



Department of Energy
Washington, DC 20585

January 27, 2010

Dr. George H. Miller
President, Lawrence Livermore National Security, LLC
Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, California 94551-0808

Dear Dr. Miller:

The U.S. Department of Energy's Office of Enforcement, within the Office of Health, Safety and Security, conducted an onsite review of the Lawrence Livermore National Security, LLC (LLNS) nuclear safety regulatory compliance program on September 16-17, 2009. The review included an evaluation of LLNS processes for: (1) identifying, screening, and evaluating nuclear safety noncompliances; (2) reporting, tracking, and trending of noncompliances in the Noncompliance Tracking System and LLNS internal tracking systems; and (3) analyzing and correcting noncompliances in a timely manner. Additionally, the Office of Enforcement looked at the areas needing improvement identified as part of the last program review conducted on June 18, 2004, and evaluated improvements since that review.

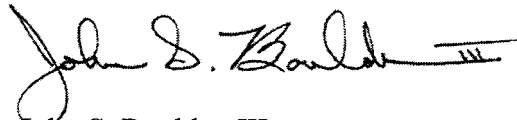
This was the first program review of the LLNS nuclear safety regulatory compliance program since LLNS began work for DOE in October 2007. Overall, LLNS's program was viewed as effective, with necessary program elements in place and a number of notable program strengths. However, the review also identified several areas for improvement that should be addressed to ensure that nuclear safety problems receive appropriate recognition and corrective action.

Correction of the issues noted in this report may allow the Office of Enforcement to consider mitigation as described in the U.S. Department of Energy Enforcement Policy (10 C.F.R. Part 820, appendix A) for any future related enforcement action against LLNS.



No reply to this letter is required. If you have any questions regarding this review, please contact me at (301) 903-2178, or your staff may contact Mr. Glenn Morris, Director, Office of Price-Anderson Enforcement, at (301) 903-7707.

Sincerely,

A handwritten signature in black ink, reading "John S. Boulden III". The signature is written in a cursive style with a horizontal line at the end.

John S. Boulden III
Acting Director
Office of Enforcement
Office of Health, Safety and Security

Enclosure

cc: Constance De Grange, LLNS
Richard Azzaro, DNFSB

**OFFICE OF ENFORCEMENT
NUCLEAR SAFETY REGULATORY COMPLIANCE PROGRAM REVIEW
LAWRENCE LIVERMORE NATIONAL SECURITY**

I. Introduction

During September 16-17, 2009, the Office of Enforcement conducted an onsite review of the nuclear safety regulatory compliance program at the U.S. Department of Energy's (DOE's) National Nuclear Security Administration, Lawrence Livermore National Laboratory, managed by Lawrence Livermore National Security, LLC (LLNS). This was the first program review of the LLNS nuclear safety regulatory compliance program since LLNS began work for DOE in October 2007. Overall, LLNS's program was viewed as effective, with necessary program elements in place and a number of notable program strengths. However, the review also identified several areas for improvement that should be addressed to ensure that nuclear safety problems receive appropriate recognition and corrective action. Results of the review are summarized below.

II. General Implementation

- LLNS has implemented a decentralized nuclear safety regulatory compliance program where each Principal Area Directorate (PAD) assigns a point of contact (POC) to implement the program.
- Each PAD has an Operations Review Board with responsibilities that include the review of potential regulatory noncompliances. LLNS has established an Institutional Operations Review Board to review regulatory compliance issues that have sitewide implications.
- The Performance Analysis and Reporting section (PAR) within the LLNS Contractor Assurance Office serves as the LLNS focal point for regulatory compliance and performs the following functions:
 - Assist the PADs and ensure that personnel understand and are trained in implementing the requirements of the regulatory compliance program.
 - Serve as the LLNS institutional POC for regulatory compliance responsible for the maintenance of implementing procedures and program self-assessment.
 - Review PAD potential noncompliance screening and reportability evaluations for appropriateness of their determinations.
 - Enter noncompliances into the Noncompliance Tracking System (NTS) and manage the reports as needed.

