Yucca Mountain Project
Quality Assurance
Program Review and
Implementation Assessment

Prepared by InfoZen, Inc.

For The

U. S. Department of Energy
Office of Civilian Radioactive Waste Management

Team Leader: Dan M. Stover
Dan Stover

October 26, 2007

Table of Contents

I Executive Summary

On April 27, 2007, The U.S. Department of Energy (DOE) awarded contract DE-AC28-07RW12383 to InfoZen Inc. to conduct an independent program review and implementation assessment of Yucca Mountain Project (YMP) quality assurance (QA). With regard to the program review, the YMP QA program consists of three individual QA program plans written and implemented by DOE's Office of Civilian Radioactive Waste Management (OCRWM), Bechtel SAIC Company (BSC), and Sandia National Laboratory (SNL), respectively. The team concluded that the three QA program plans are being implemented consistent with standard nuclear industry practices and to the extent expected given the current status of the Yucca Mountain project.

The implementation assessment focused on current Yucca Mountain project activities rather than historical or legacy issues. This was done to gauge the adequacy of today's QA program implementation. During the course of the implementation assessment, "problem statements" were identified and provided to the OCRWM Office of Quality Assurance (OQA) for disposition. The problem statements are discussed in the individual reports prepared for each of the three organizations that were assessed (Appendices B, C, D). Overall conclusions are addressed in Section II.

Lines of Inquiry were prepared and used for the implementation phase of the assessment. They are included in Attachment 1. Wherever practicable, Nuclear Regulatory Commission inspection procedures were used as guidance in developing the lines of inquiry. The team was made up of personnel with Nuclear Regulatory Commission and commercial nuclear management and quality assurance experience. Attachment 2 contains their resumes.

A key objective of this program review and implementation assessment was to determine if the Yucca Mountain QA program was "robust" enough to carry the project through licensing and into final design and construction. The team's determination of program robustness considered how well the three QA program plans were documented, but focused primarily on their implementation.

With respect to documentation, the team's goals were several: 1) confirm the flow-down of QA-related requirements from 10 CFR 63.142, through the three QA program plans, and into the implementing procedures; 2) verify that the three QA program plans provided clear and concise direction; 3) verify that the three contained commitments to the appropriate industry standards; and 4) verify that the three struck the right balance between doing and overseeing the work.

Concerning the all-important matter of QA program implementation, the team's goals were to interview personnel, observe in-process work, and confirm acceptable work results. Of particular import during the assessment's implementation phase was the consideration of attitudes and the working inter-relationships between those people doing the work and those checking the work. This issue, sometimes referred to as "nuclear culture," was also a focus of the concurrent, but separate, InfoZen-led Quality Assurance

Management Assessment. The results of this complementing assessment are presented in the Quality Assurance Management Assessment (QAMA) report.

II Overall Conclusions

The team drew the following overall conclusions regarding the documentation and implementation of the OCRWM, BSC, and SNL QA program plans.

1. The team concluded that the three QA program plans are being implemented consistent with standard nuclear industry practices and to the extent expected given the current status of the Yucca Mountain Project. As with any QA program of this complexity and magnitude, there are issues to be addressed, such as implementation effectiveness. OCRWM, BSC and SNL have recognized that continued management attention on the QA Program at all levels and in all organizations is necessary to ensure continued success. Along with this management focus, it is also essential that appropriate staffing is provided to support the increase of quality-related work anticipated as the project moves from design into construction.

2. The process for identification and flow down of requirements from the regulatory base (10 CFR 63.142) through the QARD and into the implementing procedures was found to be effective and consistent with industry practices.

3. Data Analysis and Data Qualification Reports prepared in response to condition reports relating to transparency and traceability to qualified data sources were methodical and well-documented. They provide a defensible process in regard to the methodologies used, assumptions made, software identified, and data use limitations. Details are included in the SNL QA Implementation Assessment results (Appendix D).

4. The complex QA program structure at Yucca Mountain complicates organizational interfaces, increases program maintenance costs, and may lead to confusion during program implementation. The QA Program consists of multiple program-level documents: the OCRWM QARD, the OCRWM AQAP, the BSC QMD, and the Sandia QAPD. Examples of the program's complexity include duplicative and redundant implementing procedures issued on the same subject by more than one organization.

5. The team noted what appeared to be a tendency for the OCRWM, BSC, and SNL QA organizations to assume certain organizational responsibilities that arguably belong to management and the line organizations. This assumption of responsibilities usually occurs in response to identified problems where the QA organizations "step in" to compensate for perceived weaknesses in management and the line organizations' implementation of quality assurance requirements. .

6. Site Work Control practices at Yucca Mountain do not appear to integrate quality assurance requirements so as to ensure that work affecting ITS/ITWI is properly controlled.

7. Condition Reports submitted by BSC (CR 1045 and CR 1046) in response to the Site Work Control issues identified by the team did not reflect the full scope and implications of the conditions known at the time of the submittal. This indicates the need for continued management attention on the previously identified "nuclear culture" issues that are the subject of the QAMA.

8. The question of 10 CFR Part 21 applicability needs resolution. This matter has been the subject of considerable legal and regulatory discussion in years past. Correspondence from DOE/OCRWM to and from the NRC has stated that the statutory requirement to apply 10 CFR Part 21 will not be applicable until a license has been granted for repository construction or a certificate of compliance has been issued for a transportation or storage cask. OCRWM communicated to the NRC its intent to voluntarily implement a procedure for application of 10 CFR Part 21 once "long lead time procurement activities" commence for the monitored geological repository (letter from Alan Brownstein, OCRWM Director Regulatory Coordination Division to Michael Bell, U.S. Nuclear Regulatory Commission dated October 30, 1998). Evaluation of that commitment, as it relates to current procurements, along with a defined point in time when that procedure will be implemented is warranted in light of the pending near term submittal of the License Application and the current status of the project.

APPENDIX A
Quality Assurance Program Review

I Introduction

An independent team conducted a comprehensive Quality Assurance (QA) program review of the primary top-level QA program documents in place at the Department of Energy's Yucca Mountain Project. It is the team's conclusion that the Office of Civilian Radioactive Waste Management (OCRWM) QA Requirements Document (QARD), Rev. 18 is responsive to 10 CFR 63 and NUREG-1804 and would likely be accepted by the NRC if submitted as part of the license application. However, there are improvements to the structure of the site-wide QA program, of which the QARD is a part, which could potentially enhance its usability and reduce implementation confusion that may result from its current complexity.

The team recognizes that some of the complexity and detail included in the QARD is driven by the current state of the project (scientific and early site design), the unique technical nature of the repository, and by criteria included in NUREG-1804, the Nuclear Regulatory Commission's (NRC) Yucca Mountain Review Plan Section 2.5. While the NRC review plan is not, in and of itself, a requirements document, it is none-the-less the current standard by which the OCRWM QA program plan will be evaluated. With that in mind, the conclusions and recommendations in this report take into consideration the current near-term license application and propose a managed path forward to improve the long-term viability of the overall Yucca Mountain QA program.

One of the key objectives of this review was to determine if the Yucca Mountain quality assurance program was consistent with standard nuclear industry QA practice and if it was robust enough to carry the project through licensing and into final design and construction. After review of the QA program plans, the team determined that the question of whether the program was robust enough was more a matter of implementation than of the documented program plans. At the program level, the question to be determined was whether the plans, taken as a whole, provided clear and concise direction, commitment to the appropriate industry standards, and if the QA program plans individually struck the right balance between doing and overseeing the work. Notwithstanding the individual written QA program plans, the key to assuring quality lies in the plans' implementation and the attitudes displayed by those who do the work and those who check it.

To that end, as a separate but complementing effort, INFOZEN conducted a Management Assessment, the results of which will be presented in a formal Quality Assurance Management Assessment (QAMA) report. In addition, the core team that performed the QA Program Review also conducted a QA Implementation Assessment to determine the degree to which the QA Program has been implemented at the Yucca Mountain Project. These three reports should be viewed together to determine whether the QA program at the Yucca Mountain Project is "robust."

II QA Program Review Results

Office of Civilian Radioactive Waste Management – Quality Assurance Requirements and Description (DOE/RW-0333P, Revision 18) (QARD)

During this independent QA program assessment, the OCRWM QARD was reviewed to determine its compliance with 10 CFR 63.142. The assessment also considered the likelihood that the Nuclear Regulatory Commission would favorably view the QARD during the Yucca Mountain licensing process.

The QARD establishes requirements for the OCRWM QA program that meets the requirements of the Nuclear Waste Policy Act of 1982 and 10 CFR 63.142, *Quality Assurance Criteria*. The 18 criteria specified in 10 CFR 63 are to be implemented for activities up to the time that high-level radioactive waste and spent nuclear fuel are received at Yucca Mountain for disposal.

The team reviewed the QARD to confirm that it meets the requirements of 10 CFR 63.142 and is consistent with NUREG-1804.

Level of Detail in the QARD

The QARD, as written, includes a level of detail that is not normally included in current nuclear industry quality assurance programs. The majority of today's QA Topical Reports (QA Programs submitted to the NRC) specify the "what to do" by generally providing a clear commitment to an appropriate industry standard without repeating the contents of the referenced standard. When amplification is required or an alternate position to the standard is taken, that position is clearly identified in the program level document. (See section below on Commitment Clarity.) The recently NRC-approved NEI "Quality Assurance Program Description" (NEI 06-14) is an example of the level of detail that is common in today's nuclear utility Combined Operating License (COL) QA Topical Reports.

To paraphrase 10 CFR 63.144, "*Quality Assurance Program Change"*: …*The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed is not considered a change requiring prior NRC approval*. This NRC requirement makes clear that QA program plans like the QARD need not duplicate language already in the referenced guides and standards. If implemented at Yucca Mountain, this change would simplify the QARD making it easier to implement and less costly to maintain.

Additionally, 10 CFR 63.144 permits licensees, without prior NRC approval, to update their programs to the most recent version of NRC-endorsed voluntary consensus standards. As with the removal of duplicative language just discussed, adoption of the latest NRC-endorsed version of NQA-1 would be a positive step forward in terms of updating Yucca Mountain's QA program to the latest methodologies.

Strategically, eliminating redundant information and adopting a more recent version of NQA-1 needs to be viewed from the NRC perspective. Given the NRC staff's familiarity with the more prescriptive current version of the QARD, it is prudent to avoid any wholesale program-level changes prior to licensing unless such changes are closely coordinated with and agreed to in principle by the NRC.

QA Organization's Relationship with the Line

The team noted what appeared to be a general tendency for the QA organizations to assume certain management and line organization responsibilities. Examples include assuming responsibility for developing, approving, maintaining, and interpreting the QA program plans; extensive involvement in closure of corrective actions; and involvement in the line organization's personnel qualification process. The team also observed similar guidelines in NRC Standard Review Plan NUREG-1804. With regard to the issue of QA and the line organization, neither the QARD nor NUREG-1804 reflect contemporary thinking as reflected in voluntary consensus standards like NQA-1. To the extent that Yucca Mountain chooses to revise the QARD to remove these prescriptive provisions, the changes should be closely coordinated with the NRC staff.

During the 1970's and 1980's, the commercial nuclear industry drifted away from the concept of QA organizational independence in the same manner. The NRC, in a congressionally mandated study of QA failures in the commercial nuclear industry (NUREG-1055) documented the results of this philosophical shift. The conclusion of NUREG-1055 was straightforward: The line organization, not inspector or auditors, is responsible for achieving quality. As a result, some companies have dropped the name "Quality Assurance Organization" in favor of a title better reflecting the distinction between achieving quality – which is the line organization's responsibility – and verifying quality – which is the QA organization's responsibility. This relationship and how it achieves and validates quality is part of the "Nuclear Culture." Developing that culture is not a step-change, but rather a process that matures over time in response to management leadership. Insertion of the QA organization into areas where management and the line organization are responsible impedes the growth of that culture

QARD Standards Commitment Clarity

The QAPD does not clearly call out by section, the applicable voluntary consensus standard in the body of the QARD. This lack of specificity impedes users' understanding of exactly what is required of them. As the QARD is presently written, determining the applicability of any given NQA-1 provision requires that the reader refer to a table in the back of the QAPD. Using the QARD is made more difficult in that the table lists only exceptions to NQA-1 provisions. The list of what applies is, in effect, by omission. In contrast to the QARD, most contemporary nuclear industry quality assurance program plans include in their body a direct reference to the specific NQA-1 section they endorse. Similarly, exceptions and alternative positions are discussed alongside the commitment. While a wholesale change to the QARD's format may be imprudent with the impending

license submittal and given the detail contained in NUREG 1804, specific reference to the applicable voluntary consensus standard provision in the relevant QARD section would be a positive interim step forward in realizing a more sophisticated and easier to use QARD.

Bechtel SAIC Company, LLC – Quality Management Directive (QA-DIR-10, Revision 1) (QMD)

The QMD defines the roles and responsibilities for managers and supervisors in achieving program objectives consistent with contract requirements and business needs. The QMD serves as the top-level document for defining and integrating various QA requirements for environmental protection, safety, and quality. These requirements include the Nuclear Waste Policy Act of 1982; 10 CFR 63.142; Department of Energy (DOE) Order 414.1C (Attachment 2, Contractor Requirements Document), *Quality Assurance*; DOE/RW-0333P, QARD; and DOE/RW-0565, *Augmented Quality Assurance Program* (AQAP).

The team reviewed the QMD to confirm that it meets the requirements of 10 CFR 63.142 and is consistent with the QARD and NUREG-1804. BSC has adopted voluntary consensus standard NQA-1, which is based on the NRC's 18 QA criteria.

The QMD is based on two divergent QA program requirements documents: 10 CFR Part 63.142 (NRC 18 QA criteria with emphasis on records and compliance) and DOE Order 414.1C (10 QA criteria with emphasis on QA as an overarching quality management program). This bifurcated program structure will likely cause implementation difficulties.

ITS and ITWI applications are addressed in the QMD as "additional requirements." It is not apparent how they are incorporated into the program and implementing procedures. This may result in confusion at the implementation level. There was general consensus among team members that Section 3 (Requirements) of BSC's QMD focused mostly on DOE Order 414.1C, *Quality Assurance*, with little mention of either 10 CFR 63.142 or OCRWM's QARD. While O414.1C is contractually mandated, the Order's implementation is limited at Yucca Mountain to "non-Q" or non-ITS/ ITWI structures, systems, and components. In terms of focus, the team recommends striking a better balance in Section 3 between the Order's non-Q requirements and the Q requirements of Part 63 and the QARD. In the team's opinion, this change would strengthen the QMD.

In implementing the requirements in the QARD, BSC has carried forward in the QMD requirements for the QA organizations to assume certain management and line organization responsibilities. Recommendations associated with the QA organization relationship to the line organization apply to BSC as well as to OCRWM and SNL and are included in the section III of this report.

Sandia National Laboratory – Quality Assurance Program Description (QA-PRG-001) (QAPD)

The QAPD describes the Sandia National Laboratory approach as Lead Laboratory for meeting applicable quality assurance requirements mandated by the OCRWM QARD (DOE/RW-0333P) and AQAP (DOE/RW-0565).

The team reviewed the QAPD to confirm that it meets the requirements of 10 CFR 63.142 and is consistent with the QARD and NUREG-1804. The QAPD references the upper tier OCRWM requirements with the appropriate level of detail, amplifying on the requirements where necessary. Rather than have an additional program-level document for application of quality assurance requirements of the AQAP, SNL applies a grading process to non-ITS/ITWI work and items.

In implementing the requirements in the QARD by reference, SNL has carried forward in the QAPD requirements for the QA organizations to assume certain management and line organization responsibilities. Recommendations associated with the QA organization relationship to the line organization apply to SNL as well as to OCRWM and BSC and are included in the section III of this report.

Site-Wide QA Program Structure: QARD – AQAP – QMD – QAPD

The team looked at the structure of the site-wide QA program, including the QARD, AQAP, QMD, and QAPD. First, the three ITS/ ITWI program plans were reviewed individually to determine their compliance with regulatory requirements. The AQAP was not included in this initial review because it deals exclusively with non-ITS/ITWI activities and is not based on regulatory requirements. Second, the four program plans were viewed together to assess the extent of their integration across organizational boundaries, the flow-down of requirements, and the practicality of their implementation given the overall program's structural complexity.

There were several underlying facts and philosophies that drove this part of the review and shaped its results. They were as follows:

a) The Nuclear Regulatory Commission is the licensing and regulatory authority for the Yucca Mountain Project.
b) All Yucca Mountain-related QA program plans should ideally derive from the same regulatory requirements.
c) A single site-wide QA program plan is desirable in terms of focus, organizational interfaces, policy and implementation consistency, and revision control.
d) Program-level documents, like QA program plans, should specify "what" to do not "how" to do it.
e) Industry consensus standards, such as NQA-1, should be adopted and used to develop implementing procedures.
f) Work processes and the procedures that implement them are the responsibility of those doing the work (line organization).
g) The relative importance-to-safety of the item or work process is reflected in implementing procedures.

The conclusion of the team is that the Quality Assurance program plans are duplicative, thereby complicating their implementation. At the working level, there is significant potential for confusion, particularly when activities or work involve more than one organization. In addition, the application of the AQAP as a stand-alone document with a different format (10 criteria versus the 18 in 10 CFR 63.142) further confuses users. A single site-wide Quality Assurance Program based on commitment to a single voluntary consensus standard that describes "what to do" not "how to do it" would provide those who implement the QA program with clear direction. Implementing procedures would provide the "how to do it." Generic procedures would direct performance of common tasks that OCRWM, BSC, and SNL accomplish and unique company procedures would only be required when activities are unique to the organization. Where application of grading is appropriate for non-ITS/ITWI work or activities, the grading process would be specified at the procedural level rather than in the top-level program document.

Selection of a consistent voluntary industry consensus standard for the QA Program

Selection of a single voluntary consensus standard for both ITS/ITWI and non-ITS/ITWI items and processes is paramount to achieving QA program integration, ensuring strong uncomplicated program implementation, and allowing for the development and implementation of a single site-wide quality assurance program plan (or Topical Report). Yucca Mountain's current use of multiple voluntary consensus standards, one to satisfy regulatory requirements and the other to satisfy contractual requirements, complicates organizational interfaces, increases program maintenance costs, and will be the source of unnecessary complexity that will likely compromise program implementation once design and construction commence.

The NRC has endorsed voluntary consensus standard NQA-1 as an acceptable way to implement 10 CFR 63.142. Similarly, the DOE has endorsed NQA-1 as an acceptable way to implement DOE Order 414.1C. Adopting NQA-1 for site-wide ITS/ITWI *and* non-ITS/ITWI items and processes allows for more effective integration and the simplicity that comes from using a single consistent guidance document rather than two or more organizationally and philosophically divergent guidance documents. Using this scenario, a single site-wide quality assurance program plan can be developed and implemented. The distinction between what quality assurance requirements exist for ITS/ITWI and for non-ITS/ITWI items and activities can then be more simply and cleanly drawn at the implementing procedure level.

Regarding voluntary consensus standard ISO 9001, its adoption by Yucca Mountain would separate out the non-ITS/ITWI items and processes at the program level resulting in the development and implementation of a separate quality assurance program plan exclusively for non-ITS/ITWI items and processes. Programmatically, this would be undesirable. Adopting NQA-1 for ITS/ITWI *and* non-ITS/ITWI items and processes does not preclude the use of ISO 9001 or another voluntary consensus standard by suppliers when due consideration is made for the limitations and acceptance of those standards as they apply to Yucca Mountain. The use of appropriate engineering evaluation of the critical quality characteristics and the ability of an ISO 9001 vendor to

supply to those characteristics, along with the ability to augment the requirements through the procurement process or at receipt, determines whether the ISO 9001 vendor can be used. This process is independent of selecting NQA-1 as the voluntary consensus standard for Yucca Mountain quality assurance.

III Quality Assurance Program Improvement Recommendations

Recommendations with regard to QA organizational responsibilities:

1. Reach project-wide understanding and acceptance of what "QA" is at Yucca Mountain.
2. Communicate and interface with the NRC on areas where the current Yucca Mountain Project Review Plan (NUREG 1804) appears to imply or require the QA organization assume line management responsibilities.
3. Senior management and the line organization should take responsibility for those sections of the QA program for which they are responsible.
4. The QA organizations should take responsibility for those sections of the QA program for which they are responsible.
5. The QA organizations should reach internal consensus regarding their organizational mandate.
6. The QA organizations should work to hold themselves apart from the day-to-day work so as to maintain their independence as required by Criterion 1.
7. Senior management and the line organization should engage and write the sections of the QA program plan for which they are responsible.
8. Training should be conducted to communicate and institutionalize the Yucca Mountain site's approach to QA.

Recommendations with regard to QA Program Structure:

PRE - LICENSING

1. For NRC licensing purposes, maintain the current scope and format of the QARD consistent with NUREG 1804. In the short-term, update the QARD only as necessary to include urgent management and licensing-related matters.
2. In the QARD, include any additional appropriate construction-related provisions from the ANSI N42.2 series that are not in NQA-1(1983).
3. Clarify QA commitment documents and positions by moving the information in Rev 18 Table 1 into the respective section of the QARD, indicating full commitment or the alternative positions taken.
4. Rather than have a separate AQAP for non-ITS/ITWI, use the QARD for non-ITS/ITWI items and processes. Grading of requirements for non-ITS/ITWI would be contained in implementing procedures, not in the QARD.

POST-LICENSING

5. Involve management and the line organization in future development and revisions of the QARD.

6. Consolidate the QARD, BSC QMD and SNL QAPD into a single Yucca Mountain QA Program Topical Report
7. Adopt the latest NRC-endorsed version of NQA-1 (expected to be NQA-1-2007/8) as the project-wide voluntary consensus standard for Yucca Mountain Quality Assurance.
8. As practicable, use NEI 06-14 ("Quality Assurance Program Description") as the template for the Yucca Mountain QA Program Topical Report.

APPENDIX B
OCRWM Independent Quality Assurance Implementation Assessment

1. Introduction

An independent team assessed implementation of the Quality Assurance program by OCRWM. It is the team's conclusion that the implementation is consistent with the commercial nuclear industry and is adequate for the current status of the project.

"**Problem Statements**" are identified which represent a failure to comply with specific QARD programmatic or implementing procedural requirements. The problem statements were provided to the OCRWM Office of Quality Assurance (OQA) for disposition.

"Recommendations" are provided where improvements would enhance the implementation of the QA Program.

The assessment focused on current activities being conducted for the project rather than historical or legacy issues to gauge the current level of adequacy of implementation of the QA Program.

The team consisted of personnel with Nuclear Regulatory Commission (NRC) and commercial nuclear management and quality assurance experience and used, where available, NRC inspection guides as the basis for the assessment. Resumes of the Independent Assessment Team are included in Attachment 2 of this report.

Team Leader:	Dan M. Stover – Technical And Professional Services, Inc
Team Members	Frank Hawkins - Technical And Professional Services, Inc.
	Wayne Scott - Technical And Professional Services, Inc.
	Paul Kellogg - InfoZen
	Raymond Wenderlich – Technical And Professional Services, Inc.
	Rene' Delaney - Technical And Professional Services, Inc.
	Bruce Tracey - Technical And Professional Services, Inc.

Lines of Inquiry were prepared and are included as Attachment 1 to this report. The implementation assessment included a detailed review of the flow down of the requirements from 10 CFR 63.142 through the QA Program description and into the implementing procedures.

2. Assessment Results

The OCRWM implementation of the QARD is consistent with that seen in the commercial nuclear industry at this stage of the project. 10 CFR 63.142 criteria reviewed include:

10 CFR 63.142 Quality assurance criteria

(b) Organization
(c) Quality assurance program
(e) Procurement document control
(h) Control of purchased equipment, material and services
(s) Audits

Lines of Inquiry for each of the areas reviewed are included in Attachment 1. The lines of inquiry are derived from NRC Inspection Procedures and the QARD. They provide guidelines for the respective team members from which the conclusions for this report are drawn after team discussion and consolidation of the information.

The OCRWM QA organization, under the direction of the new Director, Office of Quality Assurance (OQA), has begun a significant effort in strategic planning to better equip the organization to effectively execute their responsibilities and be positioned to transition from the current phase to support of design and construction after the NRC license application is approved. An example is the integration of OCRWM, BSC, and SNL supplier audits. While this strategic planning and its execution will take some time to accomplish, the results should be a more effective and efficient organization. The organization has the full and unqualified support of the Director, OCRWM, who is keenly focused on ensuring that the Yucca Mountain Project QA program and its implementation supports the successful submission and approval of a complete and accurate license application and the subsequent construction and operation of the Yucca Mountain repository in full compliance with all QA requirements.

Criteria 10 CFR 63.142 (b) Organization:

The organization in place at OCRWM at the Las Vegas offices is consistent with the organization that is described in the QARD. Organizational responsibilities with regard to both the attainment and verification of quality have been assigned. The personnel assigned responsibility for performing the quality assurance verification and validation functions report to the Director, OQA and have sufficient organizational freedom as required by 10 CFR 63.142 (b)(2).

The Director, OQA, a quality assurance professional with experience in the commercial nuclear industry, has the necessary qualifications and experience to execute his assigned responsibilities. The Director OQA reports to the Director, OCRWM who is located at DOE headquarters in Washington, DC. In addition to the Director, OQA there are 12 principal office directors who report to the Director OCRWM. (See QAMA discussion regarding on-site senior OCRWM management presence.)

It was noted that throughout the QARD there are examples where the QA organization has been assigned responsibilities that are usually carried out by management and the line organization. For instance, QARD section 3.2.2.K, *Design Processes*, states that, *"Design documents shall be reviewed by individuals or groups within the QA organization that do not have direct responsibility for performing the work being verified or by individuals or groups other than the one who generated the document and trained and qualified in QA practices and concepts."* Review of design documents by the QA

organization, other than in the validation/verification activities associated with surveillance and audit of these activities, sends the message to the line organization that "QA is responsible for design quality." Similarly, QARD section 4.2.2, *Procurement Document Review and Approval*, contains an almost identical statement. In the case of the procurement activities, the QA organization performs a 100% review of all procurement documents. The commercial nuclear industry abandoned this type of 100% review some time ago, recognizing that they could not "review" quality into procurement documents and that it was the line organization generating the procurement that ensured the appropriate technical and quality requirements were included.

Recommendation: OCRWM, BSC and SNL should evaluate their respective QA Program plans and practices to identify responsibilities that have been assigned to the QA Organization that potentially undermine line management responsibility and accountability for quality. Where such situations are identified, a strategy for the smooth transition of the responsibility from the QA Organization to the line organization should be developed and implemented.

10 CFR 63.142(c) Quality assurance program (including training implementation)

Quality Assurance Program:

The QA Program described in OCRWM DOE/RW-0333P "Quality Assurance Requirements and Description" was the subject of a specific detailed review (see Appendix A) that preceded this implementation assessment. The conclusion of that review was that the QA Program meets the requirements of 10 CFR 63.142, but that it was much more prescriptive and detailed than is currently the practice at commercial nuclear plants. The team recognizes that this is somewhat driven by the prescriptive detail in the NRC Yucca Mountain Project Review Plan, NUREG 1804.

In addition the team noted an issue relating to procedure development and use. Specifically, a number of instances were identified where overlapping redundant procedures were written by BSC and SNL to accomplish the same task. This practice potentially results in programmatic complexities and communication difficulties that occur when two organizations work closely together, using their own procedures. Such was the case observed during sampling activities where SNL collected the samples to an SNL procedure (TST-PRO-008) that relied on BSC Sample Management Facility procedures and forms (PA-PRO-0804). The result was a number of samples collected that were not identified correctly on the sample management form. While this was not the sole cause of the issue, it was a likely contributor.

Recommendation: OCRWM, BSC, and SNL should jointly determine (1) where multiple procedures exist for the same tasks or (2) situations exist where procedural interface is required between two or more organizations. In these cases, consideration should be given to issuing a single procedure at the appropriate level to accomplish the task.

Training Programs:

The assessment of training programs was coordinated with the QAMA team. The QAMA team concentrated on training of OCRWM personnel and it was not repeated by the implementation team. It was noted that rather than using a formal "Systematic Assessment of Training" or other recognized method to determine training requirements, most training requirements specified for OCRWM personnel were based on the "judgment" of the individuals' manager. (See QAMA report)

10 CFR 63.142(e) Procurement Document Control and 10 CFR 63.142(h) Control of Purchased Equipment, Material and Services

The procurement assessment began with a review of the flow down of QARD requirements to confirm that the implementing procedures included requirements from the QARD. This assessment included a review of the OCRWM Quality Assurance Requirements and Description (QARD) DOE/RW-0333P, revision 18 and associated implementing procedures listed in Lines of Inquiry A1.4. Requirements reviewed were reflected in the implementing procedures except for the item relating to 10 CFR Part 21 as discussed below.

