



Department of Energy
National Nuclear Security Administration
Washington, DC 20585

March 8, 2004

The Honorable John T. Conway
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, NW.
Suite 700
Washington, D.C. 20004

Dear Mr. Chairman:

Enclosed for your information are copies of Quality Assurance Program assessment reports for Pantex, Los Alamos, Nevada and Livermore Site Offices. These assessments were conducted during November-December 2003, to meet the requirements of Action 1.3.1 of the Quality Assurance Improvement Plan. We have reviewed the assessment reports and directed the Site Offices to take appropriate actions to resolve the issues identified in a timely manner.

We consider Action 1.3.1 of the Quality Assurance Improvement Plan to be complete. If there are any questions regarding the enclosures, please have a member of your staff contact Rabi Singh of my staff at (301) 903-5864.

Sincerely,

A handwritten signature in black ink, appearing to read "Everett H. Beckner".

Everet H. Beckner
Deputy Administrator
for Defense Programs

Enclosures

cc w/enclosures:

L. Brooks, NA-1
M. Whitaker, DR-1
J. Mangeno, NA-3.6

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PXSO Quality Assurance Audit Summary

A Quality Assurance Audit of the Pantex Site Office was conducted on November 3-4, 2003. The audit was conducted to fulfill a commitment made to the Defense Nuclear Facilities Safety Board in the Secretary of Energy's Quality Assurance Implementation Plan. The team noted two Opportunities for Improvement (OFI). PXSO personnel should review the detailed discussions in the Forms One attachment to ensure a full understanding of the items discussed in the below paragraphs.

OFI-1: The PXSO Quality Assurance Program and associated documents were not current and do not reflect the current QA practices. A process to continuously improve efficiency and quality of operations was not evident.

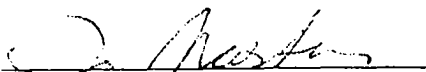
Several of the documents that were reviewed were out of date [e.g., DOE, NNSA, and PXSO organizational changes have not been captured; DOE directive system references were out of date; referenced programs (e.g., training, tracking) were not current].

PXSO does not have a documented process to document, track, and close corrective actions. CATS and the Field Activities Data Base capture some specific types of issues, but issues that are not covered by these systems are left to individual subject matter experts to manage. The team did not find any systematic process to analyze or trend issues from various feedback sources to continuously improve operations. Lessons learned from external sources are reviewed and disseminated, but the process to do so is not formal or documented.

OFI-2: The QA staff appears to be understaffed. No quality engineers are currently assigned to the PXSO staff. An analysis of QA staff levels with Headquarters input should be completed.

A review of PXSO current staffing in the QA area and discussions held during interviews indicated that the staffing was insufficient to carry out PXSO responsibilities. The QA staff consisted of 11 persons two years ago, and now consists of three persons. Of particular concern to the team is that there was no quality engineer currently on the staff. The lack of a quality engineer results in no on-site resource for conducting certain quality reviews (QAS 2.0, QAS 3.0).

From discussions during interviews and the team's review of the requirements, it appears that a QA staff of two quality engineers and 4-5 quality specialists would be adequate. The team recognizes that it could not spend a great deal of time on this analysis and that a more detailed analysis could yield a different number.



Lynn Maestas
Team Member 11/04/03



Emil D. Morrow
Team Leader 11/04/03

PXSO ASSESSMENT FORM 1

FUNCTIONAL AREA: QUALITY ASSURANCE	OBJECTIVE: 1 DATE: November 4, 2003	OBJECTIVE MET	
		YES	NO X

OBJECTIVE:

QA.1 NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P 450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program. (DOE G 450.4-1A CCE-4, CCE-6, CCE-10 and CCE-11, DOE O 414.1A and DOE P 450.5)

CRITERIA:

1. The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A)
2. NNSA Site Office implementation of documented procedures and/or mechanisms included in the quality assurance program meets or exceeds the requirements of DOE O 414.1A/QC-1/10 CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)
3. A process is established and effectively implemented to continuously improve efficiency and quality of operations. (DOE FRAM 9.6.2)

Records Reviewed:

- Letter to Sue Pererson, Office of Price-Anderson Enforcement, from William Mairson, Manager, Business Strategy and Services, BWXT Pantex, entitled "Quality Assurance Program Description, MNL00079, Issue 6 (February 18, 2003)
- Memo to Virgil Hughes, Manager, Quality Assurance Division, BWXT Pantex, from Michael Ulshafer, Chief, Weapons Quality Staff, PXSO, entitled "Quality Assurance Program Description, MNL-00079, Issue 6 (January 8, 2003)
- Transition of Quality Assurance from Assistant Manger for Operations (AMO) to Assistant Manager for Oversight and Assessment (AMOA) (undated)
- Security Self-Assessment Report of the Pantex Site Office (March 17-21, 2003)
- Procedure number 101.1.0, Revision 1, Operations Quality Assurance Program (May 13, 1999)

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- Procedure number 103.4.0, Revision 2, Functions, responsibilities and Authorities Manual (FRAM) (June 16, 2000)
- Office of Amarillo Site Operations Integrated Safety Management System Description (October 25, 2002)
- Procedure number 110.4.0, Issues Management and Tracking Program (November 29, 1999)
- Summary of Changes to Pantex Plant's Integrated Safety Management Description (August 29, 2003)
- Pantex Plant's Integrated Safety Management Description, Revision 10 (August 29, 2003)
- Selected Training and Qualification Records
- Memo to Larrie Trent, Director, Environment, Safety and Health, BWXT Pantex LLC from Dennis Kelly, Assistant Area Manager for Nuclear Materials Operations, DOE-AAO Assessment Report SHS-2001-2 (June 1, 2001)
- Memo to Memo to Larrie Trent, Director, Environment, Safety and Health, BWXT Pantex LLC, from Mark Blackburn, Chief, Safety and Health Staff, NNSA-OASO Assessment Report SHS-2002-1 (May 23m 2002)
- Memo to Karl Waltzer, Assistant Manager for Oversight & Assessments, PXSO, from Mark Blackburn, Chief, Safety, Health & Quality Staff, FY03 Office of Amarillo Site Operations Safety, Health & Quality Staff (SHQ) Assessment Schedule (Revision 1) (September 3, 2003)
- 9/2003 Analysis of DOE QA Requirements for Quality Assurance Agency (QAA'PXSO) (Blackburn), (undated)
- Pantex Site Office Weapons Quality Staff QAS 4.0 Report, 44-03-155, Test Bed Assembly (July 21, 2003)
- Pantex Site Office Weapons Quality Staff QAS 4.0 Report, 44-03-157, W62 Disassembly and Inspection (July 23, 2003)
- Pantex Site Office Weapons Quality Staff QAS 4.0 Report, 44-03-165, JTA Operation (July 28, 2003)
- Pantex Site Office Weapons Quality Staff QAS 4.0 Report, 44-03-151, JTA Assembly (July 18, 2003)
- Pantex Site Office Weapons Quality Staff QAS 4.0 Report, 44-03-150, WR Pressure Drop Test (July 22, 2003)
- Quality Assurance Activities Plan, Weapons Quality Staff (WQS), Fiscal Year 2003 (August 19, 2002)
- 10/2003 QA Workload Analysis (Based on FY03 data on Quarterly WQS Reports) (undated)
- Quality Assurance Activities Plan, Weapons Quality Staff (WQS), Second Half of Fiscal Year 2003 (March 24, 2002)
- Quality Assurance Activities Plan, Chief, Safety, Health & Quality Staff, Fiscal Year 2004 (September 29, 2003)
- Training Plans
- Procedure Number 104.1.1, Proc4edure Development, Control and Issuance (January 13, 1999)

- BWXT Pantex, Quality Assurance Program Description, NML00079, Issue 6, September 2002
- Memo to C.J. VanArsdall III, acting Division Manager, Quality Assurance, BWXT Pantex LLC and S. W. Baker, Division Manger, Product Assurance & Certification, BWXT Pantex LLC from Karl Waltzer, Assistant Manger for Oversight & Assessments, Impact Analysis of Quality Assurance Functions (August 6, 2003)
- National Nuclear Security Administration (NNSA) Weapon Quality Division (NA-121.3) Quality Assurance Procedure Manual, Table of Contents
- MIC-1000, Issue 10, Management Integration & Controls S/RID (September 30, 2002)
- Procedure number 114.1.0, Revision 4, AAO Self Assessment Program (January 30, 2001)
- Procedure Number 110.2.1, Revision 3, Amarillo Area Office Assessment Program (June 15, 2000)
- Procedure Number 104.2.0, Revision 1, Records and Information Management System (January 13, 1999)
- Procedure Number 102.1.0, Revision 1, Training and Qualification Program (June 8, 1999)
- Memo to Virgil Hughes, Manager, Quality Assurance Division, BWXT Pantex LLC, from Michael Ulshafer, Chief, Weapons Quality Staff, Conditional Delegation of Stamping Authority to BWXT for All Remaining Programs (April 17, 2002)
- (OOU) Office of Amarillo Site Operations – Pantex Plant QAA Instruction List by Part (May 1, 2002)
- Letter to Michael Ulshafer, Chief, Weapons Quality Staff, from Virgil Hughes, Manager, Quality Assurance Division, BWXT Pantex LLC, Declaration of readiness for B83 Star Stamp Delegation Authority (January 9, 2002)
- Memo to W. R. From, Manager, Operations Quality, BWXT Pantex LLC from Michael Ulshafer, Chief, Weapons Quality Staff, Removal of Conditional Stamping Delegation Status for W87 Program (April 27, 2002)
- Proposed PEMP 2002 – Quality Assurance Expectations and PBIs (October 15, 2001)
- Incoming Material Reports (IMSS) Analysis FY2000 – FY 2002 (undated)
- Letter to Donald White, Deputy Manager, PXSO from William Mairson, Manager, Business Strategy & Services, Submittal for Impact Evaluation for *Quality Assurance Functions* (September 8, 2003)
- FY04 Business Systems Oversight Program (undated)
- DOE O 414.1A, Quality Assurance (September 29, 1999)
- 10CFR830 Subpart A Quality Assurance Program (QAP)
- DOE G 414.1-1A, Management Assessment and Independent Assessment Guide (May 31, 2001)
- DOE M 411.1-1B Insert title (May 22, 2001)
- ISO 9001, Quality Management Systems – Requirements, December 15, 2000)
- QC-1, Insert Title

- QAS 1.0 Survey AL-1-2003 PX-P-1, BWXT Pantex, (April 28 – May 2, 2003)

Interviews Conducted:

Site Office Manager
Assistant Manger for Oversight and Assessment
Chief, Safety, Health and Quality
Quality Specialist (3)

Observations:

None

Discussion of Results:

1. The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A)

This criterion was met.

The PXSO quality assurance program is defined and documented in Procedure Number 101.1.0, Revision 1, *Operations Quality Assurance Program*, dated May 13, 1999. As written, the procedure captures the required procedures and mechanisms to establish an effective management system.

The procedure captures PXSO approach to implementing quality assurance for each quality assurance criterion in DOE O 414.1. Even though it is not written to DOE O 414.1A, the procedures adequately cover all of the DOE O 414.1A criteria as they did not change between the two versions of the order. Specific areas of the procedure (and references) that were reviewed include the following:

- The application of the graded approach
- Organizational structure, functional responsibilities, levels of authority and interfaces for those managing, performing, and assessing work
- Personnel training and qualification
- Detection and prevention of quality problems
- Documents and records
- Corrective Action Management
- Management Assessment

Several of the documents that were reviewed were out of date [e.g., DOE, NNSA, and PXSO organizational changes have not been captured; DOE directive system references were out of date; referenced programs (e.g., training, tracking) were not current]. If the PXSO Quality Assurance Program was up to date the procedure would meet the requirements provided in DOE O 414.1A and 10CFR830 Subpart A.

