

March 31, 2005

EA-05-047

Mr. J. L. Shepherd
President
J. L. Shepherd and Associates
1010 Arroyo Avenue
San Fernando, CA 91340-1822

SUBJECT: RESPONSE TO DISPUTED EXAMPLES OF VIOLATION AS IDENTIFIED IN
THE NUCLEAR REGULATORY COMMISSION INSPECTION REPORT 71-
0122/2004201 AND ACCEPTANCE OF CORRECTIVE ACTIONS

Dear Mr. Shepherd:

This letter refers to your correspondence dated January 27, 2005, in reply to our December 28, 2004, Inspection Report and Notice of Violation (NOV). During the NRC's November 14-18, 2004, inspection, the NRC inspection team identified one violation consisting of 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, as required by 10 CFR 71.105, "Quality assurance programs." Section 71.105 requires, in part, that the licensee complies with the requirements of sections 71.101 through 71.137, and "shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used." The violation, cited at a Severity Level (SL) IV, consists of eight examples that, for this discussion, will be referred to as "findings." In your January 27, 2005, correspondence, you indicated that while you did not contest the violation, *per se*, you did "not agree with specific findings in various respects;" however, your response provided corrective actions for all eight findings.

After receipt of your response, the NRC requested that you attend a meeting with NRC management to discuss both the inspection results and to obtain a common understanding of the steps that would be necessary to develop a path forward regarding the July 3, 2001, Order withdrawing the J.L.Shepherd & Associates (JLS&A) Quality Assurance Program approval. You reiterated your concerns about several of the November inspection findings during the February 9, 2005, management meeting conducted at NRC Headquarters.

In your January 27th response, you indicated that you did not agree with four of the eight findings, specifically, findings 1, 3, 5, and 6. Although you did not request it, the staff has treated these findings as disputed examples of the cited violation and has evaluated them in accordance with Section 4.3.6 of the NRC Enforcement Manual and the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600. For your information, the Enforcement Policy can be found on the NRC's Public Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**.

A clarification of the NRC's position with respect to findings 1, 3, 5, and 6 is provided in the enclosure to this letter. We have determined that findings 1, 3, 5 and 6 should be upheld as examples of the cited violation.

You did not take exception to the staff's characterization of findings 2, 4, 7, and 8. We have reviewed the corrective actions you proposed for findings 1, 2, 3, 4, 5, 6, 7, and 8, and have determined that they are acceptable. The corrective actions you proposed for findings 1, 2, 3, 4, 5, 6, 7, and 8 may be reviewed in future inspections.

We have contacted you by separate letter regarding your proposed path forward addressing both the Order Withdrawing Quality Assurance Approval, dated July 3, 2001, and the Confirmatory Order Relaxing Order, dated May 30, 2003, and the need to comply at all times with Part 71 requirements and the JLS&A Quality Assurance Program commitments under Docket No. 71-0122.

Please feel free to contact either James Pearson or Robert Temps, of my staff, if you have any questions. James Pearson can be contacted at 301-415-1985; Robert Temps can be contacted at 301-415-2552.

In accordance with 10 CFR 2.390 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's Public Document Room or from the Publicly Available Records (PARS) component of the 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/

Mary Jane Ross-Lee, Chief
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0122

Enclosure: Response to Disputed Examples of Violation

March 31, 2005

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Mary Jane Ross-Lee, Chief
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OFC:	SFPO		SFPO	E	OE	E	SFPO	E			
NAME:	JPearson*		MDeBose*		MSchwartz*		M.J.Ross-Lee				
DATE:	2/16/05		2/16/05		3/29 /05		4 / /05		/ /		/ /

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**Response to J. L. Shepherd and Associates' (JLS&A) reply to Notice of Violation (NOV)
(Inspection Report # 71-0122/2004201 and NOV)**

The Nuclear Regulatory Commission (NRC) offers the following response to information supplied by JLS&A in its NOV response dated January 27, 2005:

Finding 1: JLS&A did not maintain adequate configuration control of quality documents.

JLS&A agrees that finding 1 is an example of the cited violation, i.e., that contrary to the requirement in 10 CFR 71.113, "Document control," and your Quality Procedure 3.0, "Design Control," your Quality Assurance Manual (QAM) was not in accordance with the current revision indicated in the Table of Contents. However, you believe the violation was "self-disclosed" and dispute the NRC's characterization that the violation was not "self-identified." The concept of "identification" presumes that the identifier recognizes the existence of a problem, and understands that corrective action is needed. For Severity Level IV violations, identification by the licensee is one of four factors the NRC takes into consideration in determining whether to disposition the violation as a NOV or a non-cited violation.

In the instant case, you explained that you were aware of the problem before the November 2004 inspection. You stated that JLS&A became aware of the problem during an NRC inspection in April 2003, and again during the Independent Auditor's (IA) inspection in October 2004, one month before the November inspection. If, as you responded, your corrective action following the IA's finding was a completed 100% audit of the controlled manuals, then the NRC's identification a month later of the controlled copy of the QAM that had not been revised to reflect the current Table of Contents, is an example of a repetitive violation stemming from inadequate corrective action to the earlier event. Therefore, the NRC upholds this example of the cited NOV. The NRC has reviewed your proposed corrective action and finds it acceptable; therefore, no further response is required.