The applicability of 10 CFR Part 21 to Yucca Mountain was discussed extensively. Particular emphasis was placed on when Part 21 should be invoked during the procurement process. The QARD lists 10 CFR Part 21 as an item to be considered for inclusion on the procurement documents. However, none of the implementing procedures pick up this requirement. Currently, OCWRM does not apply 10 CFR Part 21 requirements to the project. QARD section 4.2.1.K requires provisions for identifying that the procurement is subject to the provisions of 10 CFR Part 21. Initially, OCRWM indicated they would voluntarily apply 10 CFR Part 21 to the Yucca Mountain Project. Following discussion with the NRC, OCRWM decided to reconsider this position. A letter to the NRC, dated October 30, 1998, states that, "OCRWM intends to postpone the voluntary implementation of the procedure until the Yucca Mountain Site Characterization Project commences long lead time procurement activities for the monitored geological repository." There is no specific defined point in time when this voluntary implementation will be undertaken.

The team was subsequently informed that Part 21 would apply to several fabricated items currently being purchased by BSC. In reviewing OCRWM's procedures, the team could not find when or how 10 CFR Part 21 would be applied to procurement documents for these type of long lead time procurements as committed to in the October 1998 letter to the NRC.

Problem Statement: Implementing procedures for the application of 10 CFR Part 21 to ITS/ITWI-related procurements have not been issued and current procedures do not include provisions for the application of 10 CFR Part 21 to vendors. The OCRWM QARD, section 4.2.1.K lists 10 CFR Part 21 as an item for consideration when issuing procurement documents for ITS/ITWI purchases. A letter to the NRC commits the project to voluntarily implementing the requirements for 10 CFR Part 21 prior to becoming a licensee for long lead time procurements.

Procurement Documents:

The team assessed a sample of procurement documents, supplier audits, and acceptance records to verify procedure implementation and compliance. The process included review of documents, interviews with personnel, and verification that the required records were being maintained. (See Line of Inquiry A1.4) All personnel interviewed during this portion of the assessment were found to be very knowledgeable and experienced in their associated areas.

It was noted during this review that the project was not taking advantage of some procurement processes currently in use in the commercial nuclear industry for calibration service suppliers.

Recommendation: OCWRM should look into using the NRC-approved process of using A2LA and NAVLAP certified calibration suppliers without performing audits or surveys. The NRC has allowed the nuclear industry to use calibration suppliers without audit or survey as long as the supplier is accredited to A2LA or NAVLAP. However, in order to take advantage of this process the NRC requires that procedures must include:

(a) Verification that the supplier registration includes the needed measurement parameters, ranges, and uncertainties of calibration being performed. It is recommended that a copy of the supplier registration be obtained and filed with the supplier records.
(b) Provision to ensure purchase orders (POs) to the supplier include a requirement for reporting as-found calibration data when calibrated items are found to be out of tolerance.
(c) Provisions to ensure POs to the supplier require that the suppliers' standards used for the calibration are recorded on the calibration certificate.
(d) Provisions in the procedure for the approved suppliers that list this method of commercial calibration supplier approval.
(e) Provisions that the re-approval/expiration dates for a supplier match the expiration date on the suppliers' registration forms to ensure tracking of their re-registration.

Assignment of Work Tasks to Sandia National Laboratory:

Recently, OCRWM set up a new contractual relationship for the Sandia National Laboratory (SNL). This change assigns SNL the responsibility for managing and performing all Yucca Mountain-related laboratory work. A new agreement was established, dated July 11, 2006, and amended on, November 27, 2006, between OCRWM and the National Nuclear Security Administration (NNSA). NNSA, also a DOE organization, issues the contract to Sandia (Contract number DE-AC04-94AL-85,000.) The agreement passes on the scope and quality requirements to NNSA for the SNL work. It also requires that "Each task assigned to SNL under a Program Guidance Memorandum will clearly indicate if it is subject to the QARD (Q) or subject to the AQAP (non-Q). SNL shall perform all tasks designated as "Q" in accordance with that portion of the QA program that meets the requirements of the QARD." However, OCRWM has not been using the Guidance Memorandum forms to assign work as required by procedure LP-4.7Q. Instead an annual letter is issued for each fiscal year and explains the work to be performed in that year. The most recent letter was reviewed and was found not to contain any indication as to whether the work is "Q" or "non-Q". SNL does issue an Annual Work Plan with each task description, including the deliverables to be provided to OCRWM for approval. This document also does not identify the quality level of the work. Neither the work plan process, nor the associated methods of specifying work to SNL process are proceduralized. During interviews with OCRWM and SNL personnel inconsistent answers were given as to what work was "Q".

Problem Statement: OCRWM has not been using Guidance Memorandum forms to assign work to the Lead Laboratory as required by LP-4.7Q. Instead, an annual letter is issued for each fiscal year that details the work to be performed in that year. The most recent letter was reviewed and was found not to contain any indication as to whether the work is subject to the QARD "Q" or subject to the AQAP "non-Q" which is a specific requirement of LB-4.7Q.

10 CFR 63.142(s) Audits

The internal audit and QARD Appendix A assessment included a review of the flow-down of QARD requirements to ensure that the implementing procedures included requirements from the QARD. This assessment included a review of the OCRWM Quality Assurance Requirements and Description (QARD) DOE/RW-0333P, revision 18; and associated implementing procedures listed in Line of Inquiry A1.10. Requirements reviewed were incorporated in the implementing procedures.

In response to a recent NEI assessment, an improvement program was initiated by OCRWM that included changes in the internal audit program. The improvement program has resulted in changes which should enhance audit program efficiency and effectiveness. Procedures need to be updated to include the new process. An example is the new process for including internal audits in the integrated audit process. OCRWM has

documented this issue as a CR for resolution (CR 10174). The recent internal audits reviewed were consistent with those seen in the commercial nuclear industry.

Recently, OCRWM integrated internal audits as a Project teaming effort, and OCRWM, BSC, and SNL are working together to perform audits. The team viewed this new process as strengthening the overall project internal audit process. This integrated process will result in a more comprehensive audit program, but the procedures need to be revised to address the new process. The audits reviewed since the CR was written were found to be very comprehensive, clear, concise, and detailed. This teaming effort has produced very good results in the recent audits that were reviewed. The recent audits were found to be much better than the older audits in the amount of detail, comprehensive process reviews, and detailed audit checklists used and documented.

Audits appear to identify many issues and as a result, CRs are written; however, the CRs seem to be open for extended periods of time. Several audits reviewed still had open CRs from previous audits conducted on the same subject. Examples are audit OQA-OCRWM-07-09 and OQA-OCRWM-07-09. This indicates that continued line organization emphasis on timely closure of corrective actions is warranted as discussed in the QAMA report, including an evaluation of the closure process itself, if necessary.
The internal audit schedules were reviewed and a sample of audits, including planning, performing, documenting and follow up, were selected for review to verify procedure implementation. The process included review of documents, interviews with personnel (list of personnel interviewed is shown below), and verification that the required records were being maintained. One isolated discrepancy was noted regarding missing checklists from an audit.

Problem Statement: The audit report package for OQA Audit OQA-SNL-07-02 did not contain the checklist used as required by Procedure LP-18.3Q section 5.4. The OQA Supervisor of Quality Assessments was informed and a CR was written to document this discrepancy (CR-10943). Based on the sample of audits reviewed, this discrepancy appeared to be an isolated incident.

Appendix A - Waste Custodian Interface:

The Interface Agreements with the DOE Office of Environmental Management sites and the Naval Nuclear Propulsion Program, required by the QARD Appendix A, were reviewed and found to meet QARD requirements. These agreements and the associated process were also discussed with OCRWM personnel. A sample of the documents required by Appendix A for OCRWM oversight of the Naval Nuclear Propulsion Program (NNPP) were reviewed and found to meet the QARD requirements. All personnel interviewed during this portion of the assessment were found to be knowledgeable and experienced.

Responsibility for Initiating Condition Reports

Discussions with OCRWM audit and support personnel indicated that it is normal practice when both internal and external audits and assessments identify "findings," the QA Organization generates the Condition Report (CR); this, as opposed to having the responsible line organization generate the CR. While this process assures that a condition report is generated, it can lead to the situation where the line organization does not have or feel ownership for the condition. While it is often the case that it is easier to have QA initiate the CR, it runs the risk of reinforcing a mindset that QA is responsible for quality. It is an important distinction that, although an assessment may have "found the condition," the line organization is responsible for its occurrence. Having the responsible line organization generate the CR reinforces that concept. The QA audit or assessment would then track the finding, including verification of closure if necessary, through the CR process and follow-up audits.

Recommendation: Consider shifting the responsibility and accountability for writing Condition Reports to the line organization responsible for the identified issue when audits and assessments (both internal and external) identify findings and deficiencies. For internal audits, the audit team would identify the finding or deficiency, but the actual initiation of the Condition Report would be the responsibility of the audited organization.

APPENDIX C
BSC, LLC Independent Quality Assurance Implementation Assessment

1. Introduction

An independent review team conducted an assessment of the implementation of the Quality Assurance program by BSC, LLC. It is the team's conclusion that the implementation is consistent with the commercial nuclear industry and is adequate for the current status of the project.

"**Problem Statements**" are identified which represent a failure to comply with specific QARD programmatic or implementing procedural requirements. Where identified, these problem statements were provided to the OCRWM Office of Quality Assurance (OQA) for disposition.

"Recommendations" are provided where the team has identified areas where improvements would enhance the implementation of the Quality Assurance Program.

The assessment focused on current activities being conducted for the project rather than historical or legacy issues to gauge the current level of adequacy of implementation of the QA Program.

The team consisted of personnel with Nuclear Regulatory Commission (NRC) and commercial nuclear management and quality assurance experience and used, where available, NRC inspection guides as the basis for the assessment. Resumes of the Independent Assessment Team are included in Attachment 2 of this report.

Team Leader:	Dan M. Stover – Technical And Professional Services, Inc
Team Members	Frank Hawkins - Technical And Professional Services, Inc.
	Wayne Scott - Technical And Professional Services, Inc.
	Paul Kellogg - InfoZen
	Raymond Wenderlich – Technical And Professional Services, Inc.
	Rene' Delaney - Technical And Professional Services, Inc.
	Bruce Tracey - Technical And Professional Services, Inc.

Lines of Inquiry were prepared and are included as Attachment 1 to this report. The implementation assessment included a detailed review of the flow down of the requirements from 10 CFR 63.142 through the QA Program plan and into the implementing procedures.

2. Assessment Results

BSC implementation of the QA program is consistent with that seen in the commercial nuclear industry at this stage of the project. 10 CFR 63.142 criterion reviewed for BSC include:

10 CFR 63.142 Quality assurance criteria
(b) Organization
(c) Quality assurance program
(d) Design control
(e) Procurement document control
(f) Instructions, procedures and drawings
(g) Document control
(h) Control of purchased equipment, material and services
(j) Control of Special Processes
(m) Control of Measuring and Test Equipment
(q) Corrective action
(r) Quality assurance records
(s) Audits

In addition, the following requirements in the QARD were included in the review. These activities are encompassed by the requirements of 10 CFR 63, but are sufficiently narrowly focused as to be amplified within the QARD by a special supplement.

- Supplement I Software
- Supplement II Sample Control

Lines of Inquiry for each of the areas reviewed are included in Attachment 1. The lines of inquiry are derived from NRC Inspection Procedures and the QARD. They provide guidelines for the respective team members from whom the conclusions for this report are drawn after team discussion and consolidation of the information

The Manager, Quality Assurance, BSC, LLC works closely with the OCRWM Director OQA and the Quality Assurance Manager, SNL to ensure that the organizations function synergistically. Together, they have begun an effort to explore methods to better equip the respective organizations to effectively execute their responsibilities and be positioned to transition from the current phase to support construction after the license application is approved. An example of the integration of OCRWM, BSC, LLC and SNL is the coordination of audits of primary contractors into an integrated audit process.

Criteria 10 CFR 63.142 (b) Organization:

The organization in place at BSC, LLC at the Las Vegas Offices is consistent with the organization that is described in QA-DIR-10, Rev. 1, "Quality Management Directive (QMD)." Organizational responsibilities with regard to achieving and verifying quality

have been assigned. The personnel assigned responsibility for performing the quality assurance verification and validation functions report to the Manager, Quality Assurance, and have sufficient organizational freedom as required by 10 CFR 63.142 (b)(2).

The Manager, Quality Assurance, is a quality assurance professional with experience in the commercial nuclear industry. He has the necessary qualifications and experience to execute his assigned responsibilities. The Quality Assurance Manager reports directly to the General Manager, BSC, LLC whose office is in Las Vegas within the BSC office complex. In addition to the QA Manager, there are 7 principal office directors who also report directly to the BSC General Manager.

It was noted that BSC has implemented the philosophy in the QARD where the QA organization is assigned or implied responsibilities that can potentially undermine line management ownership of quality. For instance, QMD Section 3.1.D.2. Design Reviews states *"Design documents for ITS/ITWI SSCs shall be reviewed by individuals or groups within the QA organization to ensure that the documents are prepared, reviewed, and approved in accordance with implementing procedures and that they contain the necessary requirements, such as inspection and test requirements, acceptance requirements, and the extent to which inspection and test results are required to be documented."*

In the case of the BSC QMD, there is no option to use someone outside the QA organization with the appropriate training. The review of design documents by the QA organization, other than in the validation/verification activities associated with surveillance and audit of these activities, sends the message to the line organization that "QA is responsible for quality." Similarly, section 4.D.1 states *"Procurement documents for the procurement of ITS/ITWI items or services shall be reviewed by individuals or groups within the QA organization."* The commercial nuclear industry abandoned this type of 100% QA Organization review quite some time ago, recognizing that they could not "review quality" into the documents. They concluded that the line organization responsible for the procurement was also responsible for ensuring that the appropriate technical and quality requirements were included in the procurement documents.

Recommendation: OCRWM, BSC and SNL should evaluate their respective QA Program plans and practices to identify responsibilities that have been assigned to the QA Organization that potentially undermine line management responsibility and accountability for quality. Where such situations are identified, a strategy for the smooth transition of the responsibility from the QA Organization to the line organization should be developed and implemented.

10 CFR 63.142(c) Quality assurance program (including training implementation)

The Quality Assurance Program described in QA-DIR-10, Rev 1, "Quality Management Directive," was the subject of a specific detailed review that preceded this implementation assessment. The conclusion of that review was that the QA Program

meets the requirements of 10 CFR 63.142, but that it was much more prescriptive and detailed than is currently the practice at commercial nuclear plants.

In addition the team noted an issue relating to procedure development and use. Specifically, a number of instances were identified where overlapping redundant procedures were written by BSC and SNL to accomplish the same task. This practice potentially results in programmatic complexities and communication difficulties that occur when two organizations work closely together, using their own procedures. Such was the case observed during sampling activities where SNL collected the samples to an SNL procedure that relied on BSC Sample Management Facility (SMF) procedures and forms. The result was a number of samples collected that were not identified correctly on the sample management form. While this was not the sole cause of the issue, it was a likely contributor.

Recommendation: OCRWM, BSC, and SNL should jointly determine (1) where multiple procedures exist for the same tasks or (2) situations exist where procedural interface is required between two or more organizations. In these cases, consideration should be given to issuing a single procedure at the appropriate level to accomplish the task.

Training:

Training records of selected individuals were reviewed to compare the training received with the training required for the individual's respective positions. In most cases, the individuals whose records were reviewed were also those with whom the team interfaced during the assessment. The review found that training requirements were identified for all critical positions. However, three individuals who performed ITS work had not received their required training. In one case at the Sample Management Facility (SMF), an individual who was recording ITS data for boring operations had not received the required training. The individual indicated that he had been given "on-the-job training" for the tasks; however, this training is not controlled or recorded and is not listed as a part of the training requirements for the position or task.

In another case, two subcontracted individuals were observed performing ITS surveying of borehole locations to support geotechnical investigations. The company for whom they worked was not on the QSL for the work being performed (see control of purchased services section below) and the individuals were listed as "Inactive" on the training records. No supervision was provided and no BSC personnel were with the surveyors as required by the subcontract statement of work.

The QMD, section 2.2.C.2.6 requires that management "Ensure indoctrination and training are completed before assigning personnel to perform work independently."

Problem Statement: During a site visit on July 12, 2007, a BSC subcontract employee (staff augmentation) who had not completed the required training for the position assigned was observed taking and recording quality-related data. (Condition Report BSC 10946 was initiated by BSC for this problem statement.)

The team followed the initiation and processing of this Condition Report and comments are provided in the section on Corrective Actions.

10 CFR 63.142(d) Design Control

The requirements of the QARD for Design are adequately passed down through implementing procedures. Personnel interviews and documentation reviews were performed to evaluate the design program implementation for the Yucca Mountain Project. BSC design engineering staff, including senior management, has significant experience in the design of commercial nuclear facilities. Implementation of the QA program for design activities is consistent with commercial nuclear industry practices.

Individuals in the BSC design organization were interviewed. They displayed an understanding of QA requirements for design and the path forward to support the design effort for both the License Application and the coming design work to complete the project. BSC is responsible for the Pre-Closure Design Basis documents, including the development and maintenance of the Q-List.

Q-List Status

In the spring of 2006 a decision was made to significantly revise the design of the facility. At that time, a Q-List was in place based on a previous design (Q-List #000-30R-MGR0-00500-000-003). This list was based on the issuance of design calculation "Safety Classifications of SSCs and Barriers" # 000-00C-MGR0-03000-000, and The Nuclear Safety Design Bases for License Application # 000-30R-MGR0-00400-000. Subsequently, a new design has been proposed and is in the engineering review stage. Engineering management appeared to have a clear picture of the path forward for the design process and the steps necessary to prepare a new Q-List based on the new design.

In the interim, BSC Engineering conducted an Engineering Study titled "Preliminary Pre-closure Safety Classification of SSCs (000-PSA-MR0-00200-000-000) dated 12/6/06 to provide a preliminary determination of the pre-closure structures, systems, and components (SSCs) based on the "revised" repository design of December 2006. This study compares the characteristics of the revised design as it relates to how they will impact the Q-List based on the similarities and differences between the revised design and the previous design. It is thoroughly done and provides a roadmap between the previous Q-List and what will eventually be the revised Q-List based on the new design. This study confirms that, with the exception of SSCs that will not be included in the new design and those specific SSCs that are new and unique to the new design (and thus not yet analyzed), there are very few changes to the Q-List for the SSCs that are common to both designs.

Procedure LS-PRO-0201 (Pre-closure Safety Analyses Process) was implemented in September 2006. This procedure applies to the analysis of applicable pre-closure hazards and initiating events, the calculation of radiological consequences, the categorization of event sequences, the derivation of procedural safety controls, and the derivation of pre-closure nuclear safety design bases and selection of structures, systems, and components (SSCs) that are ITS. ITS SSCs are summarized on the Q-List.

Procedure # LS-PRO-0203 (Q-List and Classification of Structures, Systems, and Components) was implemented for the preparation and approval of the new Q-List. The procedure provides the process description and classification criteria to identify what systems and items are ITS. The classification of SSCs is based on risk-informed safety analyses and is documented in pre-closure nuclear safety design basis documents and the Q-List. The flow down from the Q-List is through the engineering design criteria and system/facility basis to drawings, calculations, technical reports, analyses, specifications, and facility and system documents as per the requirements of EG-PR)-3DP-G04B-00005 (Configuration Management).

During the course of this assessment there was a great deal of conflicting information presented to the team as to the status of the Q-List, representing a vulnerability to the implementation of the QARD. At one point a senior member of the BSC Quality Assurance staff categorically stated to the team that "there is no Q-List." Although this statement was later revised to state that the Q-List is out of date, it none-the-less typified the confusion which exists. There is, in fact, an approved Q-List based on the old design. A revised Q-List is being prepared for the revision to the old design.

The implementation of the Quality Assurance requirements of 10 CFR 63.142 is required for those SSCs and activities affecting SSCs that are ITW/ITWI. The Q-List is the primary method of formally designating that status. It is imperative that all personnel recognize that the Q-List will change as the design matures and evolves. A smooth transition from the preconstruction phase to the construction phase will be only possible if everyone understands the purpose and function of the Q-List.

Recommendation: Consideration should be given to preparing and issuing a "position paper" to OCRWM, BSC, and Lead Lab personnel describing the purpose of the "Q-List", what is on it, how is it generated, and where it applies. Transition from the preconstruction phase to the construction phase will be enhanced if everyone understands the purpose and function of the Q-List. When construction starts, the Q-List becomes an indispensable tool in application of the quality assurance and quality control requirements in the control of work.

10 CFR 63.142(e) Procurement Document Control and 10 CFR 63.142 (h) Control of purchased equipment, materials and services.

The procurement assessment started with a review of the flow down of QARD requirements to ensure that the implementing procedures include all requirements from

the QARD. This assessment included a review of the OCRWM Quality Assurance Requirements and Description (QARD) DOE/RW-0333P, revision 18 and BSC's Quality Management Directive QA-DIR-10, revision 1 and associated implementing procedures listed in Lines of Inquiry A1.4. Requirements reviewed were reflected in the implementing procedures except for the item relating to 10 CFR Part 21.

The applicability of 10 CFR Part 21 to Yucca Mountain was discussed extensively. Particular emphasis was placed on when Part 21 should be invoked during the procurement process. The QARD lists 10 CFR Part 21 as an item to be considered for inclusion on the procurement documents. However, none of the implementing procedures pick up this requirement. Currently, OCWRM does not apply 10 CFR Part 21 requirements to the project. QARD section 4.2.1.K requires provisions for identifying that the procurement is subject to the provisions of 10 CFR Part 21. Initially, OCRWM indicated they would voluntarily apply 10 CFR Part 21 to the Yucca Mountain Project. Following discussion with the NRC, OCRWM decided to reconsider this position. A letter to the NRC, dated October 30, 1998, states that, "OCRWM intends to postpone the voluntary implementation of the procedure until the Yucca Mountain Site Characterization Project commences long lead time procurement activities for the monitored geological repository." There is no specific defined point in time when this voluntary implementation will be undertaken.

The team was subsequently informed that Part 21 would apply to several fabricated items currently being purchased by BSC. In reviewing OCRWM's procedures, the team could not find when or how 10 CFR Part 21 would be applied to procurement documents for these type of long lead time procurements as committed to in the October 1998 letter to the NRC.

Problem Statement: Implementing procedures for the application of 10 CFR Part 21 to ITS/ITWI procurements have not been issued and current procedures do not include provisions for the application of 10 CFR Part 21 to vendors. The OCRWM QARD, section 4.2.1.K lists 10 CFR Part 21 as an item for consideration when issuing procurement documents for ITS/ITWI purchases. A letter to the NRC commits the project to voluntarily implementing the requirements for 10 CFR Part 21 prior to becoming a licensee for long lead time procurements.

QA Involvement in procurement review

A sample of procurement documents, supplier audits, and acceptance records were selected for review to verify procedure implementation. The process included review of documents, interviews with personnel, and verification that the required records were being maintained. (See Lines of Inquiry A1.4) All personnel interviewed during this part of the assessment were found to be knowledgeable and experienced. The team observed that the OCRWM, BSC, and SNL QA organizations are involved in an inline procurement document review process. This review practice was turned over to the line organizations in the commercial nuclear industry many years ago.

Recommendation: The Yucca Mountain QA organizations should remove themselves from in-line procurement document reviews, turning the process over to the line organizations. The QA organizations would then include procurement document reviews as part of the normal audit and surveillance process.

Control of work scope for procured services

An integral part of the control of purchased material, equipment and services is the methods which ensure that subject work is controlled within the scope of the procurement. This was evaluated during a site visit on July 12, 2007. Observation of a subcontractor performing ITS surveying of as-built borehole locations to support geotechnical investigations was conducted. The two subcontractor personnel performing the work were from NSTech. NSTech provides services and staff augmentation to BSC. Subcontract tasks are specified on individual statements of work for the task. NSTech is on the Qualified Suppliers List (QSL) to provide "Calibration Services." The individuals performing the surveying were not accompanied or supervised during the surveys by either BSC supervision or BSC surveyors. The original work request identified the surveys as "quality affecting" in the body of the request but block 16 QA/QC was marked "No." Statement of Work (SOW) ATMT74 states *"NSTech to provide survey support personnel to assist BSC Surveyor in performing the as-built field surveys of selected testing support activities. The NSTech personnel to provide support service only and will not be performing quality affecting work (i.e. actual measurements to be taken by BSC staff)."* The Statement of Work (SOW) is marked Non-QA.

The NSTech surveyors performing the work were listed as "inactive" on the current training records for BSC, indicating that they were not working in a "staff augmentation" capacity. Thus, ITS work was performed by a subcontractor not on the QSL for the work performed and not in accordance with the quality assurance controls that would have required that BSC trained surveyors perform the survey and record the data in accordance with the BSC quality assurance program.

A review of the standing work order for surveying (13250-02) states, "*Work Scope: Provide labor, equipment, and materials to perform surface and underground Field Surveys."* This is a standing work order and not specifically issued to NSTech. A review of the work order shows that it is focused on Integrated Safety Management occupational safety and industrial safety evaluations. Nowhere on the work order is the fact that the surveys are "Important to Safety or Important to Waste Isolation" or "Q" indicated. The signature line for QA review is marked "N/A" and initialed by the Lead Planner. The Pre-Work Checklist indicated that "Worker Qualifications/Certifications" was applicable and signed by the BSC Survey Supervisor. The same two workers who were observed on July 12th signed as attending the Pre-Work Briefing on May 9, 2007, (and were the only workers signed in on the work order), indicating that they may have performed survey activities sometime prior to the July 12th observation. The as-built

bore-hole location surveys are clearly ITS and governed under the OCRWM QARD and subject to the requirements of 10 CFR 63.142.

The team noted that the surveyors indicated they were "Nevada State Licensed" for the types of surveys performed with extensive experience surveying. Upon confirmation of the Nevada State license for these individuals, it is most likely that the surveys can be accepted as valid. However, it is the process by which ITS work was allowed to be performed by a subcontractor not on the QSL, not the particular work performed, which is of concern to the team and the subject of the problem statement and discussion with BSC line management.

Problem Statement: ITS work was performed by a subcontractor not on the QSL for the work performed and not in accordance with the controls established in the Statement of Work (SOW) issued to the subcontractor. The SOW limited the work to providing the calibrated GPS survey instrument only with the work to be performed and data taken by BSC personnel. (CR-10945 as initiated by BSC)

The team has followed this condition report and a discussion is included in the section on Corrective Action in this report.

10 CFR 63.142(f) Instruction, Procedures and Drawings
10 CFR 63.142(g) Document Control,
10 CFR 63.142 (r) Quality assurance records

This portion of the assessment began with a review of the flow down of QARD requirements to ensure that the implementing procedures included requirements from the QARD. This assessment included a review of the OCRWM Quality Assurance Requirements and Description (QARD) DOE/RW-0333P, revision 18 and BSC's Quality Management Directive QA-DIR-10, revision 1 and associated implementing procedures listed in Lines of Inquiry A1.9.

The BSC procedure for the development, use and change control for instructions, procedures and drawings was reviewed. Significant emphasis has been placed on the proper use of procedures. The discussion of the existence of multiple procedures for the same tasks is included in the OCRWM assessment report. One area of performance improvement was identified. It was noted that BSC has not included provisions for expedited procedure change in the procedure that describes the preparation, use and change control of procedures. This has been identified as an area for "future action" in the procedures group. While there is no requirement that an expedited procedure change process must be in place, an effective and well controlled expedited change process is indispensable during construction/operations. As the project prepares to take the next steps in licensing and construction, an expedited procedure change program will enhance the ability to continue work in a controlled fashion and provide those who use procedures with an established and approved process to get changes made to their procedures.

Recommendation: Consider including procedural steps to allow and control expedited changes to procedures.

BSC's management of controlled documents and records ensures that records and controlled documents were readily and rapidly retrievable once placed on line through the Controlled Document Information System (CDIS) and the Records Information System (RIS). The CDIS system provides an effective method to access the latest revision to a document and ensures that only the latest documents are available for use. During the course of the assessment, personnel who required access to controlled documents were universally noted to properly retrieve the latest document through CDIS. Only two instances were found where the CDIS information may have been in error with regard to the document contained in CDIS (see Control of Special Processes section.) No instances were found where out of date documents were in use in the field.

