

JLSHEPHERD & ASSOCIATES

1010 ARROYO AVE., SAN FERNANDO, CALIFORNIA 91340-1822

818-898-2361 FAX 818-361-8095

September 11, 2006

Ms. Cynthia A. Carpenter
Director, Office of Enforcement
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

J. L. Shepherd & Associates
Docket no. 71-0122, EA-01-164):
Request for Rescission of Confirmatory Order Conditions

Dear Ms. Carpenter:

This letter responds to a request contained in NRC Inspection Report 71-0122/2006-201 and Notice of Nonconformance ("July 2006 Inspection Report"), covered by letter, NRC (R. Lewis) to J. L. Shepherd & Associates ("JLS&A"), August 18, 2006. Under a "Confirmatory Order Rescinding Shutdown Order (Effective Immediately)" (the "Confirmatory Order"), issued to JLS&A on June 30, 2005, JLS&A was permitted to resume full operations subject to five conditions, one of which was that an Independent Auditor conduct quarterly audits, and that this requirement remain in effect until the issuance of four consecutive quarterly audits "showing no violation of NRC regulations and effective implementation of the JLS&A Quality Assurance program." Both the independent Auditor and the NRC Staff have found effective implementation of the QA program. Thus the issue is whether two findings classed as "nonconformances" by the Independent Auditor in separate quarterly reports prevent a conclusion that JLS&A has had four consecutive quarterly reports without any such violations. See July 2006 Inspection Report at 13, item 8. In other words, do the "nonconformances" found by the Independent Auditor constitute "violations of NRC regulations"?

Both JLS&A and the NRC Staff agree that all conditions to the Confirmatory Order other than this one have been met, and that if the "nonconformances" do not constitute "violations of NRC regulations," JLS&A is entitled to be released from it.

For the reasons outlined below, JLS&A respectfully submits that although the relationship between the terms "nonconformance" and "violation" is not specifically defined under NRC regulations, there is a distinction between the terms and the Independent Auditor's findings of "nonconformances" were not intended to be, and should not be, treated as violations of NRC regulations; and that JLS&A is thus entitled to be released from the Confirmatory Order.

A. The Confirmatory Order

In the Confirmatory Order, the NRC Staff noted that it had concluded, following review, that JLS&A had completed all of the elements of its Near-Term Corrective Action Program, and had repeatedly demonstrated its capacity to safely transport Type B radioactive shipments both in DOT Specification 20WC overpacks and in NRC-approved COC packages under its new NRC-approved Quality Assurance Program ("QAP"). In inspections during 2003 and 2004, the Staff noted, "minor program implementation deficiencies were found, [but] these findings were of lower safety significance and none were of a severity level comparable to the original findings which precipitated the issuance of the July 2001 [Shutdown] Order." Confirmatory Order at 5.

- The Confirmatory Order also recited five conditions, summarized as follows, committed to by JLS&A in its April 7, 2005 letter, which had requested rescission of the Shutdown Order: . Condition 1 required JLS&A to continue implementing its new QA procedures in an auditable way.
- Condition 2 required that the Independent Auditor who had been reviewing JLS&A's operations ever since their initial resumption following the Shutdown Order "continue to perform quarterly audits verifying the implementation of the conditionally approved JLS&A Quality Assurance Program and Implementing Procedures.... Any area of nonconformance, not self identified by JLS&A, shall be reported to the NRC."
- Condition 3 required JLS&A to keep monthly statistics regarding QA program implementation and procedure adherence, and required the Independent Auditor to report "any areas of concern to NRC during scheduled reports."
- Condition 4 required JLS&A to immediately stop or cause stoppage of work which would result in a potential hazard to public health and safety.
- Condition 5 required that all previous conditions, including Conditions 2 and 3, remain in effect for one year following rescission of the Shutdown Order, or "until the Independent Auditor shall issue four successive quarterly reports that show no violation of NRC regulations and effective implementation of the JLS&A Quality Assurance Program."