Areas related to the implementation of QC-1 were also reviewed. The team reviewed a QAS 1.0 survey that was performed in May of 2003. Based on this information it was determined that a program is in place for PSXO to implement QA-1 requirements.

2. NNSA Site Office implementation of documented procedures and/or mechanisms included in the quality assurance program meets or exceeds the requirements of DOE O 414.1A/QC-1/10 CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

This criterion was not met.

The team's conclusion that this criterion was not met is based on their review of the implementation of Procedure Number 101.1.0, Revision 1, *Operations Quality Assurance Program*; documents referenced in procedure number 101.1.0; and interviews with personnel involved in the implementation of quality assurance. The team determined that several elements of the procedure and related documents were not currently implemented as written. Specific examples include the following:

- Procedure 101.1.0 and several referenced procedures are not current and require revision. This deficiency has been recognized by PXSO. A general initiative to review the PXSO procedures and update as necessary was identified as a priority by the PXSO Manger for FY 2003 and again in FY 2004.
- Selected procedures and implementing documents are not implemented as written. For example, Procedure 110.4.0, Issues Management and Tracking Program, describes a system by which an Issues Management Board (IMB) convenes to discuss and document high level issues on a regular basis. The process is not currently implemented and PXSO does not intend to reinstate this process. A second example is the PXSO FRAM. This document delineates safety management functions, responsibilities, and authorities. It includes provisions for revisions, but has not been revised to capture many significant NNSA and PXSO organizational changes.
- At the current time, Quality Assurance staffing is not sufficient to meet the requirements in the QAP. Several of the current functions described in procedure 101.1.0 were intended for a quality assurance engineer. PXSO is in the process of advertising to fill this vacancy. This deficiency is discussed in greater detail under the second objective of this review.
- Corrective action tracking is not systematically performed by PXSO. The Field Activities Data Base (FADB) is currently utilized by the Facility Representatives and CATS captures findings from OA assessments. The remainder of issues identified by PXSO subject matter experts and external organizations are tracked on an informal basis by selected subject matter experts. PXSO recognized this deficiency and discussed plans for utilization of a BWXT Pantex corrective action tracking system (ESTARS) when it becomes available in 2004.
- PXSO personnel have not received training on Procedure 101.1.0, rev. 1, *Operations Quality Assurance Program Procedure*, per the requirements in that procedure.

With respect to weapons quality, PXSO is in the process of discussing the transition of several quality assurance functions that are currently performed by PXSO quality assurance staff to BWXT Pantex. This transition is not complete and in the interim several quality assurance commitments have not been performed.

3. A process is established and effectively implemented to continuously improve efficiency and quality of operations. (DOE FRAM 9.6.2)

This criterion was not met.

PXSO does not have a documented process to document, track, and close corrective actions. CATS and the Field Activities Data Base capture some specific types of issues, but issues that are not covered by these systems are left to individual subject matter experts to manage. PXSO recognized this deficiency and discussed plans for utilization of a BWXT Pantex corrective action tracking system (ESTARS) when it becomes available in 2004.

The team did not find any systematic process to analyze or trend issues from various feedback sources to continuously improve operations. Lessons learned from external sources are reviewed and disseminated, but the process to do so is not formal or documented.

Conclusion:

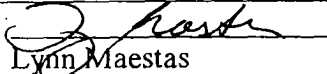
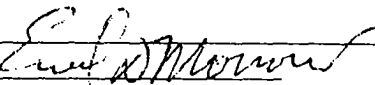
One of the three criteria were met. The PXSO quality assurance program needs to be revised and implemented.

Issues:

QA1-1: The PXSO quality assurance program is not implemented as written. The PXSO quality assurance program and associated supporting documents are not up to date and require revision.

QA1-2: A formal system is not in place to track the status of corrective actions.

QA1-3: A formal process is not in place to capture and disseminate lessons learned from external sources.

Inspector:  Lynn Maestas	Team Leader:  Emil Morrow Team Leader
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PXSO ASSESSMENT FORM 1

FUNCTIONAL AREA: QUALITY ASSURANCE	OBJECTIVE: 2	OBJECTIVE MET	
	DATE: November 4, 2003	YES X	NO

OBJECTIVE:

QA.2 PXSO procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program (QAP). (DOE G 450.4-1A, CCE-6, CCE-10 and CCE-11, DOE O 414.1A/QC-1/10CFR830 Subpart A and DOE P450.5).

CRITERIA:

1. The quality assurance program for PXSO oversight of the contractor meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A)
2. PXSO procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with DOE O 414.1A, Contractors Requirements Document, DOE 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)
3. PXSO has approved the contractor QAP and PXSO procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the PXSO for review and approval. (DOE FRAM 9.5.3, DOE O 414.1A)

Records Reviewed:

- Letter to Sue Pererson, Office of Price-Anderson Enforcement, from William Mairson, Manager, Business Strategy and Services, BWXT Pantex, entitled "Quality Assurance Program Description, MNL00079, Issue 6 (February 18, 2003)
- Memo to Virgil Hughes, Manager, Quality Assurance Division, BWXT Pantex, from Michael Ulshafer, Chief, Weapons Quality Staff, PXSO, entitled "Quality Assurance Program Description, MNL-00079, Issue 6 (January 8, 2003)
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- Procedure Number 102.1.0, Revision 1, Training and Qualification Program (June 8, 1999)
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- FY04 Business Systems Oversight Program (undated)
- DOE O 414.1A, Quality Assurance (September 29, 1999)
- 10CFR830 Subpart A Quality Assurance Program (QAP)
- DOE G 414.1-1A, Management Assessment and Independent Assessment Guide (May 31, 2001)
- DOE M 411.1-1B Insert title (May 22, 2001)
- ISO 9001, Quality Management Systems – Requirements, December 15, 2000)
- QC-1, Insert Title

- QAS 1.0 Survey AL-1-2003 PX-P-1, BWXT Pantex, (April 28 – May 2, 2003)
- Memo for Manager, Pantex Site Office from Col. Schmidt, "Fy-04 Quality Assurance Activities Plan Comments", undated.

Interviews Conducted:

Site Office Manager
Assistant Manger for Oversight and Assessment
Chief, Safety, Health and Quality
Quality Specialist (3)

Observations:

None

Discussion of Results:

1. The quality assurance program used for PXSO oversight of the contractor meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A)

The criterion was met.

As identified in Criterion 2 of Objective QA.1, the PXSO FRAM and procedures were out-of-date and do not reflect the current QA organization and practices. However, sufficient elements of PXSO processes were evident and there was sufficient detail to judge that this criterion was met.

Individuals interviewed in the areas described above demonstrated a good knowledge of the requirements for an effective Quality Assurance Program and where PXSO procedures required update

2. PXSO procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with the DOE O 414.1A *Contractors Requirements Document*, DOE O 414.1A/QC-1/10CFR30 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

This criterion was not met.

A review of PXSO current staffing in the QA area and discussions held during interviews indicated that the staffing was insufficient to carry out PXSO responsibilities. The QA staff consisted of 11 persons two years ago, and now consists of three persons. Of particular concern to the team is that there was no quality engineer currently on the staff. The lack of a quality engineer results in no on-site resource for conducting certain quality reviews (QAS 2.0, QAS 3.0).

The effect of the reduction in QA staff was apparent in a review of the FY 2003 Quality Assurance Activities plan. Of the 15 QAS 3.0 surveys assigned in the plan, only four were completed at mid-year. Of the 245 QAS 4.0 surveys assigned, only 87 were completed by mid-year. The mid-year adjustment to the plan decreased the amount of surveys to be done for the year and noted that the loss of quality engineers had reduced the QAS 3.0 survey performance. Additionally, the Quality Assurance Activities Plan for FY 2004 lists far fewer surveys to be conducted than the previous year. Exacerbating this issue is that it is not clear what constitutes a proper level of oversight in this area. Expectations and guidance from Headquarters would be helpful in this regard.

In his review of the FY 2004 plan, NA-121.3 stated:

“The PXSO FY04 Quality Assurance Activities Plan describes a change in PXSO staff as well. Reducing QA engineers to zero impacts the NNSA Product Acceptance at Pantex Plant in that some QA functions must be completed by engineers. These functions may remain uncompleted and this situation is counter to current QAPM requirements and the process that that stamping delegation was granted.”

From discussions during interviews and the team’s review of the requirements, it appears that a QA staff of two quality engineers and 4-5 quality specialists would be adequate. The team recognizes that it could not spend a great deal of time on this analysis and that a more detailed analysis could yield a different number. A more detailed analysis should be conducted with input from NA-121.3 as to what constitutes a proper level of oversight in this area. Nevertheless, the team is convinced that, at least, one quality engineer must be added to the QA staff.

3. PXSO has approved the contractor QAP and PXSO procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the PXSO for review and approval. (DOE FRAM 9.5.3, DOE O 414.1A)

This criterion was met.

The current QAP was properly approved. A revised QAP for next year is currently under review. PXSO is being assisted by the NNSA Service Center in the review of this document.

Conclusion: Two of the three criteria for this objective have been met. The team was uncomfortable with the current level of QA staffing at PXSO.

Issues:

QA2-1: PXSO currently has no quality engineers assigned to the staff. PXSO should pursue adding a quality engineer to the staff as soon as possible.

QA2-2: The QA staff appears to be understaffed. A careful analysis should be conducted to ensure that the staff is properly sized to ensure weapon product and conduct oversight.

QA3-3: NNSA Headquarters should provide expectations and guidance to PXSO with regard to oversight in order to assist the Site Manager with the QA staffing analysis.

Inspector: <u>Emil P. Morrow</u> Emil Morrow	Team Leader: <u>Emil P. Morrow</u> Emil Morrow Team Leader
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SEPARATION

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Department of Energy
National Nuclear Security Administration
Service Center



11-21-2003

Memorandum For: Ralph E. Erickson, Director LASO
From: Richard Crowe, Manager ES&HD
Subject: Los Alamos Site Office (LASO), On-Site Quality Assurance Program Review Final Report

The NNSA Service Center, Environment, Safety, and Health Department would like to thank those who supported our efforts during the On-Site Quality Assurance Program Review, which was recently performed at the Los Alamos Site Office (LASO).

This review focused on the following two objectives:

- NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program.
- LASO procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program.

As a result of this review the following issues were identified and discussed with assigned counterparts during the review closeout, which was performed on November 19, 2003. These issues are supported using the eight criteria to measure how well the two objectives were being fulfilled.

QA.1-1 The Site Office does not have an approved QAP as required by DOE O 414.1A, Quality Assurance.

QA.1-2 The Site Office FRAM is out of date and does not reflect the current organization.

QA.1-3 Some of the procedures required to implement an adequate QA program have not been identified, written, and implemented.

QA.1-4 A process for continuous improvement is not established and implemented.

QA.2-1 LASO has not developed a formal QA Program for oversight of the contractor.

QA.2-2 LASO procedures and or mechanisms in place do not meet all of the general requirements listed under DOE 414.1A, Attachment I, Contractors Requirements Document (CRD), reference sections 1, 3, 5, and 6 (section 4 was not reviewed).

QA.2-3 LASO has not reviewed or approved a contractor Institutional QAP, as required by DOE O 414.1A and 10 CFR 830.121.

QA.2-4 LASO has not reviewed or approved a contractor Institutional QAP. QA procedures for review of LANL's QAP have not been developed.