The principle difference between the CDIS system and the RIS system was in their input phases. CDIS input was about 90% electronic and placement on the CDIS is relatively rapid. BSC's Records Processing Center (RPC), on the other hand, required hard copy (or other non-electronic media) as input to RIS, and processed nearly all of the project's records by hand. This process is very labor-intensive and it was noted that it takes a record about 30 days from receipt at the RPC to availability on RIS in this pre-license

environment. Even if a document was produced electronically, such as many from the engineering design effort, it must be printed out and delivered to the RPC for processing as a hard copy through the RPC and then scanned for filing as a record. Complicating the process, personnel must manually locate and retrieve a record if a request is made for it prior to scanning into the RIS. The Records Management process does not take full advantage of current technologies to minimize the backlog of records. If this is not effectively addressed, when the pace of design quickens and construction starts, the backlog will likely be overwhelming.

Recommendation: Consideration should be given to adopting state-of-the-art electronic records management techniques.

10 CFR 63.142(j) Control of Special Processes

QARD requirements for Special Processes are addressed in BSC QA Program and implementing procedures. The BSC QA Manager was interviewed regarding BSC's involvement in the Special Process program at Yucca Mountain. BSC currently has on staff two ANSI –N45.2.6 qualified and certified Level III examiners. BSC will not fully staff up to perform Special Processes until contracts are awarded for the construction phase of the project.

It was the team's opinion that the QARD section on Special Processes contains requirements that are unclear and overly prescriptive. QARD Subsection 9.2.3.A (Control of Special Processes) states "NDE shall include radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, acoustic emission and leak testing". QARD Subsection 9.2.3.B (Control of Special Processes) states in part "Personnel who perform NDE examinations shall be qualified and Certified in accordance with QARD Subsection 2.2.11…" QARD Subsection 2.2.11.D states in part "Personnel who perform NDE Examinations shall be trained, qualified and certified in accordance with the American Society for Nondestructive Testing, Recommended Practice No. SNT-TC-1A, June 1980…"

The QMD QA-DIR-10, Revision 1 paraphrases the above QARD Subsections in Criterion 9.C.3.1, 9.C.3.2, and 2.2.C.3.5. However, the BSC implementing procedure for qualification and certification of NDE personnel, QA-PRO-1076, does not address all the examination methods listed in the QARD and QMD.

Problem Statement: BSC implementing procedure QA-PRO-1076, Revision 1 (Qualification and Certification of Nondestructive Examination (NDE) Personnel) Section 1.4 does not address all the examination methods listed in the QARD and QMD that are required to have personnel certified and qualified in accordance with SNT-TC-1A. The methods that are not included in QA-PRO-1076 are eddy current, neutron radiography, acoustic emission, and leak testing.

Note: The team recognizes that the standard SNT-TC-1A is not normally intended to be applied to eddy current, neutron radiography, acoustic emission, and leak testing. The requirements in the QARD may warrant review to ensure that it is the intent to apply SNT-TC-1a. None-the-less, if the writer of the procedure recognized this inconsistency and did not include them in the implementing procedure, it was incumbent on him/her to initiate the appropriate change.

Recommendation: The team recommends evaluation of the personnel qualification and certification requirements for NDE methods that are not included in SNT-TC-1A. The qualification for these methods should be consistent with the appropriate industry standard.

QARD DOE/RW-0333P Revision 18, Section 9 Subsection 9.2.2.F states that implementing procedures shall include or reference; "A requirement for the QA organization to be involved in special processes, personnel, equipment, and process qualification to ensure satisfactory performance. This involvement includes, but is not limited to the performance of surveillance or audit." QA-DIR-10, Revision 1 Criterion 9 Subsection 9.2.C.2.6 basically states the same requirement of QARD Section 9, Subsection 9.2.F.

Problem Statement: Implementing procedures for the Qualification and Certification of Nondestructive Examination (NDE) Personnel and Welder/Welding Operator Performance Qualification do not delineate the procedural requirements related to QA surveillance or audit specified in the QARD. Specifically, implementing procedure QA-PRO-1076 (Qualification and Certification of Nondestructive Examination (NDE) Personnel Revision 1 and implementing procedure QA-PRO-9170 (Welder/Welding Operator performance Qualification) Revision 0 do not call out the procedural requirements stated above. No QA involvement in the area of surveillance or audit is established or referenced.

NOTE: The two QA program requirements appear overly prescriptive and may require review. Line organizations should be held accountable for program establishment, implementation and assessment with the overall QA oversight function delineated in the QA program description.

Documentation associated with Special Processes was found to contain errors which render the revision levels questionable. Hard copies of implementing procedures printed from CDIS do not match the revision stated in CDIS. WPS-A36-F-T38, WPS-CS-M-A-01, and WPS-A-36-F-01 were found to have different revision dates on top of the procedures than found in the CDIS system. This condition should be resolved prior to the use of the procedures.

Implementing procedures (Welding Control) were not consistent in their use of QA:QA or QA:NA. WPS-A36-F-T38, WPS-CS-M-A-01, and WPS-A-36-A-F-01 were found not to contain the same information on the cover sheet. One was marked QA:QA and two

were marked QA:NA. Confusion exists on what QA:QA and QA:NA mean. OCRWM, BSC, and SNL personnel were asked what the difference was between QA:QA and QA:NA. There was a wide variation of answers on the meaning of QA:QA and QA:NA on documents and records. As the team understands it, the use of the identifier QA:QA is only a records identifier and not an indication as to whether the activity associated with the record is Important to Safety or Important to Waste Isolation. This was not well understood or communicated by personnel at all levels.

Recommendation: Consideration should be given to preparing a position paper on the meaning and use of the identifier QA:QA and QA:NA and ensure that all project personnel understand its meaning.

10 CFR 63.142(m) Control of Measuring and Test Equipment

During a site visit, the team evaluated the current status of calibration of equipment in use or available for use by BSC personnel. (See equipment observed in the Line of Inquiry A1.7 for M&TE) All equipment observed in use was within its calibration due dates and properly labeled/identified.

10 CFR 63.142(q) Corrective Actions

The team assessed the corrective action program and its implementation. As an ongoing effort, OCRWM has made significant improvements to the Corrective Action Program (CAP), particularly in the processing of corrective actions. The QAMA evaluated this area in detail and it was not repeated directly in this assessment. Also noteworthy is OCRWM's training and indoctrination efforts to expand all Yucca Mountain personnel's understand and use of the CAP. Continued management emphasis on the CAP will enhance the project's position to support the license application and proceed with design and construction.

Measurement of the effectiveness of the CAP program invariably includes the average age of CRs (from submission to resolution). Since CRs are written on material issues as well as programmatic issues, there are some outstanding CRs that are currently "on hold" due to curtailment of operations at the site. These include CRs that cannot be corrected until access is granted to work in the ESF past the temporary barrier placed as part of the curtailment. Access is only allowed for inspection and other limited activity. Some of these CRs will continue to remain open for some time and potentially "skew" the aging data so that improvements may be overshadowed or obscured by the relative age of these CRs on hold.

Recommendation: Include as one of the CAP program effectiveness measures an evaluation of aging (average age from CR initiation to closure, for instance) with the CRs on hold for action outside the control of the contractor (such as curtailment) removed from the calculation. Caution must be exercised to ensure that CRs are removed from this calculation only because of legitimate constraints to closure (like curtailment) not simply because it is difficult to close. The reason for removal for the calculation should be justified and explained.

Condition Report Initiation:

During this assessment several conditions were identified which the team expected the responsible BSC line management to evaluate and enter into the CR system. Extensive discussions were held with BSC line management concerning the details and nature of the conditions. Two CRs were initiated by BSC (CR 1045 and CR 1046) and one CR was initiated by SNL (CR 11050) in response to observations at the site. While this assessment was not equivalent to an NRC inspection, the methods used and level of detail involved were consistent with NRC inspections. BSC personnel were additionally given the advantage of extensive discussions with the team member who identified the conditions (which is typically not the case with an NRC inspection).

Prior to initiation of the subject CRs, most of the information related to the team's concerns had been identified to the respective BSC line manager or his representative. While BSC initiated CRs in a timely manner, the CRs were worded in a way that did not clearly identify that actual Important to Safety work was performed and did not focus the report on the actual condition as known at the time of submission. Instead, the CRs appeared to attempt to identify at some level what could be characterized as a "cause" of the condition rather than the condition itself. This tends to obscure the safety impact and does not allow the CAP Screen Team to effectively evaluate the impact and categorize the CR. In addition, they do not focus the CR on evaluation as to whether the ITS work performed can be accepted and whether there are any other work activities that must be considered. The team understands that CRs are expected to be submitted in a timely manner without waiting for a full investigation before submittal. However, it is also expected that all information known at the time of submission will be included in the CR, particularly when that information indicates that the actual performance of ITS work was involved and might require evaluation as to acceptability.

Note: The SNL initiated CR (CR 11050) more accurately described the condition and evaluated the impact on the work, evaluated why the work was acceptable, and determined the extent of condition, expanding the review beyond the single condition identified by the team.

Problem Statement: The condition reports written in response to the BSC specific activities observed at the site by the QA Implementation Assessment Team were written in a way that does not allow a complete and accurate evaluation of the safety impact of the conditions and did not appear to provide a full picture of the conditions known at the time of submittal.

10 CFR 63.142(s) Audits

The internal audit assessment included a review of the flow-down of quality requirements to ensure that the implementing procedures included requirements from the QARD and the Bechtel QMD. (see Line of Inquiry A1.10.) Requirements reviewed were incorporated in the implementing procedures.

Recently, the Yucca Mountain Project integrated internal audits as part of a Project teaming effort, where OCRWM, BSC, and SNL work together to perform audits. The team viewed this new process as strengthening the overall project internal audit process. While this integrated process improves the audit program by making it more comprehensive, procedures need to be updated to cover the new process. The audits reviewed since the CR was written were found to be very comprehensive, clear, concise, and detailed. This teaming effort has produced very good results. The recent audits were found to be much better than the older audits in terms of the amount of detail, comprehensiveness, and detail.

Audits appear to identify many issues and as a result, CRs are written; however, the CRs appear to remain open for extended periods of time. This indicates the need for continued line organization emphasis to ensure timely closure of corrective actions. This matter is discussed in the QAMA report.

The internal audit schedules were reviewed and a sample of audits, including planning, performing, documenting and follow up, were reviewed to verify procedure implementation. The process included review of documents, interviews with personnel, and verification that the required records were being maintained. (See Lines of Inquiry A1.10)

QARD Supplement I Software

The team determined that the requirements of the QARD for Software Control satisfactorily flow down to implementing procedures used by BSC and SNL. However, the software control program was found to be cumbersome and outdated and is not consistent with current nuclear industry programs.

OCRWM, BSC, and SNL each possess and maintain their own set of QA program and implementing procedures for Software Control. The “as-found” program is duplicative and redundant. One set of Software QA and implementing procedures would establish a consistent program for the end users and anyone performing oversight in this area. The

maintenance cost, organizational interface difficulties, and complexity of these programs may lead to confusion and increased cost during the design, construction, and start-up-and-test phases of the project.

Although in need of revision, the existing program has come a long way in the last few years. The software program has become stronger because of management oversight and the use of subject matters experts in OCRWM, BSC, and SNL. With management guidance, the existing personnel are more than capable of bringing the Software Control Program up to today's standards and practices. Effort should be continued to ensure efficiency, effectiveness, and timely corrective action implementation of software errors.

Recommendations:

1. Validation and Verification uses a 4 phase verification form (four forms). The four forms could be revised into one.
2. Life Cycle Methodology and Control Point Documentation Set is accomplished by way of multiple documents. The process could be streamlined into one document.
3. At present, software verification is performed at the end of the process. Reviews should be able to be performed at all points of development. See IEEE-1028-1997.
4. Software Configuration Management is performed by way of review of "Hard Copy" data. This system should be considered for change to a "Paperless" system to assure timely correction of found software errors.
5. QARD Supplement III 2.6.C.1.D should be reviewed and revised concerning "All preliminary data runs shall be rerun". This is a redundant process. They are already rerun when they are qualified.
6. The present software control system is indicative of a system from 1985. Consideration should be given to enlisting the necessary support to bring the program into line with current practices.

QARD Supplement II Sample Control

During a Site Visit the team observed sampling activities in the Sample Management Facility (SMF). Workers were packaging borehole samples following existing procedures to maintain location, orientation and traceability of the samples. Sample storage included both bulk storage in clearly labeled boxes at the SMF and storage in environmentally controlled conditions (refrigerated storage.) The temperature instrument measuring and recording conditions in the refrigerated storage units was found to be within its calibration due date and the required calibration information was clearly marked on the instrument.

(The following discussion pertains to both BSC and SNL since it relates to a problem statement that resulted at an interface point in the sample collection and recording process.)

During a site visit at the SNL Geo-Mechanical Lab in Albuquerque samples were undergoing preparation for testing. These non-core samples were carefully packaged and clearly marked with the sample identification, with orientation marked on each sample.

The sample numbers were recorded and as an indication of current sample control measures being applied, it was decided to "trace" these samples back to the initial removal from the test pits to gauge the current level of implementation of the sample control program. A SMF Specimen Custody Receipt form was reviewed which clearly showed the transfer of custody from the SMF to the person conducting the test at SNL-Albuquerque with the receipt signed for on 7/3/07. The Sample Collection Report was then requested to confirm the initial collection of the sample and records produced for that collection in accordance with PA-PRO-0804 "Collection, Submission, Return, and Documentation of Non-Core and Non-Cuttings Specimens to the Sample Management Facility." For samples SPC01041713 through SPC0104718, the Sample Collection Report did not provide the required traceability to the specific location of the sample in that it identified that the six subject samples were taken from test pits TP-WHB-5 and TP-WHB-6 with no indication as to which sample came from which pit. (See problem statement above.)

Discussions with SMF management indicated that "specific location is only required if it is important to the scientist doing the test." This is not consistent with the PA-PRO-0804 which does not provide for such a relaxation of sample collection identification and does not provide for "alternate" means of identifying the specific sample source location for these types of samples. This procedure clearly requires in section 4.1.2.2 that a report of collection that contains "Site type and site description, providing enough information to allow the site to be located by personnel (with equivalent experience) who are independent of the Collector." Statements were also made to the effect that, "the people drawing the samples were not from the SMF and we "can't make them follow our procedures." Review of the associated SNL procedure, TST-PRO-008 Rev 1, dated 2/19/07, "Sample Control" Section 6.1.3.B shows that for SNL samples collected in the field that the custodian is required to "Complete a Sample Collection Report (found in PA-PRO-0804) for each sample collected and submit the original form to the SMF. Therefore, by both BSC SMF and SNL procedure, the Sample Collection Report is required and procedural compliance as to its content is expected.

Problem Statement: The Sample Collection Report for Field Work Package FWP-SBT-PA-000011, Rev. 000, does not specify from where six "hand carved alluvium samples" were collected. The sample numbers are SPC01041713 through 718.

SNL generated a Condition Report for this condition (CR 11050). The condition report clearly identified the actual condition, the impact, and the extent of condition.

APPENDIX D
SNL Independent QA Implementation Assessment

1. Introduction

An independent review team assessed implementation of the QA program by the Lead Laboratory, Sandia National Laboratory (SNL). It is the team's conclusion that implementation is consistent with the commercial nuclear industry and is adequate for the current status of the project.

"**Problem Statements**" represent a failure to comply with specific QARD programmatic or implementing procedural requirements. Where identified, these problem statements were provided to the OCRWM Office of Quality Assurance (OQA) for disposition.

"Recommendations" are provided where the team has identified areas where improvements would enhance the implementation of the QA Program.

The assessment focused on current activities being conducted for the project rather than historical or legacy issues to gauge the current level of adequacy of implementation of the QA Program.

The team consisted of personnel with Nuclear Regulatory Commission and commercial nuclear management and quality assurance experience and used, where available, nuclear regulatory inspection guides as the basis for the assessment. Resumes of the Independent Assessment Team members are included in Attachment 2 of this report.

Team Leader:	Dan M. Stover – Technical And Professional Services, Inc
Team Members	Frank Hawkins - Technical And Professional Services, Inc.
	Wayne Scott - Technical And Professional Services, Inc.
	Paul Kellogg - InfoZen
	Raymond Wenderlich – Technical And Professional Services, Inc.
	Rene' Delaney - Technical And Professional Services, Inc.
	Bruce Tracey - Technical And Professional Services, Inc.

Lines of Inquiry were prepared and are included as Attachment 1 to this report. The implementation assessment included a detailed review of the flow down of the requirements from 10 CFR 63.142 through the QA Program description and into the implementing procedures.

2. Assessment Results

The SNL implementation of the QA program is consistent with that seen in the commercial nuclear industry at this stage of the project in so far as the similarities can be drawn between the scientific nature of the work that SNL performs. 10 CFR 63.142 criterion reviewed for SNL include:

10 CFR 63.142 Quality assurance criteria
(b) Organization
(c) Quality assurance program
(d) Design control
(e) Procurement document control
(h) Control of purchased equipment, material and services
(m) Control of Measuring and Test Equipment
(s) Audits

In addition, the following requirements in the QARD were included in the review. These activities are encompassed by the requirements of 10 CFR 63, but are sufficiently narrowly focused as to be amplified within the QARD by a special supplement.

- Supplement I Software
- Supplement II Sample Control
- Supplement III Scientific Investigation

Lines of Inquiry for each of the areas reviewed are included in Attachment 1. The lines of inquiry are derived from NRC Inspection Procedures and the QARD. They are the working documents of the respective team members from which the conclusions for this report are drawn after team discussion and consolidation of the information.

The Manager, Quality Assurance, SNL is an experienced quality assurance professional. He works closely with the OCRWM Director OQA and the QA Manger, BSC to ensure that the organizations function well together. Collectively, the three organizations have begun to explore methods to better equip the respective organizations to effectively execute their responsibilities and to transition from the current phase to support construction after the license application is approved. An example of the integration of OCRWM, BSC, LLC and SNL is the coordination of audits of primary contractors into an integrated audit process

Criteria 10 CFR 63.142 (b) Organization:

The organization in place at SNL for the YMP is consistent with the organization that is described in QA-PRG-001, Revision 1, "Quality Assurance Program Description." Organizational responsibilities with regard to both achieving and verifying quality have been assigned. The personnel assigned responsibility for performing the quality assurance verification and validation functions report to the Manager, Quality Assurance and have sufficient organizational freedom as required by 10 CFR 63.142 (b)(2).

The Manager, Quality Assurance, is a quality assurance professional with experience in the commercial nuclear industry. He has the necessary qualifications and experience to execute his assigned responsibilities. The Quality Assurance Manager reports directly to the Senior Program Manager. In addition to the QA Manager, there are 7 principal functional managers who also report directly to the Senior Program Manager.

It was noted that SNL has carried forward the philosophy in the QARD where the QA organization is assigned or implied responsibilities that can potentially undermine line management ownership of quality. For instance, SNL QAPD Section 4.2 states *"Procurement documents subject to the QARD require a technical review by someone other than the originator who is familiar with the scope of work, and an independent review by the quality assurance organization."* The commercial nuclear industry has abandoned this type of 100% QA review, recognizing that they could not "review quality" into the documents.

Recommendation: OCRWM, BSC and SNL should evaluate their respective QA Program plans and practices to identify responsibilities that have been assigned to the QA Organization that potentially undermine line management responsibility and accountability for quality. Where such situations are identified, a strategy for the smooth transition of the responsibility from the QA Organization to the line organization should be developed and implemented.

10 CFR 63.142(c) Quality assurance program (including training implementation)

The QA program plan described in QA-PRG-001 Revision 1, "Quality Assurance Program Description," was the subject of a specific detailed review that preceded this implementation assessment. The conclusion of that review was that the QA program plan meets the requirements of 10 CFR 63.142.

In addition the team noted an issue relating to procedure development and use. Specifically, a number of instances were identified where overlapping redundant procedures were written by BSC and SNL to accomplish the same task. This practice potentially results in programmatic complexities and communication difficulties that occur when two organizations work closely together, using their own procedures. Such was the case observed during sampling activities where SNL collected the samples to an SNL procedure that relied on BSC Sample Management Facility procedures and forms. The result was a number of samples collected that were not identified correctly on the sample management form. While this was not the sole cause of the issue, it may very well have been a contributor.

Recommendation: OCRWM, BSC, and SNL should jointly determine (1) where multiple procedures exist for the same tasks or (2) situations exist where procedural interface is required between two or more organizations. In these cases, consideration should be given to issuing a single procedure at the appropriate level to accomplish the task.

Training requirements and the suitability of personnel performing investigative and experimental activities is based on the educational background of the individual and an evaluation by the supervisor/management of his or her ability. General Employee training, as well as specific training in the use of applicable SNL procedures for the work, is required.

10 CFR 63.142(d) Design Control

The SNL QAPD requirements for Design Control refer the user to the Supplement III on Scientific Analysis.

SNL has been assigned responsibility for developing the post-closure Nuclear Safety Design Bases Document for the Yucca Mountain Project. Together with the pre-closure Nuclear Safety Design Bases Document, this document forms the basis for the development and maintenance of the Q-list. A Technical Work Plan (TWP) for Post-closure Nuclear Safety Design Bases (TWP-WIS-MD-000015) is currently under revision to support development of the design bases document. Several personnel in the SNL organization were previously in the BSC organization where they were responsible for the Post-closure Nuclear Safety Design Bases. Their continued involvement in the process provides confidence that institutional knowledge is maintained.

Personnel in SNL who are responsible for the design bases document appear knowledgeable about its content and confident about the path forward. The original BSC Post-closure Nuclear Safety Design Bases document was prepared using the BSC Line procedure for Scientific Analysis. The equivalent SNL procedure, SCI-PRO-005 "Scientific Analyses and Calculations," is intended to be used for the SNL activities in support of development of this document.

One of the outputs from the Postclosure Nuclear Safety Design Bases document is input into BSC procedure LS-PRO-0203 in section 4.2.4 which requires that the preparation of the Q-list include natural barriers and Engineered Barrier System Systems, Structures, and Components (SSCs).

The controls in place for the SNL scope of work and organization/personnel appear well positioned for the development of the Post-closure Nuclear Safety Design Bases document. The TWP addresses the necessary procedures to be used and controls to ensure its acceptability.

10 CFR 63.142(e) Procurement Document Control
10 CFR 63.142 (h) Control of purchased equipment, materials and services.

The procurement assessment started with a review of the flow down of QARD requirements to ensure that the implementing procedures included all requirements from the QARD. This assessment included a review of the OCRWM QARD and SNL's QAPD and associated implementing procedures listed in Lines of Inquiry A1.4. Requirements reviewed were reflected in the implementing procedures except for the item relating to 10 CFR Part 21.

There seems to be confusion, by the Yucca Mountain Project personnel, if and when 10 CFR Part 21 needs to be applied to procurement documents. The QARD lists 10 CFR Part 21 as an item to be considered for inclusion on the procurement documents. However, none of the implementing procedures pick up this requirement. Currently, OCWRM considers 10 CFR Part 21 as not applicable to the project. QARD section 4.2.1.K requires provisions for identifying that the procurement is subject to the provisions of 10 CFR Part 21. OCRWM had discussions with the NRC and determined that Part 21 will not apply to Yucca Mountain until they become a licensee. Previously, OCRWM had indicated that it intended to voluntarily implement a procedure to apply 10 CFR Part 21 to the Yucca Mountain Project. Following discussion with the NRC related to this procedure, OCRWM decided to reconsider this position. A letter to the NRC dated 10/30/1998 from the OCRWM, Director Regulatory Coordination Division states that, "OCRWM intends to postpone the voluntary implementation of the procedure until the Yucca Mountain Site Characterization Project commences long lead time procurement activities for the monitored geological repository." There is no specific defined point in time when this voluntary implementation will be undertaken, nor could the team locate correspondence revising this position.

Some of the scientific activities contracted to other laboratories by SNL involve the kinds of services (modeling, computer programs, etc) that would be subject to application of the reporting requirements of 10 CFR 21. It is unclear if these types of activities are included in the "long lead time procurement" discussed in the OCRWM letter to the NRC. In reviewing implementing procedures, the team could not find when or how 10 CFR Part 21 would be applied to procurement documents for these type of long lead time procurements as committed to in and OCRWM 10/30/98 letter to the NRC.

Problem Statement: Implementing procedures for the application of 10 CFR Part 21 to ITS/ITWI procurements have not been issued and current procedures do not include provisions for the application of 10 CFR Part 21 to vendors. The OCRWM QARD, section 4.2.1.K lists 10 CFR Part 21 as an item for consideration when issuing procurement documents for ITS/ITWI purchases. A letter to the NRC commits the project to voluntarily implementing the requirements for 10 CFR Part 21 prior to becoming a licensee for long lead time procurements.

QA Organization involvement in procurement

The team observed that the OCRWM, BSC, and SNL QA organizations are involved in an inline procurement document review process. This review practice was turned over to the line organizations in the commercial nuclear industry many years ago.

Recommendation: The Yucca Mountain QA organizations should remove themselves from in-line procurement document reviews, turning the process over to the line organizations. The QA organizations would then include procurement document reviews as part of the normal audit and surveillance process.

A sample of procurement documents, supplier audits, and acceptance records were reviewed to verify procedure implementation. The process included review of documents, interviews with personnel (list of personnel interviewed is shown in the Line of Inquiry A1.4) involved with the processes, and verification that the required records were being maintained. All personnel interviewed during this portion of the assessment were found to be very knowledgeable and experienced.

10 CFR 63.142(m) Control of Measuring and Test Equipment

An evaluation of the flow down of requirements from the QARD to the implementing procedures indicates that the requirements are adequately reflected in the implementing procedures. During the evaluation of scientific activities at SNL Albuquerque, a limited number of measuring and test equipment (M&TE) was observed in use. Implementation of M&TE control by SNL for ITS/ITWI experiments was determined to be acceptable.

One ITWI experiment was observed and the Scientific Notebook was reviewed. The instruments in use for controlling the experimental environmental conditions and data recording were identified in the notebook as required. Observation of the actual experiment in progress confirmed calibration status of the instruments used for the experiment and that the calibration date and due date were indicated on the instrument.

One non-ITWI experiment was being conducted by the same Principal Investigator (PI). It was noted that the instruments associated with this experiment were not calibrated. When questioned about this, the PI indicated that because it was non-Q there was no requirement to use a calibrated instrument. The Scientific Notebook for this experiment accurately recorded the fact that the instrument was not required to be calibrated because the data used was not to be qualified and used in ITWI applications. It was only for information to establish testing/experimental techniques which might later be used.

It was noted that a non-ITS/ITWI screening determination was not made for this experiment, as explained by the SNL QA manager, “since we treat all work as Q.” However, it is obvious that the work was not treated as Q since calibrated instruments were not used. The AQAP for non-ITS/ITWI section 2.1 WORK PROCESSES states

"Equipment used for process monitoring or data collection shall be calibrated and maintained." As with any of the AQAP requirements, this can be "graded out" based on a number of factors, but in this case it was not a decision based on application of the SNL grading procedure but the decision of the PI with concurrence from his supervisor. For further discussion of this matter see the section on Scientific Investigations as it relates to non-Q work.

Instruments to be used in the Geo-Mechanics Laboratory for mechanical property testing of alluvium samples from the site to support geotechnical investigations were observed. The installed instruments on the static mechanical properties equipment were all found to be within their calibration period. A data logger to be used for the experiment ID 56231 serial 620864 was calibrated on 5/8/07 with a due date of 5/8/08. M&TE number YMPEL-001, to be paired with a specific Linear Variable Differential Transformer (LVDT S/N 517), was also observed. The calibration was performed using an ASTM standard that was provided to the team member for review. It was noted that calibration stickers for this instrument pair were not on the instruments but were clearly traceable to the instruments by virtue of the item and serial numbers permanently affixed to them.

Subsequent to the on-site portion of this assessment, a question was raised concerning the use of instruments in on-going experiments past their calibration due date if the experiment extends past that date. NQA-1 1983 and the QARD both state that an instrument found out of calibration must be identified and **not used** (emphasis added) until recalibrated. The QARD (although not NQA-1) goes on to state that an instrument is considered "out of calibration" if: 1) its as-found condition at re-calibration is out of tolerance, 2) it is know to be inaccurate, or 3) it is past its calibration due date. A review of the NRC Safety Evaluation Report for recently submitted QA topical reports and the SER for the NEI Template QA program related to this subject, indicates that the current interpretation of the requirements for the controls specified in paragraph 3.2 of NQA-1 1994 (which are similar to the NQA-1 1983 requirements) is "The out of calibration conditions described in paragraph 3.2 Supplement 12S-1 refers to when the M&TE is found out of the required accuracy limits (i.e. out of tolerance) during calibration."

