

**Independent Oversight Review of the
Sandia Site Office Quality Assurance
Assessment of the Manzano Nuclear Operations**



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**Office of Safety and Emergency Management Evaluations
Office of Enforcement and Oversight
Office of Health, Safety and Security
U.S. Department of Energy**

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Acronyms

ACRR	Annular Core Research Reactor
CBA	Compliance Based Assessment
CFR	Code of Federal Regulations
CRAD	Criteria, Review and Approach Document
DNFSB	Defense Nuclear Facilities Safety Board
DOE	U.S. Department of Energy
MNF	Manzano Nuclear Facility
OFI	Opportunity for Improvement
QA	Quality Assurance
QAP	Quality Assurance Program
QMSD	Quality Management System Description
S/CI	Suspect/Counterfeit Items
SMP	Safety Management Program
SNL	Sandia National Laboratories
SQA	Software Quality Assurance
SSO	Sandia Site Office
TA-V	Technical Area V
WMPP	Waste Management and Pollution Prevention Department

Independent Oversight Review of the Sandia Site Office Quality Assurance Assessment of the Manzano Nuclear Operations

1.0 PURPOSE

The Office of Enforcement and Oversight (Independent Oversight), within the Office of Health, Safety and Security, conducted an independent review of the U.S. Department of Energy (DOE) Sandia Site Office (SSO) quality assurance (QA) assessment of the Manzano nuclear operations. The focus of the review, performed on site November 14-15, 2012, was to shadow SSO's QA assessment and evaluate its performance of compliance oversight of Sandia Corporation safety management programs (SMPs) at Sandia National Laboratories (SNL) hazard-categorized nuclear facilities per SSO procedure 1304.02, *Guidance and Expectations for Nuclear Safety Management Program Assessment*. The Manzano Nuclear Facility (MNF) is a hazard category 3 non-reactor nuclear facility that consists of six bunkers on Kirtland Air Force Base used to store low-level waste, transuranic waste, mixed waste, and material awaiting disposition.

2.0 SCOPE

Independent Oversight shadowed the SSO assessors, who followed an approved SSO assessment plan dated November 5, 2012, focusing on the QA SMP and using the SSO Criteria, Review and Approach Document (CRAD) shown in Appendix C. The Independent Oversight review also determined whether:

- The directive requirements appropriately flow down to SNL implementing documents.
- SNL implementing documents appropriately address any requirements levied by SSO-approved documented safety analysis and technical safety requirements.
- SNL demonstrates implementation of the program at the hazard-characterized nuclear facilities in accordance with its guidance and expectations.

3.0 BACKGROUND

In April 2012, the Defense Nuclear Facilities Safety Board (DNFSB) issued a letter and staff issue report to the National Nuclear Security Administration documenting issues involving QA and software QA (SQA) related to the Annular Core Research Reactor (ACRR) at Technical Area V (TA-V) at SNL. A previous HSS finding in 2008 had also documented that SSO and SNL have not ensured timely implementation of DOE requirements for SQA for nuclear facilities. The DNFSB had previously issued a letter in February 2012 concerning the ACRR safety basis and instrumentation and control systems, and had indicated that additional issues with QA and SQA would be addressed in a separate report. Between the issuance of the two DNFSB letters, in March 2012, SSO conducted a compliance based assessment (CBA) of SNL's QA program that identified numerous significant findings. SSO concluded that the SNL corporate QA program did not meet requirements specified in 10 CFR 830 Subpart A, *Quality Assurance Requirements*, or DOE Order 414.1D, *Quality Assurance*, and that an overall system was not in place to ensure QA implementation throughout SNL, although "pockets" of adequate QA implementation by some line organizations did exist. These issues warranted an Independent Oversight review of QA and SQA at SNL, and the scheduled SSO assessment of QA implementation at the MNF afforded a timely opportunity to review site office and contractor activities.

