM/QP 18.0 requires the QA manager prepare an annual internal and external audit schedule. Contrary to this requirement, no external audit schedule was produced for review during the inspection.

4. QAM/QP 15.0, “Control of Nonconforming Items,” step 5.2 states that: “Validated Nonconformance Reports (NCRs) shall be entered into the NCR Log or database and assigned a unique sequential tracking number. A current file copy shall be kept by QA until NCR closure. The NCR Log or databases shall contain, as a minimum, the following information: NCR number, issue date, disposition, name, and organization responsible for action, schedule completion date, and NCR closed date.” Step 6.0 states, in part, that all records generated by this procedure are considered Quality Records and shall be maintained by the department/activity involved and QA. Contrary to these requirements, a review of the NCR Log indicated that the NCR numbering scheme was not being implemented consistently and that none of the NCR Log entries contained all of the required information. Also, JLS&A QA was unable to produce a complete file of all NCRs (completed and/or pending) and the NRC noted several instances where the QA file that was produced, contained hard copies of NCRs that were not entered into the NCR Log.

5. JLS&A procedure QAM/QP 5.0, “Instructions, Procedures and Drawings,” does not provide a method for making temporary changes to procedures. Contrary to QAM/QP procedure requirements, while reviewing data inspection sheets, the NRC noted the following handwritten change had been added to the bottom of several data sheets: “REV 2: 10/22/04 (TEMPORARY) per new DOT regulations.”

6. JLS&A procedures QAM/QP 13.0, “Handling, Shipping, and Storage,” and QAM/QP 13.1, “Inspection of Packages Used in Shipping,” provide instructions on use of CoC packages; however, they are written only for the use of JLS&A CoC packages, specifically, CoC 6280 overpacks. The NRC determined that JLS&A used non-JLS&A packages, CoC packages 6574 and 9208, but that controls on their use were not recognized by approved procedures such as QAM/QP 13.0 and 13.1.

7. QAM/QP 12.0, “Control of Measuring and Test Equipment,” step 5.2.2, requires that calibration accuracy/tolerance requirements shall be set and documented for each Category 1 M&TE item and that this information shall be stated on the M&TE Master List (which is maintained as a database). Contrary to this requirement, the M&TE Master List database did not have the proper M&TE range, and accuracy/tolerance specifications for equipment included on the list.

8. Step 5.2.6 of QAM/QP 12.0 requires that requisitions for calibration services for Category 1 M&TE shall be processed in accordance with procedure QAM/QP 7.0, “Control of Purchased Materials, Parts, Components and Services,“ and that purchase requisitions shall include the following as a minium:

    - Unique M&TE number (Item serial number).
    - A complete description of the (Make, Model, Serial No., Range, etc.)
    - Required accuracy to be met.
    - Special statements, necessary to define the calibration requirements such as manufacturer’s instructions, specific checks, tests, ranges, measurement acceptance, and adjustment tolerances.

    Contrary to these requirements, no instrument range, accuracy, or tolerance was specified in the purchase order for the calibration of torque wrench QA 69.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, JLS&A is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555-0001, with a copy to Larry W. Camper, Deputy Director, Licensing and Inspection Directorate, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where

good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 28th day of December, 2004.