This allows some flexibility to use installed instrumentation, with appropriate consideration for the safety impact of the parameters monitored, past its calibration due date without requiring plant or system shutdown just for recalibration. It is reasonable to conclude that for in-process experiments where shutdown of the experiment and loss of data would result from the need to remove the instrument for recalibration, this same interpretation is valid. In such situations, the instrument would be recalibrated as soon as practical and, if found in tolerance at calibration, no further action would be required. If it was found out of tolerance, an evaluation of the impact on the validity of the data obtained from the instrument and its effect on the qualification of data from the experiment would be required. In effect, the experiment would proceed "at risk" if required with the risk being that the data might not be able to be used.

Recommendation: Work with the OCRWM staff to revise the QARD to adopt the clarification as currently used and accepted by the NRC regarding paragraph 3.2 of NQA-1 Supplement 12S-1 regarding control requirements for M&TE found out of calibration.

10 CFR 63.142(s) Audits

The internal audit assessment included a review of the flow-down of quality requirements to ensure that the implementing procedures included requirements from the QARD and the Bechtel QMD. (see Line of Inquiry A1.10.) Requirements reviewed were incorporated in the implementing procedures.

Recently, the Yucca Mountain Project integrated internal audits as part of a Project teaming effort, where OCRWM, BSC, and SNL work together to perform audits. The team viewed this new process as strengthening the overall project internal audit process. While this integrated process improves the audit program by making it more comprehensive, procedures need to be updated to cover the new process. The audits reviewed since the CR was written were found to be very comprehensive, clear, concise, and detailed. This teaming effort has produced very good results. The recent audits were found to be much better than the older audits in terms of the amount of detail, comprehensiveness, and detail.

Audits appear to identify many issues and as a result, CRs are written; however, the CRs appear to remain open for extended periods of time. This indicates the need for continued line organization emphasis to ensure timely closure of corrective actions. This matter is discussed in the QAMA report.

The internal audit schedules were reviewed and a sample of audits, including planning, performing, documenting and follow up, were reviewed to verify procedure implementation. The process included review of documents, interviews with personnel, and verification that the required records were being maintained. (See Lines of Inquiry A1.10)

QARD Supplement I Software

The team determined that the requirements of the QARD for Software Control satisfactorily flow down to implementing procedures used by BSC and SNL. However, the software control program was found to be cumbersome and outdated and is not consistent with nuclear industry expectations.

OCRWM, BSC, and SNL all have their own set of QA program and implementing procedures for Software Control. The “as-found” program is duplicative and redundant. One set of Software QA and implementing procedures would establish a consistent program for the end users and anyone performing oversight in this area. The maintenance cost, organizational interface difficulties, and complexity of these programs may lead to

confusion and increased cost during the design, construction, and start-up-and-test phases of the project.

Although in need of revision, the existing program has come a long way in the last few years. The software program has become stronger because of management oversight and the use of subject matters experts in OCRWM, BSC, and SNL. With management guidance, the existing personnel are more than capable of bringing the Software Control Program up to today's standards and practices. Effort should be continued to ensure efficiency, effectiveness, and timely corrective action implementation of software errors.

Recommendations:

1. Validation and Verification uses a 4 phase verification form (four forms). The four forms could be revised into one.
2. Life Cycle Methodology and Control Point Documentation Set is accomplished by way of multiple documents. The process could be streamlined into one document.
3. At present, software verification is performed at the end of the process. Reviews should be able to be performed at all points of development. See IEEE-1028-1997.
4. Software Configuration Management is performed by way of review of "Hard Copy" data. This system should be considered for change to a "Paperless" system to assure timely correction of found software errors.
5. QARD Supplement III 2.6.C.1.D should be reviewed and revised concerning "All preliminary data runs shall be rerun". This is a redundant process. They are already rerun when they are qualified.
6. The present software control system is indicative of a system from 1985. Consideration should be given to enlisting the necessary support to bring the program into line with current practices.

QARD Supplement II Sample Control

(The following discussion pertains to both BSC and SNL since it relates to a problem statement that resulted at an interface point in the sample collection and recording process)

During a site visit at the SNL Geo-Mechanical Lab in Albuquerque samples were undergoing preparation for testing. These non-core samples were carefully packaged and clearly marked with the sample identification, with orientation marked on each sample. The sample numbers were recorded and as an indication of current sample control measures being applied, it was decided to "trace" these samples back to the initial removal from the test pits to gauge the current level of implementation of the sample control program. A SMF Specimen Custody Receipt form was reviewed which clearly showed the transfer of custody from the SMF to the person conducting the test at SNL-Albuquerque with the receipt signed for on 7/3/07. The Sample Collection Report was then requested to confirm the initial collection of the sample and records produced for

that collection in accordance with PA-PRO-0804 "Collection, Submission, Return, and Documentation of Non-Core and Non-Cuttings Specimens to the Sample Management Facility." For samples SPC01041713 through SPC0104718, the Sample Collection Report did not provide the required traceability to the specific location of the sample in that it identified that the six subject samples were taken from test pits TP-WHB-5 and TP-WHB-6 with no indication as to which sample came from which pit. (See problem statement below.)

Discussions with SMF management indicated that "specific location is only required if it is important to the scientist doing the test." This is not consistent with the PA-PRO-0804 which does not provide for such a relaxation of sample collection identification and does not provide for "alternate" means of identifying the specific sample source location for these types of samples. This procedure clearly requires in section 4.1.2.2 that a report of collection that contains "Site type and site description, providing enough information to allow the site to be located by personnel (with equivalent experience) who are independent of the Collector." Statements were also made to the effect that, "the people drawing the samples were not from the SMF and we "can't make them follow our procedures." Review of the associated SNL procedure, TST-PRO-008 Rev 1, dated 2/19/07, "Sample Control" Section 6.1.3.B shows that for SNL samples collected in the field that the custodian is required to "Complete a Sample Collection Report (found in PA-PRO-0804) for each sample collected and submit the original form to the SMF. Therefore, by both BSC SMF and SNL procedure, the Sample Collection Report is required and procedural compliance as to its content is expected.

Problem Statement: The Sample Collection Report for Field Work Package FWP-SBT-PA-000011, Rev. 000, does not specify from where six "hand carved alluvium samples" were collected. The sample numbers are SPC01041713 through 718.

SNL generated a Condition Report for this condition. The condition report is well written and clearly identified the actual condition, impact, and the extent of condition.

QARD Supplement III Scientific Investigation

The assessment included a review of the flow down of requirements from the QARD Supplement III into the implementing procedure. The review confirmed that the requirements were properly and accurately translated into the implementing procedures.

Scientific activities at SNL were reviewed and observed. Discussions were held with QA personnel and PIs. In-process experiments were observed and Scientific Notebooks were reviewed.

Discussion with the SNL QA manager and various other SNL staff indicated that they hold the position that "they treat everything they do as "Q" or Important to Waste Isolation (hereafter called "Q" for brevity.) While on the surface this appears to be a conservative approach, it leads to vulnerabilities in implementation and sets the stage for confusion and possible errors by those who must implement the requirements. It is

believed by the team that what they really mean is that they use the same procedures for both Q and non-Q work but it is not accurate to say the work is treated the same.

An in-process Q experiment was observed (SN-SNL-SCI-036-V1 - Use of Resistance Measurement to Monitor Corrosion Kinetics.) The PI was knowledgeable of the quality requirements and procedural requirements for performing his work. The Scientific Notebook opened for this experiment was reviewed and appeared to be maintained in accordance with the established procedure with detailed information about the experiment, including difficulties encountered and changes made to the experiment. A Technical Review, required by the Scientific Notebook Procedure, had recently been completed. This review was very thorough, complete and comprehensive, identifying a number of improvements and clarifications that could be made to the notebook. It is an excellent demonstration of an in-line verification process executed by the line organization to ensure the quality of their work.

In the same room where the Q experiment was being conducted, was an experimental setup which was identified to the team as a non-Q experiment. It was noted that the instruments used for this experiment were not calibrated and the materials/chemicals used were not obtained from a vendor on the QSL. This was noted in the Scientific Notebook for the experiment. The team questioned the use of non-calibrated instruments in light of the statement by the SNL QA manager that "we treat all work as Q." There was no "Non-Q Grading sheet" prepared for this experiment or activity, presumably since it was to be treated as Q. However, it was apparent that it was not being treated as Q in light of the relaxation that was taken in quality requirements. This apparent contradiction causes potential confusion for those who implement the procedures. Using the existing SNL procedure for grading the quality requirements for non-Q activities would provide advance approval of the quality requirements to be applied and remove the potential for worker error. The alternative, saying "we treat all work as Q" and then relaxing quality requirements because it is known to be non-Q, is in effect bypassing the established procedure.

Recommendation: Instead of taking the approach that all SNL work is "Q" and then relaxing some requirements by notation in the Scientific Notebook, SNL should clearly identify work that is non-Q and use their existing procedure to grade the application of the quality requirements.

One item in the Scientific Notebook process and supervisory review process was noted that may require management consideration. The Scientific Notebook procedure states that the body of the Scientific Notebook should document "Deviations from the TWP, if any, including the justification for the deviations." Other than the Technical Review and Compliance Review there appears to be no "management level" review and approval of the deviation or change to the TWP, nor is there a requirement to have the change reviewed by the organization/persons who originally approved the TWP. SCI-PRO-002 "Planning for Science Activities" Section 6.4.1 specifies that the TWP Manager will determine if there is a need for revision to the TWP, however there is no requirement to formally notify the TWP Manager of deviations identified in the Scientific Notebook so

that he/she can adequately make this determination in a timely manner. Many "requirements" of the TWP are general in nature, but there are a few that are specific and any change should be reviewed and approved by the same organization/persons who approved the original, consistent with other change control processes required for ITS/ITWI activities. For example, Technical Work Plan for Geotechnical Investigations for Repository Facilities (TWP-MGR-GE-000007, Rev 00, dated June 2007) which controls the work observed at SNL in the Geo-mechanical Lab, states on page 29 section 2.2.4 that, "at least 10 samples of alluvium will be performed in the Geomechanics laboratory at Sandia National Laboratories" This is the type of scientific testing requirement that, if it cannot be attained, should require the review and approval of the organization that reviewed and approved the original TWP. The process as explained to the team does not provide for such a review.

Recommendation: Consideration should be given to providing guidance on when a deviation for the Technical Work Plan (TWP) identified in a Scientific Notebook should be considered as "change" or revision to the TWP and submitted for formal review and approval.

Data Analysis and Data Qualification

A sampling review of Data Analysis and Data Qualification Reports prepared in response to condition reports relating to transparency and traceability to qualified data sources was conducted. The review was not intended to be a "technical review" of the adequacy of analysis, but whether a methodical and defensible approach was used to qualify the data and if clear and unambiguous limitations were placed on the use of the data where appropriate. The results of the sampling review indicate a very methodical, well documented and defensible process with approaches used, assumptions made, software identified, and limitations on use of the data or results clearly included within the report. The documents reviewed are identified in Lines of Inquiry A1.13 for Scientific Investigation.

ATTACHMENT 1

LINES OF INQUIRY

A1.1 ORGANIZATION

A1.2 QUALITY ASSURANCE PROGRAM

A1.3 DESIGN CONTROL

A1.4 PROCUREMENT DOCUMENT CONTROL
CONTROL OF PURCHASED EQUIPMENT, MATERIAL & SERVICES.

A1.5 DOCUMENT CONTROL

A1.6 CONTROL OF SPECIAL PROCESSES

A1.7 CONTROL OF MEASURING AND TEST EQUIPMENT

A1.8 CORRECTIVE ACTION

A1.9 QUALITY ASSURANCE RECORDS

A1.10 AUDITS
QARD APPENDIX A – WASTE CUSTODIAN INTERFACE

A1.11 QARD SUPPLEMENT I SOFTWARE

A1.12 QARD SUPPLEMENT II SAMPLE CONTROL

A1.13 QARD SUPPLEMENT III SCIENTIFIC INVESTIGATION

LINES OF INQUIRY A1.1
10 CFR 63.142(b) ORGANIZATION

1	Verify that the requirements of the QARD for Organization flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURE/INSTR/DRWG/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
LP1.1Q-OCRWM Organization	Rev 2 Icn 0	5/5/06	Yes
QA-DIR-10 Quality Management Directive	Rev 1 Icn 0	3/29/07	Yes
GM-PRO-6000 Organization	Rev 2 Icn 0	3/28/07	Yes
GM-PRO-5000 Readiness Review	Rev 1 Icn 0	3/28/07	Yes
QA-PRG-001 YMP Lead Laboratory QA Program Description	Rev 1 Icn 0	1/4/07	Yes
QA-PRO-008 Quality Assurance Internal Audit Program	Rev 2 Icn 0	1/29/07	Yes

2	DOE shall establish and execute a quality assurance program. DOE may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of it, but DOE retains responsibility for it
3	The authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to waste isolation and important to safety must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of: ● Assuring that an appropriate quality assurance program is established and effectively executed; and (**This area will also be evaluated by other team members in other Lines of Inquiry.)** ● Verifying that activities important to waste isolation and important to safety functions have been correctly performed by checking, auditing, and inspection of structures, systems, and components. **This area will also be evaluated by other team members in other Lines of Inquiry.**
4	The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.
5	Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to 10 CFR part 63 are being performed must have direct access to the levels of management as may be necessary to perform this function.

REFERENCE	**63.142 Quality assurance criteria b.) Organization**
ISSUES	See report
OBSERVATIONS:	See report
RECOMMENDATIONS:	See report
ASSESSMENT/SUMMARY:	See report

List of Contacts:

NAME	TITLE
L. Newman	Manager OCRWM QA
R. Stevens	Manager LL QA
M. Carmichael	Manager BSC QA
M. Kraus	Manager Corrective Actions, Program Performance Improvement

LINES OF INQUIRY A1.2
10 CFR 63.142(c) QUALITY ASSURANCE PROGRAM

1	Verify that the requirements of the QARD for QA Program flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURE/INSTR/DRWG/NUMBER	REVISION	DATE	CORRECT REVISION
AP-2.1Q QA Requirements and Requirements Description Matrix	Rev 4 Icn 0	4/28/05	Yes
LP-2.2Q-OCRWM Development and Maintenance of OCRWM QA Program Level Documents	Rev 4 Icn 0	6/19/07	Yes
LP-2.19Q-OCRWM Personnel Training and Qualification	Rev 0 Icn 2	6/8/06	Yes
LP-2.26-OCRWM QA Surveillance	Rev 2 Icn 0	3/5/07	Yes
LP-2.29-BSC Planning For Science Activities	Rev 2 Icn 1	3/1/07	Yes
(See Continuation Sheets)			

2	DOE shall establish a quality assurance program that complies with the requirements of this subpart at the earliest practicable time, consistent with the schedule for accomplishing the activities. This program must be documented by written policies, procedures, or instructions and must be carried out throughout facility life in accordance with those policies, procedures, or instructions. **Verify that the QA Program was established prior to start of work. Documentation of the QA Program was performed by the Program Evaluation already performed, and procedures will be verified by other team members using additional Lines of Inquiry.**
3	DOE shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program must control activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety.
4	Activities affecting quality must be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.
5	**Training is a major portion of these criteria: names, titles, and activities performed by personnel will be feed from other team members. Select a sample from the names to verify adequate training and qualification.** The program must take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program must provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.
6	**This will also be an area for concentration to verify Management is involved in the QA Program.** DOE shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

REFERENCE	**63.142 Quality Assurance criteria c.) QA Program and NQA-1 Supplement 1S-1**
ISSUES	See report
OBSERVATIONS:	See report
RECOMMENDATIONS:	See report
ASSESSMENT/SUMMARY:	See report

List of Contacts:

L. Newman, Mgr OCRWM QA	M. Kraus, Mgr Corrective Actions
R. Stevens, Mgr LL QA	M. McDaniel, Mgmt Systems Mgr.
M. Carmichael, Mgr BSC QA	
M. Kavchak, OCRWM Lead Auditor	
A. Hunter, BSC Lead Performance Mgr	

PROCEDURE/INSTR/DRWG/NUMBER LP-2.4Q-OCRWM QA Program Controls	REVISION Rev 1 Icn2	DATE 9/15/06	CORRECT REVISION Yes
LP-2.5Q-OCRWM Management Assessment	Rev 2 Icn 2	9/26/06	Yes
QA-PRO-1001 Maintenance of the QMD and the QA Policy	Rev 1 Icn 0	3/26/07	Yes
QA-PRO-1045 Audit Personnel Qualification	Rev 4 Icn 0	6/25/07	Yes
AP-16.7 OCRWM Trend Program	Rev 0 Icn 0	4/10/07	Yes
TQ-PRO 1001 Personnel Training and Qualification	Rev 6 Icn 0	5/16/07	Yes
QA-PRO-1075 General Inspection and Test Personnel Certification for QA/QC	Rev 3 Icn 0	2/13/07	Yes
QA-PRO-1976 Qualification and certification of NDE Personnel	Rev 1 icn 0	2/13/07	Yes
EG-PRO-3DP-G04T-00905 Determination of Quality Levels	Rev 3 Icn 0	5/15/07	Yes
EG-PRO-3DP-G06B-00010 Specifying Supplies QA Program Requirements	Rev 2 ICN 0	5/15/07	Yes
EG-PRO-3DP-G06B-00001 Material Requisitions	Rev 5 Icn 0	5/18/07	Yes
EG-PRO-3DP-G03B-00001 Design Process	Rev 3 Icn 0	3/9/07	Yes
LSD-PRO-0201 Preclosure Safety Analysis Process	Rev 2 Icn 0	9/26/06	Yes
LS-PRO-0203 Q-List and Classification of Structures, Systems and Components	Rev 2 Icn 0	9/26/06	Yes
PA-PRO-0201 Peer Review	Rev 2 Icn 0	3/27/07	Yes
PA-PRO-0202 Expert Elicitation	Rev 2 Icn 0	3/27/07	Yes
PA-PRO-0203 Tracers, Fluids, and Materials Data Reporting and Management	Rev 1 Icn 0	9/25/06	Yes
LP-2.29Q-BSC Planning for Science Activities	Rev 2 Icn 1	7/1/07	Yes
OP-PRO-9130 Field Sketches and As-Builts	Rev 0 Icn 0	4/13/06	Yes
TS-PRO-1001 Transportation Fieldwork Control Processes	Rev 1 Icn 0	12/15/05	Yes
TQ-PRO-1002 Training Needs Analysis	Rev 1 Icn 0	11/16/06	Yes
TQ-PRO-1003 Training Analysis	Rev 1 Icn 0	9/25/06	Yes
TQ-PRO-1004 Training Design	Rev 1 Icn 0	9/25/06	Yes
TQ-PRO-1005 Training Development	Rev 2 Icn 0	3/19/07	Yes
TQ-PRO-1006 Training Implementation	Rev 1 icn 0	9/25/06	Yes
TQ-PRO-1008 Training Program Description	Rev 2 icn 0	4/17/07	Yes
RQ-PRO-1000 Managing Requirements	Rev 4 Icn 0	5/9/07	Yes
OP-PRO-9101 Work Control Process	Rev 3 Icn 0	5/7/07	Yes
OP-PRO-9105 Facility Work Control Process	Rev 1 Icn 0	9/28/06	Yes
GM-PRO-1001 Procedure Development	Rev 6 icn 0	4/26/07	Yes
GM-DIR-10 Performance Document Management System	Rev 2 Icn 0	4/24/07	Yes
GM-DIR-50 ISM Description Document	Rev 1 Icn 0	9/14/06	Yes

PROCEDURE/INSTR/DRWG/NUMBER LP-2.4Q-OCRWM QA Program Controls	REVISION Rev 1 Icn2	DATE 9/15/06	CORRECT REVISION Yes
GM-DSK-2020 Resolution 0f Differing Professional Opinion	Rev 0 Icn0	2/6/06	Yes
GM-DSK-6000-6000 Documenting Delegations of Authority	Rev 0 Icn 0	3/28/07	Yes
RM-DSK-7003 Preparation and Distribution of BSC ORG Charts	Rev 2 Icn 0	9/26/06	Yes
PI-PRO-001 Preparing and Approving Programmatic Procedures	Rev0 icn0	8/14/06	Yes
QA-PRO-001 QA Trend Evaluation, Analysis, and Reporting	Rev 0 Icn 0	9/18/06	Yes
QA-PRO-003 QA Surveillance	Rev 0 Icn0	9/23/06	Yes
QA-PRO-007 Audit Personnel and Quality Compliance Specialist Qualification	Rev 2 Icn 0	4/24/07	Yes
QA-PRO-008 QA Internal Audit Program	Rev 2 Icn 0	1/29/07	Yes
QA-PRO-010 Maintenance of the QA Policy, Program Description and Requirements Matrix	Rev 1 Icn 0	4/27/07	Yes
SCI-PRO-002 Planning for Science Activities	Rev 2 Icn 0	3/19/07	Yes
SCI-PRO -005 Scientific Analyses and Calculations	Rev 3 Icn 0	3/30/07	Yes
SCI-PRO-006 Models	Rev 3 Icn0	5/30/07	Yes
SCI-PRO-007 Determination of Importance and Site Performance Protection Evaluation	Rev 1 Icn 0	4/27/07	Yes
MGT-PRO-001 Readiness Review	Rev 0 Icn 0	8/22/07	Yes
MGT-PRO-002 QA Management Assessments	Rev 0 Icn 0	8/22/06	Yes
SO-PRO-001 Peer Review	Rev 0 Icn0	8/23/06	Yes
SO-PRO-002 Expert Elicitation	Rev 1 Icn 0	2/7/07	Yes
TRN-PRO-001 Personnel Training and Qualification	Rev 1 Icn 0	2/8/07	Yes
Ap-16.1Q Condition Reporting and Resolution	Rev 10 Icn 0	3/1/07	Yes
OP-DSK-9102-AP-16.1 NCR Hold Tag Process	Rev 1Icn 0	8/25/05	Yes
AP-17.1Q OCRWM Trend Program	Rev 0 Icn 0	4/10/07	Yes
LP-16.2Q-OCRWM Management of Conditions Adverse to Quality for External Organizations	Rev 2 Icn 1	3/22/07	Yes
LP-16.7Q-OCRWM OCRWM QA Management Stop Work Orders	Rev 0 Icn 1	11/2/05	Yes
GM-PRO- 5001 Management Stand Downs	Rev 0 Icn 0	9/22/06	Yes
QA-PRO -1022 QA Management Stop Work Orders	Rev 3 Icn 0	4/3/07	Yes

PERSONNEL INDOCTRINATION/TRAINING/QUALIFICATION

NAME, STAMP, AND JOB TITLE	GENERAL QA INDOCTRINATION AND TRAINING COMPLETED	QUALIFICATION/CERTIFICATION - CERT. TYPE AND LEVEL
Brian Taylor, Geologist	Site Access (SA), GET.	Scientific Support Tech (SST)
Steve Bobo, NS Tech	Not Active in System, Site Access	
Juan Lucero, NS Tech	Not Active in System, Site Access	
Steve Hopkins, BSC	GET, GUT, Licensing Support Network(LSN),	ERT, SST
Jose Gonzoles, Geologist	GET, LSN, Site Access	Lacked SST required for independent quality work
John Dinsmoor, BSC	GET, GUT, ES&H, Cyber Security, OUO, Property Basics, LSN	
Brain Dozier, BSC	GET, GUT, ES&H, Cyber Security, OUO, Property Basics, LSN	
Ron Taylor	GET, LSN	
Randy Cunningham, Survey Supervisor	Procedure Preparer, ERT, GET, GUT, Welding, Fall Protection	
Ron Stevens, LL QA Mgr	GET, GUT, CI, ES&H, Cyber Security, OUO, Property Basics, LSN	
Fred Walden, BSC Records Document Mgr	GET, GUT, SA,	Apparent Cause Analyst (ACA)
Scott Bowlinger, BSC Document Control	GET, SA,	Record Coordinator
Mary McDaniel, BSC Mgmt System Mgr.	GET, SA, ERT,	Team Mgr, M&S, ACA
Andrea Hunter, BSC Lead Performance Mgr	GET, SA,	ACA, Independent Technical Review, Procedure Review
Deborah Kirby, LL QA Org	GET, GUT, CI, ES&H, Cyber Security, OUO, Property Basics, LSN	
David Hathcock, OCRWM Lead Auditor	GET, SA	, Lead Auditor (LA), Procedure Preparation
Marlyn Kavchak, OCRWM Lead Auditor	GET, SA,	LA , Procedure Preparation
J. Maupin, LL Manager Audits and Surveillances	GET, GUT, CI, ES&H, Cyber Security, OUO, Property Basics, LSN	
Tim Benoit, OCRWM Lead Auditor	Inactive, GET, SA	, LA, Procedure Preparation
Pat Auer, OCRWM Lead Auditor	GET, SA	, LA, Procedure Preparation, ACA
Roxanna Scaglione, LL Lead Auditor	GET, GUT, CI, ES&H, Cyber Security, OUO, Property Basics, LSN	
Spence Peterson, OCRWM Procurement/Contract	GET, GUT, CI, ES&H, Cyber Security, OUO, Property Basics, LSN	
Rosa Gome, OCRWM Contract Specialist	GET, GUT, CI, ES&H, Cyber Security, OUO, Property Basics, LSN	

PERSONNEL INDOCTRINATION/TRAINING/QUALIFICATION

NAME, STAMP, AND JOB TITLE	GENERAL QA INDOCTRINATION AND TRAINING COMPLETED	QUALIFICATION/CERTIFICATION - CERT. TYPE AND LEVEL
Bob Toro, OCRWM Audits of Waste Custodians	GET, SA,	LA, Procedure Preparation, ACA
Mike Apfel, BSC Procurement	GET	, M&S, Requirements Area Owner
S.A. Gauthier, BSC Lead Auditor	GET, SA,	ACA, Review Coordinator, LA
Dan Klemas, BSC QA Auditor	GET, Site Access,	ACA, M&S, Review Coordinator, LA, Procedure Preparation
Dawn Perry, BSC Procurement	GET,	M&S
Ed Miller, LL Software Engineer	GET, GUT, ES&H, Cyber Security, OUO, Property Basics, LSN	
George Crews, BSC Software Engineer	GET,	Industrial Tech Reviewer (ITR), Email Sensitive Information (INST)
Mike Myers, Software & Cyber Security Mgr	GET	, M&S, INST
Tom Mulkey, BSC Engineering	GET, M&S,	Procedure Preparation, ITR
Kirk Lachman, BSC Engineering	GET	ACA, Rad Cont, Procedure Preparation
Robert Slovic, BSC Engineering	GET,	ACA, Project Engineer, M&S,

GET – General Employee Training, SA- Site Access Training, GUT – General Underground Training

LINES OF INQUIRY A1.3 10 CFR 63.142(c) DESIGN CONTROL			
1	Verify that the requirements of the QARD for Design flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.		
PROCEDURE/INSTR/DRAW/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
Design Criteria (EG-PRO-3DP-GO4B-00001) (BSC)	Rev. 9	06/27/07	Yes
Design Change Control (EG-PRO-3DP-GO4T-00901) (BSC)	Rev. 4	04/11/07	Yes
Configuration Management EG-PRO-3DP-G04B-00005) (BSC)	Rev. 4	03/22/07	Yes
Managing Technical Product Inputs (PA-PRO-0301) (BSC)	Rev. 3	06/21/07	Yes
Calculations and Analyses EG-PRO-3DP-GO4B-00037 (BSC)	Rev. 8	04/25/07	Yes
Preparation, Review, and Approval of Performance Specifications LP-3.37Q-OCRWM	Rev. 0	07/31/06	Yes
Planning for Science Activities LP-2.29Q-BSC	Rev. 1	03/16/07	Yes
ASME III Design Specification EG-PRO-3DP-GO4T-00050 (BSC)	Rev. 2	03/05/07	Yes
Commercial Grade Dedication EG-PRO-3DP-G04T-00909 (BSC)	Rev. 4	04/16/07	Yes
Q-List (000-30R-MGR0-00500-000-003) (BSC)	Rev. 3	09/29/05	Yes
Q-List and Classification of Structures, Systems, and Components (LS-PRO-0203) (BSC)	Rev. 2	10/02/06	Yes
Nuclear Safety Design Bases for License Application (000-30R-MGR0-00400-000) (BSC)	Rev. 3	09/29/05	Yes
Posy Closure Nuclear Safety Design Bases (ANL-WIS-MD-000024) (BSC)	Rev. 0	08/2006	Yes
Safety Classification of SSCs and Barriers (BSC) 000-00C-MGR0-03000-000	Rev. 00A	08/05/05	Yes
Preclosure Safety Analysis Process LS-PRO-0201	Rev. 2	10/02/06	Yes
Commonly Used Regulatory Terms LS-DSK-2003 (BSC)	Rev. 2	06/25/2007	Yes
Preliminary Preclosure Safety Classification of SSCs 000-PSA-MGR0-00200-000-000	Rev 0	12/20/06	Yes
2	Verify that the design program is adequately defined and includes effective procedures that identify design interfaces, translate quality standards into design documents, and control deviations from standards.		
3.	Verify that design process is controlled to ensure correct design, proper classification of structures, systems and components; suitable application of materials, parts, equipment, and		

LINES OF INQUIRY A1.3 10 CFR 63.142(c) DESIGN CONTROL	
	processes; and accurate translation of requirements onto specifications, drawings, procedures, and instructions
4	Verify that design verification is adequate through effective qualification testing or independent verification.
5	Verify design changes are controlled and are subject to design control measures commensurate with those applied to the original design.
6	Verify that procedures are established, implemented, and controlled that address; the following. 1.Design Standards • Review the design basis documents, specifications, and drawings of SSC's to identify applicable quality standards. Verify that the appropriate quality standards are identified for the SSC and are documented in the design particular SSC. Verify that the quality standards and regulatory requirements are translated into the design, procurement, and procedural documents. Verify that deviations from quality standards are identified, documented and controlled in accordance with established procedures. 2. Design Interfaces • Verify that interfaces between participating design organizations are identified and a process for coordinating and controlling these interfaces is established. Verify design interface procedures are established for each design organization. 3. Classification and Design of SSC's • Review the procedure for classifying SSCs according to their importance to safety and waste isolation. Verify that the process described in the procedure is consistent with the requirements in 10CFR Part 63, and the QARD. Verify that the current listing of SSCs that are important to safety and waste isolation are documented on a Q-list. Verify that the requirements for the Q-list items are adequately translated into specifications, drawings, procedures, and instructions. Verify that procedures are established that require documented verification of dimensional accuracy and completeness of design drawings and specifications. Verify that procedures are established requiring design drawings and specifications to be reviewed by the QA organization. 4. Design Controls • Verify that design inputs are identified and documented and that their selection is reviewed and approved by those responsible for the design. Verify that design analysis is planned, controlled, performed in a timely manner, and documented. • Verify that computer software used to perform design analysis is developed or qualified and used in accordance with established procedures. • Verify that personnel who perform design analysis, approve design analysis are qualified and trained. Verify qualification and training is documented. • Verify that any design deficiencies are documented in the corrective action program. • Verify that design personnel are aware of limitations for the use of SSCs. • Verify that design personnel are aware of 10CFR Part 21 requirements related to reporting defects. • Verify that procedures are established that control the design and control of any commercial grade assemblies/items deemed to be a SSC. 5. Design Verification • Verify that the design verification process is established and documented. Verify that the responsibilities of verifier are documented. • Verify that, if any previously verified designs are changed, the design is re-verified, including the evaluation of the effects of the change. • Verify that any design changes that impact related implementing documents, other design organizations, or training programs are documented and provided to affected organizations. • Verify that design inputs for interfacing organizations are specified in the design documents. 6. Test Program • Verify that requirements are established for qualification testing to be conducted in accordance with established requirements. Verify that test procedures provide criteria for when verification testing is to be performed.