If you have any question concerning this subject or need further information on the attached final report, please contact Johnnie Nevarez at (505) 845-6142.

Original Signed By
Albert MacDougall
11/21/2003

Richard Crowe
Manager,
Environmental, Safety, and Health Department

cc w/attachment:

D. Martinez, LASO
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J. Nevarez, SRD



SERVICE CENTER

OFFICE OF TECHNICAL SERVICES

ENVIRONMENT, SAFETY, AND HEALTH DEPARTMENT

ON-SITE QUALITY ASSURANCE PROGRAM

FINAL REPORT

FOR THE

LOS ALAMOS SITE OFFICE (LASO)

November 2003

Final Report Approval

A handwritten signature in black ink, appearing to be 'R. Crowe', written over a horizontal line.

Richard Crowe, NNSA Team Leader

A handwritten signature in black ink, appearing to be 'Johnnie Q. Nevarez', written over a horizontal line.

Johnnie Q. Nevarez, NNSA Team Member

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PURPOSE

As part of a Defense Nuclear Facilities Safety Board (DNFSB) commitment, the Department of Energy has initiated a Quality Assurance (QA) Lessons Learned and Best Practices process involving many of the National Laboratories, and NNSA Site Offices. This was initiated in response to a letter from the DNFSB dated December 1, 1999. As part of this initiative, DP-1 issued a memorandum on October 11, 2000, which established a process to review and resolve Defense Program (DP) QA concerns across the complex.

The on-site review of the Los Alamos Site Office (LASO) was conducted during the week of November 17th, 2003. This review was done in accordance with the Criteria Review and Approach Documentation (CRAD)s identified within the document titled, *NNSA Service Center Office of Technical Services, Environment, Safety and Health Department, On-Site Quality Assurance Program Review Plan for the Los Alamos Site Office (LASO)*, dated November 13th, 2003.

The purpose of this review was to determine how well the LASO has established and implemented the key elements of a QA Program within their processes, which oversee and authorize work activities for the Los Alamos National Laboratory (LANL).

RESULTS OF THE REVIEW

The Objectives of the review are summarized below including issues noted. Details of the review are in Attachment A.

NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program.

Although required by DOE O 414.1A, the Site Office does not have an approved QAP. A draft Quality Assurance Program Manual (QAPM) has been prepared as part of the ISO 9000 effort but this document is not scheduled for approval and implementation until 2005. The Site Office FRAM (AL 1120) is out of date. As a result of the issuance of the NNSA FRAM in October, 2003, the Senior Safety Advisor has been directed to develop a Site Office FRAM by January, 2004. Many of the QA implementing procedures are yet to be written and implemented. The Site Office QA Program does not meet the requirements due to the lack of an approved QAP, up to date FRAM, and complete set of implementing procedures.

The areas of issues management, self-assessments, and lessons learned were reviewed. Although an issues management procedure is still in effect for the Office of Facilities Operations, implementation was discontinued in 2002. A LASO self-assessment program is not

in place. Review of procedures and interviews indicate that a formal lessons learned program does not exist in the Site Office.

ISSUES:

- QA.1-1 The Site Office does not have an approved QAP as required by DOE O 414.1A, Quality Assurance.
- QA.1-2 The Site Office FRAM is out of date and does not reflect the current organization.
- QA.1-3 Some of the procedures required to implement an adequate QA program have not been identified, written, and implemented.
- QA.1-4 A process for continuous improvement is not established and implemented.

LASO procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program.

It was determined during this review that LASO is making progress in developing procedures and mechanisms to be used to evaluate the effectiveness of the LANL QAP. LASO has performed oversight reviews that demonstrate their oversight functions regarding LANL's QA processes. Issues identified during this review identify the need to comply with DOE O 414.1A and 10 CFR 830 Subpart A, in directing and instituting a QAP within the Contractor organization.

LASO has performed several independent assessments regarding LANL's QA processes. In addition, the assessment performed in September 2001 was a follow-up assessment to the DOE HQ QA Best Practice Review, March 2001.

ISSUES:

- QA.2.1 LASO has not developed a formal QA Program for oversight of the contractor. Reference QA1.1 of this report.
- QA.2.2: LASO procedures and or mechanisms in place do not meet all of the general requirements listed under DOE 414.1A, Attachment I, Contractors Requirements Document (CRD), reference sections 1, 3, 5, and 6 (section 4 was not reviewed).
- QA.2.3: LASO has not reviewed or approved a contractor Institutional QAP, as required by DOE O 414.1A and 10 CFR 830.121.
- QA.2.4: Reference QA.2.3. LASO has not reviewed or approved a contractor Institutional QAP. QA procedures for review of LANL's QAP have not been developed.

ATTACHMENT A

LASO QA ASSESSMENT FORM

QUALITY ASSURANCE

CRITERIA MET: No

OBJECTIVE: QA.1

NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program. (DOE G 450.4-1A CCE-4, CCE-6, CCE-10 and CCE-11, DOE O 414.1A and DOE P450.5)

CRITERIA

QA 1.1: The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O414.1A)

QA 1.2: NNSA Site Office procedures and/or mechanisms ensure the implementation of a quality assurance program that meets or exceeds the requirements of DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

QA 1.3: A process is established and effectively implemented to continuously improve efficiency and quality of operations. (DOE FRAM 9.6.2)

1. PROCESSES OBSERVED:

None

2. RECORDS REVIEWED:

- NNSA Los Alamos Site Office Quality Assurance Program Manual, Rev 0, Draft A, August 22, 2003
- NNSA Federal ISO Certification Schedule, 6/27/03
- Safety Management Functions, Responsibilities, and Authorities Manual (NNSA FRAM), October 15, 2003
- Integrated Safety Management System Description, U.S DOE, LAAO, May, 2000
- DOE Order 414.1A, Quality Assurance
- DOE AL FRA Database AL 1120, LAAO
- LASO Procedure MP 4.1, Preparation and Maintenance of OLASO Procedures, October 1, 2002
- LASO Procedure MP 10.1, Independent Assessments, November 19, 2002
- LASO Procedure MP 4.2, Document Review, November 19, 2002
- LASO Procedure MP 1.1, Integrated Project Team, Roles and Responsibilities, November 19, 2002
- LASO Procedure OA-2001, QA Reviews, Surveillances, Audits, and Corrective Action Disposition, April 23, 2001
- LASO Procedure OPM SI-4, Issues Management, March 30, 2000

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- LASO Procedure OPM SI-9, Required Reading Program, May 5, 2000
- LASO Procedure OPM SI-11, Technical Representative Safety and Health Team Program Management, February 15, 2000
- Final Corrective Action Plan to the OA March, 2002 Assessment, Actions 2/2 and 2/5
- Office of Los Alamos Operations FY 2002 Operational Plan
- Corrective Action Completion Package for OA Review Action 2/2

3. INTERVIEWS CONDUCTED:

- Assistant Manager, Facilities Operations
- Assistant Manager, Project Management
- Senior Safety Advisor
- QA Engineer
- QA Consultant
- Program Manager for Industrial Hygiene

4. DISCUSSION / OBSERVATIONS:

QA 1.1 The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O414.1A)

Although required by DOE O 414.1A, the Site Office does not have an approved QAP. A draft Quality Assurance Program Manual (QAPM) has been prepared as part of the ISO 9000 effort but this document is not scheduled for approval and implementation until 2005. The draft QAPM as written contains the basics of an adequate QAP but states that the Site Office QA Program includes a Site Office Functions, Responsibilities, and Authorities Manual and the LASO Procedures System.

The Site Office FRAM (AL 1120) is out of date. The Los Alamos Area Office Integrated Safety Management System Description approved in May 2000 lists some roles and responsibilities but it is out of date. As a result of the issuance of the NNSA FRAM in October, 2003, the Senior Safety Advisor has been directed to develop a Site Office FRAM by January, 2004.

The QAPM says the LASO Procedures System describes the "how" for the QAPM. Many of these implementing procedures are yet to be written and implemented.

The Site Office QA Program does not meet the requirements of the cited references due to the lack of an approved QAP, up to date FRAM, and complete set of implementing procedures.

This criterion was not met.

QA 1.2 NNSA Site Office procedures and/or mechanisms ensure the implementation of a quality assurance program that meets or exceeds the requirements of DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

The procedures used to implement the QA criteria were reviewed. Some procedures have been identified, a smaller number of these have been written, and an even smaller number have been

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approved and implemented. A comprehensive list of all the procedures needed to implement an adequate QA program has not been developed.

This criterion was not met.

QA 1.3 A process is established and effectively implemented to continuously improve efficiency and quality of operations. (DOE FRAM 9.6.2)

The areas of issues management, self-assessments, and lessons learned were reviewed. Although an issues management procedure is still in effect for the Office of Facilities Operations, implementation was discontinued in 2002. The OLASO FY 2002 Operational Plan has an action to "Develop and implement effective and auditable oversight reporting, tracking, and trending tools". There is no Site Office issues management program or procedure. This was identified in an OA assessment in 2002 but the corrective action has been delayed until April, 2004.

Site Office Procedure OA-2001, requires all Assistant Directors, Project Managers, and Team Leaders to conduct self-assessments at least annually. The only evidence of this requirement being met is in the Facility Representative Program. This was identified in the 2002 OA assessment. Although the corrective action to the OA assessment is noted as complete, the deliverable, OLASO Procedure MP 10.1, Independent Assessments, does not address self-assessments. A LASO self-assessment program is not in place.

Review of procedures and interviews indicate that a formal lessons learned program does not exist in the Site Office. Some lessons are shared but it appears to be sporadic.

A process for continuous improvement is not established and effectively implemented.

This criterion was not met.

ISSUES:

QA.1-1 The Site Office does not have an approved QAP as required by DOE O 414.1A, Quality Assurance.

QA.1-2 The Site Office FRAM is out of date and does not reflect the current organization.

QA.1-3 Some of the procedures required to implement an adequate QA program have not been identified, written, and implemented.

QA.1-4 A process for continuous improvement is not established and implemented.

5. **ASSESSED BY:** Richard Crowe

DATE: November 19, 2003

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CRITERIA MET: No

OBJECTIVE : QA.2

LASO procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program. (DOE G 450.4-1A CCE-4, CCE-6, CCE-10 and CCE-11, DOE O 414.1A/QC-1/10CFR830 Subpart A and DOE P450.5)

CRITERIA

QA.2.1: The QA Program used for LASO oversight of the contractor meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A and DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A.

QA.2.2: LASO procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with the DOE 414.1A *Contractors Requirements Document*, DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

QA.2.3: LASO has reviewed and approved the contractor QAP.

QA.2.4: LASO procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the LASO for review and approval. (DOE FRAM 9.5.3, DOE 414.1A)

QA.2.5: LASO has taken appropriate actions in the closure of findings or issues documented under the QA Lessons Learned and Best Practices Review, performed at LANL, March 2001. As referenced by DOE Memorandum Erickson to Site Managers, October 30, 2001, subject "Results and Future Actions For Complex Wide QA Reviews At Defense Nuclear Facilities".

1. PROCESSES OBSERVED:

No field process observed.

