



Department of Energy

Washington, DC 20585

November 1, 2012

Dr. Penrose C. Albright, President
Lawrence Livermore National Security, LLC
Lawrence Livermore National Laboratory
7000 East Avenue, L-001
Livermore, California 94551-0808

Dear Dr. Albright:

The Office of Health, Safety and Security's Office of Worker Safety and Health Enforcement conducted an onsite regulatory assistance review of the Lawrence Livermore National Security, LLC (LLNS) worker safety and health regulatory compliance program during April 17 - 19, 2012. The review included an evaluation of LLNS's programmatic processes for identifying, reporting, and tracking worker safety and health regulatory noncompliances; trending of regulatory compliance performance indicators; and self-assessment activities for monitoring the performance of the worker safety and health compliance program.

The LLNS worker safety and health regulatory compliance program is supported by documented policies and procedures, qualified staff to develop and support the program, and a network of LLNS organizations that demonstrate ownership of noncompliant issues and corrective actions. LLNS has fostered a mature program aligned with the guidance set forth within the Department of Energy's *Enforcement Process Overview* document.

The results of this review, described in the enclosed report, identified a number of strengths as well as recommendations for your consideration that provide opportunities to further improve implementation of the LLNS worker safety and health regulatory compliance program. Notably among LLNS strengths were a proactive training program; robust mechanisms for identifying and evaluating potential noncompliances; an electronic issues reporting tool; effective issues management techniques; and a comprehensive self assessment process.

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. Kevin Dressman, Director, Office of Worker Safety and Health Enforcement, at (301) 903-0100.

Sincerely,

A handwritten signature in black ink that reads "John S. Boulden III".

John S. Boulden III
Director

Office of Enforcement and Oversight
Office of Health, Safety and Security



Enclosure: Regulatory Assistance Review Report

cc: Constance DeGrange, LLNS
Kimberly Davis, LSO

Office of Worker Safety and Health Enforcement
Regulatory Assistance Review
Lawrence Livermore National Security, LLC

I. Introduction

During April 17-19, 2012, at the request of Lawrence Livermore National Security, LLC (LLNS), the Office of Worker Safety and Health Enforcement, within the Office of Health, Safety and Security, conducted a regulatory assistance review of LLNS's worker safety and health regulatory compliance program. Regulatory assistance reviews facilitate, encourage, and support contractor processes for the prompt identification and correction of noncompliances. The regulatory assistance review was planned and conducted in accordance with the guidance provided in the U.S. Department of Energy's (DOE) *Enforcement Process Overview* (EPO). The EPO document is located on the Office of Health, Safety and Security website at: http://www.hss.doe.gov/enforce/process_guidance.html.

The goal of the regulatory assistance review was to understand LLNS's processes for noncompliance identification and reporting, implementation of LLNS's internal self-assessment program, and LLNS's trending of regulatory noncompliances. In addition, the regulatory assistance review evaluated LLNS's effectiveness in resolving both noncompliant conditions and program deficiencies that can lead to noncompliances with the potential to adversely affect worker safety and health. The Office of Worker Safety and Health Enforcement gained first-hand information on LLNS's program effectiveness and had the opportunity to exchange feedback regarding implementation of the LLNS program. Finally, regulatory assistance reviews assist the DOE contractor community by enhancing the uniformity of worker safety and health noncompliance identification and reporting.

Overall, LLNS's regulatory compliance program enables LLNS to effectively identify, evaluate, track, and correct worker safety and health noncompliances to prevent recurrence. The review team identified a number of program strengths as well as opportunities to enhance the LLNS worker safety and health regulatory compliance program. The review identified a few recommendations for consideration that would improve implementation of the Lawrence Livermore National Laboratory (LLNL) worker safety and health compliance program. The results of the review are summarized below.

II. General Implementation

- LLNS has implemented a worker safety and health regulatory compliance program where each principal directorate (PD) assigns a point of contact (POC) to implement the program and coordinate with the Performance Analysis and Reporting Section (PARS).

