U.S. Department of Energy
Office of River Protection
P.O. Box 450, MSIN H6-60
Richland, Washington 99352

AUG 24 2007

07-ESQ-120

Mr. W. S. Elkins, Project Director
Bechtel National, Inc.
2435 Stevens Center Place
Richland, Washington 99354

Dear Mr. Elkins:

CONTRACT NO. DE-AC27-01RV14136 – ASSESSMENT REPORT A-07-ESQ-RPPWTP-010 – WASTE TREATMENT AND IMMOBILIZATION PLANT IMPLEMENTATION OF THE GRADED APPROACH TO THE QUALITY ASSURANCE (QA) PROGRAM (QAP) IMPLEMENTATION FROM FEBRUARY 9 THROUGH MAY 31, 2007

This letter transmits the results of the U.S. Department of Energy (DOE), Office of River Protection assessment of the Bechtel National, Inc. (BNI) implementation of the Graded Approach to the QAP implementation. The assessment was performed from February 9, 2007 through May 31, 2007. The purpose of the assessment was to determine effective implementation of 10 Code of Federal Regulations (CFR) 830 Subpart A, "Quality Assurance" (QA Rule) and the Graded Approach to implementation of the QAP requirements for items designated as Commercial Material (CM). As part of the assessment to determine if proper grading of quality requirements had been applied, the assessment team evaluated procurement activities where a nuclear hazard was present and the procurement was graded as CM.

The Assessment Team concluded that BNI's approach to implementation of the quality program for CM procurements does not consistently meet DOE QA Rule, DOE O 414.1B, "Quality Assurance" (QA Order), and BNI QA Manual (QAM) requirements. The correct use of consensus standards forms the foundation on which grading of QA is performed. BNI's decision to use International Standards Organization (ISO) 9001 instead of Nuclear Quality Assurance (NQA)-1 for the Laser Ablation procurement without evaluation of the delta between ISO 9001 and NQA-1 results in the procurement not meeting the DOE QA Order and the BNI QAM. The lack of specificity and formality across the interface between BNI and CH2M HILL Hanford Group, Inc. (CH2M HILL) can result in the glove box not meeting CH2M HILL's requirements for installation into the 222-S Laboratory.

The Team identified two Findings and two Observations. These were:

A-07-ESQ-RPPWTP-010-F01: BNI has not consistently demonstrated a process for evaluating CM items and activities for application of 10 CFR 830, Subpart A, as required by Subpart A.

A-07-ESQ-RPPWTP-010-F02: BNI did not apply NQA-1-1989, "Quality Assurance Requirements for Nuclear Facilities," as the consensus standard for implementing QA requirements for nuclear activities, other than for safety related items, as required by DOE O 414.1B and the ORP/BNI contract.

A-07-ESQ-RPPWTP-010-O01: The Assessment Team's review of BNI's implementing procedures for application of a graded approach to all elements of the QA program did not identify processes for grading the QA Rule implementation for other areas of rule applicability besides procurement.

A-07-ESQ-RPPWTP-010-O02: BNI procedures for Research and Development nuclear related activities do not establish guidance for application of a graded approach to QA implementation differently than for standard nuclear related items and activities procurements as allowed by NQA-1-2000, Subpart 4.2.

Within 30 days of receipt of this letter, BNI should respond to the assessment Findings. A response to the above Observations is not required. The response should include:

- The cause of the issue.
- The corrective actions taken to control or remove any adverse impact to identified noncompliance situations (remedial actions) and the results achieved.
- The corrective actions taken or that will be taken to prevent similar issues in the future. This should also include the results of an extent of condition review.
- The date by when all corrective actions are to be completed, verified, and compliance to applicable requirements is achieved.

If you have any questions, please contact me, or your staff may call William J. Taylor, Assistant Manager, Office of Environmental Safety and Quality, (509) 376-7851.