2. RECORDS REVIEWED:

- LASO, Office of Facility Operations Standing Instruction 11, Subject Matter Expert, Line Management Oversight Safety and Health Team, Rev. 4, February 28, 2003
- LASO, Office of Facility Operations Standing Instruction 2, Contractor Appraisal, Rev. 4, October 1999
- LASO Annual Assessment Planning Matrix, Rev 2.0, October 2002
- LASO Annual Assessment Planning Matrix, Rev 0, 2003
- LASO Facility Operations FY 2003 Appraisal/Assessment Plan, (DOE O 450.5, "Line ES&H Oversight).
- LASO FR Standing Instruction 004, Issues Management, Rev. 0
- OLASO Management Procedure, Preparation and Maintenance of OLASO Procedures, MP 4.1, Rev. 0, October 1, 2002
- OLASO Management Procedure, Document Review, MP 4.2, Rev. 0, November 19, 2002
- OLASO Management Procedure, Independent Assessments, MP 10.2, Rev. 0, November 19, 2002
- OLASO Management Procedure, Integrated Project Teams, Roles and Responsibilities, MP 1.1, Rev. 0, November 19, 2002

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- OLASO Management Procedure, Suspect/Counterfeit Items, MP 5.1, Rev. 0, October 1, 2002
- LASO Quality Assurance Policy Statement, May 19, 2003
- LASO Quality Assurance Manager, Memorandum OPM-7JC-0003-0008, May 20, 2003
- LANL Performance Surety Division, Institutional Quality Management Implementation Plan, IQMIP-RO, April 16, 2003
- LANL Institutional Quality Management Program Description, Rev. 0, LA_UR-03-2355, March 30, 2003

3. INTERVIEWS CONDUCTED:

- Assistant Manager, Facility Operations
- Assistant Manager, Project Management
- Senior Science Advisor
- Industrial Hygienist
- Quality Assurance Support Contractor
- Quality Assurance Engineer

4. DISCUSSION / OBSERVATIONS:

QA.2.1: The QA Program used for LASO oversight of the contractor meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10 CFR 830 Subpart A and DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A.

Reference issues identified under Objective QA.1 of this report, which states that LASO has not developed a QAP.

Even though LASO has not developed a QAP or an up to date FRAM, there are procedures in place that are used to assess LANL's progress in QA processes. Reference discussion below under QA.2.2.

This criterion was not met.

QA.2.2: LASO procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with the DOE O 414.1A *Contractors Requirements Document*, DOE O 414.1A/QC-1/10 CFR 830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

LASO procedures and or mechanisms in place do not meet all of the general requirements listed under DOE O 414.1A, Attachment I, Contractors Requirements Document (CRD), reference sections 1, 3, 5, and 6 (section 4 was not reviewed).

For example under the CRD, LASO is to ensure that the Contractor has performed the following:

CRD General Requirement 1: Assign and identify the senior management position responsible for Quality Assurance Program (QAP) development, implementation, assessment, and improvement.

During interviews and document reviews there seems to be no supporting documents to conclude that there was clear direction from LASO to assign this responsibility to LANL. During the review, the

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LANL Performance Surety Division, Institutional Quality Management Implementation Plan, IQMIP-RO, was presented as an effort to meet this requirement. After further review, only concurrence was provided by LASO on this document. There was no forwarding NNSA memorandum identified to support this concurrence, or to provide further guidance or direction to meet the CRD requirement.

CRD General Requirement 2: Develop a QAP for the work as specified in its contract by applying the quality assurance criteria specified in Paragraph 2 below. The QAP must— (a) discuss how the QA criteria will be satisfied; (b) use a graded approach to apply the QA criteria; (c) describe how the graded approach will be applied; (d) integrate and satisfy quality requirements from sources other than Paragraph 2; (e) integrate the QA criteria with the safety management system (SMS) description developed for 48 Code of Federal Regulations (CFR) 970.5204-2, or describe how the QA criteria will be applied to the SMS; (f) describe how the QA criteria will be applied to subcontractors and suppliers.

LASO has concurred on a LANL Performance Surety Division, Institutional Quality Management Implementation Plan, IQMIP-RO, which will be used to develop the LANL QAP. As stated above, during document reviews and interviews there seems to be a lack of clear guidance from LASO to LANL directing them to develop the LANL QAP as required by DOE O 414.1A.

CRD General Requirement 5: Determine the subcontractors and suppliers to whom the QA criteria will be applied.

In discussion and document reviews it was not clear how LASO or LANL has met this requirement. In reviewing the LANL IQMIP, there is no discussion regarding subcontractors or suppliers, or the application of the QA criteria.

CRD General Requirement 6: Submit the QAP to the Department of Energy (DOE) for approval prior to starting work under the contract or as specified by DOE.

LANL does not have an approved QAP, see discussion under QA.2.3

CRD General Requirement 2: Implement the quality assurance criteria in a manner sufficient to achieve adequate protection of the workers, the public, and the environment, taking into account the work to be performed and the associated hazards.

The following identifies a sampling of procedures are used by LASO to assess LANL's ability to ensure safety to the worker, the public, and the environment:

LASO, Office of Facility Operations Standing Instruction 11, Subject Matter Expert, Line Management Oversight Safety and Health Team, Rev. 4, February 28, 2003 and Office of Facility Operations Standing Instruction 2, Contractor Appraisal, Rev. 4, October 1999. The scope and applicability of these procedures provide guidance to the LASO Office of Facility Operations (OFO) staff in how to plan, perform, and document LANL assessments. Included is reference to the "Annual Appraisal Plan", and Facility Representatives Daily, Weekly, Monthly, and Quarterly Routines.

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In reviewing the FY03 and 04 Annual Appraisal Plans, there was documented evidence to support the fact that OFO performed LANL assessments regarding several of the QA criteria, specifically design, procurement and records management. The Annual Appraisal Plans are a compilation of all LASO appraisals performed at LANL, which are coordinated within LASO organizations, and with counterparts at LANL.

Issues identified by the LASO OFO are documented in Quarterly Reports, individually tracked and verified to closure, as per the OFO Standing Instruction 002, Contractor Appraisal procedure, and OFO Standing Instruction 004, Issues Management.

In reviewing these procedures improvements are needed in updating some of the more recently acquired positions, which are within OFO. For example, OFO Standing Instruction 11, Line Management Oversight does not identify any functions relating to the Maintenance Program Engineer, who has oversight responsibilities for the contractors Vital Safety System programs.

Two other LASO procedures that are used as oversight documents include Independent Assessments, MP 10.2, Rev. 0 and Integrated Project Teams, Roles and Responsibilities, MP 1.1, Rev. 0. Both procedures identify roles and responsibilities regarding independent reviews and assessments based on QA requirements and DOE O 450.5.

With the lack of an approved LANL QAP, this criterion was not fully met.

.2.3: LASO has reviewed and approved the contractor QAP.

LASO has not reviewed or approved a contractor Institutional QAP. During interviews and in document reviews it was noted that LANL does not have an NNSA approved QAP, as required by DOE O 414.1A and 10 CFR 830.121.

The requirement cited under 10 CFR 830.121.(b) is as follows: *(1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date. (2) Modify the QAP as directed by DOE. (3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements.* This requirement has not been met.

In place of a LANL QAP, LANL has Laboratory Program Requirement (LPR) there is a QA Policy, 308-00-00.1, and several other QA procedures in place to institute elements of QA program. LASO has identified this as an issue, and has been working with LANL in the development of a QAP.

Under LASO concurrence LANL has developed a Institutional Quality Management Implementation Plan (reference document LANL Performance Surety Division, Institutional Quality Management Implementation Plan, IQMIP-RO, April 16, 2003), and a Program Description Document (reference LANL Institutional Quality Management Program Description, Rev. 0, LA_UR-03-2355, March 30, 2003).

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However, in reviewing the IQMIP-RO it was noted that the document failed to have firm commitments regarding schedules and deliverables for implementation. The document does not assign ownership to ensure that the ten elements are developed and implemented. Assignment to the Institutional Quality Management Team is vague and lead responsibilities reside under the Quality Steering Group Members who are not identified by organization or title. In addition, Attachment D, Primavera Schedule, was not included. Further discussion identified that this schedule was difficult to obtain based on LANL's inability to make firm commitments or assignment by title and organization.

This criterion was not met.

QA.2.4: LASO procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the LASO for review and approval. (DOE FRAM 9.5.3, DOE 414.1A)

Reference QA.2.3. LASO has not reviewed or approved a contractor Institutional QAP. During interviews and in document reviews it was noted that LANL does not have an NNSA approved QAP, as required by DOE O 414.1A and 10 CFR 830.121.

This criterion was not met.

QA.2.5: LASO has taken appropriate actions in the closure of findings or issues documented under the QA Lessons Learned and Best Practices Review, performed at LANL, March 2001. As referenced by DOE Memorandum Erickson to Site Managers, October 30, 2001, subject "Results and Future Actions For Complex Wide QA Reviews At Defense Nuclear Facilities".

LASO performed an independent assessment of LANL's Implementations of DOE O 420.1 and 414.1, which was completed in September 2001. This review did provide for a more in-depth review of the CMRU project at LANL, which was the focus of the review cited above. Findings, which were identified, are being tracked and verified to closure by LASO.

This criterion was met.

ISSUES:

- QA.2.1: LASO has not developed a formal QA Program for oversight of the contractor. Reference QA1.1 of this report.
- QA.2.2: LASO procedures and or mechanisms in place do not meet all of the general requirements listed under DOE 414.1A, Attachment I, Contractors Requirements Document (CRD), reference sections 1, 3, 5, and 6 (section 4 was not reviewed).
- QA.2.3: LASO has not reviewed or approved a contractor Institutional QAP, as required by DOE O 414.1A and 10 CFR 830.121.

QUALITY ASSURANCE

QA.2.4: Reference QA.2.3. LASO has not reviewed or approved a contractor Institutional QAP. QA procedures for review of LANL's QAP have not been developed.

5. **ASSESSED BY:** Johnnie Q. Nevarez

DATE: November 18, 2003

SEPARATION

PAGE

NSO Quality Assurance Audit Summary

A Quality Assurance Audit of the Nevada Site Office was conducted on November 20-12, 2003. The audit was conducted to fulfill a commitment made to the Defense Nuclear Facilities Safety Board in the Secretary of Energy's Quality Assurance Implementation Plan. The team noted two Opportunities for Improvement (OFI). NSO personnel should review the detailed discussions in the Forms One attachment to ensure a full understanding of the items discussed in the below paragraphs.

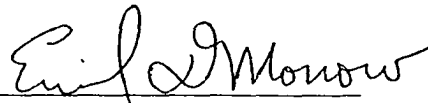
The objectives of the two Criteria, Review, and Approach Documents were not met. Five of the six criteria were not met.

OFI-1: NSO must establish a Quality Assurance Program (QAP) as required by DOE O 414.1A. NSO, in conjunction with the contractor, did conduct a rigorous self-assessment of quality assurance in July-August of this year. A Corrective Action Plan, based on the self-assessment, has been promulgated. The plan is good and should help NSO establish a QA program. However, NSO should request additional QA expertise to assist them in developing the processes and mechanisms for an effective QA program.

OFI-2: The completion of the Technical Qualification Program for the staff's Quality Assurance Safety Management Specialist should be completed on a priority basis. Sixteen of the 24 competencies in the Quality Assurance Standard have not been completed. Fourteen of the remaining competencies require a working level knowledge of the subject material and, additionally, four of the remaining competencies require formal training courses.