Finding 3: JLS&A did not provide an external audit schedule for 2004 by the conclusion of the November 2004 inspection.

Contrary to your assertion in response to finding 3, the NRC team did not cite JLS&A for not providing adequate detail in audit reports. The team did point out that JLS&A's more recent audit reports did not contain the detail that previous audits had contained because, in part, JLS&A had gone to a "checklist approach." However, 10 CFR 71.137, "Audits," allows the use of checklists; therefore, such use, *per se*, is not a violation of NRC regulations as long as such checklists include the information that is required by this regulation, i.e., that it is comprehensive enough to verify compliance with all aspects of the quality assurance program, that audit results are documented and reviewed by management having responsibility in the area audited, and that follow-up action, including re-audit of deficient areas, is taken where indicated.

However, the NRC notes an apparent misunderstanding that stems from the lack of specificity regarding the timing of the violation, as reflected in your statement regarding the 2005 audit schedule. Your statement is correct and the fact that you did not have a 2005 audit schedule

Enclosure

prior to the November 2004 inspection, is not an element of finding 3. The NRC's basis for finding 3 is that during the November 2004 inspection, NRC inspectors were unable to identify a schedule for the 2004 external audits. Because the NRC inspectors were unable to identify a schedule for the 2004 external audits during the November 2004 inspection, and you have not provided this schedule since the inspection, the NRC was left to conclude that no such schedule existed at the time of the inspection, contrary to the requirement in 10 CFR 71.137 and Step 5.2 of QAM/QP 18.0 that requires you to prepare an internal and external audit schedule. The NRC upholds this example of the cited NOV. The NRC has reviewed your proposed corrective action for this finding which would be applied to your 2005 external audit schedule, and found it acceptable; therefore, no further response is required.

Finding 5: JLS&A changes to an inspection sheet were of a substantive nature and were not made pursuant to provisions in QAM/QP 5.0.

JLS&A responded to finding 5 that changes made on the bottom of an inspection sheet were an enhancement of the information provided on that form, rather than a substantive change. Specifically, information on line 15 of the form that contains instructions on the proper labels to affix to packages was lined through and new information handwritten into the procedure. While you state that the change was to a form used to document performance, the facts are that the form itself is part of a procedure that directs specific actions to be taken and then documented on the form. While the term "enhancement" has not been defined in a regulatory context, a general definition would include an action that improves the quality or condition of something; however, as cited in the NOV, the change to the form was clearly not an enhancement because specific instructional information was changed, i.e., had JLS&A followed the instructions that were lined through, the information contained on the label would have violated DOT regulations which, in turn, would have violated the terms for an NRC general license in 10 CFR 71.5, "Transportation of licensed material." Therefore, the change was not an enhancement to the form which could have been made informally; rather, it was one of content and intent that required you to follow the requirements in 10 CFR 71.113, "Document control," and your procedures in QAM/QP 5.0, to make the change. In your NOV corrective action response, you state that your procedure change process will be clarified. The NRC notes that many licensees, particularly Part 50 QA program holders, have procedural controls in place that allow for quick, formal content changes to be made and JLS&A may wish to consider these as you revise QAM/QP 5.0. The NRC upholds this example of the cited NOV. The NRC has reviewed your proposed corrective action and finds it acceptable; therefore, no further response is required.

Finding 6: JLS&A did not understand why the NRC cited inadequate controls on non-JLS&A certificate of compliance (CoC) packages as an example of the cited violation.

Section 71.111, "Instructions, procedures, and drawings", requires licensees to "prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed." Contrary to this requirement, JLS&A did not prescribe how non-JLS&A packages would be procured nor did it prescribe how controls would be placed on their use to ensure that activities affecting quality are implemented appropriately. JLS&A's response includes information regarding the acceptance of other Part 71 QA program holders activities and also provides excerpts from the QAP/QMs that appear to provide some control over non-JLS&A packages. Despite this additional information, however, with respect to the use of the

non-JLS&A CoC packages, there is still no clear path set out in JLS&A's QAP/QMs as to how non-JLS&A CoC packages will be procured nor the controls to be placed on their use. Your current approach gives little assurance that such controls will be consistently implemented. For example, in your response you stated that JLS&A issued a cover sheet that was approved by your Quality Assurance Department that allowed you to "adopt" the procedures of the CoC holder; however, that process is not described in any of JLS&A's QAM/QPs nor is it allowed by QAM/QP 5.0, "Instructions, Procedures and Drawings." As a corrective action to this finding, you stated that JLS&A has undertaken the revision of QAM/QP 13.1, "Inspection of Packages Used in Shipping," to provide a specific paragraph dedicated to use of CoCs owned by others. The corrective action you propose for this finding should provide greater assurance that non-JLS&A CoC packages will be appropriately and consistently handled in the future. The NRC upholds this example of the cited NOV. The NRC has reviewed your proposed corrective action and finds it acceptable; therefore, no further response is required.