- Each PD has an Operations Review Board with responsibilities that include the review of potential regulatory noncompliances. LLNS has established an Institutional Operations Review Board and an Operations Excellence Council to review regulatory compliance issues that have site-wide implications.
- PARS is within the Compliance Assurance Office (CAO), which serves as the LLNS focal point for regulatory compliance and performs the following functions:
 - Mentors the PDs and ensures personnel are trained in, and understand, the requirements of the regulatory compliance program.
 - Serves as the LLNS institutional POC for regulatory compliance assurance, maintenance of implementing procedures, and regulatory compliance program self-assessment.
 - Reviews PD potential noncompliance screening and Noncompliance Tracking System (NTS) report evaluations for appropriate determinations.
 - Oversees preparation of NTS reports and enters noncompliances into the NTS and manages the reports as needed.
 - Reviews issues entered into the LLNS Issues Tracking System (ITS) to ensure all noncompliances have been appropriately screened by the PD regulatory compliance POCs.
 - Reviews noncompliances and identifies potential repetitive or programmatic issues.
- The LLNS enforcement coordinator is the manager of PARS and reports to the contractor assurance officer, who reports to the LLNL director and deputy director.
- LLNS has defined 31 functional areas within the Laboratory and has assigned a functional area manager (FAM) to each area. The FAM is responsible for reviewing information to identify cross-cutting issues involving repetitive or programmatic noncompliances. Three functional areas fall under the scope of 10 C.F.R. Part 851: Emergency Management, Occupational Medicine, and Worker Safety and Health.
- Each quarter, the PARS presents LLNS management with a status report on regulatory compliance activities. PARS includes in this presentation metrics associated with timeliness in reporting noncompliances, overdue NTS corrective actions, and the discovery method of noncompliances. In addition, the PARS may discuss emerging issues such as incident trends, training effectiveness, and events that may impact multiple organizations.
- LLNL document DES-0083, *Regulatory Compliance Assurance Program for DOE Safety and Security Requirements*, describes the overall site program for regulatory compliance assurance.
- LLNL requires its subcontractors to perform work under the site's worker safety and health (WSH) programs including those related to noncompliance reporting. This

requirement allows senior management to maintain consistency in safety controls, provide effective oversight, and effectively promote the site's safety culture.

Strengths:

- The individuals participating in the LLNS regulatory compliance program are knowledgeable, experienced, and motivated to ensure that noncompliances are identified and accurately reported.
- DES-0083 *Regulatory Compliance Assurance Program for DOE Safety and Security Requirements*, provides detail adequate for program implementation. The document provides specific roles and responsibilities for personnel including the principal associate director and associate directors and the FAMs. DES-0083 clearly delineates the means by which noncompliances can be identified and the procedures for reporting, tracking, and correction. The tables and appendices in the document effectively support and explain the main text.

Recommendations: None.

III. Procedures and Training

- LLNS has developed and implemented the following procedures and documents to govern the screening, reporting, and tracking of WSH noncompliances:
 - PRO-89 *Reporting and Tracking Noncompliances with DOE Safety Requirements*
 - PRO-42 *Issues and Corrective Action Management*
 - PRO-73 *Analyzing Events and Conditions for Apparent Cause*
 - PRO-77 *Conducting an Effectiveness Review*
 - Doc 4.7 *Analysis Methods* (Extent of Condition, Performance Analysis, Root Cause Analysis)
- LLNS has established a training program to ensure that assigned personnel are aware of their responsibilities for identifying, reporting, and tracking WSH regulatory noncompliances. This training program consists of the following:
 - Regulatory Compliance Assurance Orientation Training (CA0100) is required for LLNS managers and individuals who have responsibilities for an operation or activity subject to DOE safety requirements.
 - Regulatory Compliance Assurance Evaluator Training (CA0200) is required for LLNS personnel whose responsibilities include identifying, or overseeing the identification of, DOE WSH regulatory noncompliances; and those responsible for reporting or tracking noncompliances. PARS delivers this training, and biennial refresher training is required.
 - Causal Analysis Methods and Techniques Overview, Apparent Cause Analysis, Root Cause Analysis, and Effectiveness Review training is provided to personnel with these focused program responsibilities.