Paul Chimah
Team Member 11/21/03



Emil D. Morrow
Team Leader 11/21/03

NSO ASSESSMENT FORM 1

FUNCTIONAL AREA: QUALITY ASSURANCE	OBJECTIVE: 1 DATE: November 21, 2003	OBJECTIVE MET	
		YES	NO X

OBJECTIVE:

QA.1 NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P 450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program. (DOE G 450.4-1A CCE-4, CCE-6, CCE-10 and CCE-11, DOE O 414.1A and DOE P 450.5)

CRITERIA:

1. The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A)
2. NNSA Site Office implementation of documented procedures and/or mechanisms included in the quality assurance program meets or exceeds the requirements of DOE O 414.1A/QC-1/10 CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)
3. A process is established and effectively implemented to continuously improve efficiency and quality of operations. (DOE FRAM 9.6.2)

Records Reviewed:

- Organization Chart, Nevada Site Office, October 20, 2003
- Safety Management Functions, Responsibilities, and Authorities Manual (NNSA FRAM), October 15, 2003
- Functions, Responsibilities and Authorities Manual, NV M 111.XB, July 3, 2003
- Position Description, Quality Assurance Safety Management Specialist
- Physical Scientist in Training Two Year Training Plan/Agreement, December 3, 2002
- DOE O 414.1A, Quality Assurance, with Change 1, July 12, 2001
- 10 CFR 830, Nuclear Safety Management
- DOE/NNSA Quality Management Policy (QC-1), Rev 10, June 30, 2003
- Nevada Site Office NV 10XE.1A, Quality Management, October 12, 1995
- Nevada Site Office, NV M 10XE.1A-1, Quality Management Manual, October 12, 1995

- Nevada Site Office, NV M 220.XC, NNSA/NSO Oversight Management System, October 20,2003
- Bechtel Nevada ltr of September 11, 2003, Subject: Bechtel Nevada (BN) Process Description PD-0001.002, Quality Assurance Program (QAP), Revision 3
- Quality Assurance Review of the Nevada Site Office and Bechtel Nevada, July 28 – August 7, 2003
- Nevada Site Office NV M 414.X, Quality Assurance Program, draft
- Manager, NSO ltr of January 16, 2003, Approval of Bechtel Nevada (BN) Process Description PD-0001.002, Quality Assurance Program (QAP), Revision 2

Interviews Conducted:

Site Office Manager
 Deputy Assistant Manager for National Security
 Assistant Manager for Safety and Security Programs
 Director, Environment, Safety and Health Division
 Director, Performance Assurance Division
 Senior Program Manager
 Director, Facility Representative Division
 Quality Assurance Safety Management Specialist
 Training Manager

Observations:

None

Discussion of Results:

1. The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A)

This criterion was not met.

The requirement in DOE Order 414.1A ;(4)(b)(1) and 830 Subpart A;(c)(1)(i) is “The QAP must describe management processes, including, planning, scheduling, and resource considerations.” The Quality Assurance Program(QAP) must describe how the QA Criteria are satisfied. Management must define the work to be performed. Because all items, processes and services do not have the same impact on safety and reliability the rigor with which the quality assurance program is applied must be determined using a graded approach. The NNSA/NSO has yet to develop the site specific QAP Document in order to meet DOE requirements. Further, it is required that the organization implement and maintain a written Quality Assurance Program (QAP). The QAP shall describe the organization structure, functional responsibilities, level of authority and interface. The current Manual NV M414.X “Quality Assurance Program” describes the NSO Quality Management System which uses criteria from ISO 9001 for functions performed by federal personnel. This document should include a crosswalk

between DOE 414.1A and ISO 9001. Also how the document is going to satisfy QC-1 requirements should be addressed.

2. NNSA Site Office implementation of documented procedures and/or mechanisms included in the quality assurance program meets or exceeds the requirements of DOE O 414.1A/QC-1/10 CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

This criterion was not met.

The team's conclusion that this criterion was not met is based on review of supporting procedural documents. The NSO has not developed the Quality Assurance Program document and its implementation documents to indicate schedules and milestones for the implementation of the NSO QAP. When the QAP is developed, other procedures may be required to be developed with links to the QAP.

Selected procedures are being revised at this date, such as NV M414.X DMC "Quality Assurance Program" and "NSO, Self-Assessment Program," need to be updated as necessary to include comments from the recent assessment conducted by NSO and Bechtel Nevada.

NSO does not provide adequate oversight for fabrication, inspection, and testing of Bechtel Nevada fabricated items.

Not all NSO divisions have committed trained resources to focus on Quality Assurance for programmatic improvement.

At the current time, Quality Assurance staffing is sufficient to meet the requirements.

The federal functional responsibilities for contractor oversight associated with higher risk programmatic or support activities are not addressed.

NSO does not participate in contractor's design review as required by DOE O 414.1A. NSO needs to define management' expectations and NSO involvement in contractor/user design review and oversight activities.

3. A process is established and effectively implements continuous improvement. (DOE FRAM 9.6.2)

This criterion was not met.

NSO does not have feedback and improvement system in place for quality assurance.

NSO Issue Management needs improvement based on assessments conducted by NSO.

Issues from the assessments are not fed back into the continuous improvement process.

The team did not find any systematic process to analyze or trend issues from various feedback sources to continuously improve operations. The process in use is not formal or documented.

There is not an effective Lessons Learned program. During interviews personnel stated that there were not resources available to support a Lessons Learned program.

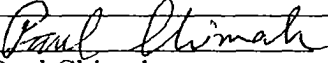
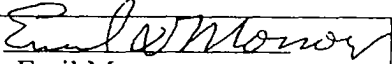
Conclusion:

The objective was not met. All three criteria were not met. The NSO Quality Assurance Program document needs to be developed and implemented.

Issues:

QA1-1: The NNSA/NSO does not have a documented Quality Assurance Program (QAP) The NSO quality assurance program and associated supporting documents are not up to date and some documents need to be developed.

QA1-2: A formal process is not in place to capture and disseminate lessons learned.

Inspector:  Paul Chimah	Team Leader:  Emil Morrow Team Leader
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NSO ASSESSMENT FORM 1

FUNCTIONAL AREA: QUALITY ASSURANCE	OBJECTIVE: 2 DATE: November 21, 2003	OBJECTIVE MET	
		YES	NO X

OBJECTIVE:

QA.2 NSO procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program (QAP). (DOE G 450.4-1A, CCE-6, CCE-10 and CCE-11, DOE O 414.1A/QC-1/10CFR830 Subpart A and DOE P450.5).

CRITERIA:

1. The quality assurance program for NSO oversight of the contractor meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A)

2. NSO procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with DOE O 414.1A, Contractors Requirements Document, DOE 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

3. NSO has approved the contractor QAP and NSO procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the NSO for review and approval. (DOE FRAM 9.5.3, DOE O 414.1A)

Records Reviewed:

- Organization Chart, Nevada Site Office, October 20, 2003
- Safety Management Functions, Responsibilities, and Authorities Manual (NNSA FRAM), October 15, 2003
- Functions, Responsibilities and Authorities Manual, NV M 111.XB, July 3, 2003
- Position Description, Quality Assurance Safety Management Specialist
- Physical Scientist in Training Two Year Training Plan/Agreement, December 3, 2002
- DOE O 414.1A, Quality Assurance, with Change 1, July 12, 2001
- 10 CFR 830, Nuclear Safety Management
- DOE/NNSA Quality Management Policy (QC-1), Rev 10, June 30, 2003
- Nevada Site Office NV 10XE.1A, Quality Management, October 12, 1995
- Nevada Site Office, NV M 10XE.1A-1, Quality Management Manual, October 12, 1995

- Nevada Site Office, NV M 220.XC, NNSA/NSO Oversight Management System, October 20, 2003
- Bechtel Nevada ltr of September 11, 2003, Subject: Bechtel Nevada (BN) Process Description PD-0001.002, Quality Assurance Program (QAP), Revision 3
- Quality Assurance Review of the Nevada Site Office and Bechtel Nevada, July 28 – August 7, 2003
- Nevada Site Office NV M 414.X, Quality Assurance Program, draft
- Manager, NSO ltr of January 16, 2003, Approval of Bechtel Nevada (BN) Process Description PD-0001.002, Quality Assurance Program (QAP), Revision 2

Interviews Conducted:

Site Office Manager
 Deputy Assistant Manager for National Security
 Assistant Manager for Safety and Security Programs
 Director, Environment, Safety and Health Division
 Director, Performance Assurance Division
 Senior Program Manager
 Director, Facility Representative Division
 Quality Assurance Safety Management Specialist
 Training Manager

Observations:

None

Discussion of Results:

1. The quality assurance program used for NSO oversight of the contractor meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A)

This criterion was not met.

The Quality Assurance Plan for NSO, NV M 10XE.1A-1 is outdated. The QAP was promulgated in October, 1995 and has not been revised as required by DOE O 414.1A when that order was issued in September, 1999. From discussions during interviews and review of records, it appears that the NSO QA program had been dormant until a year ago.

NSO, in conjunction with the contractor, did conduct a rigorous self-assessment of quality assurance in July-August of this year. A Corrective Action Plan, based on the self-assessment, has been promulgated. The plan is good and should help NSO establish a QA program. However, NSO should request additional QA expertise to assist them in developing the processes and mechanisms for an effective QA program.

2. NSO procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with the DOE O 414.1A *Contractors Requirements Document*, DOE O 414.1A/QC-1/10CFR30 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

This criterion was not met.

The draft of NV M 414.X, Quality Management Program, which is intended to replace the outdated QAP, is based on ISO 9001 and does not address DOE O 414.1A. The criteria used in the draft are ISO 9001 acceptance criteria. The requirements for DOE/NNSA QA programs are contained in DOE O 414.1A. NV M 414.X should be cross-walked against DOE O 414.1A to ensure that all requirements are captured in the new QA program.

During interviews, personnel stated that NSO was not conducting oversight of the national laboratories' operations as required in NV M 220.XC, NNSA/NSO Oversight Management System.

The Quality Assurance Safety Management Specialist is the person on NSO staff charged with QA responsibilities. The person currently in this position does not have a technical degree. A rigorous training program was developed to provide the technical expertise that is required. The required college technical courses have been completed. However, the person has not yet completed the Technical Qualification Program requirements. Sixteen of the 24 competencies in the Quality Assurance Standard have not been completed. Fourteen of the remaining competencies require a working level knowledge of the subject material and, additionally, four of the remaining competencies require formal training courses. NSO should pursue TQP completion for the Quality Assurance Safety Management Specialist as a priority.

3. NSO has approved the contractor QAP and NSO procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the NSO for review and approval. (DOE FRAM 9.5.3, DOE O 414.1A)

This criterion was met.

NSO approved revision 2 of the contractor's QAP on January 16, 2003. The contractor submitted revision 3 of the QAP on September 11, 2003. The Manager NSO has until December 11, 2003 to approve or reject revision 3 to the QAP.

Conclusion:

The objective was not met. Two of the three criteria were not met. The QA program at NSO had become dormant over time. NSO has conducted a recent self-assessment and developed a Corrective Action Plan that, when implemented, should establish a QA

program. Additional QA expertise should be used to assist NSO in establishing an effective QA program.

Issues:

QA2-1: NSO does not have a Quality Assurance Plan based on the requirements of DOE O 414.1A (See also QA 1-1).

QA2-2: The Quality Assurance Safety Management Specialist should complete the Technical Qualification Program as a matter of priority.

Inspector: <u>Paul Chimah</u> Paul Chimah	Team Leader: <u>Emil Morrow</u> Emil Morrow Team Leader
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QUALITY ASSURANCE

OBJECTIVE:

QA.1 NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program. (DOE G 450.4-1A CCE-4, CCE-6, CCE-10 and CCE-11, DOE O 414.1A and DOE P450.5)

CRITERIA:

1. The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O414.1A)
2. NNSA Site Office procedures and/or mechanisms ensure the implementation of a quality assurance program that meets or exceeds the requirements of DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

A process is established and effectively implemented to continuously improve efficiency and quality of operations. (DOE FRAM 9.6.2)

APPROACH

Record Review: Review the FRAM/FRA, 10 CFR 830 Subpart A, QC-1, appropriate DOE orders/manuals (e.g. DOE P450.4, DOE P450.5, DOE O 414.1A, and DOE G 414.1-2), and the OKSO QAP to determine if a Quality Assurance Program has been properly established in accordance with DOE 414.1A/QC-1.