Reference	NRC Inspection Procedure78060 “Design Control” (Pre-Licensing and Construction) NRC Inspection Manual Chapter 2300 “Yucca Mountain Pre-Operation Inspection Program” 10CFR63.142 Quality Assurance Requirements and Description DOE/RW-0333P Rev. 18 Section 3.0 QA-DIR-10 Revision 1 Criterion 3.1 QA-PRG-001 Revision 1 Section 3.0 Regulatory Guide 1.201, Revision 1, May 2006, “Guideline for Categorizing Structures, Systems, and Components in Nuclear Power Plants According To Their Safety Significance”. Nuclear Energy Institute (NEI) NEI-00-04, Revision 0, July 2005, “10CFR50.69 SSC Categorization Guideline”.
Issues:	See Report
Observations:	See Report
Recommendations:	See Report
Assessment/Summary	See Report

List of Contacts:

NAME	TITLE
Tom Mulkey	BSC Engineering, Special Projects
Kirk Lachman	BSC Engineering, Design
Robert Slovic	BSC Engineering, Manager Nuclear Surface Facilities
Mark Wisenberg	BSC Preclosure Safety Analysis
Ralph Wagner	SNL
Robert Howard	SNL (UNLV)

LINES OF INQUIRY A1.4
10 CFR 63.142(e) PROCUREMENT DOCUMENT CONTROL
10 CFR 63.142(h) CONTROL OF PURCHASED EQUIPMENT, MATERIALS AND SERVICES.

1	Verify that the requirements of the DOE/QARD, Sandia Labs and BSC QA Program Documents for Procurement Document Control, Control of Procured Items and Services, Receipt Inspection, and Vendor Approval and Audits flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURE/INSTR/DRWG/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
18.4Q DOE EM/RW Oversight Process	0	12/19/2003	Yes
QA-PRO-001 Procurement Documents	1	05/24/2007	Yes
QA-PRO-003 Quality Assurance Surveillance	0	10/2/2006	Yes
QA-PRO-004 Supplier Evaluation and Qualified Supplier List Maintenance	1	11/22/06	Yes
QA-PRO-005 Managing Supplier Condition Reports	2	3/19/2007	Yes
QA-PRO-006 Supplier Surveys/Audits	1	4/26/2007	Yes
QA-PRO-008 Augmented Quality Assurance Program Graded Approach	0	10/02/2006	Yes
QA-PRO-009 Acceptance of Products and Services	3	6/9/2007	Yes
EG-PRO-3DP-G06B-0001 Material Requisitions	5	5/24/2007	Yes
EG-PRO-3DP-G06B-00002 Subcontracts	6	5/24/2007	Yes
EG-PRO-3DP-G06B-00005 Bid Evaluation	3	4/18/2007	Yes
EG-PRO-3DP-G06B-00010 Specifying Supplier Quality Assurance Program Requirements	2	5/24/2007	Yes
LP-18.5Q-OCRWM OCRWM Contractor Surveys/Audits	2/ICN 1	6/12/2007	Yes
LP-2.26Q-OCRWM Quality Assurance Surveillance	2	3/9/2007	Yes
LP-4.1Q-OCRWM Procurement Actions	7	6/25/2007	Yes
LP-4.2Q-OCRWM Processing Agreements for Acceptance of High Level Radioactive Waste and Spent Nuclear Fuel From Waste Custodians	2	1/18/2007	Yes
LP-4.7Q-OCRWM Controls for Use of Guidance Memoranda to Obtain National Laboratory Services	2/ICN 3	6/19/2007	Yes
LP-7.5Q-OCRWM Reviewing Deliverable Acceptance Criteria, and Reviewing and Accepting or Rejecting Deliverables	0/ICN 1	6/14/2007	Yes
LP-7.9Q-OCRWM Supplier Evaluation and Maintenance of the Qualified Suppliers List	1/ICN 1	6/1/2007	Yes
LP-7.10Q-OCRWM Evaluation and Acceptance of Principal Contractor Quality Assurance Program	0/ICN 1	6/05/2007	Yes
PROCEDURE/INSTR/DRWG/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
PM-PRO-001 Procurement Documents	1	5/24/2007	Yes
PM-PRO-1006 Receipt, Identification, and Handling of Materials	0	12/20/2006	Yes
PM-PRO-1008 Property and Materials Issue and Return to Warehouse	0	12/20/2006	Yes
QA-PRO-1042 Supplier Evaluation and Qualified Suppliers List	4	4/10/2007	Yes
QA-PRO-1043 Managing Supplier Condition Reports	5	4/10/2007	Yes

QA-PRO-1044 Supplier Survey/Audits	3	4/13/2007	Yes
QA-PRO-1047 Supplier Evaluation and 414.1 Supplier List Maintenance	5	4/17/2007	Yes
QA-PRO-1071 Acceptance of Items and Services	3	4/13/2007	Yes
QA-PRO-1072 Suspect/Counterfeit Item Reporting	1	4/13/2007	Yes
QA-PRO-1079 SUSPECT/COUNTERFEIT ITEM INSPECTION	3	4/17/2007	Yes
EG-PRO-3DP-G04B-00057 Technical Services Contracts	5	5/24/2007	Yes
EG-PRO-3DP-G04B-00058 Supplier Engineering and Quality Verification Documents	6	4/16/2007	Yes
EG-PRO-3DP-G04B-00063 Supplier Deviation Disposition Requests	5	6/12/2007	Yes
PR-PRO-3.2 Evaluation and Selection of Potential Suppliers	4	7/17/07	Yes
PR-PRO-2.02 Procurement Files	4	3/16/07	Yes
PR-PRO-3.02 Subcontract/Purchase Order Formation	4	6/26/07	Yes
LP-18.7Q Office of Quality Assurance Overview Activities of The Naval Nuclear Propulsion Program Quality Assurance Program	1 / ICN 0	06/02/2006	Yes

2	Procurement Procedures. Review procedures used for procurement activities. Verify that procedures require the following information to be provided in procurement documents. Ensure the following requirements are also included in procurement documents, and changes, for items and services, as applicable a. Statement of work to be performed. b. Design basis or references to the design basis. c. Applicable regulatory, design, technical, administrative, and reporting requirements (e.g., 10CFR Part 21 reporting requirements). d. Drawings, specifications, codes, and industry standards. i. Identification of applicable QA program requirements. f. Test, inspection, and acceptance requirements. g. Provisions for establishing hold points. h. Access for audit or inspection by the purchaser and the U.S. Nuclear Regulatory Commission. i. Identification of documentation to be submitted to the purchaser or retained by the supplier, including any retention times. j. Schedule for submitting any documents to the purchaser for information, review, or acceptance. k. Requirements for reporting and dispositioning nonconformances. l. Special process requirements. m. Identification of any spare or replacement parts or assemblies and the appropriate technical and QA data required for ordering. n. Identification of deliverable records.
3	Verify that procedures require procurement documents to be prepared, reviewed, and approved in accordance with QA program requirements and ensure the procurement documents met these requirements.
4	Verify that the procurement documents were reviewed and approved before issuance by affected organizations or disciplines, and by representatives from technical and QA organizations, in accordance with established procedures. These reviews should include considerations for applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. Verify that comments resulting from the reviews were documented and resolved before approving the procurement document.
5	Verify that any changes to the procurement documents were reviewed by organizations affected by the change and were subject to the same degree of control as used in the preparation of the original documents. If any changes were incorporated into a procurement document as the result of proposal/bid evaluations or pre-contract negotiations, verify that an evaluation of the change was completed before awarding the contract. Verify that changes were evaluated against appropriate requirements, additional or modified design criteria, and analysis of exceptions or changes requested or specified by the supplier. Verify that evaluations include a determination of the impact such changes have on the intent of the procurement documents or quality of the material, equipment, or services to be furnished.
6	Interview several persons who have reviewed procurement documents. Verify that the reviewers were not involved in the preparation of the documents. Verify that the reviewers are technically competent in the areas discussed in the procurement document in which they have completed reviews. Verify that the reviewers had available and used, as necessary, pertinent background information or data.

7	Verify that adequate measures are established and implemented for the receipt inspection of materials, components and parts. Verify these documents include, as applicable: a) Test and or inspection to be performed at receipt. b) Specifications, work instructions, drawings, etc., including document revision. d) Acceptance criteria contained in applicable design or procurement documents. e) Appropriate Inspection equipment, tools, gages, and instrumentation (correct type, range and accuracy). f) Characteristics to be inspected. g) Test prerequisites identified and met. h) Personnel. I) Results are approved by responsible authority. j) Action taken relative to any deficiencies noted.
8	Verify that sampling plan(s) used for receipt inspection are controlled and acceptably implemented.
9	For the selected procurement documents, verify that audits of the suppliers or contractors were performed, and verify that the audits were adequate and pertinent for the material, equipment, or service being procured. Review the audits to verify that any areas of noncompliance identified were corrected. Verify that the suppliers are on the approved vendors list and that any restrictions assigned to the suppliers, if applicable, are referenced on the list and are appropriately accounted for in the procurement documents. Verify the supplier's program ensures surveys of commercial grade suppliers and audits of Appendix B suppliers. a) Verify evaluations are performed prior to award of contract, and at the specified frequency. b) Verify that the scope of approval of the sub-supplier is commensurate with the requirements of the procurement documents. c) Verify that only approved suppliers are used.
10	(a) Verify that measures are established and implemented to ensure a comprehensive system of planned and periodic external audits (b) Verify that the audits were conducted by qualified personnel and are of sufficient depth and scope to ensure adequacy and effectiveness of the sub-suppliers program. (c) Verify that checklists or procedures were used with objective evidence documented and that follow-up action is taken where needed. NOTE: When 3rd party audits e.g., Consultant performed, are used as a basis for supplier qualification the evaluation shall be documented and shall address: (a) Performance of the audit by qualified personnel. (b) Performance of the evaluation by qualified personnel to ensure the users program requirements are satisfied. (c) The Scope of the audit envelops the current scope of procurement. (d) The applicable regulatory and/or commercial program requirements are adequately addressed in the audit scope. (e) Sufficient objective evidence is available to support conclusions of the audit.

REFERENCES	**NRC Inspection Procedure 78070 " Procurement Document Control" NRC Inspection Procedure 88108 "Control of Materials, Equipment, and Services" NRC Inspection Procedure 88115 "Supplier/Vendor Inspection" NRC Inspection Procedure 78300 "Supplier/Vendor Inspection" 10 CFR 63 142 "Procurement Document Control" and "Control of Procured Material and Services" NQA 1 "Procurement Document Control" and "Control of Procured Material and Services" NQA-1 Supplement 7S-1, NQA-1 Supplement 18S-1 NQA-1 Supplements 10S-1,and 11S-1**
Problem Statements:	See report
OBSERVATIONS:	See report
RECOMMENDATIONS:	See report
ASSESSMENT/SUMMARY:	See report

List of Contacts:

NAME	TITLE
Spencer Peterson (OCRWM)	Supervisor OCRUM Procurement Contracts
Rosa Gomez (OCRWM)	Contract Specialist OCRUM Procurement
C. Newberry (OCRWM)	OCRM Procurement

NAME	TITLE
Jim Raleigh (SNL)	Senior Nuclear Licensing Engineer
Don Trybul (BSC)	Manager Procurement and Property
Bob Toro (OCRWM)	OQA Lead Auditor
Ram Murthy (OCRWM)	Supervisor Quality Systems Engineering
Mike Apfel (BSC)	Procurement Operations Manager
Dan Klimas (BSC)	External Audit Lead
Bob Habbe (BSC)	Internal Audit Lead
David Hathcock (OCRWM)	Quality Assessments
Jim Maupin (SNL)	Audit and Surveillance Manager
Dawn Perry (BSC)	RPM Project Acquisitions Manager
Larry McGraph (BSC)	Quality Engineer
Jim Stevens (BSC)	Procurement
Ronda Mackie (BSC)	Procurement
Mike Ulshafer (OCRWM)	OQA Special Projects
Patrice Sanchez (SNL)	Manager Procurement
Bob Jones (SNL)	Sandia Delegated Representative
Sandra Gonzales (SNL)	Organizational Assurance

LIST OF DOCUMENTS REVIEWED FOR PROCUREMENT

OCRWM Procurement

ITEM DESCRIPTION NAME (P/N, S/N, MODEL NO., SOFTWARE NAME)	SUPPLIER AND LOCATION	P.O. NUMBER AND DATE	METHOD AND DATE OF SUPPLIER EVALUATION	SCOPE OF SUPPLIER APPROVAL
Agreement for Sandia National Lab from OCRWM to act as the lead Lab NNSA Contract # DE-AC04-94AL-85000	Sandia Site Office through Sandia Corp. in Albuquerque, NM	Contract Letter dated, 11/27/2006 and July 11, 2006 NNSA Contract # DE-AC04-94AL-85000	Audits are now being handled as Integrated Internal Audits	Lead Lab for Yucca Mountain Project
Contract for Management and Operating Yucca Mountain for work 04/01/07 through 03/31/08	Bechtel SAIC Company Site Office in Las Vegas, NV	Contract Number DE-AC28-05RW12101 Revision 12 Modification A102, dated 03/30/07	Audits are now being handled as Integrated Internal Audits	Management
Technical Services for Aging System Analyses	Holtec International Marlton, NJ	Contract DE-AC28-05W12362 M001 12/14/2005	Audit	This contract is being handled in the OCRWM DC Office. (see observation # 3)
Provide Support in Preparation and review of license application for YMC	AECL Technologies Gaithersburg, MD	Contract DE-AC28-04RW 12240 Amendment M001 dated 5/14/04, Task 001 A002, 8/11/04, Amendment A008, 2/16/06	Audit	Scientific investigation

BSC Procurement

ITEM DESCRIPTION NAME (P/N, S/N, MODEL NO., SOFTWARE NAME)	SUPPLIER AND LOCATION	P.O. NUMBER AND DATE	METHOD AND DATE OF SUPPLIER EVALUATION	SCOPE OF SUPPLIER APPROVAL
Subcontract for Waste Package Structural Design	Anatech	Contract QA-HC4-03VS	QA Review of records audit planed for 7/16/07	Structural Design
Fabrication and Assembly of the Prototype Waste Package	Joseph Oat Camden NJ	PO QA-POA-00002 revisions 1-5, dated 2/7/07	Audit	Waste Package Fabrication and Assembly
Geotechnical Investigations for drilling operations. Provide surveyor and equipment under BSC procedures and direction by BSC Site representative	NS Tech Las Vegas, NV	QA-HC9-00457 Modification 7, dated 6/22/07 Work package number ESML20	N/A Working under BSC Procedures and guidance	N/A this work is under BSC Procedures. (See problem statement re surveying at the site)

Sandia Procurement

ITEM DESCRIPTION NAME (P/N, S/N, MODEL NO., SOFTWARE NAME)	SUPPLIER AND LOCATION	P.O. NUMBER AND DATE	METHOD AND DATE OF SUPPLIER EVALUATION	SCOPE OF SUPPLIER APPROVAL
Provide professional staff to support Sandia activities.	AREVA Lynchburg, VA.	PO 631561 revision 3, 12/1/2/2006	Not required all work to be performed under the direction of Sandia personnel and to Sandia procedures. Qualification of personnel to be verified by Sandia	N/A all work to be performed under the direction of Sandia personnel and to Sandia procedures. Qualification of personnel to be verified by Sandia
Calibration Services various	National Security Technologies, LLC (NS Tech)	PO 637585, dated 10/10/2006 and revision 3	Audit	Calibration Services
Staff Augmentation for Burn-up Credit Validation planning	Oak Ridge National Lab Oak Ridge Tn	PO 659130, dated 12/18/2006	Not required PO for staff augmentation to work under Sandia's QA Program.	Staff Augmentation
Various Chemical Standards	Spex Certiprep, Inc Metuchen, NJ	PO 637940, 04/17/2007	Audit	Mass Spectrometry Analytical Standards
Various Chemical Standards	Ultra Scientific North Kingstown, RI	PO651190, dated 12/21/2006	Audit	Inorganic chemical standards

LIST OF AUDITS/SURVEYS/SOURCE VERIFICATIONS REVIEWED

SUPPLIER NAME, LOCATION AND DATE(S) PERFORMED	EVALUATION METHOD (APPENDIX B AUDIT, COMMERCIAL GRADE SURVEY, SOURCE VERIFICATION)	SCOPE	AUDITORS	NUMBER OF DEFICIENCIES (OPEN/ CLOSED)	CORRECTIVE ACTION VERIFICATION METHOD AND DATE
Sandia Site Office through Sandia Corp. in Albuquerque, NM	Handled as a Principal Contractor and audits are performed throughout the year (reference recommendation #5)	Sample of Audits performed listed in Lines of Inquiry Internal Audits	Various	N/A	N/A
Bechtel SAIC Company Site Office in Las Vegas, NV	Handled as a Principal Contractor and audits are performed throughout the year (reference recommendation #5)	Sample of Audits performed listed in Lines of Inquiry Internal Audits	Sample of Audits performed listed in Lines of Inquiry Internal Audits	N/A	N/A
Joseph Oat Camden NJ 4/26/28/05	QA Program BQA-AS-05-04	Complete QA Program except design	D.Z. Hathcock Dan Klemas James George	4 closed	Fabrication and Assembly of the Prototype Waste Package
Joseph Oats Camden NJ	Surveillance Report BQA-SE-06-052	Heat Treating Process	S.A.Gauthier	0	N/A
Joseph Oats Camden NJ	Surveillance Report OQA-SE-07-006	Final Documentation Review Oversight of BSC	David Hathcock	0	N/A
Anatech	Supplier Evaluation to place on the QSL, dated 6/28/07	Evaluation of Records Review including QA Manual and Project Plan Audit scheduled for 7/16/07 Structural Design Services	S. A. Gauthier	N/A Audit pending	N/A
Battelle Energy Alliance (BEA) 03/15/2007	Audit LLQA-EA-07-001, performed 03/6-7/2007	Corrosion Testing of Neutron Absorber Alloys	R. L. Scaglione Lead SNL R. L. Maudlin BSC	1 SCR LL-07-N-002	N/A Open
Argonne National Laboratory 01/09/2007	Audit OQA-AS-07-03 Performed 12/19-20/2006	Complete QA Program for Scientific Investigation Activities	T. J. Benoit Lead OQA P. V. Auer OQA J. K. Kirkwood Technical Specialist	0	N/A
Primary Standards Laboratory (PSL) Albuquerque, NM 02/28/2007	Audit OQA-AS-07-09 Performed 02/21-22/2007	Complete QA Program for Calibration Services	P. Auer Lead OQA B. Foster OQA	0	N/A

LIST OF AUDITS/SURVEYS/SOURCE VERIFICATIONS REVIEWED

SUPPLIER NAME, LOCATION AND DATE(S) PERFORMED	EVALUATION METHOD (APPENDIX B AUDIT, COMMERCIAL GRADE SURVEY, SOURCE VERIFICATION)	SCOPE	AUDITORS	NUMBER OF DEFICIENCIES (OPEN/ CLOSED)	CORRECTIVE ACTION VERIFICATION METHOD AND DATE
Pacific Northwest National Laboratory (PNNL) 06/14/2007	Audit OQA-AS-07-10 06/5-6/2007	Complete QA Program for Scientific Investigation Activities	D. Z. Hathcock Lead OQA S. A. Gauthier OQA	1 Open Response Received	N/A
General Atomics (GA) 07/09/2007	Audit OQA-AS-07-17 06/20-21/2007	Complete QA Program for Engineering Services	D. Z. Hathcock Lead OQA P.A. Auer OQA	0	N/A

RECEIPT, ACCEPTANCE OF DELIVERABLES, TESTSAND OR INSPECTION LIST

PO NUMBER AND ITEM DESCRIPTION (NAME, P/N, S/N, ETC.)	RECEIPT TEST/INSPECTION DATE Or Acceptance of Deliverables	CONTROLLING TEST/INSPECTION DOCUMENT NUMBER AND REV./DATE	INSPECTOR/ TESTER/ Reviewer NAME/STAMP	ID NUMBER OF M&TE USED CALIBRATION CURRENT	RESULTS SAT. OR UNSAT. IF UNSAT., RECORD NCR NO. IF APPLICABLE
Contract for Sandia National Lab from OCRWM to act as the lead Lab NNSA Contract DE-AC04-94AL-85000 Saturated Zone In-Situ Testing PAD822S	7/6/07	LP-7.5Q rev. 0ICN1, 6/14/07	Signed by J.R. Dyer Review performed by Drew Coleman	N/A	SAT with comments
Contract for Sandia National Lab from OCRWM to act as the lead Lab NNSA Contract DE-AC04-94AL-85000 Simulation of Net Infiltration for Present-Day and Potential Future Climates PAD804S	7/6/07	LP-7.5Q rev. 0ICN1, 6/14/07	Signed by Russ Dyer Review performed by Eric Smistad	N/A	SAT with comments
Contract for Sandia National Lab from OCRWM to act as the lead Lab NNSA Contract DE-AC04-94AL-85000 Geochemical Modeling of Mineral Water Interactions in Dilute Systems PAD844S	6/9/07	LP-7.5Q rev. 0/ICN1 6/14/07	Signed by Russ Dyer Review performed by Debbie Barr	N/A	SAT
SNL PO 637940 Various Laboratory Standards from Spex Certiprep	01/30/07	QA-PRO-009 rev. 3, 06/05/2007	T. J. Reshel/ R. E. SPencer	N/A Chemicals accepted by review of documentation	Items SAT, but CR 10654 written for use of wrong acceptance form, corrected by use of the CR and revised procedure

RECEIPT, Acceptance of Deliverables, TESTS AND OR INSPECTION LIST

PO NUMBER AND ITEM DESCRIPTION (NAME, P/N, S/N, ETC.)	RECEIPT TEST/INSPECTION DATE Or Acceptance of Deliverables	CONTROLLING TEST/INSPECTION DOCUMENT NUMBER AND REV./DATE	INSPECTOR/ TESTER/ Reviewer NAME/STAMP	ID NUMBER OF M&TE USED CALIBRATION CURRENT	RESULTS SAT. OR UNSAT. IF UNSAT., RECORD NCR NO. IF APPLICABLE
SNL PO 651190 Various Laboratory Standards and chemicals from Ultra Scientific	05/30/07	QA-PRO-009 rev. 3. 06/05/2007	D. Enos / J. K. Devers	N/A Chemicals accepted by review of documentation	All items accepted previsously one item Sodium Nitrate rejected on NCR LL-07-002 Trend CR 10611, scraped and replaced and accepted on 05/30/07.
SNL PO 637585 Calibration of M&TE from NS Tech Fluke Model Scope Meters serial numbers DM6882054 and DM6882059	06/19/07	QA-PRO-009 rev.3 06/05/2007	R. F. Sievert / J. K. Devers	N/A calibration service accepted by review of documents	SAT

LINES OF INQUIRY A1.5
10 CFR 63.142(g) DOCUMENT CONTROL

1	Verify that the requirements of the QARD for Document Control flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURE/INSTR/DRWG/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
AP-5.1Q	Rev. 4, ICN 8	10/03/2006	Yes
LP-SV.2Q-OCRWM	Rev. 0, ICN 2	04/02/2007	Yes
PI-PRO-001	Rev. 0	10/02/2006	Yes

2	Document Control Program. Verify that a program is established and the types of controlled documents are identified. Controlled documents are required to include, as a minimum, design documents (e.g., calculations, drawings, specifications, analyses), including documents related to computer software; procurement documents; instructions and testing, and inspection; as-built documents; QA and quality control manuals and quality-affecting procedures; SAR; nonconformance/deficiency reports; and corrective action reports, including changes thereto.
3	Verify that procedures are established to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner. Verify that procedures for the review, approval, and issuance of documents and changes are established to assure technical adequacy and inclusion of appropriate quality requirements before implementation. Verify that procedures are established to assure that documents are available at the location where the activity will be performed before beginning the work.
4	Verify that procedures are established to assure that changes to documents are reviewed and approved by the same organizations that performed the initial review and approval. Verify that a master list or equivalent document control system is established to identify the current revision of instructions, procedures, specification, drawings, and procurement documents. Also the list should be distributed to predetermined responsible personnel.
5	Verify that a process exists for expediting changes in a timely manner. Verify that the expediting change process identifies the level of management with the authority to make expedited changes. Verify that a process exists for the control and distribution of editorial changes; correcting grammar or spelling; renumbering sections or attachments that do not affect the chronological sequence of work; changing the title or number of the document; and updating organizational titles. Verify that editorial changes are approved by the responsible organization.
6	Document Distribution. Select in-process work locations and verify that work documents are made available and used at the work locations. Verify that effective dates are established for approved implementing documents. Verify that obsolete or superseded documents are not part of the work package. The organizational position responsible for approving the document for release shall be identified. (record documents verified on the attached list)
7	Instructions, Procedures, and Drawings Availability. Select a sample of important activities. Verify that appropriate instructions, procedures, or drawings are available for conducting those activities and contain the following information, as appropriate: a. Responsibilities and interfaces of the organizations affected by the instructions, procedures, or drawings. b. Identification of associated items and activities. c. A detailed description of the work to be performed. d. Proper review and approval signatures.
8	Instructions, Procedures, and Drawings Content. Select a sample of procedures for important activities. Verify that instructions, procedures, and drawings for those activities contain quantitative (e.g., dimensions, tolerances, operating limits) and qualitative (e.g., workmanship samples, analyses) acceptance criteria for determining that important activities have been satisfactorily accomplished. Verify that the instructions, procedures, and drawings also contain, as appropriate, the following information: a. Technical and regulatory requirements. b. Prerequisites, limits, precautions, process parameters, and environmental conditions. c. Quality verification points and hold points.
9	Instructions, Procedures, and Drawings Implementation. Select a sample of important activities. Verify that the activities are accomplished through implementation of instructions, procedures, and drawings. Verify that methods are provided for demonstrating that the work was performed as required such as provisions for recording inspection and test results, checkoff lists, or signoff blocks. This will also be verified for each activity reviewed during the assessment.
10	Instructions, Procedures, and Drawings Changes. Verify that any changes to instructions, procedures, and drawings are documented and verified in a timely manner by authorized personnel.
11	Document Changes. Select several work documents and verify that review criteria are established for document changes. The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. Verify that the review of changes was performed by individuals other than the preparer. Verify that the reviewers are technically competent regarding the subject area of the document changes being reviewed. Verify that the work document defines the method used to incorporate changes. A history of changes shall be documented and maintained and reviewed each time additional changes are proposed

REFERENCE	**NRC INSPECTION PROCEDURE 78090 "Document Control" And NRC INSPECTION PROCEDURE 78080 "Instructions, Procedures, and Drawings"**
NONCOMPLIANCE:	See Report
OBSERVATIONS: **UNRESOLVED ITEMS:**	See Report
RECOMMENDATIONS:	See Report
ASSESSMENT/SUMMARY:	See Report

List of Contacts:

NAME	TITLE
Frederick Walden	BSC/Manager, Records/Document Control
Scott Bowlinger	BSC/Lead, Document Control
Lynne Purdy	BSC/Supervisor, Records Processing Center
Kathleen Steel	BSC/Lead, Records Processing Center
David Warriner	OCRWM/Member, Performance Improvement & Assessment Team
Mary McDaniel	BSC/Supervisor, Management Systems
Andrea Hunter	BSC/Lead, Performance Document Management Systems
Stacy Steel	BSC/Project Administration Assistant, BSC Engineering Support
Deborah Kirby	SNL(Longenecker)/Lead, Quality Systems
Ronald Stevens	SNL/Manager, Quality Assurance

LINES OF INQUIRY A1.6
10 CFR 63.142(j) CONTROL OF SPECIAL PROCESSES

1	Verify that the requirements of the QARD for Special Processes flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURES/INSTRUCTION/NUMBER	REV.	DATE	CORRECT REVISION (YES/NO)
Magnetic Particle Examination (MT) (QA-PRO-1084) (BSC)	1	07/12/06	Yes
Qualification/Certification of NDE Personnel (QA-PRO-1076) (BSC)	1	02/15/07	Yes
Welder/Welding Operator Performance Qualification (OP-PRO-9170) (BSC)	0	04/28/06	Yes
Welding Procedure Development, Control, and Application (OP-PRO-9171) (BSC)	0	04/28/06	Yes
Welding Filler Material Control (OP-PRO-9172) (BSC)	2	08/08/06	Yes
Welding Procedure Specification (WPS P1-TA-U-01) (BSC)	1	01/26/04	Yes
Welding Procedure Specification (WPS-A36-A-F-01)	1	01/19/05	See Attachment
Welding Procedure Specification (WPS-A36-F-T38	0		See Attachment
Welding Procedure Specification (WPS-CS-M-A-01	0		See Attachment

2	Verify that requirements are established to assure that special processes are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria and other special requirements.
3	Verify that procedures for special processes including welding, heat treating, chemical cleaning, and nondestructive testing, have been established and controlled.
4	Verify that for special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualification of personnel, procedures or equipment is specified or referenced in implementing documents
5	Verify that implementing procedures ensure that process parameters are controlled and that specified environmental conditions are maintained.
6	Verify implementing procedures contain; • Organizational responsibilities • Documentation requirements for data recorded • Qualification requirements for personnel, implementing documents and equipment • Certificates of qualification for each process • Criteria used to qualify personnel • Conditions required to perform special process • Requirements of applicable codes, standards, or specifications including acceptance criteria for the special process • Requirement for the QA organization to be involved personnel, equipment, and process qualification.
7	Verify that personnel that perform nondestructive examination (radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, acoustic emission and leak testing) are trained, qualified and certified in accordance with SNT-TC-1A June 1980 Edition.