4.0 METHODOLOGY

Independent Oversight performed selected document reviews, attended interviews, and made other observations while shadowing the SSO assessment team. In addition to the defined scope of the SSO assessment plan, Independent Oversight also compared and contrasted corporate QA implementation at MNF and TA-V as related to DNFSB concerns.

5.0 RESULTS

The SSO final report summarized the QA assessment results as follows:

"There were no significant deficiencies noted with MNF implementation of QA during this assessment. There were three observations noted. One observation related to documenting their graded approach and two observations pertaining to safety software issues. Although SNL continues to work on the corporate QA Plan as a result of the CBA, it was determined that QA requirements within the scope of this assessment had been adequately flowed down from DOE O 414.1D, *Quality Assurance*, and 10 Code of Federal Regulation (CFR) 830 Subpart A, *Quality Assurance Requirements*. The corporate SNL QA Program is regularly reviewed and considered during development and implementation of the MNF QA Program development and implementation. Several external assessments of QA are regularly performed on this operation. The RadTrack and WCT software are under configuration control and are referenced in facility procedures."

Independent Oversight concurs with the SSO results. However, Independent Oversight notes that SSO observation "PLA 93-33, *Nuclear Operations Quality Assurance Plan*, and associated procedures should provide additional detail describing the use of grade approach" did not sufficiently address the flowdown of the corporate QA documents to MNF. The capstone corporate process CG 100.5, *Ensure Quality*, references the *Quality Management System Description* (QMSD), which defines the Integrated Laboratory Management System as SNL's Quality Management System. However, neither CG 100.5 nor the QMSD is specifically referenced in the Waste Management and Pollution Prevention (WMPP) Department's PLA 96-33, *Nuclear Operations Quality Assurance Project Plan*, for MNF, but CG 100.5 is referenced in PLA 10-09, *Software Quality Assurance Project Plan*. This inconsistency raises a concern that corporate QA does not ensure that its policies flow down accurately and completely to subordinate organizations. (See OFI-1 in Section 10.)

Independent Oversight notes that SNL-QMSD-072012, *Sandia National Laboratories Quality Management System Description*, and SS-R89727, *Specific Use Specification, Sandia Software Quality Assurance Program*, are comprehensive documents that adequately reference various applicable industry QA standards to cover the variety of types of work and customers at different SNL facilities. These corporate QA documents are adequately referenced in the QA and SQA plans at TA-V, but need to be better referenced in WMPP documents for MNF and perhaps elsewhere at SNL.

6.0 CONCLUSIONS

SSO's QA assessment of the Manzano nuclear operations was adequate and conducted in compliance with the expectations of SSO procedure 1304.02. Independent Oversight concurs with the results and conclusions of the site office assessment team but identified one opportunity for improvement (OFI) regarding the flowdown of corporate QA documents.

7.0 FINDINGS

None.

8.0 UNRESOLVED ITEMS

None.

9.0 ITEMS FOR FOLLOW-UP

Independent Oversight will continue to monitor the progress of corrective actions taken at SNL in response to the DNFSB letter of April 2012 regarding QA and SQA issues at TA-V.

10.0 OPPORTUNITIES FOR IMPROVEMENT

This Independent Oversight review identified the following OFI. This potential enhancement is not intended to be prescriptive or mandatory. Rather, it is offered to the site to be reviewed and evaluated by the responsible line management organizations and accepted, rejected, or modified as appropriate, in accordance with site-specific program objectives and priorities.

OFI-1: SNL corporate QA should conduct independent assessments to ensure accurate and complete flowdown and implementation of SNL Corporate QA requirements to all line organizations.