Review approved NNSA Site Office procedures used to implement this QAP (e.g., administrative procedures, organizational charts, position descriptions, or internal memoranda) establish the roles, responsibilities, interfaces, and staffing levels for the quality assurance organization.

Interviews: Interview selected NNSA Site Office line managers and personnel assigned QA responsibilities to determine if they are familiar with their roles, responsibilities, and interfaces with respect to the NNSA Site Office QAP. Verify adequate knowledge of NNSA Site Office QA procedures.

Observations: Select a QA related self-assessment activity within NNSA Site Office organization and witness its performance by NNSA Site Office personnel, if possible or review a recent output from such a process.

QUALITY ASSURANCE

OBJECTIVE:

QA.2 NNSA Site Office procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program (QAP). (DOE G 450.4-1A CCE-4, CCE-6, CCE-10 and CCE-11, DOE O 414.1A/ QC-1/10CFR830 Subpart A and DOE P450.5)

CRITERIA:

1. The quality assurance program used for NNSA Site Office oversight of the contractor meets or exceed the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O414.1A)
2. NNSA Site Office procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with the DOE 414.1A *Contractors Requirements Document*, DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)
3. NNSA Site Office has approved the contractor QAP and NNSA Site Office procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the NNSA Site Office for review and approval. (DOE FRAM 9.5.3, DOE 414.1A)

APPROACH

Record Review: Review the FRAM/FRA, 10 CFR 830 Subpart A, QC-1, appropriate DOE orders/manuals (e.g. DOE P450.4, DOE P450.5, DOE O 414.1A, and DOE G 414.1-2), OKSO QAP, and NNSA Site Office implementing guidance to determine if a Quality Assurance Program has been properly implemented.

Review NNSA Site Office or Operations Support Office approval of the contractor's Quality Assurance Program. Determine if this approval reviewed the documentation (e.g., administrative procedures, organizational charts, position descriptions, or internal memoranda) that establish the roles, responsibilities, interfaces, and staffing levels for the quality assurance organization.

Interviews: Interview selected NNSA Site Office line managers and personnel assigned QA responsibilities to determine if they are familiar with their roles, responsibilities, and interfaces with respect to the NNSA Site Office QAP and oversight responsibilities toward the contractor's QAP. Verify adequate knowledge of NNSA Site Office QA oversight procedures.

Observations: Select a QA surveillance of the contractor and witness its performance by NNSA Site Office personnel.

SEPARATION

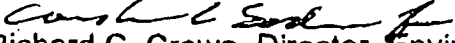
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Department of Energy
National Nuclear Security Administration
Service Center



12-22-2003

Memorandum For: Camille Yuan-Soo Hoo, Manager, LSO
 From: 
 Richard C. Crowe, Director, Environment, Safety and Health
 Department
 Subject: Transmittal of Report on the Livermore Site Office (LSO)
 Assessment of the LSO Quality Assurance Program (QAP)

This memorandum transmits the audit report on the LSO QAP (Enclosure). The audit is associated with a Department of Energy commitment to the Defense Nuclear Facilities Safety Board, and is intended to provide NNSA management with a status on Site Office programs, and to provide you with information on areas for improvement.

This review focused on the following two objectives:

- NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P 450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program.
- LSO procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program.

As a result of this review, the following issues were identified and discussed with assigned counterparts during the review closeout, which was performed on December 10, 2003. These issues are discussed in the report, in the context of the eight criteria used to measure how well the two objectives were being fulfilled.

QA-1.1/1 - LSO needs to revise its quality assurance program documentation to demonstrate that it meets all requirements identified in Paragraphs 4 and 5 of DOE O 414.1A and to address the current organization.

QA-1.3/1 - LSO needs to establish and implement a formal process for continuous improvement. QA.2.3/1 - LSO should take credit for reviews of LLNL directorate quality assurance programs by including them in the FISHE system.

QA.2.3/2 - LSO should document its process for reviewing LLNL quality assurance program documents.

The NNSA Service Center, Environment, Safety, and Health Department would like to thank those who supported our efforts during the On-Site Quality Assurance Program Review, which was recently performed at the LSO. If you have any question concerning this subject or need further information on the attached final report, please contact Paul Chimah at (505) 845-6362.

Attachment (1):

"Service Center Office of Technical Services Environment, Safety, and Health Department On-Site Quality Assurance Program Final Report for the Livermore Site Office (LSO)"

cc w/attachment:

P. E. Hill, LSO
S. J. Lasell, LSO
A. C. Cordis, LSO
R. C. Crowe, ESHD, GTN
C. L. Soden, ESHD, AL
P. Chimah, ESHD, AL
N. A. Morley, SRD, AL



SERVICE CENTER
OFFICE OF TECHNICAL SERVICES

ENVIRONMENT, SAFETY, AND HEALTH DEPARTMENT

ON-SITE QUALITY ASSURANCE PROGRAM


FINAL REPORT

FOR THE

LIVERMORE SITE OFFICE (LSO)

December 2003

Final Report Approval:



Paul Chimah, NNSA Team Leader

12-22-2003
Date



Nathan Morley, CQA, NNSA Team Member

12/22/2003
Date

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PURPOSE

As part of a Defense Nuclear Facilities Safety Board (DNFSB) commitment, the Department of Energy has initiated a Quality Assurance (QA) Lessons Learned and Best Practices process involving many of the National Laboratories, and NNSA Site Offices. This was initiated in response to a letter from the DNFSB dated December 1, 1999. As part of this initiative, DP-1 issued a memorandum on October 11, 2000, which established a process to review and resolve Defense Program (DP) QA concerns across the complex.

The on-site review of the Livermore Site Office (LSO) was conducted during the week of December 8, 2003. This review was done in accordance with the Criteria Review and Approach Documentation (CRAD) identified within the document titled, *NNSA Service Center Office of Technical Services, Environment, Safety and Health Department, On-Site Quality Assurance Program Review Plan for the Livermore Site Office (LSO)*, dated November 13, 2003.

The purpose of this review was to determine how well the LSO has established and implemented the key elements of a QA Program within their processes, which oversee and authorize work activities for the Livermore National Laboratory (LLNL).

RESULTS OF THE REVIEW

The Objectives of the review are summarized below including issues noted. Details of the review are in Attachment A.

Objective 1: NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P 450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program.

Although required by DOE O 414.1A, the Site Office does not have a documented quality assurance program that addresses the LSO organization as a result of the December 2002 NNSA reorganization. The overall program is described in two documents, *Oakland Operations/NNSA Quality Assurance Plan*, approved May 31, 2002, and the *Livermore Site Quality Assurance Program*, approved April 15, 2002, which provides site office specific requirements, but focuses on oversight of the Lawrence Livermore National Laboratory. These documents follow the 10 criteria required to be addressed for a quality assurance program by the general requirements paragraph of DOE O 414.1A, *Quality Assurance* [DOE O 414.1A, ¶4.a]. However, neither document identified a graded approach as required in the general requirements and there has not been a documented process established to identify how the guidance contained in DOE G 414.1-1A, G 414.1-2, and G 440.1-6 were used in developing the program.

LSO has a series of procedures, which they use to cover areas such as management and independent assessment, quality improvement, design, and procurement. However, like the

quality assurance program documentation they have not been updated to reflect current roles and responsibilities based on the new organizational structure.

Discussions with LSO personnel and review of the recently completed LSO Quality Assurance Self-Assessment indicates that they have identified that quality assurance documentation needs to be updated to address the revised organization and to address current processes through the quality assurance implementing documents. However, this effort has not taken place due to the organization adjusting to its new role, a change and higher-level priorities, and decisions on consolidating program documentation such as their Functions, Responsibilities, and Authorities Manual (FRAM) and their Integrated Safety Management (ISM) system description. In addition, LSO is also being asked to implement weapons quality and software quality assurance and to implement NNSA management's decision to use the ISO 9001:2000 standard as the method to implement DOE O 414.1A requirements at the same time.

LSO does not have a formal quality improvement process in place as outlined in "Oakland Operations/NNSA Quality Assurance Plan." LSO documents problems, but does not always identify the root cause of the problems and therefore does not always prevent recurrence of the problems. In addition, LSO has not formalized the feedback and improvement process. Lessons learned are not always incorporated into operations or operational oversight and the lessons learned process is not well documented or implemented. Review of procedures and interviews indicate that a formal lesson learned program does not exist in the Site Office. While lessons learned are sometimes shared, it appears even this part of the process is sporadic.

The criteria for this objective were identified as not being met. Therefore, the objective was not met.

ISSUES:

QA-1.1/1 LSO needs to revise its quality assurance program documentation to demonstrate that it meets all requirements identified in Paragraphs 4 and 5 of DOE O 414.1A and to address the current organization.

QA-1.3/1 LSO needs to establish and implement a formal process for continuous improvement.

Objective 2: LSO procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program.

It was determined during the review that LSO is making progress in developing procedures and mechanisms to be used to evaluate the effectiveness of the LLNL QAP. LSO has performed oversight reviews that demonstrate their oversight functions regarding LLNL's QA processes. The Functional Information on Safety, Health and Environment (FISHE) database provides a good place to capture and track issues identified by LSO oversight activities of LLNL. Issues identified during this review indicate the need for LSO to take credit for reviews of lower tier QAPs currently being conducted and to document its process for reviewing LLNL QAPs.

The criteria for this objective were identified as being met. Therefore, the objective was met.

ISSUES:

QA.2.3/1: LSO should take credit for reviews of LLNL directorate quality assurance programs by including them in the FISHE system.

QA.2.3/2: LSO should document its process for reviewing LLNL quality assurance program documents.

ATTACHMENT

LSO QA ASSESSMENT FORM

QUALITY ASSURANCE

CRITERIA MET: No

OBJECTIVE: QA.1

NNSA Site Office procedures and mechanisms are in place to establish an effective management system to achieve and maintain quality, minimize environmental, safety, and health risks and impacts while maximizing reliability and performance and that is consistent with the principles and functions of DOE P 450.4. NNSA Site Office procedures and mechanisms incorporate processes to review, evaluate, and improve its overall performance using a rigorous assessment process based on an approved Quality Assurance Program. (DOE G 450.4-1A CCE-4, CCE-6, CCE-10 and CCE-11, DOE O 414.1A and DOE P 450.5)

CRITERIA

QA 1.1: The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O414.1A)

QA 1.2: NNSA Site Office procedures and/or mechanisms ensure the implementation of a quality assurance program that meets or exceeds the requirements of DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

QA 1.3: A process is established and effectively implemented to continuously improve efficiency and quality of operations. (DOE FRAM 9.6.2)

1. PROCESSES OBSERVED:

- Operation of the Functional Information for Safety, Health and Environment (FISHE) database

2. RECORDS REVIEWED:

- Oakland Operations/NNSA *Quality Assurance Plan*, May 2002
- Oakland Operations Office *Safety Management System Description*, Revision 1.1
- Oakland Operations Office *Technical Qualification Program Plan*, dated April 23, 2002
- Oakland Operations Office Supplemental Directive 1321.1A, *Oakland Operations Office Supplemental Directives System*, dated June 26, 2001
- LSO Line Oversight / Contractor Assurance System (LO/CAS) Description, dated September 18, 2003
- NNSA/UC Contract Modification No. M467, Contract Number: W-7405-ENG-48, *Appendix F Standards of Performance*
- NNSA/UC Contract Modification Appendix O, *Program Performance Initiatives*
- OAKSDM411.1-2, *Environment, Safety and Health Function, Responsibilities & Authorities Manual (FRAM)*, Revision 6
- AMNS-PLA-00123-04.0, *Integrated Safety and Safeguard and Security Management Plan*, Revision 4
- AMNS-PLA-000130.01.4, *Annual Operational Awareness Implementation Plan*, Revision 1.4