Sincerely,

for Shirley J. Olinger, Acting Manager
Office of River Protection

ESQ:SAV

Attachment

cc w/attach:
D. E. Gergely, BNI
D. J. Jantosik, BNI
D. E. Kammenzind, BNI
BNI Correspondence

Attachment
07-ESQ-120
A-07-ESQ-RPPWTP-010

U.S. DEPARTMENT OF ENERGY
Office of River Protection
Environmental Safety and Quality

ASSESSMENT:	Bechtel National, Inc. Waste Treatment and Immobilization Plant Application of Graded Approach to Quality Assurance Program Implementation
REPORT:	A-07-ESQ-RPPWTP-010
FACILITY:	Waste Treatment and Immobilization Plant Construction
LOCATION:	Richland, Washington
DATES:	February 9 through May 31, 2007
ASSESSORS	S. A. Vega, ORP, Lead Assessor W. L. Smoot, Assessor
APPROVED BY:	P. P. Carier, Team Leader Verification and Confirmation Official

Executive Summary

The U.S. Department of Energy (DOE), Office of River Protection (ORP), conducted an assessment of Bechtel National, Inc. (BNI) procurement quality from February 9, 2007, through May 31, 2007. The purpose of the assessment was to determine effective implementation of 10 Code of Federal Regulations (CFR) 830, Subpart A, "Quality Assurance" (QA Rule) and the graded approach implementation of the Quality Assurance (QA) program requirements for items designated as Commercial Material (CM). As part of the assessment, the Assessment Team evaluated procurement activities for a procurement where a nuclear hazard was present and the procurement was graded as CM.

BNI issued a letter (CCN: 147984) to ORP on November 29, 2006, responding to an ORP request for an explanation of BNI's Graded Approach for application of QA program requirements to nuclear activities. ORP's review of that letter resulted in ORP conducting this assessment and the procurement assessment discussed below.

ORP conducted a procurement assessment from January 22 through January 31, 2007. The assessment focused on QA requirements applied for items that were designated as defense-in-depth [Additional Protection Class (APC)]. Assessment Report A-07-ESQ-RPPWTP-002 documented the results of the assessment. Because BNI normally purchases APC items as CM, issues the Assessment Team identified during the APC assessment are similar to the issues identified during this broader assessment of CM graded approach application.

The current assessment identified issues dealing with CM items and activities which supported the findings of the January 2007 APC assessment. As a result of discussions with BNI engineering and quality personnel, review of BNI implementing procedures for CM procurements, and review of the Inductively Coupled Plasma Atomic Emission spectrometer with Laser Ablation procurement, the Assessment Team concluded that BNI's approach to implementation of the quality program for CM procurements did not consistently meet DOE QA Rule, DOE O 414.1B, "Quality Assurance" (QA Order), and BNI QA Manual (QAM). The correct use of the Nuclear Quality Assurance (NQA)-1 consensus standard forms the basis on which grading of QA is performed. BNI's decision to use International Standards Organization (ISO) 9001 instead of NQA-1 for the Laser Ablation procurement without evaluation of the delta between ISO 9001 and NQA-1 resulted in the procurement not meeting the DOE QA Order and the BNI QAM. The lack of specificity and formality across the interface between BNI and CH2M HILL Hanford Group, Inc. (CH2M HILL) resulted in BNI not being able to provide a formal record of CH2M HILL concurrence with procurement decisions which could result in the glove box not meeting CH2M HILL's requirements for installation into the 222-S Laboratory. The lack of formal interface control document between CH2M HILL and BNI covering this activity contributed to this issue.

The Team identified two findings and two observations. These were:

A-07-ESQ-RPPWTP-010-F01: BNI has not consistently demonstrated a process for evaluating CM items and activities for application of 10 CFR 830, Subpart A, as required by Subpart A.

A-07-ESQ-RPPWTP-010-F02: BNI did not apply NQA-1-1989, "Quality Assurance Requirements for Nuclear Facilities," as the consensus standard for implementing QA requirements for nuclear activities, other than for safety related items, as required by DOE O 414.1B and the ORP/BNI Contract.

A-07-ESQ-RPPWTP-010-O01: The Assessment Team's review of BNI's implementing procedures for application of a graded approach to all elements of the QA program did not identify processes for grading the QA Rule implementation for other areas of rule applicability besides procurement.

A-07-ESQ-RPPWTP-010-O02: BNI procedures for Research and Development nuclear related activities do not establish guidance for application of a graded approach to QA implementation differently than for standard nuclear related items and activities procurements as allowed by NQA-1-2000, Subpart 4.2.