- Review issues entered into the LLNS Issues Tracking System (ITS) to ensure all noncompliances have been screened by the PAD regulatory compliance POCs.
- Review noncompliances for identification of potential repetitive or programmatic issues.
- The LLNS enforcement coordinator, who also serves as the manager of the PAR, reports to the Contractor Assurance Officer, who reports to the Director and Deputy Director of LLNS.
- LLNS has defined 31 functional areas within the Laboratory. A Functional Area Manager (FAM) has been assigned to each of these areas and is responsible for reviewing information to identify cross-cutting issues involving repetitive or programmatic noncompliances.
- Every quarter PAR presents LLNS management with a status report of its regulatory compliance activities. Included in this presentation are metrics associated with timeliness in reporting noncompliances, overdue NTS corrective actions, and method of noncompliance discovery. In addition, current PAR activities are discussed.
- In October 2007, LLNS was awarded the contract to manage the Laboratory and in April - May 2008, PAR performed its initial self-assessment of the LLNS regulatory compliance program. This assessment did not identify many program weaknesses.
- In November 2008, LLNS contracted with the enforcement coordinator for the Idaho National Laboratory to conduct an independent assessment of its regulatory compliance program. Multiple program weaknesses were identified as part of this review.

Strengths:

- The individuals participating in the LLNS regulatory compliance program were interviewed and found to be skilled, experienced, and motivated.

Weaknesses/Challenges:

- Current staffing levels within the PAR (one manager and three technical support personnel) appear to challenge its ability to support its function as the focal point for LLNS regulatory compliance based upon interviews with PAR staff and the Office of Enforcement review of the roles and responsibilities assigned to the PAR. The Office of Enforcement learned during the onsite review that the PAR was losing an additional member, which will further increase the workload for the remaining staff.
- The LLNS decentralized approach to safety regulatory compliance relies heavily on the PAD POCs and their expertise within the PAD to screen and report regulatory noncompliances. This approach relieves the PAR from this responsibility and allows

PAR personnel to focus on responsibilities such as training, mentoring, and data analysis. However, this decentralized approach presents a challenge to LLNS's, and in particular PAR's, ability to ensure that PAD regulatory compliance POCs and FAMs are accurately and consistently performing their regulatory compliance function to LLNS expectations. The Office of Enforcement review of LLNS PAD screening and reporting of potential noncompliances indicates some need for improvement (details will be discussed later in this report). Enhanced LLNS performance-based assessment of PAD and FAM safety regulatory compliance activities is recommended.

- The PAR self-assessment of the LLNS regulatory compliance program lacked depth and was not technically inquisitive. As such, program weaknesses were overlooked, which were subsequently identified by the independent assessment contracted by LLNS, as well as this program review.

III. Procedures and Training

- LLNS has the following two documents to govern the screening, reporting, and tracking of safety noncompliances:
 - UCRL-AM-133867, Environment, Safety, and Health (ES&H) Manual, Document 4.4, *Identifying, Reporting, and Tracking Noncompliances with Nuclear Safety and Worker Safety and Health Requirements*, is a Laboratory-wide document describing the process and requirements for identifying, reporting, and tracking safety noncompliances. In addition, the document specifies training requirements and defines the roles and responsibilities for those involved in LLNS safety regulatory compliance.
 - CAO-PAR-0002, *Worker Safety and Health and Nuclear Safety deficiency screening process and documentation of noncompliance determinations in the Issues Tracking System (ITS)*, is a PAR procedure that provides additional detail on the approach used by LLNS to screen and document safety noncompliances in accordance with the ES&H Manual, document 4.4.
- LLNS has established a training program to ensure that Laboratory personnel are aware of their responsibilities for identifying, reporting, and tracking safety regulatory noncompliances. This training program consists of the following:
 - General Nuclear Safety Awareness Training is required of all Laboratory personnel. This training addresses Price-Anderson Amendments Act indemnification and the fact that the Laboratory is subject to enforcement actions and civil penalties for violations of DOE nuclear safety requirements.
 - Regulatory Compliance Assurance Orientation Training is required for LLNS managers who have line responsibilities for any facility, operation, or activity subject to DOE safety requirements. This training is provided by PAR.

- Regulatory Compliance Assurance Evaluator Training is required for LLNS personnel whose responsibilities include identifying or overseeing the identification of DOE safety regulatory noncompliances and those personnel responsible for reporting and/or tracking noncompliances. This training is provided by PAR, and biennial refresher training is required.

Strengths:

- During the 2004 Office of Enforcement nuclear safety regulatory compliance program review, it was noted that “LLNL has not provided adequate training and supplemental guidance or structure at the Associate Director’s level to ensure consistent program implantation.” As a result of this observation, LLNS has implemented a significant improvement in the area of training and procedural guidance to better ensure consistent program implementation. ES&H Manual, document 4.4 was developed to proceduralize the LLNS regulatory compliance assurance program. Additionally, the creation of Regulatory Compliance Assurance Orientation Training and Evaluator Training is viewed by the Office of Enforcement as an improvement to better ensure consistent implementation of the regulatory compliance program at the Laboratory.