REFERENCE:	QARD DOE/RW-0333P Revision 18 Section 10.0
	QA-DIR-10 Revision 1 Criterion 9
	SNT-TC-1A, June1980 Edition
ISSUES:	See report
OBSERVATIONS:	See report
RECOMMENDATIONS:	See report
ASSESSMENT/SUMARY:	See report

LIST OF CONTACTS

NAME	TITLE
Mike Carmichael	BSC QA Manager

LINES OF INQUIRE A1.7
10 CFR 63.142(m) CONTROL OF MEASURING AND TEST EQUIPMENT

1	Verify that the requirements of the QARD for Calibration flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURE/INSTR/DRWG/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
Quality Management Directive (QA-DIR-10) (BSC) criterion 12	1	04/02/07	Yes
Control of Measuring and Test Equipment (CO-PRO-1001) (BSC)	1	03/19/07	Yes
Calibration of Sample Management Facility M&TE (PA-PRO-1202) (BSC)	2	06/15/07	Yes
Control of Survey Equipment (OP-PRO-9191) (BSC)	0	12/08/06	Yes
Inspection of Test Devices (QA-PRO-1082) (BSC)	3	04/13/07	Yes
Control of Measuring and Test Equipment (TST-PRO-002)	0	10/02/07	Yes

2	Verify that the calibration program requires measuring and test equipment, including equipment that contains software or programmable hardware, to be calibrated, adjusted, and maintained, as a unit, at prescribed intervals, or before use, against reference calibration standards having traceability to National recognized standards. If no Nationally recognized standards or physical constants exist, the basis for calibration shall be required to be documented. Verify that calibration of the equipment is against standards that have an accuracy of at least 4 times the required accuracy of the equipment being calibrated or, when this is not possible, that have an accuracy that assures that the equipment being calibrated will be within required tolerances. List equipment verified on the attached List.
3	Verify that procedures are established for the control of measuring and test equipment, including instruments, tools, gauges, fixtures, reference and transfer standards and nondestructive equipment used in the measuring, inspection and monitoring of SSCs. Calibrations and controls are not required for rulers, tape measures, levels and other normally commercial equipment that provide adequate accuracy. Review the procedures to verify that sufficient detail is provided for the calibration (including technique and frequency), maintenance, and control of the equipment. Verify that procedures define the method and interval of calibration of each device, based on the type of equipment, stability characteristics, required accuracy, intended use, degree of use, and conditions affecting measurement control. For measuring and test equipment used in one-time-only applications, the calibration shall be done both before and after use.
4	Procedures should establish criteria for selecting proper measuring and test equipment, for use in processes, inspections, and tests that: (1) are of the type appropriate for measuring specified characteristics of items being processed, inspected, or tested; and (2) have sufficient range, accuracy, and tolerance to determine conformance to specified.
5	Verify that measuring and test equipment software developed or modified by the user shall be controlled in accordance with Supplement I, "Software," of the QARD and that updates to software that affect calibration require recalibration of the equipment prior to use.
6	Calibration of Equipment. Select several items of equipment controlled under the measuring and test equipment program and verify that the equipment is labeled or tagged or "otherwise controlled," to indicate the due date or interval of the next calibration. Verify that the controls and calibration frequency are consistent with procedural or program requirements for the control of the equipment.
7	Verify, with selected users of the equipment, that when the accuracy of the equipment is suspect, that a calibration check method is available for the user to verify acceptable performance of the equipment, or the equipment will be returned for recalibration
8	Verify that the use of calibrated equipment is being documented. As appropriate, this documentation should include the process monitored, data collected, or items inspected or tested, since the last calibration
9	Review the calibration records for the equipment. Verify the equipment is traceable, through some unique identifier, to the calibration test data. Verify that the equipment was calibrated against a standard having an accuracy of at least 4 times the required accuracy of the equipment. If the calibration standard did not meet this requirement, review the basis for acceptance of the calibration used and verify approval of the calibration process by responsible management, in accordance with the calibration program
10	Verify maintenance of calibrated equipment and records. Review the equipment and records for the following, as applicable: a. Identification of the measuring or test equipment calibrated; b. Traceability to the calibration standard used for calibration; c. Calibration data; d. Identification of the individual performing the calibration; e. Identification of the date of calibration and the recalibration due date or interval, as appropriate; f. Results of the calibration and statement of acceptability; g. Reference to any actions taken in connection with out-of-calibration or nonconforming measuring and test equipment, including evaluation results; and h. Identification of the implementing document (including revision level) used in performing the calibration. NOTE If sub-suppliers are used, pass on information to auditor responsible for procurement and external audits.

11	Out-of-Calibration or Lost Equipment. Verify that program requirements are established such that when measuring and test equipment is found to be out of calibration, measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration. For any inspections or tests on items determined to be suspect, the inspection or test shall be repeated Verify that controls are established for out-of-calibration equipment, to ensure the equipment is tagged, segregated, or otherwise controlled to prevent use until recalibrated. During tours of work areas and calibration labs, verify that equipment available for use is calibrated. For any equipment not in calibration, verify that controls have been implemented to prevent use. Verify that the criteria for determining when equipment is out-of-calibration include: (1) the calibration due date, or interval passed without recalibration; and (2) the device producing results known to be in error. Verify that requirements are established for equipment found out of calibration during recalibration, to validate the results obtained from using that equipment since its last valid calibration. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested, and shall be documented. Any equipment consistently found to be out of calibration during the recalibration process shall be repaired or replaced. Verify that requirements are established for validating data when the measuring and test equipment is lost. This evaluation should include review of all data collected since the last calibration. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested, and shall be documented. Review selected calibration records and repair records to determine if any equipment was found out of calibration during the recalibration process, or had been lost, and review documentation generated to validate the data collected by the instrument.
12	Select several standards used for calibration of equipment. Verify that the standards are traceable to nationally recognized standards. Where traceability to nationally recognized standards does not exist, review the documentation that justifies the use of the standard. Verify that standards are calibrated by calibration standards that have greater accuracy. Calibration standards that have the same accuracy as the standard being calibrated may be used if this level of accuracy can be demonstrated to be adequate for the requirements and provided that the basis of acceptance is documented and authorized by responsible management, consistent with procedural and calibration program requirements.
13	Select several standards used for calibration of equipment. Verify that the standards are traceable to nationally recognized standards. Where traceability to nationally recognized standards does not exist, review the documentation that justifies the use of the standard. Verify that standards are calibrated by calibration standards that have greater accuracy. Calibration standards that have the same accuracy as the standard being calibrated may be used if this level of accuracy can be demonstrated to be adequate for the requirements and provided that the basis of acceptance is documented and authorized by responsible management, consistent with procedural and calibration program requirements.
14	Verify that calibration is performed in an environment that is controlled to the extent necessary to assure required accuracy.

REFERENCE	**NRC INSPECTION PROCEDURE 78160 "**CONTROL OF MEASURING AND TEST EQUIPMENT (PRE-LICENSING AND CONSTRUCTION)" QARD DOE/RW-0333P Revision 18 Section 12 QA-DIR-10 Revision 1 Criterion 12 QA-PRG-001 Revision 1 Section 12
PROBLEM STATEMENTS:	See report
OBSERVATIONS:	See report
RECOMMENDATIONS:	See report
ASSESSMENT/SUMMARY:	See report

List of Contacts:

NAME	TITLE
Douglas Weaver	SNL. SME Calibration of M&TE
Dennis Dugas	BSC/YMP/Construction Manager
Dennis Jew	BSC/YMP/Construction Field Manager
Bill Howard	BSC/SMF
David Bronowski	SNL/Geo-Mechanical Lab
David Enos	SNL – Principal Investigator

List of M&TE Verified

Name and M&TE I.D. (Serial No)	Calibration Procedure And Rev/Date	Cal. Date	Due Date	Cal. By	Standards Used	NIST/ Industry (Yes/No)	Results Sat or Unsat If Unsat, Record NCR No.	Purchase Order Number if sub-supplier
Elec Temp Recorder ID 1000084		3/12/07	3/12/08					
Elec Temp/Humidity Recorder ID 1000028		4/4/07	4/4/08					
Elec Temp Recorder		3/12/07	3/12/08					
Cal Standard for Calibrating Temp Recorders 1000073		1/23/07	1/23/08			Yes		
Cal Standard for Calibrating Temp Recorders 1000074		5/30/07	5/30/08			Yes		
2 Kg Standard for calibrating	ASTM	3/27/07	3/27/10			Yes		NSTech (On QSL for

Name and	Calibration					NIST/	Results	Purchase
M&TE	Procedure	Cal.	Due	Cal.	Standards	Industry	Sat or Unsat	Order Number
I.D. (Serial No)	And Rev/Date	Date	Date	By	Used	(Yes/No)	If Unsat, Record NCR No.	if sub-supplier
scales 1000038								Calibration Svcs) 993444
Data Logger 56231 (SNL in Geo-Physics Lab)	OM-DA-PRO-5300	5/8/07	5/8/08					
LVDT SN 517 (SNL in Geo Physics Lab)	ASTM F 2537-06							
373LHX Ser 06-0811 (SNL experiment	CP-RTD-60	5/29/07	5/29/08	CJF				

LINES OF INQUIRY A1.8
10 CFR 63.142(q) CORRECTIVE ACTION

1	Verify that the requirements of the QARD for Corrective Action and Nonconforming Material, Parts, or Components flows down to implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURE/INSTRUCTION/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
AP16.1Q Condition Reporting and Resolution	Rev 10 Icn 1	3/1/07	Yes
CO-PRO-4MP-T81-07104 Control Of Deficient Items	Rev 2 Icn 0	6/25/07	Yes
CO-PRO-4MP-T81-07107 Nonconformance Reporting and Control	Rev 2 Icn 0	6/25/07	Yes
LS-PRO-3002 Identification and evaluation of Defects and Noncompliance	Rev 1 Icn 0	4/25/07	Yes
EG-PRO-3DP-GO4B-00061 Disposition of Nonconformance or Deficiency Reports	Rev 1 Icn 0	2/28/07	Yes
PA-PRO- Requesting , Transferring, and Returning YMP Specimens from the Sample Management Facility	Rev 2 Icn 0	6/11/07	Yes
GM-PRO-4000 Management Self Assessments and Organizational Self Assessments	Rev 2 Icn 0	3/28/07	Yes
QA-PRO-1072 Suspect/Counterfeit Item Reporting	Rev 1 Icn 0	4/6/07	Yes
QA-PRO-1079 Suspect/ Counterfeit Item Inspection	Rev 3 Icn 0	4/12/07	Yes
EG-PRO-3DP-G06B-00001 Material Requisitions	Rev 5 Icn 0	5/18/07	Yes
EG-PRO-3DP-G06B-00002 Subcontracts	Rev 6 Icn 0	5/18/07	Yes
EG-PRO-3DP-G04B-00049 Engineering Specifications	Rev 4 Icn 0	4/5/07	Yes
PI-PRO -006 Nonconformance Reporting and Resolution	Rev 3 Icn 0	5/11/07	Yes

2	Verify that the corrective action program is adequately defined by effective procedures that identify and correct conditions adverse to quality and preclude recurrence of significant conditions adverse to quality.
3	Verify that the nonconforming materials, parts and components program is adequately defined by effective procedures that establish the requirements for the control of items that do not meet specified requirements to preclude inadvertent installation of use.
4	Verify that measures are established to assure conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformances are promptly identified.
5	Verify a process exists for the documenting and reporting of adverse to quality or nonconforming conditions to the appropriate levels of management responsible for the conditions, and to the organization responsible for tracking.
6	Verify that closure of corrective actions and nonconformances is completed in a timely manner. Verify that criteria is established for quality trending. Determine if trending information is distributed to affected organization management and used to identify significant conditions adverse to quality.
7	Verify that problems are adequately described and labeled with unique identifiers. Verify the problems are classified by significance.
8	Verify that the QA organization concurs with proposed corrective actions and dispositions of nonconformances.
9	Verify that significant conditions adverse to quality are evaluated for a stop work condition by the QA organization.
10	Verify that all nonconforming conditions are evaluated for potential reportability as per the requirements of 10CFR Part 21.

REFERENCE:	NRC Inspection Procedure # 78200 “Corrective Action” 10CFR Part 21 Regulatory Guide 1.28, Revision 3, QA Program Requirements (Design and Construction) NQA -1-1983
ISSUES:	See report
OBSERVATIONS:	See Report
RECOMMENDATIONS:	See Report
ASSESSMENTS SUMMARY:	See Report

List of Contacts

NAME	TITLE
L. Newman	Manager OCRWM QA
M. Kraus	Manager BSC Corrective Actions

LINES OF INQUIRY A1.9
10 CFR 63.142(r) QUALITY ASSURANCE RECORDS

1	Verify that the requirements of the QARD for QA Records flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURE/INSTR/DRWG/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
AP-17.1Q	Rev. 4, ICN 5	03/09/2007	Yes
DM-PRO-002	Rev. 2	06/04/2007	Yes

2	**Records will be reviewed by all team members during the assessment, to ensure records are legible and identifiable. This section should concentrate on verification that adequate measures are established and implemented to assure that all QA records are maintained in facilities that provide storage, retention requirements and protection against environmental effects, damage and loss.** Verify that records are legible, identifiable, and retrievable. Records should include the following, as applicable: 1. Scientific, engineering, and operational data and logs; laboratory and field notebooks and logbooks; and data reduction documents 2. Results of reviews, inspections, tests, audits, and material analysis 3. Monitoring of work performance 4. Maintenance and modification procedures and related inspection results 5. Reportable occurrences 6. QA program changes that reduce commitments 7. Computer software supporting a safety or waste isolation function 8. Qualification of personnel, procedures, and equipment 9. Documentation such as design records, drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, corrective action reports, and as-built drawings 10. Other records required by preclosure and postclosure operating conditions 11. Construction records required by 10 CFR 63.72.
3	10 CFR 63.72 Construction records require. DOE shall maintain records of construction of the geologic repository operations area at the Yucca Mountain site in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3). The records required must include at least the following: (1) Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to readily identifiable surface features or monuments; (2) A description of the materials encountered; (3) Geologic maps and geologic cross-sections; (4) Locations and amount of seepage; (5) Details of equipment, methods, progress, and sequence of work; (6) Construction problems; (7) Anomalous conditions encountered; (8) Instrument locations, readings, and analysis; (9) Location and description of structural support systems; (10) Location and description of dewatering systems; (11) Details, methods of emplacement, and location of seals used; and (12) Facility design records (e.g, design specifications and “as built” drawings).

REFERENCE	**10 CFR 63.142 Quality Assurance criteria r.) QA Records, 10 CFR 63.72 Records, and NQA-1 Supplement 17S-1, 6S-1**
ISSUES	See Report
OBSERVATIONS:	See Report
RECOMMENDATIONS:	See Report
ASSESSMENT/SUMMARY:	See Report

List of Contacts:

NAME	TITLE
Ronald Stevens	Manager, Quality Assurance
Frederick Walden	Manager, Records/Document Control
Lynne Purdy	Supervisor, Records Processing Center
Kathleen Steel	Lead, Records Processing Center
David Warriner	Member, Performance Improvement & Assessment Team

LINES OF INQUIRY A1.10
10 CFR 63.142(s) AUDITS
QARD Appendix A - Waste Custodian Interface

1	Verify that the requirements of the QARD for Internal Audits and QARD Appendix A flow down to the implementing procedures. Record the procedures/instructions used to verify implementation in this area.

PROCEDURE/INSTR/DRWG/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
LP-18.3Q QA Internal Audit Program	2/ICN 1	6/12/2007	YES
LP-18.7Q Office of Quality Assurance Overview Activities of The Naval Nuclear Propulsion Program Quality Assurance Program	1	6/02/2006	YES
LP-7.10Q Evaluation and Acceptance of Principal Contractor Quality Assurance Program	0/ICN 1	6/5/2007	YES
QA-PRO-1046 Quality Assurance Internal Audit Program	3	4/13/2007	YES
LP-2.26Q Procedure Quality Assurance Surveillance	2	03/09/2007	YES
QA-PRO-008 Quality Assurance Internal Audit Program	2	1/31/2007	YES

2	*Audits*. DOE shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, must be taken where indicated.
3	Verify that measures are established and implemented to ensure a comprehensive system of planned and periodic internal audits. Verify that the participants have no direct responsibility in the areas audited. Verify that checklists and/or procedures were used with objective evidence documented, that audit results were documented and those results reviewed by management having responsibility in the area audited. Verify follow-up action is taken where needed.
4	**A.1.2. Federal Waste Custodians** A. The OCRWM interfaces directly with federal waste custodians and their principal contractors to obtain information and/or data to support activities subject to the QARD (e.g., scientific document development, design, etc.). The OCRWM has developed the requirements described in this appendix to ensure that appropriate QA controls are implemented by federal waste custodians and their principal contractors. B. Federal waste custodians and their principal contractors perform activities to ensure and document that their HLW and SNF will meet OCRWM waste acceptance criteria. In some cases federal waste custodians and/or their principal Contractors also design and fabricate items that will be considered important to safety or waste isolation. Although these activities do not affect DOE's ability to comply with 10 CFR 63 at this time, they will in the future (i.e., during and after waste acceptance). Federal waste custodians and/or their principal contractors work to QA programs that meet the applicable requirements of either an NRC-approved 10 CFR 50, Appendix B, QA program, or a 10 CFR 63.142 QA program. The applicable requirements of these QA programs are flowed down to their principal contractors by the federal waste custodians. The controls identified in this appendix also apply to work performed to support future HLW and SNF acceptance.
5	C. Interfaces between the OCRWM and federal waste custodians are defined in formal agreement documents (i.e., Memoranda of Agreement or Understanding). Agreement documents also identify requirements that the federal waste custodians will need to meet for OCRWM to use their work products (e.g., License Application input and designed or fabricated items that will be considered important to safety or waste isolation) and accept their HLW or SNF for disposal. The OCRWM will verify the implementation of these requirements through audits, surveillance, reviews, or observations prior to accepting their work products or accepting HLW or SNF.
6	D. Federal waste custodians normally contract some or all of the work addressed in this appendix to their principal contractors. Agreement documents will be executed between the OCRWM and senior management of the office that encompasses the federal waste custodians. Federal waste custodians are responsible for passing the appropriate provisions of the agreement document down to their principal contractors.
7	E. Agreement documents are not procurement documents; however, for the purpose of providing the appropriate level of control over OCRWM and federal waste custodian interface, the applicable requirements of 10 CFR 63.142 will be applied to the development, control, and revision of agreement documents.
8	A. The OCRWM's agreement with the **Office of Environmental Management** (EM) identifies the technical and quality requirements that apply to work associated with HLW and SNF and identifies the requirements of 10 CFR 63.142 that are applicable to EM federal waste custodians' principal contractors.
9	B. The agreement also describes the oversight of EM federal waste custodians and their principal contractors performing work covered in the agreement. EM and the OCRWM jointly perform audits of EM federal waste custodians and their principal contractors. Audit teams include at least one OCRWM OQA team member. Audits are performed in accordance with approved OCRWM implementing documents.

10	C. The EM National Spent Nuclear Fuel Program provides the OCRWM with information related to DOE SNF, so it is treated as a waste custodian even though it does not actually possess SNF or HLW.
11	An agreement document defines the interface between the Naval Nuclear Propulsion Program (NNPP) and OCRWM for the purpose of OCRWM acceptance of naval SNF for disposal. This agreement specifies that the NNPP QA program shall be defined and administered solely by the NNPP in accordance with its statutory obligations and that the NNPP is responsible for conducting all oversight of NNPP activities related to acceptance of naval SNF. Under the agreement, OCRWM is responsible for reviewing NNPP QA practices regarding naval SNF and for determination of the sufficiency of these practices for disposal at the repository. The agreement provides for OCRWM observations of NNPP QA practices and periodic discussion and updates regarding these practices so that the OCRWM can fulfill its responsibilities under the agreement.
12	The OCRWM monitors the NNPP QA program to ensure it remains acceptable to the OCRWM. Monitoring activities include periodic observations of NNPP QA program oversight of various NNPP QA program elements and contractor QA program activities, as well as annual reviews of NNPP QA audits, surveillance, inspection reports, implementing document revisions, compliance matrices, and organizational changes.

REFERENCE	**63.142 Quality Assurance criteria s.) Audits, OCRWM QARD APPENDIX A, and NQA-1 Supplement 18S-1**
FINDINGS	See Report
OBSERVATIONS:	See Report
RECOMMENDATIONS:	See Report
ASSESSMENT/SUMMARY:	See Report

List of Contacts:

NAME	TITLE
Ram Murthy	OCRWM Supervisor Quality Systems
Larry Newman	Director OCRWM Office of Quality Assurance
Michael Ulshafer	OCRWM Supervisor Quality Systems Special Projects
Marilyn Kavchak	OCRWM Supervisor Quality Assessments
Robert Toro	OCRWM Quality Assessments
Jim Maupin	SNL Lead Audit and Surveillance
R. Stevens	SNL Manager Quality Assurance
H. Mike Carmichael	BSC Manager Quality Assurance
Bob Habbe	BSC Quality Audit Internal Lead

INTERNAL AUDITS
OCRWM

AUDIT SCOPE AND DATE	AUDITOR(S)	NUMBER OF DEFICIENCIES & STATUS (OPEN/CLOSED)	CORRECTIVE ACTION VERIFICATION METHOD AND DATE
BSC Implementation of the QA Program Audit Number OQA-OCRWM-07-09 / 05/7-10/2007	W. J. Glasser OQA (Lead) H. T. Green BSC R. A. Toro OQA L. W. Wagner OQA	2 CRs Open 3 still open from audit OQA-OCRWM-06-15	N/A Open
OCRWM, BSC, and SNL Audit Number OQA-BSC-07-03 for Corrective Action, Self Assessment, and trending programs, 01/22/2007	K. O. Gilkerson Lead W. J. Glasser OQA M. A. Kavchak OQA L. W. Wagner R. I. VanDillen	Program Ineffective as Identified in Audit OQA-BSC-06-02 and CR-9774 and 2 additional CRs	N/A Open
SNL Audit QA Program OQA-SNL-07-02, 01/24/2007	R. A. Toro Lead M. A. Kavchak C. M. Palay	4 CRs IOpen	N/A

AUDIT SCOPE AND DATE	AUDITOR(S)	NUMBER OF DEFICIENCIES & STATUS (OPEN/CLOSED)	CORRECTIVE ACTION VERIFICATION METHOD AND DATE
	L. W. Wagner		
BSC Design Engineering Organization OQA-BSC-07-01, 12/08/2006	T. J. Benoit Lead R. C. DeKlever D. J. Harris W. J. Glasser OQA	2 CRs Open	N/A
OCRWM & BSC Activities in the Washington, DC Office OQA-OCRWM-07-09, 06/13/2007	W. J. Glasser OQA Lead H. T. Green BSC R. A. Toro OQA L. W. Wagner OQA	2 New CRs – Open 3 CRs From Previous Audit still open Audit OQA-OCRWM-06-15	N/A

INTERNAL AUDITS
BSC

AUDIT SCOPE AND DATE	AUDITOR(S)	NUMBER OF DEFICIENCIES & STATUS (OPEN/CLOSED)	CORRECTIVE ACTION VERIFICATION METHOD AND DATE
BSC Interface Controls Audit BQA-BSC-07-03 01/15/2007	C. Warren Lead BSC W. Ang BSC A. Duncan BSC G. Heaney BSC F. Sanda BSC	5 CRs Issued Open	N/A Still Open
BSC Flow Down of Requirements BQA-BSC-07-01, 01/19/2007	R. D. Habbe Lead BSC J. E. Clark BSC S. A. Gauthier BSC C. O. Wright BSC	3-CRs Issued Open	N/A Still Open
BSC Yucca Mountain Site Activities BQA-BSC-07-04, 03/30/2007	C. O. Wright BSC Lead S. A. Gauthier BSC C. O. Wright BSC R. D. Habbe BSC L. McGrath BSC R. Strohl BSC J. Therien BSC R. Weeks BSC	13 CRs Open ! CR 9774 from previous audit and still open	N/A

INTERNAL AUDITS
SNL

AUDIT SCOPE AND DATE	AUDITOR(S)	NUMBER OF DEFICIENCIES & STATUS (OPEN/CLOSED)	CORRECTIVE ACTION VERIFICATION METHOD AND DATE
SNL QA Requirements Flowdown Audit Number LLQA-IA-07-001, 12/7/2006	R. L. VanDillen SNL Lead J. K. Devers SNL	3 CRs Open	N/A
SNL QA Program Audit Number OQA-SNL-07-02, 01/12/2007, performed by OQA to allow independent evaluation of the SNL QA Organization	R.A. Toro Lead OQA M. A. Kavchak OQA C. M. Palay OQA L. W. Wagner OQA	4 CRs Closed	Verification of Corrective Action

LINES OF INQUIRY A1.11
QARD SUPPLEMENT I SOFTWARE

1	Verify that the requirements of the QARD for Software (QARD Supplement I Software) flow down to implementing procedures. Record the documentation used to verify implementation in this area.