The Assessment Team noted that the APC assessment documented a finding that BNI's procedures did not establish sufficient criteria to implement a consistent process for applying QA requirements using a graded approach during procurement of APC items and activities. The Team also recognizes that BNI is developing actions for improving the grading activity for APC procurements that, when fully developed, should address all CM procurements that affect nuclear safety. ORP considers it acceptable that Observation O01 from this assessment and Finding F01 from the APC assessment be addressed by a single comprehensive corrective action if the extent of condition for the APC finding includes addressing all CM procurements and QA Rule applicability.

Table of Contents

List of Acronyms

ANSI	American National Standards Institute
APC	Additional Protection Class
ASME	American Society of Mechanical Engineers
ASQ	American Society for Quality
BNI	Bechtel National, Inc.
CFR	Code of Federal Regulations
CH2M HILL	CH2M HILL Hanford Group, Inc.
CM	Commercial Material
DOE	U.S. Department of Energy
EGS	Enforcement Guidance Supplement
ISO	International Standards Organization
ITS	Important-to-Safety
M&TE	Measuring and Test Equipment
MR	Material Requisition
NQA	Nuclear Quality Assurance
OCRWM	Office of Civilian Radioactive Waste Management
ORP	Office of River Protection
QA	Quality Assurance
QA ORDER	DOE O 414.1B, Quality Assurance
QA RULE	10 CFR 830, Subpart A, Quality Assurance
QAM	Quality Assurance Manual
QARD	Quality Assurance Requirements Document
R&D	Research and Development
WTP	Waste Treatment and Immobilization Plant

Bechtel National, Inc. (BNI)
Application of Quality Assurance (QA) to
Commercial Material (CM)

1. Details

This assessment evaluated BNI QA processes for CM procurements to determine if proper grading of quality requirements as specified in 10 Code of Federal Regulations (CFR) 830, Subpart A, "Quality Assurance" (QA Rule) and the U.S. Department of Energy (DOE) O 414.1B, "Quality Assurance" (QA Order) had been applied. Other recent DOE QA assessments have evaluated procurement activities for safety items and services; items that are non-safety Structures, Systems, and Components but provide a defense-in-depth [Additional Protection Class (APC)] function; and the commercial grade dedication process.

As a result of discussions with BNI engineering and quality personnel, review of BNI implementing procedures for CM procurements, and review of the Inductively Coupled Plasma Atomic Emission spectrometer with Laser Ablation procurement, the Assessment Team concluded that BNI's approach to implementation of the quality program for CM procurements did not consistently meet DOE QA Rule, QA Order, and BNI QA Manual (QAM). The correct use of the Nuclear Quality Assurance (NQA)-1 consensus standard forms the basis on which grading of QA is performed. BNI's decision to use International Standards Organization (ISO) 9001 instead of NQA-1 for the Laser Ablation procurement without mitigation of the delta between ISO 9001 and NQA-1 resulted in the procurement not meeting the DOE QA Order and the BNI QAM. The lack of specificity and formality across the interface between BNI and CH2M HILL Hanford Group, Inc. (CH2M HILL) resulted in BNI not being able to provide a formal record of CH2M HILL concurrence with procurement decisions which could result in the glove box not meeting CH2M HILL's requirements for installation into the 222-S Laboratory. The lack of formal interface control document between CH2M HILL and BNI covering this activity contributed to this issue.

Background for Application of the QA Rule

10 CFR 830.121(a), "Quality Assurance Program," states that "Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria of § 830.122." The QA Rule further specifies in § 830.121(c)(1), "The QAP must describe how the quality assurance criteria of § 830.122 are satisfied." It is further stated in § 830.121(c)(4), "The QAP must describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122."

Office of General counsel; Ruling 1995-1; "Ruling concerning 10 CFR Parts 830 (Nuclear Safety Management) and 835 (Occupational Radiation Protection)," Section B.1 states in part that the requirements of Parts 830 and 835 cover all activities under DOE's auspices with the potential to cause radiological harm. Section B.1 further states: "Because all ionizing radiation has the potential to cause harm, the Department did not limit the application of the nuclear safety requirements in Parts 830 and 835."