Appendix A Supplemental Information

Dates of Review

Onsite Review: November 14-15, 2012

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Appendix B

Documents Reviewed, Interviews, and Observations

Documents Reviewed

- ASM-PQA-11.20.2012-481090, *Safety Management Program (SMP) Assessment of Quality Assurance (QA) at the Manzano Nuclear Facilities (MNF)*, 12/14/12
- *Center 1300 Software Quality Assurance Plan*, Rev. D, 3/11/11
- CG 100.5, *Ensure Quality*, 10/24/12
- DOE Order 414.1D, *Quality Assurance*, 4/25/11
- *Independent Oversight Inspection of Environment, Safety, and Health Programs at the Sandia National Laboratories*, April 2008
- Letter to Cook from Winokur, Subject: *Quality Assurance and Safety Software Quality Assurance, Annular Core Research Reactor*, 3/7/12
- Letter to Hommert from Beausoleil, Subject: *Sandia Site Office Quality Assurance Compliance Based Assessment of 2012*, 5/31/12
- Letter to Jarry from Loftis, Subject: *Sandia Site Office Quality Assurance Assessment of the Manzano Nuclear Operation*, 11/5/12
- Letter to Jarry from Loftis, Subject: *Sandia Site Office Quality Assurance Assessment of the Manzano Nuclear Operation*, 12/14/12
- PLA 96-33, *Nuclear Operations Quality Assurance Project Plan*, Rev. 10, 1/12/12
- PLA 10-09, *Software Quality Assurance Project Plan*, Rev. 00, 1/9/12
- Sandia Site Office Crosscutting Procedure 1304.02, *Guidance and Expectations for Nuclear Safety Management Program Assessment*, Rev. 0, 10/3/12
- SNL-QMSD-072012, *Sandia National Laboratories Quality Management Systems Description*, 7/31/12
- SS-R89727, *Specific Use Specification, Sandia Software Quality Assurance Program*, 10/19/11
- TA-V *Safety Software Quality Assurance Procedure*, Rev. 2, 5/17/11

Interviews

- Department Manager, Waste Management and Pollution Prevention
- Manager, Nuclear Operations
- Quality Assurance Program Project Leader
- Nuclear Operations Training Supervisor
- Waste Characterization Team Project Leader (Safety Software)

Observations

- Tour of Bunker 37057
- TA-V Safety Software Quality Review Board meeting

Appendix C
Sandia Site Office Criteria, Review and Approach Document
(Manzano QA Program)
November 2012

OBJECTIVE

QA.1: Organizational Level Program: Review the organizational QA description and/or organizational program to ensure that a management process is established for the work.

CRITERIA (Identified in DOE Order 414.1D, Attachment 2, *Quality Assurance Criteria*)

1. The organization conducts its work under an approved documented QA program (QAP) that addresses the implementation of the QA Criteria, suspect/counterfeit items (S/CI), and the SQA.
2. The QAP defines the organization's graded approach used in the implementation of requirements based on hazards and mission.
3. The QAP describes the management processes (including planning, flowdown of requirements, improvement, flow, etc.).
4. An individual is responsible for development, maintenance, and leadership of the QAP.
5. For nuclear facilities or nuclear facility oversight applications, the QAP references and implements the applicable edition of Nuclear Quality Assurance (NQA)-1 (or equivalent).
6. For non-nuclear facilities or oversight, the QAP identifies the appropriate standards used to develop the QAP.
7. The process is established for determining the quality requirements applicable to contractors/suppliers and passing those requirements down through contracts clearly defined.
8. Software Quality Assurance Plans that define the methods, techniques, and tools to accomplish the corporate expectations are implemented at the organizational level.

APPROACH

Record Review:

- Review the organizational QAP and implementing documents.
- Review documentation of implementation of CG 100.5, including the *Manager's Record of Quality Assurance Review* if an organization specific QAP is not needed.
- Review assessment schedules, plans and reports to determine whether the organization provides adequate oversight of contractors that are not using a SNL developed QAP to perform work.

OBJECTIVE

QA.2: Documents and Records/Work Processes/Training and Qualification: Documents and records management system is effective in supplying documents for personnel to perform their assigned responsibilities, and work is being conducted to approved documents. Work processes are carried out by qualified personnel using approved procedures to achieve a planned result.