B. JLS&A Implementation of the Confirmatory Order

JLS&A has implemented its new QA procedures, as required by Condition 1. There have been no stop-work events of the kind contemplated by Condition 4. With respect to the other three Conditions -- 2, 3 and 5 -- they involve the contents of reports by the Independent Auditor. As required by Condition 2, he has issued four quarterly reports since the issuance of the Confirmatory Order. Each of them was based on an audit at least three days in length. In them, the Independent Auditor used three terms to characterize the "nonconformances" on which he was required to report: Findings, Observations, and Items Warranting Management Attention. Each report also contained an assessment of the effectiveness of QA program implementation. A tabular summary of the results of these reports is as follows:

REPORT	FINDINGS	OBSER- VATIONS	MGMT ATTN	AREAS OF CONCERN	EFFECTIVE QA IMPLEMENTATION
Report 05-003 (July-Sep 05)	1	2	0	0	yes
Report 05-004 (Oct-Dec 05)	0	0	1	0	yes
Report 06-001 Jan-Mar 06)	0	5	0	0	yes
Report 06-002) Apr-Jun 06)	1	5	0	0	yes

As would be expected with a series of detailed audits by a knowledgeable auditor familiar both with NRC requirements and with JLS&A operations, each audit identifies, pursuant to Condition 2, various minor inconsistencies with the terms of JLS&A's QA program or implementing procedures. None of them involved, however, either violations of safe transportation or handling practices for radioactive sources. To the contrary, each report specifically finds effective implementation of the JLS&A QA program. Further, not one of them was such as to lead the Independent Auditor to find any distinct "area of concern" to the NRC under Condition 3 of the Confirmatory Order, as would have been expected had he observed any such area. Of them, all of them have been remedied by JLS&A, and some of them had been self-identified, in at least anecdotal form, by JLS&A personnel even as of the time of the audit. The important point is that while the Independent Auditor identified small numbers of issues with JLS&A's internal QA requirements or policies in each regular quarterly report -- and would likely do so each time, forever, given the degree of scrutiny inherent in regular multi-day visits to a small facility -- none of them triggered any need to stop work, and or rose to the level of an "area of concern," or raised any heightened concern in the eye of a seasoned reviewer.

Two of these inconsistencies were classified by the Independent Auditor as "findings," which he identified as "nonconformances" with the JLS&A QA program. One of them, found in the report for July-September 2005, involved the timeliness of return of equipment whose calibrations had expired. See Quarterly Report 05-003 at §1.6.5.1. That condition was corrected to the Independent Auditor's satisfaction. See Quarterly Report for January-March 2006, Report 06-001, at §1.7.7. The other "finding", noted in the Quarterly Report for March-June 2006, related to inconsistencies in maintenance of JLS&A QA Procedures manual, the QAM/QP Manual. Quarterly Report 06-002, §1.7.7. During the audit itself, JLS&A initiated corrective actions for the inconsistencies.

C. NRC Inspection, July 25.27, 2006

On July 25.27, 2006 the NRC conducted an inspection of JLS&A facilities and identified two findings involving procedural non-compliances. They were cited by the NRC as nonconformances with 10 CFR Part 71 Subpart H because they “constitute failures to meet commitments in JLS&A’s NRC-approved QAP.” Letter, NRC (R. Lewis) to JLS&A (J. L. Shepherd), August 18, 2006, covering NRC Inspection Report 71-0122/2006-201 and Notice of Nonconformance” (July 2006 inspection Report”). JLS&A does not challenge either of these findings, and has responded to this report separately in a Reply to Notice of Nonconformance dated September 15, 2006. The NRC inspectors also found that JLS&A had satisfied the first four conditions of the Confirmatory Order and that it had effectively implemented its QA program, but were “indeterminate” as to condition 5, and asked JLS&A to communicate directly with the Office of Enforcement on this subject.

D. Four Quarters without a Violation of NRC Regulations

Condition 5 of the Confirmatory Order requires that its conditions remain in effect for one year or until four consecutive quarterly reports have been issued by the Independent Auditor without any finding of a violation of NRC regulations. It does not require that there be no nonconformances. The reports do not find, or purport to find, any violations of NRC regulations, nor any concern with operational safety; and each of them has found effective implementation by JLS&A of its QA program.

It may be that only the NRC can determine, following an enforcement proceeding, that a violation of its regulations has occurred; and the NRC has not initiated any such proceeding. And not every nonconformance with an internal QA requirement or expectation amounts to a violation of NRC regulations. However, the inspectors who issued the July 2006 Inspection Report proclaimed themselves uncertain whether the “nonconformances” found by the Independent Auditor” amounted, in essence, to violations of NRC regulations, and thus prevent the conclusion that four violation-free reports have been issued. *Id.* at 13, item 8.