Enforcement Guidance Supplement (EGS) 00-03, Section 1, states in part, "specifically, this guidance reaffirms that quality assurance (QA) controls required by 10 CFR 830 are not in any way limited by language contained in SARs, TSRs, or technical specifications documents. The EGS provides illustrative examples of PAAA non-compliances in situations that did not directly involve safety systems or structures. They supported the conclusion that all work in nuclear facilities may have the potential to affect nuclear safety in a nuclear facility." The supplement goes on the state, "The argument that 10 CFR 830 only applies to safety equipment or systems that are specifically referenced in the SAR, TSR, or Technical Specifications has no basis in the text of the Rule."

EGS 99-01, "Enforcement of 10 CFR Part 830.120 for Facilities Below Hazard Category III," states in part, "The QA Rule applies in a graded approach to all DOE reactor and nonreactor nuclear facilities. Non reactor nuclear facilities are defined as those that conduct activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public..." It further states that this rule does not specify any minimum for such a hazard. The EGS also states that Standard 1027 provides guidance for determining whether a facility, activity, or area requires a Safety Analysis Report, but it does not provide a basis for exclusion from the provisions of the QA Rule.

§ 830.7 Graded Approach, "Where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE ..."

Application of the QA Rule to CM Procurements

In Fiscal Year 2006, DOE Office of River Protection (ORP) requested that BNI provide information regarding how the QA Rule was applied with a graded approach to nuclear activities at the Waste Treatment and Immobilization Plant (WTP). On November 29, 2006, BNI issued a letter (CCN: 147984) to ORP responding to the ORP request for an explanation of BNI's graded approach for application of QA program requirements to nuclear activities. ORP's review of the letter resulted in ORP conducting this assessment and the procurement assessment of APC items discussed below.

To evaluate the application of the QA Rule to CM procurements, the assessment team reviewed information provided in the letter, BNI procedures referenced by the letter, and a random CM procurement that included discussions with BNI personnel associated with the procurement.

Discussion with two Operations Engineers and one System Engineer responsible for the Laser Ablation and waste analysis activity identified that the individuals considered that prototype work that was being done to a proven technology and/or process did not have to comply with the QA Rule, QA Order, NQA-1, or Quality Assurance Requirements Document (QARD). Part of the rationale was that the procurement and testing of the equipment and glove box process flow using actual tank waste was being performed in 222-S Laboratory and was screened as a non-safety item and activity. It was therefore CM. It was also considered that, as long as the hold point in the installation work was followed, NQA-1 would be applied at the appropriate time prior to installation of the actual process glove box on the WTP hot cell. The Assessment Team notes that the above discussion is consistent with BNI procedures as discussed below.

24590-WTP-GPG-M-036, "Determining Quality and Seismic Classification of Sub-Components, Assemblies, Sub-Assemblies, and Parts," Section 2.2.3, states that CM are items and activities that are not Q. This includes both APC and Non-Important-to-Safety (ITS). CM items are commercially available without any special or extraordinary requirements and may be procured from suppliers available to the general public (e.g., catalog sales or "over the counter"). While this may be true for a subset of items and activities within the CM category, procurement of items must still meet rule requirements if the item or activity meets the QA Rule definitions of non-reactor nuclear facility and hazards.

24590-WTP-GPG-ENG-037, "Supplier Document Request and Review," Paragraph 5.6.2.13 provides direction for review of a supplier's QAM. The rigor and who performs the QAM review is significantly different based on whether it is a Q or CM level procurement. The procedure states that in accordance with 24590-WTP-GPP-PSQ-021, "Supplier QA Program Review," Supplier QAM for Q orders must be reviewed and accepted by the QA organization. It further states that "Quality Assurance or Quality Control Manuals (QAM) for CM or CD orders (after award), when required by the G-321-E form, are not reviewed by QA." Engineering reviews CM order QAM to requirements identified by Engineering in the Purchase Order. BNI did not provide objective evidence that engineers who determine and validate adequate QA requirements for CM procurements have sufficient training and knowledge as required by the QA Rule. Without QA involvement in the development and evaluation of QA program elements, and/or without adequate training of Engineers to QA Rule and BNI QAM requirements, it is unclear how BNI is assuring that CM procurements meet QA Rule requirements.