QUALITY ASSURANCE

- AMNS-SOP-000162.01.1, *LSO Procedure for Startup and Restart of Facilities*, Revision 0.1
- AMNS-SOP-000228-02.0, *Facility Operational Awareness Program*, Revision 2
- AMNS - SOP 000236.00.00, *Quality Assurance Plan*, dated April 15, 2002
- LSO-SOP-000202.01.00, *Controlled Document Procedure*, Revision 1
- NNSA/LSO SOP, *Federal System Engineering Program*, dated January 9, 2003
- LSO WSS/ISM CCB Procedure, *Work Smart Standard/Integrated Safety Management Change Control Board Procedure*, Revision 0
- DOE-NNSA-LSO Procedure, *Verification/Validation Process*, dated September 8, 2003
- NNSA/LSO SOP, *Senior Management Operational Awareness Implementation Plan*, dated September 29, 2003
- Selected Position Descriptions, Performance Standards and Technical Qualification Program Records
- Selected LSO Monthly Stoplight Charts and Quarterly Performance Metric Reports
- Selected Functional Information for Safety, Health and Environment (FISHE) Quality Assurance Reports and miscellaneous FISHE Tracking/Trending Reports
- Federal System Engineering Program Standard Operating Procedure
- Work Smart Standard (WSS) Change Control Board Process Procedure
- Facility Operational Awareness Program
- Annual Operational Awareness Implementation Plan (Senior Management and Livermore Safety Oversight Division)
- QA portion of the *Competency Qualification Plan* for Senior Technical Safety Managers, Revised June 5, 2003
- *Specific Performance Objectives* for the QA Manager
- Control Document Procedure Standard Operating Procedure
- Oakland Operations Office Supplemental Directives System
- Example of Documents in the LSO Document Management System
- Oakland Operations Office Records Management Procedure
- Oakland Operations Office Records Management Section
- Oakland Operations Office Records Disposition Procedure (Web Page)
- Oakland Operations Office Simplified Acquisition Procedures
- Oakland Operations Office Use of the Government Purchase Card, dated November 29, 2003
- Oakland Operations Office *Environment, Safety and Health (ES&H) Self-Assessment Guidelines*, August 14, 2000
- FISHE Activity Report ACT_000jbc, *LLNL Calibration Program Review for NNSA/OAK ES&H 201 Findings/Corrective Actions*, June 4 - 5, 2003
- 2001 and 2002 Oakland Operations Office and LSO Self-Assessment Reports
- CRAD No. 1 and 2 (QA-1 and 2) from the FY 2003 LSO self-assessment
- 2003 LSO Self-Assessment Quality Assurance CRADs Results
- Memoranda:
 - Hooper to Anastasio, *Quality Assurance Program for 10 CFR 830 and DOE O 414.1A and Completion of Appendix O Quality Assurance Milestone*, December 20, 2001
 - Corey to Yuam-Soo Hoo, *Oakland Operations Office 2001 Environment, Safety and Health (ES&H) Self-Assessment*, October 11, 2001
 - Hooper to Kopenhagen, *AMNS ES&H Self Assessment for Fiscal Year 2002*, May 1, 2002

QUALITY ASSURANCE

- Ingram to Distribution, *The Qualification Plan for OAK TQP Participants in the QUALITY ASSURANCE STANDARD*, dated May 28, 2002
- Liddle to Yuan-Soo Hoo, *Oakland Operations Office 2002 Environment, Safety and Health (E,S&H) Self-Assessment*, May 29, 2002
- Hooper to Mara, *Transmittal of Revised Laboratory Quality Assurance Program*, dated January 23, 2003
- Hill to Fisher, *NNSA/LSO Approval to Startup Inventory Reduction Operations at Building 251 (Heavy Element Facility)*, August 20, 2003
- Fisher to Hill, *Transmittal of Revised Laboratory Quality Assurance Program*, September 24, 2003
- Hill to Fisher, *Recommendation 2002-1 Implementation Plan Commitment 4.2.3.2 (Doc. # LSONST:030066)*, October 8, 2003
- Fisher to Hill, *LLNL Action Plans for DOE QA Improvement Plans for DOE Software QA Implementation Plan*, December 5, 2003
- E-mail:
 - Kopenhagen to Cordis, *FW A925 RE: Approval of Oakland Operations Office QA Plan (IDRMS 2002-02819)*, July 29, 2002
 - McLemore to Chimah, *FW: QA Best Practices Report*, dated December 17, 2003

3. INTERVIEWS CONDUCTED:

- Team Lead of the Facility, Projects and Emergency Management Team
- Senior Safety Advisor and acting Assistant Manager for the Livermore Safety Operations Division
- Quality Assurance Manager
- Former Quality Assurance Manager
- Program Management Analyst

4. DISCUSSION / OBSERVATIONS:

QA 1.1 The quality assurance program for the NNSA Site Office meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.4.1.6 and 9.5.3, DOE O414.1A)

The Livermore Site Office (LSO) quality assurance program is described in two documents. As identified by LSO personnel the overall program is identified in the *Oakland Operations/NNSA Quality Assurance Plan*, approved May 31, 2002, and the *Livermore Site Quality Assurance Program*, approved April 15, 2002, which provides site office specific requirements, but focuses on oversight of the Lawrence Livermore National Laboratory.

These documents follow the 10 criteria required to be addressed for a quality assurance program by the general requirements paragraph of DOE O 414.1A, *Quality Assurance* [DOE O 414.1A, ¶4.a]. In addition, the Oakland program was submitted to NNSA/Headquarters for review and concurrence as required in the Responsibilities paragraph for the Field Element Managers [DOE O 414.1A, ¶5.e.(1)]. LSO personnel identified that they had received comments on the program from NNSA/Headquarters; however, there was no evidence that final concurrence was received.

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However, neither document identified a graded approach as required in the general requirements and there is no documented evidence to identify how the guidance contained in DOE G 414.1-1A, G 414.1-2, and G 440.1-6 were used in developing the program. Also, there has not been a formal assignment of authority for an individual in a senior management position to develop, approve, and implement a QAP governing the work of the field element in accordance with the requirements identified in Paragraph 4 of the Order, as applicable.

Furthermore, discussions with LSO personnel and review of the recently completed LSO Quality Assurance Self-Assessment indicates that they have identified that quality assurance documentation needs to be updated to address the revised organization and to address current processes through the quality assurance implementing documents. However, this effort has not taken place due to the organization adjusting to its new role, a change and higher-level priorities, and decisions on consolidating program documentation such as the FRAM, and ISM system description. In addition, LSO is also being asked to implement weapons quality and software quality assurance and to implement NNSA management's decision to use the ISO 9001:2000 standard as the method to implement DOE O 414.1A requirements at the same time. Based on this increased workload, LSO has identified a need for an additional QA position with responsibility for weapons quality assurance and/or software quality assurance.

With the reorganization of the National Nuclear Security Administration in December 2002, the Oakland Operations Office was eliminated and the LSO was elevated to report directly to NA-10 at NNSA/Headquarters. Based on this reorganization, roles and responsibilities have been modified to meet the changes in organizational responsibilities and the quality assurance documents above have become obsolete and do not meet the requirements for a quality assurance program identified in Criterion 1, Program, of DOE O 414.1A. The LSO quality assurance program documentation has not been updated to reflect the current organization. This issue has been previously identified in the 2003 LSO self-assessment.

LSO needs to revise its quality assurance program documentation to demonstrate that it meets all requirements identified in Paragraphs 4 and 5 of DOE O 414.1A and to address the current organization. (Issue QA-1.1/1)

This criterion was met.

QA 1.2 NNSA Site Office procedures and/or mechanisms ensure the implementation of a quality assurance program that meets or exceeds the requirements of DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

The current quality assurance program documentation identifies implementing documents used to identify "how" LSO address the 10 criteria in DOE O 414.1A. At present, LSO uses existing Oakland Operations Office documents to perform day to day activities to meet the requirements of the DOE O 414.1A and 10 CFR 830, Subpart A, and as is the case with the quality assurance program documentation, not all of these the implementing procedures have been brought up to date with the current roles, responsibilities, and processes. Implementing procedures need to be reviewed and updated to address changes caused by the reorganization. (Issue QA-1.1/1)

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This criterion was not met.

QA 1.3 A process is established and effectively implemented to continuously improve efficiency and quality of operations. (DOE FRAM 9.6.2)

The areas of issues management, self-assessments, and lessons learned were reviewed.

LSO does not have a formal quality improvement process in place as outlined in "Oakland Operations/NNSA Quality Assurance Plan." LSO documents problems, but does not always identify the root cause of the problems and therefore does not always prevent recurrence of the problems. In addition, LSO has not formalized the feedback and improvement process. Lessons learned are not always incorporated into operations or operational oversight and the lessons learned process is not well documented or implemented. While lessons learned are sometimes shared, it appears even this part of the process is sporadic.

LSO needs to establish and implement a formal process for continuous improvement.

This criterion was not met.

ISSUES:

QA-1.1/1 LSO needs to revise its quality assurance program documentation to demonstrate that it meets all requirements identified in Paragraphs 4 and 5 of DOE O 414.1A and to address the current organization.

QA-1.3/1 LSO needs to establish and implement a formal process for continuous improvement.

5. ASSESSED BY: Nathan Morley/Paul Chimah **DATE:** December 22, 2003

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CRITERIA MET: YES

OBJECTIVE: QA.2

LSO procedures and mechanisms are implemented to ensure an effective QA contractor oversight system is in place that reviews, evaluates, and improves overall performance of the contractor using a rigorous assessment process based on an approved Quality Assurance Program. (DOE G 450.4-1A CCE-4, CCE-6, CCE-10 and CCE-11, DOE O 414.1A/ QC-1/10CFR830 Subpart A and DOE P 450.5)

CRITERIA

QA.2.1: The QA Program used for LSO oversight of the contractor meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10CFR830 Subpart A and DOE FRAM 9.4.1.6 and 9.5.3, DOE O414.1A.

QA.2.2: LSO procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with the DOE 414.1A Contractors Requirements Document, DOE O 414.1A/QC-1/10CFR830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

QA.2.3: LSO has reviewed and approved the contractor QAP.

QA.2.4: LSO procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the LSO for review and approval. (DOE FRAM 9.5.3, DOE 414.1A)

QA.2.5: LSO has taken appropriate actions in the closure of findings or issues documented under the QA Lessons Learned and Best Practices Review, performed at LLNL, March 2001. As referenced by DOE Memorandum Erickson to Site Managers, October 30, 2001, subject " Results and Future Actions For Complex Wide QA Reviews At Defense Nuclear Facilities."