Weaknesses/Challenges:

- The roles and responsibilities of the Operations Review Board and the Institutional Operations Review Board in the LLNS regulatory compliance program are not addressed in ES&H Manual, document 4.4.

IV. Identification and Screening

- LLNS uses ITS as its institutional issues management tool. This database provides a single system for recording observations and deficiencies, tracking associated corrective actions, and accessing status information. ITS has recordkeeping capability, including archiving of documents that verify corrective action completion. LLNS indicated that ITS is the database used to capture all issues identified and screened for potential nuclear safety noncompliances.
- PAD regulatory compliance POCs are responsible for identifying and screening regulatory noncompliances within their organization through the review, trending, and analysis of the issues contained within the ITS, and then documenting the noncompliance screening determinations in the ITS. In addition, the PAD regulatory compliance POCs are responsible for identifying repetitive and programmatic noncompliances within their organizations, based on their reviews of ITS data, and documenting any observed noncompliances in ITS.
- FAMs are responsible for reviewing data in their function areas to identify any repetitive or programmatic noncompliances.

- PAR is to assist the PAD regulatory compliance POCs as necessary to ensure that identification and screening of potential regulatory noncompliances meet program expectations.
- PAR is responsible for reviewing information from a variety of sources and identifying any repetitive or programmatic noncompliances.
- The Office of Enforcement reviewed nine assessments performed by LLNS and found that all nine were captured in ITS and appropriately screened.

Strengths:

- PAR has implemented procedure CAO-PAR-0001, *Analyzing Performance*, to systematically review data to identify repetitive issues and analyze their common causes. This analysis includes the trending of data to determine improving or deteriorating performance. Quarterly safety analysis reports are published and were found to be comprehensive and technically inquisitive.
- The LLNS change from DefTrack to ITS represents an improvement in its ability to track issues identified both internally and externally.

Weaknesses/Challenges:

- The Office of Enforcement sampling of approximately 100 ITS entries indicates that 6 potential nuclear safety noncompliances may not have been correctly screened in accordance with LLNS requirements.
- The Office of Enforcement reviewed LLNS nuclear safety NTS reports submitted from January 2008 through May 2009. Of the 10 reports submitted during this time period, 3 required more than 50 days for the screening to be accomplished (67, 104, and 129 days).
- The LLNS ITS only provides for the entry of one compliance code. In many circumstances, an issue or event may involve multiple compliance codes. This restriction in ITS limits the PAR's ability to confidently analyze safety noncompliances by the type of compliance code involved.
- The Office of Enforcement reviewed the LLNS Health Physics Field Operations Reports for 2007 and 2008 and determined that several of the nuclear safety related events listed for Building 332 were not captured in the ITS. During interviews with the cognizant FAM and PAR personnel, there seemed to be some confusion as to who was responsible for screening the events listed in the reports. LLNS should ensure that the processes in place to capture and screen potential regulatory noncompliances are sufficiently understood and implemented across the Laboratory.

- The Office of Enforcement review of the LLNS Health Physics Field Operations Reports for 2007 and 2008 identified a potential repetitive noncompliance associated with Building 332 glovebox glove contaminations and activation of continuous air monitor alarms. LLNS has analyzed the glovebox glove failure trend and causes with the goal to prevent recurrence; however, they did not provide documentation that the contaminations and alarms were analyzed for reporting of potential noncompliances. LLNS should evaluate the effectiveness of PAD and FAM screening of data for potential repetitive or programmatic issues.

V. Evaluation of NTS Reportability

- For those items identified as regulatory noncompliances in the ITS, LLNS PAD regulatory compliance POCs perform an NTS reportability evaluation using criteria established by the Office of Enforcement.
- PAR reviews the PAD NTS reportability determinations and works with the PAD to resolve any disagreement with regard to the determinations.
- If it is determined that a reportable regulatory noncompliance has occurred, the PAD regulatory compliance POC prepares an NTS report and submits it to PAR for review and entry into the NTS.
- LLNS has established a 20-day window for reporting regulatory noncompliances into the NTS once it has been determined that a regulatory noncompliance has occurred. Within 45 days after NTS report submission, LLNS requires that all associated corrective actions be entered into the NTS. Corrective actions entered into the NTS are not required to have been completed within this 45-day period.

Strengths:

- The Office of Enforcement reviewed all LLNS nuclear safety NTS reports submitted from January 2006 through May 2009 and evaluated whether the issues were identified internally by LLNS or by some other means such as external assessment or a self-disclosing event. The result of this review determined that 58 percent of all issues associated with the nuclear safety NTS reports were self-identified by LLNS. This result is encouraging and suggests that LLNS is proactive in identifying and correcting problems leading to nuclear safety regulatory noncompliances.