BNI Procedure 24590-WTP-3DP-G06B-00010, Section 2.0 states that Engineering is responsible for specifying the appropriate supplier QA program requirements in procurement documents. Exhibit C to the procedure provides guidance to the engineer for the specification of appropriate QA requirements based on the type of Q level procurement that is being performed. The data sheet also states that each supplier in the supply chain is required to document and implement a QA program that complies with, as a minimum, the requirements defined herein based upon the type or scope of work to be performed. Each supplier is required to flow-down required QA program requirements, as defined herein, to each successive tier in the

supply chain. The implementing procedures do not provide a similar exhibit with the same flow down requirements for CM procurements. QA Management stated that a similar document that provided guidance for determining QA requirements for CM procurements was deleted in December 2005.

Supplier QA Program Requirements, Figure 1, "Quality Program Implementing Standards," states that the Quality Program Implementing standard for CM will be as defined in procurement documents. The relevant supplier QA program requirements data sheet is listed as "as defined in specifications." Note 3 states, "Items/services that are commercially dedicated will use the same supplier QA program requirements as CM items/services." Note 4 states, "Generally, no quality requirements need to be identified for CM procurements beyond the procurement general conditions." Because the procedure does not make a distinction between nuclear related CM and non-nuclear CM and does not provide guidance to the engineer to ensure that the applicable elements of the QA Rule are addressed, the procedure is deficient.

In discussions, BNI pointed out that this procedure also provided direction to engineers that allowed the use of an ISO 9001 program to be applied to CM procurements for items and services that are a nuclear activity. Review of the procedure did not identify direction or guidance that allowed the broad application of ISO 9001 to all CM procurements. The procedure stated in Exhibit A, Paragraph 3.1, "For items or services covered entirely by ISO 9001, evidence of ISO 9001 certification is adequate in lieu of the QA program." This allowance does not provide a discussion as to how the engineer determines if the items or services are covered entirely by ISO 9001. It should also be noted that this allowance is without guidance to determine how to mitigate the differences between NQA-1/DOE O 414.1B and an ISO 9001 program.

The assessment team did not identify a reference in BNI procedures that established QA Rule applicability consistent with the requirements of § 830.120, Subpart A, discussed above as they relate to CM activities. (A-07-ESQ-RPPWTP-010-F01)

Issues with Inductively Coupled Plasma Atomic Emission Spectrometer with Laser Ablation Procurement

A specific example of the lack of QA Rule and Order implementation is the Inductively Coupled Plasma/Atomic Emission Spectroscopy with Laser Ablation procurement. As discussed above, the responsible Operations and Project Engineers considered this a CM procurement and as such, the Supplier QA Program Requirements Data sheet for Commercial Procurements and the resultant ISO 9001 certification letter from the vendor was sufficient to ensure an appropriate level of quality.

BNI cancelled the requirement for the CM data sheet referenced above in December 2005. BNI QA and Engineering Managers stated that BNI is developing an acceptable method to consistently flow down QA requirements for CM procurements; however, since 2005, additional procedural guidance has not been provided to engineers who determine quality requirements for CM procurements.

A review of the Supplier QA Program Requirements Data Sheet for Commercial Procurements identified that the elements required for an acceptable program were directive statements from the QA Rule and only covered the areas of documents and records, work processes, design, procurement, and inspection and acceptance testing. As such, the data sheet did not include a listing of all the potential elements of the QA Rule that must be evaluated for applicability. Training, assessments, and quality improvement are QA Rule elements that were not areas evaluated for CM procurements even though they may have been appropriate for vendors supporting nuclear activities.

According to the data sheet for the procurement reviewed, the vendor had two options to satisfy the deliverable. The vendor could either provide their QA program manual or a signed ISO 9001 certification. While the Assessment Team recognized that the referenced data sheet is no longer used, BNI did not provide objective evidence that a replacement procedure and data sheet has been developed and provides appropriate guidance for evaluation of applicability of QA Rule requirements to CM procurements. Specifically,

- DOE O 414.1B and the BNI/DOE Contract specifies the use of NQA-1 as the consensus standard for the application of QA requirements for nuclear related activities as discussed below. The BNI QAM applies NQA-1 to all activities on a graded approach. BNI QA management and BNI procedures stated that NQA-1 data sheets were only used when working a Q level procurement. BNI did not use a similar exhibit to assist the responsible engineer to develop a rationale for the level and extent of quality to be applied to this procurement.