PROCEDURES/INSTRUCTIONS/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)	
Software Independent V & V (IM-PRO-005) (Sandia)	Rev. 0	10/2/06	Yes	
Software Management (IM-PRO-003) (Sandia)	Rev. 2	03/01/07	Yes	
Software QA (IT-PRO-0021 (BSC)	Rev, 1	06/12/07	Yes	
Software Compliance (IT-PRO-0015)(BSC)	Rev. 4	03/16/07	Yes	
Software Independent V&V (IT-PRO-0013)(BSC)	Rev. 4	03/16/07	Yes	
Qualification of Software (IT-PRO-0012)(BSC)	Rev. 4	03/16/07	Yes	
Software Management (IT-PRO-0011) (BSC)	Rev. 5	05/21/07	Yes	
Quality Management Directive QA-DIR-10 (BSC)(Criterion 3.2)	Rev. 1	03/2007	Yes	
QA Program Description (QA-PRG-001) (Sandia)	Rev. 1	01/10/07	Yes	
Independent Verification and Validation of Legacy Code (IM-PRO-006) (Sandia)	Rev. 0	10/02/06	Yes	
Qualification of Software (IM-PRO-004) (Sandia)	Rev. 2	03/01/07	Yes	

2	Verify software acquisition, development, modification, and maintenance is performed in a planned, traceable, and orderly manner utilizing a defined software life cycle methodology. A defined software life cycle methodology addresses the following phases; • Requirements • Design • Implementation • Testing • Installation • Checkout • Operations • Maintenance • Retirement
3	Verify that software verification and validation activities are planned, documented, and performed for software, software changes, or system configurations that are determined to impact software. The validation test plans, test cases, and test results are documented, reviewed, and approved prior to the use of the software. Software verification is performed at the end of the requirements, design, implementation, and testing life cycle phase.
4	Software verification and validations activities are performed by individuals not associated with the development of the software. In those instances where this level of independence may not be achieved, an individual associated with the development of the software may perform these activities with a higher level of management approval and documented justification.
5	• **o**
6	**Software Configuration Management** • Verify that a software configuration management (SCM) system is established that includes configuration identification, configuration change control and status accounting. • Verify that software is not used on SSCs or items important to waste isolation unless it has been qualified and base-lined. Software used in activities affecting quality is limited to copies obtained from SCM. • Verify software configuration management implementing procedures address; 1. Configuration items to be controlled 2. Configuration documentation 3. Configuration change control 4. Configuration status accounting
7	**Problem Reporting and Resolution** 1. Verify a problem reporting and resolution system is implemented for software errors and failures. 2. Verify the problem reporting and resolution system is integrated with the SCM system. 3. Verify problems are identified, evaluated, documented , and if required corrected. 4. Problems are assessed for impact. 5. Corrections and changes are controlled in accordance with applicable configuration change control requirements.

	6. Notification of the error, its impacts, and how to avoid the error, pending implementation of corrective actions, is provided to the user organization. If a problem that constitutes a condition adverse to quality is identified in software, the condition is documented and controlled in accordance with QARD Section 16.0 (Corrective Action).
8	**Software Procurement** Verify that individuals or organizations developing and supplying software under contract are required to have polices and procedures that meet the applicable requirements of supplement I. Software is to be procured as specified in QATR sections 4.0 and 7.0.
9	Verify that implementing procedures control the use of software. Controls are established to permit authorized access and prevent unauthorized access to computer systems.

REFERENCES:	See Section 1
ISSUES:	See Report
OBSERVATIONS:	See Report
RECOMMENDATIONS:	See Report
ASSESSMENT/SUMMARY:	See Report

LIST OF CONTACTS

NAME	TITLE
Ed Miller	SNL./Lead Software Engineer
George Crews	BSC/SME, Software Engineer
Mike Myers	BSC/Software and Cyber Security Mgr.
Alesia Boone	OCWRM. IT, Systems and Data Manager

LINES OF INQUIRE A.12
QARD SUPPLEMENT II SAMPLE CONTROL

1	Verify that the requirements of the QARD (Supplement II Sample Control) flow down to implementing procedures. Record the documentation used to verify implementation.		
PROCEDURES/INSTRUCTIONS/NUMBER	REVISION	DATE	CORRECT REVISION (YES/NO)
Calibration of Sample Management Facility Measuring and Test Equipment: PA-PRO-1202	2	06/15/07	Yes
Disposal of Samples Curated by the Sample Management Facility: PA-PRO-0810	0	06/15/07	Yes
Examination of Borehole Samples Curated by the Sample Management Facility: PA-PRO-0802	2	06/15/07	Yes
Sample Management Facility Field Logging, Handling, and Documentation of Borehole Samples: PA-PRO-0806	2	06/15/07	Yes
Collection, Submission, Return, and Documentation of Non-core and Non-cuttings Specimens to the Sample Management Facility: PA-PRO-0804	2	06/20/07	Yes
Requesting, Transferring, And Returning Yucca Mountain Project Specimens From The Sample Management Facility: PA-PRO-0803	2	06/15/07	Yes
Removal, Shipment, And Return Of Specimens Curated By The Sample Management Facility: PA-PRO-0809	3	06/15/07	Yes
Sample Management Facility Monitoring And Documentation Of Drilling Activities And Depth Control: PA-PRO-0805	2	06/15/07	Yes
Sample Nonconformance Reporting And Control At The Sample Management Facility: PA-PRO-0808	0	06/15/07	Yes
Interface With The OCRWM Sample Overview Committee: PA-PRO-0801	0	06/15/07	Yes
Scientific Notebooks: PA-PRO-0304	0	03/14/07	Yes
Scientific Notebooks: TST-PRO-003	1	04/30/07	Yes
Sample Management Facility Transport, Receipt, Admittance, And Processing Of Borehole Samples: PA-PRO-0807	3	06/15/07	Yes
Sample Control: TST-PRO-008	1	02/19/07	Yes

2	Verify that a implementing procedures are established for "Sample Control" and they address the following; • Samples are controlled and identified in a manner consistent with their intended use. • Controls identify responsibilities, including interfaces between organizations, for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use. • Controls include specifics on orientation relative to the location that was sampled, as appropriate.
3	Traceability Sample identification methods ensure that traceability is established and maintained from samples to applicable implementing documents or other specifying documents. Sample traceability ensures that the sample can be traced at all times from its collection through final use.
4	Identification • Identification is maintained on samples or in a manner that ensures that identification is established and maintained. • Sample identification is documented and checked before the sample is released for use or analysis. • Samples identification methods include the use of physical markings. If physical markings are either impractical or insufficient, other means are employed (i.e., physical separation, labels or tags attached to containers, or other procedural control). • Physical markings when used are applied using materials and methods that provide a clear and legible identification. Markings are transferred to each identified sample part when the sample is subdivided.
5	Sample Storage

	If sample storage is required, then methods are established for the control of sample identification that is commensurate with the planned duration and conditions of storage. Implementing documentation specifies the representative samples to be archived if the need to archive samples is identified.
6	Handling, Storage, and Shipping • Handling, storage, cleaning, packaging, shipping, and preservation of samples are conducted in accordance with established implementing documents or other specified documents. • Markings and labels are consistent with above section 4. • Special handling tool and equipment is controlled as necessary. Tools and equipment is inspected and tested in accordance with implementing documents and at specified time intervals. • Operators of special handling and lifting equipment are experienced and trained to use the equipment.
7	Disposition of Nonconforming Samples Samples that due not meet requirements specified in work-controlling documents are documented, evaluated, identified, and segregated in accordance with QARD section 15.0 Nonconforming Material, Parts, or Components. The disposition of nonconforming samples is identified and documented and is limited to “use-as-is”, “limited use”, or “reject”.

REFERENCES:	QARD DOE/RW-0333P revision 18 Supplement II QA-DIR-10 Revision 1 Criterion 8 QA-PRG-001 Revision 1 Section 8
PROBLEM STATEMENS:	See Report
OBSERVATIONS:	See Report
RECOMMENDATIONS:	See Report
ASSESSMENT/SUMMARY:	See Report

List of Contacts

Name	Title
Douglas Weaver	SNL
William Watson	BSC
Dean Stucker	DOE
Jose Gonzales	BSC/NSTech
Brian Taylor	BSC/NSTech

LINES OF INQUIRY A.13
QARD SUPPLEMENT III SCIENTIFIC INVESTIGATION

1	Verify that the requirements of QARD Supplement III Scientific Investigation flow down to implementing procedures. Record the documentation used to verify implementation in this area.			
PROCEDURE/INSTRUCTION/NUMBER		**REVISION**	**DATE**	**CORRECT REVISION (YES/NO)**
Scientific Analyses (LP-SIII.9Q) (OCRWM)		Rev. 1/ICN1	10/02/06	Yes
Scientific Analyses and Calculation (SCI-PRO-005)(Lead Lab.)		Rev. 3	06/01/07	Yes
Quality Management Directive (QA-DIR-10) (BSC)(Criterion 3.3)		Rev. 1	03/2007	Yes
Quality Assurance Program Description (QA-PRG-001) (Sandia)(Section 21)		Rev. 1	01/10/07	Yes
Planning For Science Activities (LP-2.29Q-BSC) (OCRWM)		Rev. 2	03/16/07	Yes
Qualification of Unqualified Data (LP-SIII.2Q-BSC) (OCRWM)		Rev. 0	09/28/06	Yes
Managing Technical Product Inputs (PA-PRO-0301) (BSC)		Rev. 3	06/21/07	Yes
Scientific Notebooks (PA-PRO-0304) (BSC)		Rev. 0	03/14/07	Yes
Scientific Notebooks (TST-PRO-003) (SNL)		Rev. 1	04/30/07	Yes
Planning for Science Activities (SCI-PRO-2) (SNL)		Rev 2	03/21/07	Yes

2 Verify that the implementing procedures address:

1. Planning scientific investigations
   - Planning is coordinated with the organizations providing input to or using the results of the investigation.
   - Planning addresses provisions for determining the accuracy, precision, and representative ness of results.
2. Performing Scientific Investigations:
   - All documentation resulting from scientific investigation shall be transparent, identify principal lines of investigation considered, and be legible and in a form suitable for reproduction, filing, and retrieval. Investigations are performed using notebooks, implementing documents, or a combination of both.
   - Scientific notebooks contain:

   1. Description of work to be performed or reference to implementing documents.
   2. Identification of method(s) and computer software used.
   3. Identification of any samples or M&TE used.
   4. Results of investigation, names of individuals performing the work, and dated initials or signature, as appropriate, of individual making the entries.
   5. Description of any changes made to methods used.
   6. Scientific notebooks are reviewed by an independent qualified individual to verify detail.

3. Data Identification
   - Data is identified in a manner that ensures traceability to associated documentation, to its qualification status, and to assure traceability is maintained throughout the lifetime of the data.
4. Data Review, Adequacy, and Usage
   - Data is reviewed by individuals other than those who collected or reduced the data to ensure technical correctness.
   - Unqualified data may be used in scientific investigation provided traceability to its status as unqualified data is maintained.
   - Unqualified data developed from scientific investigation activities that are used as direct input to site characterization, scientific analysis or performance modeling that address safety or waste isolation issues is qualified.
   - The qualification process is planned and documented.
5. Model Development and Use
   - Model development and approaches to validation are planned, controlled, and documented. Planning for model validation identifies the validation methods and the validation criteria used.
   - Computer software used to develop or execute the model is qualified with the requirements of QARD Supplement I.

REFERENCE:	QARD DOE/RW-0333P Revision 18 Supplement III QA-DIR-10 Revision 1 Criterion 3.3 QA-PRG-001 Revision 1 Supplement III
PROBLEM STATEMENTS:	
OBSERVATIONS:	
RECOMMENDATIONS:	
ASSESSMENT/SUMMARY:	The documents reviewed were:

ANL-NBS-HS-000055 Rev 00 incl ACN-001 and CAN-002	Data Analysis for Infiltration Modeling: Development of Soil Units and Associated Hydraulic Parameter Values
TDR-NBS-HS-000019 Rev 00	Technical Evaluation and Review of Results, Technical Procedures, and Methods Related to the Collection of Moisture Monitoring Data Using Neutron Probes in Shallow Boreholes
ANL-NBS-HS-000054 Rev 00 incl ACN-001	Data Analysis for Infiltration Modeling: Bedrock Saturated Hydraulic Conductivity Calculation
ANL-NBS-HS-000077 Rev 00	Data Analysis for Infiltration Modeling: Technical Evaluation of Previous Soil Depth Estimation Methods and Development of Alternate Parameter Values
TDR-NBS-GS-000030 Rev 00	Data Qualification Report Ground Cover and Geographic Coordinate Data from Ecological Study Plots at Yucca Mountain, Nevada

LIST OF CONTACTS

NAME	TITLE
Kathryn Knowles	SNl/ Performance Assessment
Peter Swift	SNL
David Enos	SNL Principal Investigator
Tom Pfeifle	SNL
Russell Jarcek	LV
Susan Boggs	SNL
Doug Wall	SNL

ATTACHMENT 2
INDEPENDENT QUALITY ASSURANCE IMPLEMENTATION ASSESSMENT TEAM RESUMES

Team Leader:	Dan M. Stover –	Technical And Professional Services, Inc
Team Member :	Frank Hawkins -	Technical And Professional Services, Inc.
	Wayne Scott -	Technical And Professional Services, Inc.
	Paul Kellogg –	InfoZen
	Raymond Wenderlich –	Technical And Professional Services, Inc.
	Rene' Delaney -	Technical And Professional Services, Inc.
	Bruce Tracey -	Technical And Professional Services, Inc.

Dan M. Stover

PROFESSIONAL SUMMARY

Over 32 years experience in management, operations, assessment/surveillance and quality assurance at commercial nuclear, DOE, and Army Chemical Demilitarization Facilities. Experience in Oversight Planning, Performance Based Assessment, Surveillance and Auditing, Safety System Functional Inspections (SSFI), Operational Readiness Reviews (ORR), Integrated Safety Management Systems (ISMS) Verification, and Training. Extensive experience in Conduct of Operations, Design/Safety Basis development and training (10CFR830), Engineering Design Review, Un-reviewed Safety Questions (10CFR50.59), Self Assessment and Quality Assurance.

DIRECT RELEVANT EXPERIENCE TO SOW:

- QA Division Manager – A/E
- QA advisor to A/E Nuclear Plant Project Manager
- Lead Auditor – audits/surveillances at nuclear facilities and suppliers
- DOE ORRs/RAs Team Member and train DOE personnel in Performance-Based Assessment
- Commercial Utility SSFI QA functional area reviews
- DOE HQ core team member for Tritium Task Force, Chemical Risk Review and Hanford Tank Farms review

EXPERIENCE

Technical And Professional Services, Inc. Fayetteville, TN **4/86 To Present**

Owner and President

9/02 to present – Member of Army Headquarters Design Review team for Pueblo and Blue Grass Chem Demil facilities, specializing in operations and maintenance areas. Participated in performance based construction completion evaluation/audit team for a chemical munitions destruction facility at Aberdeen. Assisted in development and execution of the assessment plan for the construction completion audit including development of review requirements and lines of inquiry. Assisted Army HQ/Field personnel in construction completion and field surveillance activities at the Newport Chem Demil facility. Served over six months as shift advisor in Conduct of Operations improvement program for restart of the Tooele Chem Demil facility. Assigned on rotating shifts working with Shift Managers/Supervisors and all shift personnel to develop and implement a formal and disciplined Conduct of Operations program. Performed engineering reviews of critical systems comparing original design to as built conditions and evaluating operability status based on current equipment condition and maintenance. Developed Issues Management and Corrective Action Planning procedures for the Los Alamos National Lab activities at the DOE Nevada Test Site.

Recent Consulting Projects

Provided Safety Basis Training (10CFR830) to various DOE and contractor organizations. Engineering Team Member on Contractor ORR at the DOE Hanford site, including development of Engineering Area CRADs and Lines of Inquiry supporting the ORR. Assisted in ISMS verification workup in area of Management Assessment at Y-12 Plant. Consultant to Bechtel Nevada for performance based assessment as part of extensive Integrated Safety Management System Phase II validation effort. Developed the oversight protocol, performance based CRADs, and lines of inquiry for the ISMS validation. Team member for Safety System Function Inspections (SSFI) at D.C Cook and Beaver Valley. Consultant to commercial nuclear power utilities and U.S. Department of Energy and various DOE support contractors. Provide specialized technical and professional personnel to client companies to assist in implementing performance based assessment programs in conduct of operations, Authorization Basis, and self-assessment programs and in performing special assessments and reviews of DOE safety and health programs. Personal consultant assignments have included:

Dan M. Stover

Provide training to line managers, project managers, and Readiness Assessment personnel in ORR/RA, Development of CRAD's and Lines of Inquiry, Authorization/Safety Basis & Design Basis (10CFR830), Basis for Interim Operations (BIO), Unreviewed Safety Question (USQ) processing, Performance Based Assessment and other related topics. Developed and presented 3 day qualification course in ORR/RA processes to DOE-OH and Fluor Daniel Fernald including oversight planning and development of CRAD's and Lines of Inquiry. Assisted in a Plutonium waste handling facility restart at the Nevada Test Site. Participated and consulted in numerous ORRs/RAs for both DOE and contractors including Mound, Fernald and Hanford including development of CRAD's and Lines of Inquiry in assigned areas.

Consultant To US DOE, Office of Environmental Safety And Health (EH)
Member of the core team for EH Mentoring. Provided EH Mentoring, under direction and control of the EH HQ Technical Assistance Director in areas of Conduct of Operations, Safety Evaluations/USQ, Authorization Basis, Performance Based Assessment, ORR/RA Training. Assisted in EH Mentor Program development and in preparation of the Oversight Protocol. Member of the EH Team for a Special Review of Occupational Safety and Health Programs for the Hanford High-Level Waste Tanks. Review areas included Un-reviewed Safety Question determinations and Conduct of Operations at the Tank Farms. Member of the EH Task Group on Oversight of Chemical Safety at the Department of Energy. Core member of the Secretary of Energy's select task group (Tritium Task Force) to investigate and report to the Secretary on the management practices, specializing in Conduct of Operations, at DOE tritium facilities. Selected as the only member to be on both assessment teams to provide overall continuity between the teams. Consultant to EH-30 to develop and implement performance based assessment programs for the EH Site Representative Program.

Consultant To US DOE, Office Of Nuclear Safety
Participated in Office of Nuclear Safety performance assessments at Savannah River K Reactor and at Rocky Flats Plant, including assessments of Control Room Operations, Facility Operations, SAR/OSRs, Issue Management, Emergency Preparedness, Maintenance, Modification/Design Control, Lockout/Tagout, and Conduct of Operations. Member of the NS ORR team for startup of Mound SW Building Operations and Rocky Flats Building 559. Team member for the NS Safety Evaluation Report (SER) review at the Savannah River K-Reactor. Developed and presented a 3 day course on performance based assessment to NS personnel in cooperation with the DOE Training Department. Developed a Workshop in assessment techniques which was adapted by DOE Training Department for use as one of the core workshops for the executive level DOE Conduct of Operations training.

Consultant To Argonne National Laboratories-West, EBR-II
Developed a performance based QA program meeting the requirements of NQA-1 at ANL-W, EBR-II. Assisted in development of the QA Program Plan and presented Performance Based QA training to virtually all personnel at EBR-II.

Instructor For "Performance Based Audit and Surveillance" Course
Taught at nuclear facilities throughout the country. Responsible for all classroom instruction of this course, which is patterned after an identical course for the Nuclear Regulatory, Commission titled "Inspecting For Performance". Course content includes concepts, background, and techniques for implementing a performance-based audit and surveillance program. Alternate Instructor for the NRC Inspecting For Performance course.

Consultant To Niagara Mohawk Power Corporation
At Nine Mile Point nuclear station to develop a performance based audit program. Provided recommendations to management on necessary changes to become performance based. Also

participated in scheduled audits as a method of training personnel in the techniques of performance based assessments.

Consultant At Peach Bottom Atomic Power Station, PECo
For implementation of the operations QA Program for restart following NRC mandated shutown. Conducted training programs for utility Systems Engineers by conducting PRA based and performance based walkdowns with system engineers, maintenance engineers, HP personnel and modification engineers, thereby ensuring that they understand performance based concepts as currently used by the NRC. Performed procedure reviews for procedure upgrades required for restart, developed surveillance checklists for shift operations monitors, and performed special assessments of health physics activities and special monitoring of operations activities.

Consultant at Susquehanna Steam Electric Station, PP&L
Performed surveillances of ongoing plant operations, control room operations, maintenance, and radiological controls. Performed reviews of station procedures and reviews of Nonconformance Reports for operability/reportability concerns. Certified as a Lead Auditor by PP&L. Performed surveillances of engineering activities and performed reviews of engineering packages for procurement of nuclear grade items. Performed various short term consultant assignments. Participated in audit of Overall Plan Operations and in Quality Assurance Programs at the Indian Point Nuclear Station, Unit 2 (Con Edison).

Gilbert/Commonwealth, Inc., Reading PA **1/81 To 4/86**
Held various technical and managerial positions
9/85 - 4/86 Program Manager, Operation Quality Services Responsible for G/C QA Division clients in the Southeastern region. Duties included client interface, response to client requests for personnel and services, establishing and maintaining existing contracts, and developing additional business opportunities.

Supervisor, Operations Quality Services **1/84 - 9/85**
Responsible for staffing, administration, management, and technical direction of G/C QA Engineers and Specialists in this 60 person field service section.

Senior Quality Engineer/Quality Engineer **1/81 - 12/83**
Assigned at various field locations in operations quality assurance. Assignments included increasing levels of responsibility in implementation and development of quality assurance programs at operating nuclear utilities. Served for one year as the special assistant to the G/C Project Manager, Perry Nuclear Power Plant

UNITED STATES NAVY **6/73 to 12/80**
Commissioned Officer in the Navy Nuclear Power Program. Held various positions of responsibility through and including serving as the Engineer Officer on an operating nuclear submarine.

EDUCATION	MSE Nuclear Engineering, University of Michigan, 1974 BS Marine Engineering, United States Naval Academy, 1973
AFFILIATIONS, CERTIFICATIONS, HONORS	**REGISTRATIONS**: Professional Engineer (Nuclear) - Pennsylvania PE-032276-E CLEARANCES: "Q" Clearance, US Dept of Energy (inactive)

Dan M. Stover	
	CERTIFICATIONS: Lead Auditor per ANSI N45.2.23 Level II Mechanical & Electrical per ANSI N45.2.6 Instructor Certification (G/C, Inc.) Certified Hoisting & Rigging Inspector Hazardous Waste Operations and Emergency Response (24 HR) **SOCIETIES:** American Nuclear Society American Society for Quality Control

Frank Hawkins, P.E.

PROFESSIONAL SUMMARY

Over 30 years of professional experience in engineering, management, nuclear safety, quality assurance and oversight/assessment. Experience includes responsibility for development of DOE Orders and direct involvement in DOE rulemaking in the area of Quality Assurance. Professional experience includes commercial nuclear construction Quality Assurance, NRC inspection and inspection policy management, development and management of DOE nuclear safety policy and programs and management of the DOE office of health studies.

DIRECT RELEVANT EXPERIENCE TO SOW:

- Primary author of the Department of Energy's quality assurance order (5700.6C) and rulemaking (10 CFR 830.120) and the International Atomic Energy Agency's quality assurance code (50-C-QA)
- Over 30 years of nuclear experience – commercial and DOE
- Formulated, developed, and institutionalized performance-based inspection methodology (NUREG/CR-5151, "Performance-Based Inspections") that has been adopted by many U.S. and international nuclear power utilities
- Former NRC QA senior manager
- NRC Quality Assurance Section Chief

EXPERIENCE

HAWKINS CONSULTING, LLC **12/2004 – Present**

Independent Contractor, Department of Energy

In response to Defense Nuclear Facilities Safety Board Recommendation 2004-1, developed a draft DOE-wide Safety Oversight Manual on behalf of DOE's Office of Nuclear and Facility Safety Policy. Conducted a retrospective study of DOE's development and implementation of nuclear safety policy and standards beginning with DNFSB Recommendation 90-2 through today. The study resulted in short and long-range strategies and recommendations to improve nuclear safety implementation across the DOE complex.

UNITED STATES DEPARTMENT OF ENERGY **7/2000-Retired 4/2002**

Chief Operating Officer, Office of Health Programs

Directed the Department's research and public health programs aimed at promoting the health and safety of workers and communities surrounding Department of Energy facilities. ($70 million annual budget). The Office's portfolio included both health studies and health services.

- The *health studies* program provided information on the long-term health effects of ionizing radiation and chemical exposures to workers and community members. It consisted of the Japan program (Radiation Effects Research Foundation); Russian health effects studies at the MAYAK Production Facility and along the Techa River; Chernobyl health effects studies in Belarus and the Ukraine; U.S. Transuranium and Uranium Registries; and multiple research and public health studies with the National Institute for Occupational Safety and Health (NIOSH), the National Center for Environmental Health (NCEH), and the Agency for Toxic Substances and Disease Registry (ATSDR).
- The *health services* program supported delivery of medical services; medical surveillance of former workers and affected civilian populations; and epidemiologic surveillance of current workers. It consisted of former workers medical surveillance; Marshall Islands medical surveillance and environmental monitoring; former Beryllium worker medical surveillance;

Beryllium-associated worker registry; epidemiologic surveillance of the current DOE workforce; Rocky Flats former radiation worker medical surveillance; Palomares, Spain medical surveillance and environmental monitoring; and occupational medicine.

Director, Office of International Health Programs **7/1995-7/ 2000**

Office of Health Studies. Managed an international portfolio of radiation health studies and medical/environmental surveillance work designed to examine and define the effects of ionizing radiation and its effect on human health ($25 million annual budget). Represented the United States government on health studies-related matters at the European Commission, World Health Organization, and the International Atomic Energy Agency.

Director, Division of Nuclear Safety Policy, **2/1990-7/1995**
Office of Nuclear Safety Policy and Standards
Developed and managed DOE's nuclear safety program. Represented DOE on nuclear safety matters at national and international standards organizations, including the American National Standards Institute's Nuclear Safety Board, the American Society of Mechanical Engineers' (ASME)/ Nuclear Quality Assurance (NQA) Main Committee, the ASME/NQA Subcommittee for Standards Coordination, and the ASME/NQA Working Group on Research and Development. Regularly spoke at international and national conferences relating to nuclear safety, nuclear waste management, environmental restoration, and quality assurance. In addition to his responsibilities as Director, Mr. Hawkins was the primary author of the Department of Energy's quality assurance order (5700.6C) and rulemaking (10 CFR 830.120) and the International Atomic Energy Agency's quality assurance code (50-C-QA).(NRC Reg's)

UNITED STATES NUCLEAR REGULATORY COMMISSION **9/1986-2/1990**
Chief, Quality Operations Section, Office of Performance and Quality Evaluation
Recommended and carried out national quality assurance policy for the commercial nuclear industry and oversaw implementation of the quality assurance inspection program for the NRC's five regional offices. Developed and implemented policies and procedures affecting the NRC and the utilities it regulates, including NUREG 0800 (Quality Assurance Standard Review Plan Chapter 17.3), NRC Commission Paper SECY-87-220 ("Assurance of Quality"), NUREG/CR-4640 ("Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry"), NUREG/CR-5147 ("Fundamental Attributes of a Practical Configuration Management Program for Nuclear Plant Design Control"), and NUREG-1278 ("Vogtle Unit 1 Readiness Review"). Formulated, developed, and institutionalized a new performance-based inspection methodology (NUREG/CR-5151, "Performance-Based Inspections") that has been adopted by many U.S. and international nuclear power utilities.

UNITED STATES NUCLEAR REGULATORY COMMISSION **5/1984-9/1986**
(Region 3)
Chief, Management Programs Section
Oversaw implementation of the Region's reactor inspection program (nine Midwestern states) for commercial power reactors under construction, test, and operation in the areas of maintenance, surveillance testing, non-licensed personnel training, design, modifications, management programs, and quality assurance. Contributed to the issuance of operating licenses for five Region 3 commercial nuclear facilities and one Region 4 (Dallas) facility.