Weaknesses/Challenges:

- The Office of Enforcement reviewed all LLNS Occurrence Reporting and Processing System (ORPS) reports from January 2007 through June 2009 that met the nuclear safety NTS reporting thresholds established by the Office of Enforcement. This review found that nine of these ORPS reports did not result in the issuance of an LLNS nuclear safety NTS report. Discussion with PAR personnel revealed that three of these ORPS reports did not involve a noncompliance with nuclear safety

regulations. However, the remaining six ORPS reports should have led to the submission of a nuclear safety NTS report but did not. LLNS has recently submitted NTS reports to address three of these six ORPS-related issues. LLNS PAR indicated that they would work with the DOE Livermore Site Office Enforcement Coordinator to address the remaining three ORPS issues.

- The Office of Enforcement reviewed all LLNS nuclear safety NTS reports submitted from February 2006 through May 2009 to determine the timeliness of reports submitted into the NTS. The results of this review demonstrated that it took LLNS an average of 90 days to submit a nuclear safety NTS report from the time the noncompliance determination had been made (LLNS's requirement for this submission is 20 days). Seven of the 44 NTS reports reviewed exceeded 200 days to report into the NTS. Several factors were discussed as causes for this lack of timeliness in NTS report submission, including contract transition, loss of key personnel, and the LLNS practice of completing causal analyses of ORPS-reported occurrences, during which time they identify the noncompliances, prior to submitting NTS reports. The lack of timeliness in NTS report submission has been known to exist for some time by LLNS. LLNS actions to improve timeliness in NTS report submission have not been effective in meeting LLNS requirements or DOE expectations.

VI. Regulatory Noncompliance Issue Management and Trending

- Upon determination that a regulatory noncompliance has occurred, LLNS uses a graded approach to the application of causal analyses, extent-of-condition reviews, and corrective action effectiveness reviews. Extent-of-condition reviews and effectiveness reviews are required for all NTS-reportable noncompliances. Root cause analysis is required for NTS-reportable noncompliances with the exception of ORPS significance category 2, 3, and 4, in which only an apparent cause is required. Site-reportable noncompliance causal analysis, extent-of-condition review, and effectiveness review are applied based on the issue significance, with the exception of OPRS significance category 1, R, and operational emergencies, in which these analysis tools are required.
- The LLNS PADs are responsible for regulatory noncompliance corrective action identification. Once corrective actions for NTS noncompliances are identified, they are entered into the ITS by PAR personnel. If the corrective actions in response to an assessment are associated with an NTS-reportable noncompliance, they are conveyed to PAR for entry into the NTS.
- For NTS-reportable noncompliances, the final corrective action will be the conduct of a corrective action effectiveness review. This occurs no earlier than 6 months and no later than 18 months after completion of the corrective actions.

- PAR coordinates corrective action effectiveness reviews for NTS-reportable noncompliances. For site-reportable noncompliances, the PAD is responsible for conducting the corrective action effectiveness review, based on the significance of the issue.
- The Office of Enforcement performed a review of all 13 LLNS nuclear safety NTS reports in which at least 1 corrective action remained open as of August 2009. There were a total of 198 corrective actions included in these NTS reports. This review determined that there currently was 1 corrective action that was overdue and that 11 corrective actions were completed beyond the target completion date. Twenty-seven of the 198 corrective actions had the target completion date extended at least once.

Strengths:

- Causal analyses, extent-of-condition reviews, and corrective action effectiveness reviews are well integrated into the processes used by the LLNS regulatory compliance program.
- PAR reviews the causal analyses performed by the LLNS PADs and provides feedback to the analysts to improve their analyses.

Weaknesses/Challenges:

- PAR tracks LLNS performance in closing NTS corrective actions. In September 2008, PAR noted that 23 percent of the NTS report corrective actions were overdue. While the Office of Enforcement August 2009 review of overdue NTS corrective actions demonstrated improved performance in the timely closure of the actions, LLNS should remain vigilant in this area of corrective action closure, and take actions necessary to ensure that the percentage of overdue corrective actions is reduced to near-zero levels.

VII. Conclusion

The above summarizes the Office of Enforcement's review of the LLNS nuclear safety regulatory compliance program conducted during September 16-17, 2009. Overall, the LLNS program was viewed as effective, with necessary program elements in place and a number of notable program strengths. However, the review also identified several areas for improvement that should be addressed to ensure that nuclear safety problems receive appropriate recognition and corrective action. Any actions taken to address these items should be appropriately coordinated with the local DOE office.