- The DOE QA Guide states that the QA Rule and QA Order requirements are performance expectations and do not always specify methods for achieving the desired performance. Consequently, unless otherwise specified, organizations should identify, document, and use appropriate standards to develop and implement the management system. The use of the QA Rule verbiage in the QA requirements data sheet for CM procurement does not provide the procurement engineer, the supplier, and the QA organization with a sufficient level of detail on the expectation of QA for the procurement.

DOE O 414.1B indicates that DOE contractors are required to develop a QA Program that "Uses appropriate national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used." When the Assessment Team discussed the Laser Ablation procurement with BNI staff and management, BNI indicated that for Research and Development (R&D) projects the application of QA requirements was different than for normal WTP project work. However, the Assessment Team was not able to identify where the BNI QAM allowed this latitude, nor could the Assessment Team find any QA criteria (based on a consensus standard) in the QAM to cover the differences in the application of QA to R&D.

NQA-1-1989 does not provide specific guidance for a graded application of QA to R&D activities. However, NQA-1-2000, Subpart 4.2, provides guidance for applying QA to

R&D activities. The Assessment Team recognizes that NQA-1-2000 was not specified in the BNI contract, but felt the Standard would be beneficial in assessing BNI's understanding of applying NQA-1 to R&D activities that fall under the QA Rule such as the Laser Ablation procurement. The NQA-1 Guide stated that R&D projects include two types of activities: 1) science activities; and 2) support activities (procurement, maintenance facility operations, calibration of Measuring and Test Equipment [M&TE], etc.).

- Science Activities:

  The Guide states that for applying QA to the science activities "A graded approach based on importance and significance of the activity is key to successful application of the NQA-1 Standard to R&D."

- Support Activities:

  The Guide states, "Support activities are those which are conventional and secondary in nature to the advancement of knowledge or development of technology." The Guide indicated that for support activities, the application of QA and the graded approach was established "with regard to safety considerations, cost, schedule, and programmatic mission, e.g., importance of data accuracy." The Guide also stated for support activities "The graded approach methods of implementation and documentation are formally defined."

The Guide further makes it clear that grader latitude is allowed for the "science activities," and that this latitude is based on importance and significance of the activity, but for the "support activities" QA is applied the same as other QA activities (based on safety considerations, cost schedule and programmatic mission considerations, etc.). The Assessment Team found that BNI's understanding, as discussed with BNI staff and management, did not match the NQA-1 guidance. The Assessment Team ran out of time and was not able to locate procedures that discussed the application of QA requirements to R&D science and support activities nor how the graded approach was formally defined for use with R&D. (A-07-ESQ-RWPWWTP-010-O02)

Use of Consensus Standards to Support Nuclear Work

DOE O 414.1B, "General Quality Requirements," 2.a(2) states, "use the appropriate national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used. Appropriate standards include the following:

- American Society of Mechanical Engineers (ASME) NQA-1-2000, "Quality Assurance Requirements for Nuclear Facility Applications" (for nuclear-related activities)

- American National Standards Institute (ANSI)/ISO/American Society for Quality (ASQ) Q 9001-2000, "Quality Management System: Requirements" (for non-nuclear activities)"

The responsible Operations and Project Engineers considered that the Inductively Coupled Plasma/Atomic Emission Spectroscopy with Laser Ablation procurement was a CM procurement and as such the Supplier QA Program Requirements Data sheet for Commercial Procurements and the resultant ISO 9001 certification letter from the vendor was sufficient to ensure an appropriate level of quality.

Based on DOE O 414.1B discussed above, the assessment team expected to see NQA-1 as the standard by which the QA program requirements were implemented and passed to the vendor given the nuclear application of the procurement. An acceptable method to ensure the appropriate level of QA is to specify additional quality requirements to cover the difference between a potential supplier's QA program certification (ISO 9001) and an expectation for performance (NQA-1).