Strengths:

- LLNS approaches site-wide training in a proactive manner. As an example, starting in 2011 and continuing to the present, LLNS evaluated whether the appropriate personnel are receiving training consistent with their work responsibilities. Additionally, LLNS assessed course completion rates by those who were assigned to attend. As a result, LLNS anticipates being able to better identify populations requiring training and the subsequent completion of the assigned sessions.

Recommendations: None.

IV. Identification and Screening

- LLNS relies on four mechanisms to identify noncompliances. These are outlined below and further detailed in the remainder of this section:
 - Events, and conditions,
 - Assessment results including management observations and inspections conducted by the directorates that are usually screened by the directorates; and independent assessments that are screened by PARS at the institutional level,
 - Performance analysis conducted by PARS using data from the ITS and events or conditions to identify systemic, significant, or repetitive issues,
 - Worker feedback using LLNL processes like the BSAFE Hotline, Employee Voice, and the Quick ITS.
- LLNS developed the 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. The ITS has recordkeeping capability, including archiving of documents that verify corrective action completion. The ITS database is used to capture issues identified and screened for potential WSH noncompliances and for site-reporting.
- PD regulatory compliance assurance personnel are responsible for identifying and screening regulatory noncompliances within their organization through the review, trending, and analysis of the issues. The PD personnel document noncompliance screening determinations in the ITS. In addition, PD regulatory compliance personnel review the ITS and other data to identify repetitive and programmatic noncompliances within their respective organizations.
- FAMs are responsible for reviewing data in their functional areas to identify any repetitive or programmatic noncompliances.
- PARS oversees the PD regulatory compliance POCs as necessary to ensure that identification and screening of potential regulatory noncompliances meet program expectations.

- PARS reviews information from a variety of sources to identify repetitive or programmatic noncompliances.

Strengths:

- PARS has ensured effective identification of noncompliances using four different mechanisms involving multiple levels of the organization.
- PARS 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 identify improving or deteriorating performance. The PARS publishes performance analysis reports, which were found to be comprehensive and technically inquisitive.

Recommendations:

- The ITS “Add Issue” page permits one compliance code per issue. This does not allow for issues that may involve multiple citations. LLNL should consider providing for input of multiple compliance codes per issue in the ITS, to facilitate more detailed tracking and trending of the compliance data, and to encourage LLNL personnel to think more comprehensively about the causes and outcomes of noncompliances.

V. Evaluation of NTS Reportability

- LLNS reviews applicable requirements when determining a WSH noncompliance, including at a minimum:
 - 10 C.F.R. Part 850 *Chronic Beryllium Disease Prevention Program*
 - 10 C.F.R. Part 851 *Worker Safety and Health Program*
 - Implementing documents and procedures in the LLNL Worker Safety and Health and Chronic Beryllium Disease Prevention Programs; and the Environmental Safety and Health Manual
 - The Integrated Safety Management System
- The PD regulatory compliance POCs evaluate NTS reportability using criteria established by the Office of Enforcement and Oversight for those items identified as regulatory noncompliances in the ITS.
- PARS developed document LL6570# (v6 dated 11/11), *LLNL ORPS/NTS Reporting Form*, for preparing noncompliance and occurrence reports. This form integrates the common DOE requirements for worker safety and health and nuclear safety and is signed by the principal associate director where the noncompliance occurred.
- PARS reviews the PD NTS reportability determinations and works with the PD to resolve any disagreement. The PD regulatory compliance POC then prepares an NTS report (if appropriate) and submits it to PARS for review and entry into the NTS.