CRITERIA (Identified in 10 CFR 830 and DOE Order 414.1D, Attachment 2, *Quality Assurance Criteria*)

1. Documents to prescribe processes, specify requirements, or establish design are prepared, reviewed, approved, issued, used, and revised.
2. Records are specified, prepared, reviewed, approved, and maintained.
3. Work is consistent with technical standards, administrative controls, and other hazard controls to meet regulatory or contract requirements with the use of approved instructions or procedures.
4. Worker qualifications are defined and maintained. Personnel are capable of performing their assigned work and continuing training is provided to maintain job proficiency. Adequate resources are available to support training and qualification.
5. Electronic document and records systems meet SS-R89727, *Specific Use Specification, Sandia Software Quality Assurance Program*.

APPROACH

Record Review:

- Review the SNL and/or organizational QAP to determine the methods used to implement the criteria, including the use of the graded approach.
- Review training records to identify that personnel have the required training for the work they are assigned.
- Review implementing documents identified in the applicable QAP for this criteria to determine the adequacy of the processes.
- Verify that the key functions such as procedures relating to the quality criterion (e.g., design, procurement, work control, inspection, testing) are described in approved documentation.
- Ensure that the approved work documents (procedures, instructions, etc.) meet regulatory and/or contract requirements.

OBJECTIVE

QA.3: Quality Improvement: Management actions are initiated for improving the quality of products, processes, and services by establishing priorities, promulgating policy, allocating resources, communicating lessons learned, and resolving significant management issues and problems that hinder the organization from achieving its quality objectives, as well as assuring worker qualification and training requirements are defined and implemented to ensure personnel achieve and maintain the capabilities to perform assigned work.

CRITERIA (Identified in 10 CFR 830 and DOE Order 414.1D, Attachment 2, *Quality Assurance Criteria*)

1. Processes have been established and implemented to detect and prevent quality problems.
2. Items, services, and processes that do not meet established requirements are identified, controlled, and corrected.
3. Corrective action planning includes the identification of the causes of problems and prevention of recurrence.
4. Item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement are being reviewed.
5. Management has implemented a “lessons learned” program to identify potential quality improvement processes.
6. Issues identified during previous reviews/assessments have been appropriately resolved, corrective actions have been completed and are adequate, or a clear path to completion is indicated.

APPROACH

Record Review:

- Review the SNL QAP to determine the methods SNL is using to implement the criteria, including the use of the graded approach. Review implementing documents identified in the QAP for this criterion to determine the adequacy of the processes.
- Determine whether corrective actions are being adequately addressed and effectively implemented.

OBJECTIVE

QA.4: Management Assessment/Independent Assessment: Assessments are conducted periodically by managers and independently to determine how well SNL organizations are meeting both customer and management performance expectations and mission objectives, to identify strengths or opportunities for improving performance, and to correct identified problems for SNL programs, projects, contractors, and suppliers.

CRITERIA (Identified in 10 CFR 830 and DOE Order 414.1D, Attachment 2, *Quality Assurance Criteria*)

1. Management assesses their management processes and identifies and corrects problems that hinder the organization from achieving its objectives.
2. Assessments are planned and are performed by individuals who are technically qualified and knowledgeable in the areas they are assessing and who have sufficient authority and freedom from line management to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

APPROACH

Record Review:

- Review the SNL QAP to determine the methods SNL is using to implement the criteria, including the use of the graded approach. Review implementing documents identified in the QAP for this criterion to determine the adequacy of the processes.
- Review management and independent assessment schedules, plans, and reports for assessments specifically of the QAP, as well as the functional areas that are included in QA criteria, S/CI, and SQA, such as documents, records, training, procurement, receiving, and design.

Interviews (applies to all CRADs):

- Interview the SNL individual assigned QA responsibilities to assess knowledge of the SNL management and independent assessment programs.
- Interview selected SNL managers and personnel on their knowledge of the SNL assessment programs, what QAP is covering their organization and activities, and who is responsible for QA at SNL. Identify whether managers understand that management assessments are to be performed by them directly, and not by someone else at their request.
- Interview management and independent assessment personnel to determine their involvement in, interface with, and understanding of the SNL quality management system.
- Address previous management assessment results and improvements in quality.