1. PROCESSES OBSERVED:

Operation of the Functional Information for Safety, Health and Environment (FISHE) database

2. RECORDS REVIEWED:

- LSO Line Oversight / Contractor Assurance System (LO/CAS) Description, dated September 18, 2003
- NNSA/UC Contract Modification No. M467, Contract Number: W-7405-ENG-48, *Appendix F Standards of Performance*
- NNSA/UC Contract Modification Appendix O, *Program Performance Initiatives*
- AMNS-PLA-000130.01.4, *Annual Operational Awareness Implementation Plan*, Revision 1.4
- AMNS-SOP-000162.01.1, *LSO Procedure for Startup and Restart of Facilities*, Revision 0.1
- AMNS-SOP-000228-02.0, *Facility Operational Awareness Program*, Revision 2
- NNSA/LSO SOP, *Federal System Engineering Program*, dated January 9, 2003
- LSO WSS/ISM CCB Procedure, *Work Smart Standard/Integrated Safety Management Change Control Board Procedure*, Revision 0
- DOE-NNSA-LSO Procedure, *Verification/Validation Process*, dated September 8, 2003
- NNSA/LSO SOP, *Senior Management Operational Awareness Implementation Plan*, dated September 29, 2003

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- Selected LSO Monthly Stoplight Charts and Quarterly Performance Metric Reports
- Selected Functional Information for Safety, Health and Environment (FISHE) Quality Assurance Reports and miscellaneous FISHE Tracking/Trending Reports
- Federal System Engineering Program Standard Operating Procedure
- Work Smart Standard (WSS) Change Control Board Process Procedure
- Facility Operational Awareness Program
- Annual Operational Awareness Implementation Plan (Senior Management and Livermore Safety Oversight Division)
- FISHE Activity Report ACT_000jbc, LLNL. *Calibration Program Review for NNSA/OAK ES&H 201 Findings/Corrective Actions*, June 4 - 5, 2003
- Memoranda:
 - Hooper to Anastasio, *Quality Assurance Program for 10 CFR 830 and DOE O 414.1A and Completion of Appendix O Quality Assurance Milestone*, December 20, 2001
 - Hooper to Kopenhaver, *AMNS ES&H Self Assessment for Fiscal Year 2002*, May 1, 2002
 - Ingram to Distribution, *The Qualification Plan for OAK TQP Participants in the QUALITY ASSURANCE STANDARD*, dated May 28, 2002
 - Hooper to Mara, *Transmittal of Revised Laboratory Quality Assurance Program*, dated January 23, 2003
 - Hill to Fisher, *NNSA/LSO Approval to Startup Inventory Reduction Operations at Building 251 (Heavy Element Facility)*, August 20, 2003
 - Fisher to Hill, *Transmittal of Revised Laboratory Quality Assurance Program*, September 24, 2003
 - Hill to Fisher, *Recommendation 2002-1 Implementation Plan Commitment 4.2.3.2 (Doc.#:LSONST:030066)*, October 8, 2003
 - Fisher to Hill, *LLNL Action Plans for DOE QA Improvement Plans for DOE Software QA Implementation Plan*, December 5, 2003

3. INTERVIEWS CONDUCTED:

- Team Lead of the Facility, Projects and Emergency Management Team
- Senior Safety Advisor and acting Assistant Manager for the Livermore Safety Operations Division
- Quality Assurance Manager
- Former Quality Assurance Manager
- Program Management Analyst

4. DISCUSSION / OBSERVATIONS:

QA.2.1: The QA Program used for LSO oversight of the contractor meets or exceeds the requirements provided in DOE O 414.1A/QC-1/10 CFR 830 Subpart A and DOE FRAM 9.4.1.6 and 9.5.3, DOE O 414.1A.

The LSO has developed *LSO Senior Management Operational Awareness Implementation Plan*. This procedure requires Senior Management Operational Awareness for the oversight programs, security, safety health and environmental conditions of the Livermore Site Office activities and facility operations. In addition, LSO senior managers shall conduct and ensure that operational awareness visits are documented in the Functional Information on Safety, Health and Environment (FISHE)

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database. The FISHE database is capable of searching, retrieving, and trending. The FISHE system identifies a quality assurance functional area, but also has separate functional areas for quality assurance functions, such as procurement, and documents and records.

The Team Leader and the Quality Assurance Manager for the Facility, Projects and Emergency Management Team, and other subject matter experts (SMEs) based on the functional area(s) being reviewed, participate in day-to-day activities, which provide LSO oversight of LLNL. We reviewed a yearly FISHE activity participant list to see how many times each individual performed walkthroughs of the LLNL contractor as part of their oversight role. The combined participation of the Team Leader, the Quality Assurance Manager, and other SMEs of oversight of contractor's activities was satisfactory.

As identified in the discussion under QA.1.1, LSO line management have self identified the need for improved operating procedures by developing business systems for inspections, surveillance, and validation of the self-assessments.

LSO develops monthly Stoplight Charts and Quarterly Metric Reports to identify how well LLNL is performing and highlight any significant areas of concern. LSO applies the Line Oversight/Contractor Assurance System (LO/CAS) concept that builds on Integrated Safety Management to the broader concept of Integrated Management in their oversight of LLNL.

The QA Manager is in process of completing her technical qualification program requirements. She is only missing one requirement on trending analysis before she is qualified. The current QA Manager developed the LSO qualification standard while serving as the Quality Assurance Manager at the former Oakland Operations Office. Having her complete the qualification program she developed appeared to LSO to be a conflict of interest. Therefore, LSO asked the author of the DOE O 414.1A in EH-31 to conduct the qualification process and to assess the LSO QA Manager's qualifications. The response back from EH-31 was that the QA Manager was qualified for the position and that the qualification program was one of the best they had reviewed at a DOE organization.

This Criterion was met.

QA.2.2: LSO procedures and/or mechanisms ensure that the contractor implements a quality assurance program in accordance with the DOE O 414.1A Contractors Requirements Document, DOE O 414.1A/QC-1/10 CFR 830 Subpart A. (DOE FRAM 9.5.3, DOE O 414.1A)

As discussed under Criterion QA.2.1, LSO has established an oversight process of LLNL primarily through the implementation of the LO/CAS concept. In addition, LSO has developed *Livermore Site Office, Verification/Validation Process*. This procedure provides roles, responsibilities, and processes for Livermore Safety Operations Division personnel to perform verification/validation of corrective actions developed to meet actions tracked under DOE's Corrective Action and Non-Compliance Tracking Systems, and Occurrence Reporting and Processing System. In addition, this system tracks corrective actions addressing issues identified at the local level through the FISHE system, LSO formal reviews/appraisals of LLNL activities, and those issues that the LSO Manager and Deputy Managers require to be tracked and verified/validated. Every corrective action required to be tracked as identified

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above must be verified before acceptance for closure under this process.

The Office of Independent Oversight and Performance Assurance perform independent appraisals of the contractor to determine the effectiveness of line management oversight and operations.

As discussed in Criteria QA.2.3 and 2.4, we reviewed quality assurance requirements placed on LLNL in the current UC Contract Appendix F and previous Appendix O and found the requirements to be acceptable to meet this criterion as well as Criteria QA.2.3 and 2.4.

This criterion was met.

QA.2.3: LSO has reviewed and approved the contractor QAP.

QA.2.4: LSO procedures and mechanisms ensure that changes to the contractor QAP over the previous year are submitted annually to the LSO for review and approval. (DOE FRAM 9.5.3, DOE 414.1A)

Subparagraph 5.e.(2) of DOE O 414.1A requires Field Element Managers to "Review and, where delegated authority to do so, approve new and revised QAPs for contractors within their purview. QAP must be reviewed and approved – or rejected – within 90 days from receipt of the contractor." Documentation provided by LSO indicates that LSO has approved the last two LLNL quality assurance program documents provided in 2001 and 2002. LSO's review of the LLNL's quality assurance program met the 90-day requirement for 2001 but not for 2002. The memorandum providing approval for the 2002 program identified that the LLNL submitted the 2002 plan on September 25, 2003. Based on this date the 90 days review period expired on December 24, 2003; however, the LSO did not approve the program until January 23, 2003. LSO needs to be mindful of the 90-day requirement. The LLNL provided the quality assurance program for 2003 on September 24, 2003. Per the Order requirement, LSO's response is due by December 25, 2003.

Discussions with LSO personnel identified that a system to ensure LLNL updates their QAP has been put in place in the UC Contract. A review of the previous Appendix O to the contract identified that, Program Performance Initiatives, provided identified that Section 3.2.1 of this Appendix states "10 CFR 830 Initiatives: LANL and LLNL will be accountable for ensuring implementation of the quality assurance criteria and the unreviewed safety question requirements in accordance with 10 CFR 830." This requirement was in place for Fiscal Years 2001 and 2002. With the start of Fiscal Year 2003, the requirement was moved from Appendix O to Appendix F. The Appendix F first level, or "Tier 1," requirement states, "Maintain a secure, safe, environmentally sound, effective and efficient operations and infrastructure basis in support of mission objectives" [Performance Objective # 8]. This requirement is broken down into Performance Measure. Performance Measure 8.3 states, "Continue to comply and improve performance in meeting requirements of 10 CFR 830, Subparts A and B." 10 CFR 830, Subpart A requires that "The contractor responsible for a DOE nuclear facility must... Submit a QAP to DOE for approval..." [10 CFR 830.121.(b)(1)]. In addition, the contractor must "Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements" [10 CFR 830.121.(b)(3)].

In addition, LLNL has established an internal requirement for each of its 12 directorates to update their

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quality assurance programs within 60 days of receipt of LSO approval of the institutional quality assurance program. LLNL has also provided these directorate level programs to LSO for approval. A review of the draft results from LSO's 2003 self-assessment identified that the results of these reviews were not being placed into LSO's issues management system (FISHE). Neither DOE O 414.1A, 10 CFR 830, Subpart A, or DOE G 414.1-2 identify the level of quality assurance programs within an organization that require review and acceptance by DOE, but it is usually taken as the highest level document describing the program for the contractor. Based on this assumption and the statement made by the self-assessment team, LSO should take credit for these reviews by including them in the FISHE system. (Issue QA-2.3/1)

Although discussions and the review of the documents discussed above there is a requirements mechanism in place to assure that LLNL provides a revised quality assurance program to LSO for review, there is no indication that the internal LSO review process has been documented. The individual with the assigned responsibility for quality assurance within LSO has changed in 2003. The individual who previously provided LSO's review of LLNL's institutional and directorate quality assurance programs is leaving the Division for another position within LSO, and there is a second quality assurance specialist will be hired. With this move, the potential for the loss of corporate knowledge on the review of the quality assurance programs becomes a real possibility and the process should be documented. (Issue QA-2.3/2)

This criterion was met.

QA.2.5: LSO has taken appropriate actions in the closure of findings or issues documented under the QA Lessons Learned and Best Practices Review, performed at LLNL, March 2001. As referenced by DOE Memorandum Erickson to Site Managers, October 30, 2001, subject "Results and Future Actions For Complex Wide QA Reviews At Defense Nuclear Facilities."

LSO performed an independent assessment of LLNL's Implementations of DOE O 420.1 and 414.1, which was completed in September 2001. This review provided a more in-depth review of the CMRU project at LLNL, which was the focus of the review cited above.

In response to NNSA Quality Assurance Lessons Learned and Best Practices Review Program (Report dated August 2001, LLNL/B332/LSO Site Visit Summary), LLNL has taken the following measures:

LLNL has taken steps to standardize QA procurement practices for the entire site. A QA representative is now working full time with the Procurement and Materiel Department to oversee this effort.

The receiving inspection process has also been improved Laboratory-wide. All procurement orders designated "Quality Significant" now require receipt inspection. At the Plutonium Facility, i.e., at the building level, receipt inspections are more formalized, beginning with Like-in-Kind items procured to support maintenance activities.

Findings, which were identified, are being tracked and verified to closure by LSO.

This criterion was met.

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ISSUES:

QA.2.3/1: LSO should take credit for reviews of LLNL directorate quality assurance programs by including them in the FISHE system.

QA.2.3/2: LSO should document its process for reviewing LLNL quality assurance program documents.

5. ASSESSED BY: Nathan Morley/Paul Chimah **DATE:** December 22, 2003