- LLNS uses the 20-day guideline established by DOE for reporting regulatory noncompliances into the NTS once it has been determined that a reportable regulatory noncompliance has occurred. Within 60 days after the NTS report submission, LLNS requires that the causal analysis be completed and all associated corrective actions be entered into the NTS. Corrective actions are not necessarily required to be completed within the same 60-day period.
- The Office of Worker Safety and Health Enforcement reviewed 11 assessments performed by LLNS between February 2010 and March 2012 and found that all were captured in the ITS and evaluated for reporting criteria. Ten were appropriately screened for Occurrence Reporting and Processing System and NTS eligibility. Two of these were noteworthy in depth of analysis and proactive corrective actions. One case met NTS reporting criteria but was screened out due to the short duration of exposure to the hazard. Removing issues from consideration for noncompliance screening and NTS reporting due to prompt correction inhibits trending for repetitive and programmatic weaknesses.

Strengths:

- In 2011, LLNS self-identified 65 percent of all issues associated with WSH noncompliances, indicating that LLNS is proactive in identifying and correcting problems leading to WSH deficiencies.

Recommendations:

- LLNS reported that the average time to report a noncompliance to DOE in calendar year (CY) 2011 was 43 days after the date of determination. This average included reports entered into the NTS (both nuclear safety and worker safety and health) and in the Safeguards and Security Information Management System. LLNS reported 3 of the 12 worker safety and health NTS cases in excess of 50 days after the date of determination. The CY 2011 average exceeded the *DOE Enforcement Process Overview* expectation of reporting within 20 days following noncompliance determination. LLNS identified the complexity of recent cases as a cause. However, the Office of Worker Safety and Health Enforcement recommends that LLNS consider actions to improve timeliness of NTS report submission.
- LLNS should ensure that all noncompliances are screened for NTS reportability, even when they are considered to be of short duration, promptly abated, or otherwise of low significance to the organization.

VI. Regulatory Noncompliance Issue Management and Trending

- LLNS performs causal analyses, extent-of-condition reviews, and corrective action effectiveness reviews for noncompliances entered into the NTS based on the significance category and nature of the event or condition. PARS independently verifies corrective actions entered into the NTS.

- The PDs are responsible for identifying regulatory noncompliance corrective actions. The corrective actions for NTS noncompliances are entered into the ITS by PARS personnel. Corrective actions in response to an assessment associated with an NTS-reportable noncompliance are also conveyed to PARS for entry into the NTS.
- The final action for NTS-reportable noncompliances is an effectiveness review between 6 and 18 months after completion of the corrective actions.
- PARS ensures that corrective action effectiveness reviews for NTS-reportable noncompliances are conducted as required. For site-reportable noncompliances, the directorate conducts the review based on the significance of the issue.
- PARS tracks the following metrics regarding noncompliances to assess effective implementation of the regulatory assurance program:
 - Self-identification
 - Timely reporting
 - Timely analysis and resolution
 - Adequate demonstration of abatement
- All four metrics are updated on a quarterly basis. PARS reviews two of the metrics internally (second and fourth listed above); and publicizes the other two in the quarterly CAO assurance report. The director's monthly performance review and the Operations Excellence Council examine the status of the first and third in a "yellow" or "red" status.
- PARS issues a Weekly Report and provides other presentations to senior managers that identifies:
 - Weaknesses or systemic problems
 - Compliance issues
 - Safety and security performance issues
 - Enforcement actions of interest elsewhere in DOE
 - Overall status of the LLNL Regulatory Compliance Assurance Program
- In addition to the above, LLNS tracks progress on actions to reduce the severity of, or entirely prevent, injuries and illnesses. LLNS has targeted populations with the most frequent or severe injuries and illnesses, and LLNS has consistently reduced its injury and illness rates each year. LLNS employs the following mechanisms to achieve the injury and illness reduction goal:
 - Improve the LLNL hearing conservation program
 - Train 500 employees in identified high-risk groups in injury-prevention techniques
 - Reduce the strains/sprains Days Away Cases rate in the high risk groups of

- security, environment safety and health technicians, and facilities and infrastructure by a factor of 5 percent from the prior 3-year average
- Control exposures of personnel to chemical, physical and biological hazards
 - Improve implementation and consistency of the institution-wide work planning control system and the quality of pre-job briefs
 - Improve the rigor of work planning and control in the facilities and infrastructure directorate.