JLS&A believes that the independent Auditor’s findings of one “nonconformance” in each of two reports do not constitute “violations” of NRC regulations. No clear definition of these terms relative to one another has been found in NRC regulations, but under basic rules of construction, distinct terms presumably have distinct meanings; thus, unless contrary evidence is found from context, they are presumed not to be identical in meaning. NRC practice suggests a difference in meaning. The NRC’s Enforcement Policy discusses issuance of both Notices of Violation and Notices of Nonconformance distinctly.¹ Similarly, NRC cases distinguish between nonconformances and violations.² What seems to be the case is that nonconformances involve a

¹ Compare NRC Enforcement Policy VI., Disposition of Violations, with VI.E, Related Administrative Actions (e.g., notices of nonconformance, notices of deviation, confirmatory action letters) (NRC Enforcement Policy 16 et seq., 30, as found on NRC web site on September 10, 2006). See also *id.* at V., Predecisional Enforcement Conferences, at 13: “When the NRC learns of a potential violation for which escalated enforcement action

(continued...)

departure from NRC expectations or requirements in the broadest sense, and may lead to a finding of violations, but do not in and of themselves constitute violations of NRC regulations.

Here, neither of the "nonconformances" found by the Independent Auditor over the course of four detailed audits involved operational safety issues. He found nothing which he labeled a "violation" or "apparent" violation of NRC regulations, nor is there any indication that he believed such violations had occurred. Nor has the NRC Staff undertaken any kind of enforcement action with respect to either of these findings, which it has now had in one case for almost a year, and in the other case nearly two months. Both the NRC Staff and the Independent Auditor have found effective implementation by JLS&A of its QA program. In this context, JLS&A respectfully submits that the two findings of "nonconformances" by JLS&A over four detailed audits should not be construed as violations of NRC regulations, and thus that the conditions of the Confirmatory Order should be found to have been satisfied. Thus, JLS&A

appears to be warranted, or recurring nonconformance on the part of a contractor, the NRC may provide an opportunity for a predecisional enforcement conference with the licensee, contractor, or other person before taking enforcement action." (Emphasis supplied.)

² E. g. In the Matter of NORTHEAST NUCLEAR ENERGY COMPANY (Millstone Nuclear Power Station, Unit 1), Docket No. 50-245; (License No. DPR-21); DD-99-9, NUCLEAR REGULATORY COMMISSION OFFICE OF NUCLEAR REACTOR REGULATION, 50 N.R.C. 59; 1999 NRC LEXIS 122, July 27, 1999:

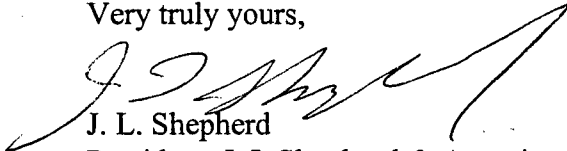
The NRC concluded that the failure of Licensee management to establish standards to ensure that the plant was maintained and operated as designed, and to ensure [*13] that nonconforming conditions were promptly identified and corrected, constituted careless disregard of requirements. As such, the violations that resulted from that deficient safety culture, which fostered such disregard, were considered willful in accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions NUREG-1600" (Enforcement Policy). (Emphasis supplied.)

In the Matter of LONG ISLAND LIGHTING COMPANY (Shoreham Nuclear Power Station, Unit 1) [PART 1 of 4], Docket No. 50-322-OL; LBP-83-57, NUCLEAR REGULATORY COMMISSION ATOMIC SAFETY AND LICENSING BOARD, 18 N.R.C. 445; 1983 NRC LEXIS 58, September 21, 1983:

According to Staff witnesses, the QA/QC problems in the electrical separation area ended with I&E Inspection Report 82-24. Even though an additional nonconformance is described in that report, it was not considered to be a violation since the item was involved in the overall final program that was still taking place (Finding K-845).

should be required to observe all NRC requirements like any other licensee or certificate holder, but should no longer be subject to the heightened requirements of the Confirmatory Order.

Very truly yours,

A handwritten signature in black ink, appearing to read 'J. L. Shepherd', written in a cursive style.

J. L. Shepherd
President, J. L Shepherd & Associates

cc: Robert J. Lewis, Section Chief, Transportation and Storage Safety and inspection Section
Donald R. Neely
Donald P. Irwin