Lead Civil Engineer **8/1978 – 5/1984**
Responsible for implementing the NRC inspection program for concrete, soils, reinforcing and structural steel, protective coatings, and post-tensioning work at 16 nuclear power construction sites.

Frank Hawkins, P.E.	
BECHTEL POWER CORPORATION **1/1977-8/1978** Quality Engineer Shift supervisor of the materials testing laboratory at Hope Creek Generating Station in New Jersey. Administered the contract for the concrete manufacturer and managed the laboratory's testing of concrete, soils, reinforcing steel, and other construction materials. **TENNESSEE VALLEY AUTHORITY** **8/1975-1/1977** Materials Engineer Materials engineer at the Watts Bar Generating Station in Tennessee. Responsible for construction and inspection of the Unit 1 reactor building concrete and reinforcing steel.	
EDUCATION	▪ Bachelor of Science - Civil Engineering; University of Missouri-Rolla; 1975.
AFFILIATION, CERTIFICATIONS, HONORS	▪ Registered Professional Engineer in Illinois.

INFOZEN

Wayne E. Scott

PROFESSIONAL SUMMARY

Over 45 years experience in project management, nuclear engineering and operations, systems engineering, management information systems, simulations, integrated logistics support, and regulation of commercial nuclear power plants (NPPs). Experience in independent assessment, and quality assurance of commercial nuclear facilities. Extensive experience in monitoring the effectiveness of maintenance at NPPs. Further experience with Performance Based Assessment, Surveillance and Auditing, Safety System Functional Inspection (SSFI), Operational Readiness Review (ORR), Quality Verification Function Inspection (QVFI), Maintenance Rule Baseline Inspection (MRBI), and certain special inspections, including employee concerns issues.

DIRECT RELEVANT EXPERIENCE TO SOW:

- Over 25 years of direct nuclear experience with NRC and as a consultant
- Experience in independent assessment, and quality assurance of commercial nuclear facilities
- Performed in the Quality Assurance Branch of Office of Inspection and Enforcement (I&E), and later in NRR when I&E was dissolved.
- Developed proposed Revision 3 to Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operations)."
- SSFIs and Quality Verification Function Inspections

EXPERIENCE

U.S. Nuclear Regulatory Commission 1983-2003

- Participated in review and inspection of licensee scoping and screening methodology for several license renewal applications, in accordance with certain portions of Chapter 2 of the Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants (NUREG-1800).
- Participated in review of proposed new reactor AP-1000.
- Performed as lead staff for the 1999 amendment to 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants" (Maintenance Rule) and revisions to the applicable industry guidance document, NUMARC 93-01. Participated in the development of Regulatory Guide 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants."
- Participated in 10 CFR 50.65 initial baseline inspections at about 15 operating nuclear power plants (NPPs), beginning at the rule's effective date.
- Instructed over 1000 staff members on the rule's requirements. Gave short familiarization courses, 1-day courses for inspection personnel, and 3-day courses for inspectors participating in the baseline inspections.
- Participated in Office of Nuclear Reactor Regulation (NRR) section that independently evaluated NPP performance for 4 years. Led the group in an acting capacity for over a year.
- Served as Project Manager, Big Rock Point and D.C. Cook. Reviewed and/or coordinated review of numerous license amendment submittals.
- Performed in the Quality Assurance Branch of Office of Inspection and Enforcement (I&E), and later in NRR when I&E was dissolved.
- Developed proposed Revision 3 to Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operations)."

Wayne E. Scott

- Led staff in developing and implementing quality assurance policies and procedures affecting the NRC and the utilities it regulates, including NRC Commission Paper SECY-87-220, "Assurance of Quality;" NUREG/CR-4640, "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry;" NUREG/CR-5147, "Fundamental Attributes of a Practical Configuration Management Program for Nuclear Plant Design Control;" and NUREG-1278 "Vogtle Unit 1 Readiness Review."
- Program Area Leader for NRC quality assurance of commercial nuclear reactors. Developed a new approach to assessing licensees' QA organizations' performance vice simple compliance with programmatic regulations. Institutionalized the new performance-based inspection methodology, NUREG/CR-5151, "Performance-Based Inspections," that has been adopted by many U.S. and international nuclear power utilities. The NRC formal training course on that methodology is required for qualification of every NRC inspector.
- Represented NRC on the American Nuclear Society (ANS) 3.2 (Operations QA) subcommittee
- Represented NRC on the American Society for Quality Control (ASQC) Energy Division ANS-3.2 subcommittee.

Bradford National Corporation **1979 -1983**

- Principal consultant to the Naval Sea Systems Command for the purpose of transferring selected TRIDENT System management responsibilities for the TRIDENT Ship Acquisition Project Manager (SHAPM) to the TRIDENT Ship Logistics Manager (SLM).
- Member of the NAVSEA TRIDENT System Configuration Management (CM) Program Steering Committee. Participated in formulation of CM policies and procedures for the TRIDENT System. Participated in the writing, review, and revision of TRIDENT SYSTEM CM plans, including the "TRIDENT System Change Control Plan," "Logistics Data System (LDS) CM Plan," "LDS Configuration Audit Plan," and the "USS OHIO Physical Audit Plan."
- Member of TRIDENT Logistics Data System Working Group.

Computer Science Corporation **1978 - 1979**

- Marketing Manager, responsible for computer software marketing in the area of Navy underwater systems. Successfully marketed sole source contracts awarded in such areas as sonar, torpedo, cruise missile, fire control, command and control, and advanced computer architecture systems.
- Efforts contributed to a doubling of the staff from about 30 to 70 in a year and initiated activities which subsequently permitted selective, controlled growth.

Essex Corporation **1977-1978**

- Project Manager for development efforts for TRIDENT Maintenance Management System. Formulated a desired package of requirements and procedures for a maintenance system to support the TRIDENT Submarine System.
- Analyzed and documented the existing system of Navy maintenance management requirements and procedures.
- Developed and assisted implementation of changes to existing requirements and procedures to legitimize the new system.

Logistics Management Institute **1969-1976**

- Project Director.

Wayne E. Scott

- Directed the design and implementation of a Submarine Maintenance Management Support Office (SMMSO) maintenance planning system.
- Directed a project for the Assistant Secretary of Defense (ASD) for Manpower and Reserve Affairs (M&RA) to evaluate the costs and potential benefits of providing Armed Forces members and dependents with embossed identification cards.
- Directed a project for the Deputy Chief of Staff for Logistics, U.S. Army, to identify requirements for and sources of Base Operations data; defined the OSD-Army (budget) Program 11 (Base Operations) programming and budgeting interface, and recommended significant changes in the accounting structure; implemented a computer system for developing, displaying, analyzing, and revising budget data.
- Research Fellow. Participated in a Joint Logistics Commanders' major project to consolidate military maintenance depot workloads.
- Implemented analysis by creating a data base, generating a matrix, and running a very large scale mixed-integer linear programming package.
- Director of Data Processing. Supervise up to 6 programmers and analysts.

NUS Corporation **1967-1969**

- Project Manager for production of submarine technical manuals.
- Wrote "A Functional Analysis of the SSBN 640 Class (U)" for the Navy Underwater Long Range Missile System (ULMS), later named TRIDENT, Project Office.
- Analyst in the verification of the Engineering Design Reviews and Engineering Safety Certification for the SSBN-608 Class submarine overhauls.
- Performed stress environmental analyses on hull fittings and piping systems, and audited weld and brazing records.
- Analyst for a project which produced "ULMS Cost Effectiveness Study (U)" for the Navy Strategic Systems Project Office (SSPO).
- Analyst in the model testing and simulation model verification of the icebreaking bow design for the ESSO oil tanker S.S. MANHATTAN's proposed journey through the Northwest Passage.
- Analyst for a project which produced the "Proposed Technical Approach for New Class of Nuclear Attack Submarines (U)," which became the USS Los Angeles (SSN-688) Class.

U.S. Navy **1958- 1967**

- Department Head and Division Officer. Supervised and trained up to 2 officers and 60 enlisted men in various ship's departments aboard a destroyer and 3 nuclear-powered submarines.
- Qualified and performed as SRO-equivalent on 3 different submarine nuclear power Certified "Qualified to be Engineer Officer of a Nuclear Powered Ship."
- Performed as Auxiliaries Division Officer and Engineer Officer of the Watch during construction, testing, and operation of a new, large submarine.
- Monitored construction of systems, wrote operating procedures, participated in system turnover demonstrations, and assumed ship's responsibility for those systems.
- In addition, performed as a Naval Reservist, supporting the Naval Air Forces in its first Systems Analysis Unit, 1967-1974; supporting Naval Headquarters in its Navy Command Center Unit, 1974-1980; and supporting the Deputy Chief of Naval Operations for Submarines (OP-02) in its like-named unit.

EDUCATION	▪ MBA, The American University, 1972; Major - Computer Systems ▪ BS, US Naval Academy, 1958 (general engineering)

Paul J. Kellogg

PROFESSIONAL SUMMARY

Mr. Kellogg has over 35 years of management and technical experience within the nuclear industry. His consulting experience includes causal analysis, problem resolution, corrective action effectiveness, readiness reviews, and project management. Mr. Kellogg has prepared for and been a member of numerous start-up reviews in the areas of waste stream packaging/shipments and conduct of operations. He has extensive knowledge of QA standards and regulations, both as regulator and a consultant. His corrective action experience includes problem identification, Root Cause Analysis (RCA), developing solutions, and verifying action completeness and effectiveness. Additionally, he is proficient in planning, managing, and dispositioning low-level radioactive waste streams, including planning and preparation associated with their shipment.

- Successfully completed, as implementation manager, the preparation for implementing the new Documented Safety Analysis and Technical Safety Requirements for the Remediation Contractor at Portsmouth Gas Diffusion Plant.
- Performed relevancy reviews and homeland security reviews for the Yucca Mountain Licensing Support Network Contractor. Acted as the Contractors Project Management Office Action Officer.
- Reviewed Conduct of Operations at Honeywell's UF6 Conversion plant and mentored operators in watch standing practices.
- Conducted Root Cause Analysis for improper stacking of Enriched Restricted Material (ERM) and authored a Type B report on the activities associated with the improper stacking.
- Prepared for and successfully completed a Readiness Assessment (RA) on the movement of ERM. Previous RAs and Operational Readiness Reviews (ORRs) were reviewed and corrective actions from these reviews were verified to be in place and continuing to be effective. Corrective actions that were not in place or effective were revised to bring them up to date.
- Conducted safety basis reviews for several facilities at the Oak Ridge Reservation. The purpose of these reviews was to determine if accurate safety basis documentation existed for the facilities.
- Conducted four assessments of vendors for Oak Ridge Operations (ORO) Office of Asset Utilization (AU). There assessments were conducted on facilities that receive material from DOE sites for processing and disposition. As assessment team member, conducted assessments in the areas of Management Systems, Quality Assurance, and Industrial Safety.
- Prepared six RCAs for findings contained the OA assessment report for ES&H activities at ETTP. These included findings in the areas of emergency management and DOE ES&H oversight activities.
- Created an integrated assessment schedule for ORO activities.

Paul J. Kellogg

DIRECT RELEVANT EXPERIENCE TO SOW:

- 35 years of management and technical experience within the nuclear industry
- Prior NRC QA experience
- DOE and commercial nuclear experience
- Conducted safety basis reviews for several facilities at the Oak Ridge Reservation to determine if accurate safety basis documentation existed for the facilities.
- Extensive knowledge of Quality Assurance programs including ASME NQA-1, DOE Order 414.1, 10 CFR 830.120, and 10 CFR 50, Appendix B, with broad knowledge of corrective action processes including identification, cause determination, corrective action plans, closure, and action effectiveness

EXPERIENCE

Independent Consultant **1998 To Present**

As a consultant, Mr. Kellogg is responsible for providing consulting and assessment assistance, regulatory program development, oversight support, and project management to commercial and government clients. Much of his focus is in the area of assessments and performance improvements. He has an extensive knowledge of Quality Assurance programs including ASME NQA-1, DOE Order 414.1, 10 CFR 830.120, and 10 CFR 50, Appendix B, with broad knowledge of corrective action processes including identification, cause determination, corrective action plans, closure, and action effectiveness. He provided assistance to Fluor Fernald's Waste Management program at the Fernald site. As the lead Project Engineer for Low-Level Waste, he was responsible for project management including readiness review preparation, performing assessments, problem resolution, corrective actions, and action effectiveness verification.

Mr. Kellogg assisted with Readiness Reviews and assessments including determining programmatic compliance and performance-based aspects of waste activities. He reviewed work plans, process controls, and procedures and their implementation for packaging, storage, and shipping activities. Mr. Kellogg conducted technical reviews and assessments of material sampling, waste characterization, packaging, storage, and shipping of low-level waste. This included reviewing manuals, plans, and procedures and their implementation. He performed assessments of various activities including nonconformances, corrective actions, and verified completeness and technical adequacy of actions taken to resolve various issues. He was involved in investigation of occurrences, determining their root causes, and developing action plans. He was also responsible for verification of corrective actions and tracking actions to completion. He has performed Management Systems and Quality Assurance reviews of DOE contractors and assisted in writing the Standards/Requirements Identification Document (SRID) for a new facility at the Savannah River site.

United States Nuclear Regulatory Commission **1987-1998**

As Section Chief for Operational Programs and Tennessee Valley Authority (TVA) Projects, Mr. Kellogg directed the routine and non-routine inspection activities at several commercial nuclear plants. These activities included accident/incident investigations as well as special emphasis inspections, i.e., Service Water Operational Inspections, Safety System Engineering Inspections, Maintenance Rule Implementation Training, Plant Restart Activities, Project Management, and Independent Plant Assessments. Prior to that, Mr. Kellogg was assigned as a Reactor Engineer within the Operational Programs Section. In this capacity he was responsible for participation and /or leading inspections at commercial nuclear facilities within Region II.

Aloette Cosmetics Southern Region Inc. **1982- 1987**

Paul J. Kellogg	
As the Chief Financial Officer and Chief Operations Officer of a rapidly growing retail company, Mr. Kellogg managed the growth of the company from formation to $800,000 in monthly retail sales. His responsibilities included setup of finance, record keeping, accounting, training of franchise owners in finance, inventory control, tax liability, and office management. **Nuclear Regulatory Commission** **1974- 1982** Mr. Kellogg held various positions of responsibility in the inspection program including Pre-operational, Initial Criticality, Low Power Physicist Testing, and Power Ascension Testing. He directed the first Operational Quality Assurance Inspections in Region II. He also directed the hiring of resident inspectors and oversight on the operational inspection programs at eight nuclear sites. **United States Navy** **1965-1974** Mr. Kellogg held various positions in the engineering departments of two nuclear fast attack submarines including the position of Chief Nuclear Engineer. Mr. Kellogg was also a Submarine School Instructor in advanced tactics and weapons.	
EDUCATION	• MBA, Executive Program • B.S., U.S. Naval Academy
AFFILIATIONS, CERTIFICATIONS, HONORS	• Root Cause Training, U.S. NRC Human Performance Evaluation Training • Q-Clearance

INFOZEN

Raymond L. Wenderlich

PROFESSIONAL SUMMARY

A proven leader with a long track record of successes in leadership positions in such diverse disciplines as: naval engineering; commercial nuclear power plant operations, maintenance, engineering, training, quality assurance and acquisitions; customer care to residential and general business customers; and energy sales and service to major industrial, commercial and government customers. Consistent track record with respect to learning new positions. High energy, results-oriented with a sense of urgency, and a bias for action. Committed to excellence. A lifelong student of leadership and management. Has taught leadership in a variety of organizations. Has also taught successful career management and provided 1-on-1 coaching to people in various organizations.

DIRECT RELEVANT EXPERIENCE TO SOW:

- Commercial nuclear utility executive
- SRO
- On site and Off site nuclear safety review committees
- Over 25 years of nuclear experience

EXPERIENCE

SUCCESS BUILDERS, INC **2004 – Present**

Provides leadership and successful career management training and 1-on-1 coaching.

CONSTELLATION ENERGY/BALTIMORE GAS & ELECTRIC **1979 – 2004**

Vice President – Constellation Generation Group 2002 – 2004

Responsible for Organic (internal) growth in the generation fleet.

- Led the "power netting" initiative for the Nine Mile Point Nuclear Station that resulted in $13.8 million in savings.
- Led the CGG Tax Minimization Initiative, which resulted in savings of $10 million.
- Led the Controls Optimization initiative that resulted in significant revenue increases for the CP Crane Plant and the HA Wagner Plant.
- Led the initiative to increase revenue in Constellation New Energy through contacts, ideas and insights from the Generation part of Constellation Energy. Net revenue: $1.2 million.

Nine Mile Point Nuclear Station **2001 – 2002**

Vice President

Senior Constellation officer responsible for the Nine Mile Point Nuclear Station. Led a 1300 person workforce with $440 million annual revenues, $210 million O&M budget and $115 million EBIT. Chaired Management Committee for NMP U-2 with LIPA (U-2 co-tenant). Served on Board of Constellation Nuclear Power Plants, Inc.

- Led the successful transition of Nine Mile Point into Constellation Energy.
- Led the negotiation team for a new collective bargaining agreement with the union (IBEW).
- Significantly improved the Station's generation and financial performance.
- Energized the workforce with a new sense of hope and optimism for the future.
- Established strong relationships with employees and with the union, the Building Trades, LIPA and NY State politicians and community leaders.

Raymond L. Wenderlich

Manager – Nuclear Projects (Nuclear Acquisitions) **1999 – 2001**

Responsible for acquisition of nuclear power plants. Led due diligence teams for evaluating and bidding on these plants.

- Led the successful bidding and purchase effort for the $815 million Nine Mile Point Nuclear Station.
- Qualified as Recovery Officer for the Calvert Cliffs Nuclear Power Plant (Emergency Response Plan).

Manager – Customer Care (1999)

Led a 300-person organization, including a 200-person call center, with a $19.75 million annual budget. Responsible for customer care to over one million BGE residential and general business customers.

- Taught leadership to new supervisors throughout the Company.
- Received two Outstanding Leadership Awards.

Manager – Energy Sales and Services **1994 – 1999**

Led a 120-person organization with an $11 million annual budget. Responsible for energy sales to BGE industrial, commercial, government and residential customers. Responsible for servicing all BGE industrial, government and large commercial accounts, including issues with electric and gas service, electric system reliability, power quality, billing, etc.

- Met over 650 of these industrial, government and large commercial customers and established close working relationships with many of them.
- Developed and implemented BGE's first department-wide Leadership Development Program.
- Participated in BGE's transition from a regulated monopoly to the competitive energy marketplace, featuring customer choice.
- Taught leadership to new supervisors throughout the company.
- Received two Outstanding Leadership Awards.

Operations Superintendent – Calvert Cliffs Nuclear Power Plant **1989 – 1994**

Led a 190-person organization with a $12.6 million annual budget. Responsible for the operation of two nuclear generation units. Served on the Plant On-Site Safety Review Committee and Off-Site Safety Review Committee . Served as the primary alternate to the Plant General Manager.

- Instituted very strong programs for nuclear safety and personnel safety while achieving high levels of power production.
- Experienced no lost or restricted work cases in 5½ year tenure.
- Developed an event-free operation program that significantly reduced operating events/accidents. This program received national recognition in the American Nuclear Society's *Utility Quarterly* and INPO's *The Nuclear Professional*.
- Led Operations to significantly improved SALP ratings, including two consecutive SALP-1 scores (the NRC's highest rating).

Other Positions At Calvert Cliffs **1979 – 1989**

- Promoted through various positions from Performance Engineer & Plant Training Coordinator to Senior Engineer – Operations, Quality Assurance Auditing Supervisor, Supervisor – Management Systems, and General Supervisor – Electrical and Controls (maintenance and modifications).
- Obtained NRC Senior Reactor Operator License.
- Planned and implemented significant upgrading of training programs for licensed operators in the wake of the TMI-2 accident of March 1979.
- Chaired the Mid-Atlantic Nuclear Training Group.

U.S. NAVY **1973 – 1979**

Raymond L. Wenderlich	
• Electrical Officer and Reactor Controls Officer on U.S.S. Mississippi, a guided missile nuclear cruiser. (CGN-40) • Nuclear Training Officer on U.S.S. Nimitz, a nuclear aircraft carrier. (CVN-68) • Qualified as: Engineering Officer of the Watch (on three separate plants); Propulsion Plant Watch Officer; Propulsion Plant Drill Team Leader; Engineering Duty Officer; Engineer Officer of a Navy Nuclear Powered Ship; Officer of the Deck; Surface Warfare Officer; Command Duty Officer. • Taught mathematics at Barstow College.	
EDUCATION	• George Washington University, Masters Degree in Engineering Administration – 3.92 GPA • U.S. Naval Academy, Bachelor of Science • AT&T College of Call Center Excellence • University of Virginia's Darden Graduate School of Business Administration • Continuing Education • University of Pittsburgh's Katz Graduate School of Business Administration • Management Program for Executives • Earned NRC Senior Reactor Operator License at BGE's Calvert Cliffs Nuclear Power Plant
AFFILIATION, CERTIFICATIONS, HONORS	▪ Received three Outstanding Leadership Awards ▪ Chairman – American Red Cross Chesapeake LifeBoard ▪ Member – Baltimore Services Academies Business Professionals ▪ Member – U.S. Naval Academy Alumni Association ▪ Prior Membership: American Society of Naval Engineers, American Society of Mechanical Engineers, Engineering Society of Baltimore, Electric Council of New England, PJM Joint Operating and Nuclear Working Group, Mid-Atlantic Nuclear Training Group (Chairman), Regional Manufacturing Institute (Executive Committee of the Board), EEI Customer Service Committee, Rotary Club of Baltimore, BWI Business Partnership, Association of Professional Energy Managers, American Teleservices Association, James Madison University Honors Program Advisory Board, American Nuclear Society, American Society for Training and Development.

INFOZEN

Rene Delaney	
PROFESSIONAL SUMMARY • Performed more than 300 Quality Assessments, Audits, Commercial Grade Surveys – National and International, both NUPIC and Nine Mile Point Specific • Performed more than 200 inspections at supplier locations • ANSI N.45.2.23/ NQA-1 Certified Lead Auditor since 1986 • Senior Lead Auditor since 1996 • Certified ANSI N.45.2.6 Mechanical Inspector since 1982 • Past Nuclear Certifications include; ANSI N45.2.6 Level II inspector in Civil, Structural, and Welding disciplines • Certified ASME Section XI VT 1-4 Level III. Was corporate level III during Start Up and Test of Nine Mile Point Unit 2 • 30+ years Quality Assurance Experience (24 years in Nuclear Utility QA Operation) • Corrective Action analysis • Subject matter expert in the verification of implementation of 10CFR 50 Appendix B and NQA-1 quality programs.	
DIRECT RELEVANT EXPERIENCE TO SOW: • Certified Lead Auditor • Over 30 years QA experience • Corporate Level III for startup and test of Nine Mile Point 2 • 10CFR50 experience	
EXPERIENCE • Constellation Energy, Nine Mile Point Nuclear Station Lycoming, NY. (24 Years) 1982-2006 QA Department. • Performed as internal and external Lead Auditor and Inspector. Performed in Procurement QA from 1995-August 2006. Maintained 60+ vendors on the NMPNS Approved Suppliers List. NMPNS Quality Assurance Fuel QA Rep. at Global Nuclear Fuels-Americas (GNF-A) Wilmington, NC. Performed as Lead Auditor, Auditor, Inspector and performed Commercial Grade Surveys. • County of Onondaga, New York. Building Inspector, Structural Analyst, Mechanical/Welding Inspector. 1976-1982	
EDUCATION	• Onondaga Community College- Syracuse NY, Business Administration • American Society for Metals, Metals Engineering Institute • Diploma in "Testing and Inspection"
AFFILIATIONS, CERTIFICATIONS, HONORS	▪ Certified Lead Auditor ▪ Corporate Level III

INFOZEN

Bruce A. Tracey

PROFESSIONAL SUMMARY

Forty one (41) years experience in the nuclear industry, thirty two of which are in the field of Nuclear Quality Assurance. This Quality experience included QA Program evaluation, surveillances, source verifications, commercial grade surveys and audits. These audits and commercial grade surveys included leading and participating in Nuclear Utility Procurement Issues Committee (NUPIC) activities. Led the Calvert Cliffs Nuclear Power Plant Quality Oversight Team for the Dry Spent Fuel Storage Facility, the Enhanced Service Structure, and other major projects. This oversight included the design construction and fabrication of all associated equipment. Obtained a thorough working knowledge of all related CFR, ISO, ASME, IEEE, AWS codes and standards.

DIRECT RELEVANT EXPERIENCE TO SOW:

- 41 years of nuclear industry experience
- 32 years of QA experience
- Led the Calvert Cliffs Nuclear Power Plant Quality Oversight Team for the Dry Spent Fuel Storage Facility
- Thorough working knowledge of all related CFR, ISO, ASME, IEEE, AWS codes and standards
- Certified Lead Auditor

EXPERIENCE

Constellation Energy (Calvert Cliffs Nuclear Power Plant, Inc.) (Formerly Baltimore Gas and Electric Co.)

PRIVATE CONSULTANT/CONTRACTOR November 2006 - Present

Subsequent to retirement from Constellation Energy, now available to provide services as a Quality Consultant or Contractor for utilities and manufacturers. Services include but are not limited to audits, surveillances, source inspections, and other quality functions.

CONSTELLATION ENERGY (Calvert Cliffs Nuclear Power Plant) 1974 – November 1, 2006

Constellation Energy is a multifaceted utility company which owns and operates several Nuclear Power Plants throughout the United States.

Progressive career starting at the entry level in the Quality Assurance Department and ending as a Senior Quality Assurance Specialist.

Conducted in-depth Quality program audits/evaluations for supplier approval to provide safety related spare parts, equipment, and services.

- Led and participated in facility audits, facility commercial grade surveys, review of Quality Assurance Manuals, and technical performance reviews.
- Performed extensive vendor oversight, source surveillances, and source inspections, of all vendor types including mechanical, electrical, engineering, and ASME Code vendors.
- Participated in the resolution of vendor concerns and receiving inspection problems.

INFOZEN

Bruce A. Tracey	
Senior Assessor/Lead Auditor *7/79 - Present* Conducted in-depth Quality program audits/evaluations for supplier approval to provide safety related spare parts, equipment, and services. This activity was accomplished through leading and participating in facility audits, facility commercial grade surveys, review of Quality Assurance Manuals, and technical performance reviews. Participated in the resolution of vendor concerns and receiving inspection problems. Continuously evaluated Industry Bulletins on vendors, NRC inspections and impact of violations, and reacted to negative supplier information from utility NUPIC Representatives, NRC, and others. Has led the Calvert Cliffs Nuclear Power Plant Quality Oversight Team for the Dry Spent Fuel Storage Facility, the Enhanced Service Structure, and other major projects. This oversight included the design construction, fabrication, of all associated equipment. *Quality Auditor* *7/74 – 7/79* Planned, coordinated, and scheduled internal program and external vendor audits and surveys. Provided input for and participated on the development team for the Calvert Cliffs Nuclear Power Plant Operations QA Program. Reviewed procurement documents for acceptable technical and quality requirements. This activity was accomplished through participating in facility audits, facility commercial grade surveys, review of Quality Assurance Manuals, and technical performance reviews. Resolved vendor concerns and receiving inspection problems. Continuously evaluated Industry Bulletins on vendors, NRC inspections and impact of violations, and reacted to negative vendor information from utility NUPIC Representatives, NRC, and others. Bruce A. Tracey(410-526-2505) Page 2 *Auditor in Training* *2/74 – 7/74* Planned, coordinated, and scheduled internal program and external vendor audits and surveys under the direction of a certified Lead Auditor. Developed and worked on the team that wrote the Calvert Cliffs Nuclear Power Plant Operations QA Program. During this period, reviewed procurement documents for acceptable technical and quality requirements. Procured, monitored delivery and verified receipt of purchased material. Developed instructions and procedures related to the procurement program. *US Navy* *6/65 – 2/74* Involved in all aspects of Nuclear Power Plant Chemistry, Radiological Controls, Nuclear Power Plant Maintenance / Operation, Personnel Management / Motivation, Training, Administration. Served on several Fast Attack Nuclear Submarines. Achieved the final position of Machinist Mate Petty Officer First Class (E-6) supervising the mechanical and the Chemistry/Radiological Control Department.	
EDUCATION	• Bachelor of Science Degree in Business Administration with a concentration in Management. – Towson State University - 1986 • Associates of Arts Degree in Business – Catonsville Community Collage – June 1980 • Navy Nuclear Power Plant Training - 1968 • High School Graduate - 1965