Strengths:

- PARS effectively integrates causal analyses, extent-of-condition reviews, and effectiveness reviews into the regulatory compliance program.
- PARS reviews the causal analyses performed by the LLNS PDs and provides feedback to the analysts to improve their analyses.
- LLNS tracks performance via metrics and communicates progress or areas of concern.
- PARS assesses the effectiveness of the reported metrics and proposes additional measures that may support implementation of the program. For instance, PARS is considering a future metric to quantify and track the quality of the response to noncompliances (e.g., causal analysis, extent of condition). Additionally, the CAO initiated a six-sigma project in December 2011 to address issues and actions across LLNL. Expected completion date was scheduled for July 2012.

Recommendations: None.

VII. Assessments

- LLNL conducts both formal and informal internal assessments. Formal assessments are managed by the CAO through the Institutional Assessment Plan (IAP), which is maintained in the ITS database. Informal assessments are managed by the line organization and are included in the ITS database as required and at line management's discretion.
- From most formal to least, the internal assessments consist of:
 - Internal Audit in compliance with DOE regulations to assess operational, financial, and management control systems
 - Internal Independent Assessment in areas of high risk, or with the greatest need for improvement; and requiring an impartial evaluation
 - Joint FAM/Line Management Assessment to evaluate requirement or risk based performance across one or more line organizations
 - Management Self-Assessments used by line managers to evaluate the control and performance of their work

- Management Observation, Verification and Inspection to provide line managers a means to continuously improve organizational safety and security.
- Assessment team leaders, team members, FAMs and line assessors are required to complete training and qualification as prescribed by the quality assurance officer or as otherwise required by LLNL training requirements.
- The CAO publishes resulting IAP data via the quarterly report distributed to senior managers.

Strengths:

- LLNL has proactively established an internal assessment program to evaluate performance against worker safety and health regulatory requirements. The program draws on input from multiple levels of the organization.

Recommendations:

- The Worker Safety and Health Functional Area Assessment Program relies, at least in part, on residual risk (i.e., the risk remaining after controls are instituted) to rank major program areas for evaluation. LLNL should consider an approach that ranks programs with consideration for the inherent risk (i.e. the risk that exists without controls in place) of a potential hazard. This better reflects the rationale for an assessment program, which is to evaluate the effectiveness of the controls and the degree to which they are properly implemented. Assessing a program less frequently based on the controls already in place presupposes that the controls will always operate effectively, which may not always be the case. Additionally, personnel may vary in their understanding of the hazard and the degree or effectiveness with which they implement the required controls.
- The Office of Worker Safety and Health Enforcement noted that at least one recently reported NTS noncompliance could have been avoided by a greater emphasis on actual field observations of program implementation during assessments. LLNS should consider increasing field observations of jobs in progress as a component of assessments to determine program effectiveness.

VIII. Summary

LLNS has established and maintains a regulatory compliance program appropriate for the activities and hazards at LLNL. The LLNS program contains all functional elements necessary for identifying, screening, and reporting worker safety and health regulatory noncompliances and managing corrective actions consistent with the guidelines delineated in the DOE EPO.

LLNS should evaluate the recommendations identified during this review as opportunities for improving worker safety and health performance and avoiding or

reducing the severity of worker safety and health noncompliances. Improvements to the LLNS worker safety and health program will promote appropriate recognition and corrective action for worker safety and health program weaknesses; facilitate the Office of Worker Safety and Health Enforcement's exercise of discretion for noncompliant conditions considered to be less significant; and support mitigation consideration in any future enforcement action. Any corrective actions taken to address these recommendations should be coordinated with the Livermore Site Office.