BNI did not perform an evaluation at the program level to determine that an ISO 9001 certified program met NQA-1 and DOE O 414.1B requirements. This evaluation is necessary to support the blanket use of the Supplier QA Program Requirements Data sheet for Commercial Procurements that support nuclear applications. A similar evaluation could have been performed for this specific procurement with any additional QA requirements necessary for the procurement to meet the level of NQA-1 determined through the grading process provided to the vendor in the procurement specifications. Accepting just a certificate without assessing the vendor's processes was not sufficient to meet NQA-1 requirements.

The DOE/BNI Contract, Standard 7, (3) provides specific direction on the application of the QA Rule, DOE QA Order, Office of Civilian Radioactive Waste Management (OCRWM) program requirements, and consensus standards. The contract further states that the Contractor's QA program documentation shall be submitted to DOE for review and approval. Section (3)(iv) and (3)(v) of the contract provide direction on non-QARD programs and expected that work be done in accordance with DOE O 414.1B. In Section (3)(v) the contract specified the use of NQA-1 (1989 Revision) as the standard for nuclear facility construction or nuclear safety-related work.

As such, the use of ISO 9001 as the consensus standard for nuclear activities that are performed in accordance with DOE O 414.1B without a linkage to NQA-1 is not in accordance with the BNI contract. Additionally, the BNI QAM provided to DOE for review and approval identified NQA-1 as the consensus standard applicable and does not include the use of ISO 9001 as being appropriate for nuclear or non-nuclear activities. The QAM invokes a graded approach to applying the requirements in the QAM. While the QAM includes NQA-1 as part of its requirement base, based on discussion with Engineering management and review of procedures, NQA-1 requirements are not flowed down specifically during CM procurements. (A-07-ESQ-RPPWTP-010-F02)

Requirement Grading

During the February 2007 part of the assessment, the assessment team reviewed BNI procedures and interviewed Engineering managers regarding the process for applying the grading of the QA program. This assessment team found similar issues for CM procurements as those that were identified for APC items. Issues documented in the APC assessment included:

- The Procedure 24590-WTP-3DP-G06B-00010, "Specifying Supplier Quality Assurance Program Requirements," explained how to specify QA program requirements for Q-level procurements but not for CM procurements. It referred persons identifying requirements for CM procurements to the engineering specification for the purchased item. However, the procedure provided no direction on how to identify QA requirements for CM procurements.

- There was no direction for making graded decisions on when to request QAMs or evidence of a QA program from CM suppliers. Personnel interviewed said that some procurement engineers routinely requested QAMs or evidence of a QA program from CM suppliers and others almost never did.

- There was no management direction for making graded decisions on when the QA organization should review CM QAMs and programs.

- There was no acceptance criteria when Engineering accepted supplier QA manuals.

This issue was documented as Finding A-07-ESQ-RPPWTP-002-F01: BNI did not establish a process for consistently selecting QA activities using a graded approach during procurement of items with defense-in-depth functions as required by 10 CFR 830.7. The initial BNI response only addressed corrective actions for the APC procurements and has not been revised to date to address the broader DOE ORP issue. However, BNI has established within their corrective action management system an extent of condition to address the APC issue that includes the broader CM items and activities. As such, this assessment report will not document the extent of the Grading of QA requirements issue to CM procurements as a finding.

24590-WTP-3DP-G04T-00905, Revision 7, Section 3.5, "Gradation of Quality Requirements," stated that grading specifies the quality elements and the technical, inspection, and testing requirements in drawings, specifications, and procurement documents necessary to meet the specific design, task, or operation. Examples of typical grading factors are provided. Specifically:

- Consequence of failure of the item

- Importance of the data being collected or analyzed

- Complexity of design or fabrication of the item or design or implementing of the activity
- Reliability of the process
- Reproducibility of the results
- Uniqueness of the item or service quality
- History of the item or service quality
- Necessity for special controls or processes
- Degree to which functional compliance can be demonstrated through inspection or test

While the factors may be useful to the grading process, the factors are not consistent with § 830.3 – Definitions: "Graded Approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part are commensurate with:

- The relative importance to safety, safeguards, and security
- The magnitude of any hazard involved
- The life cycle stage of a facility
- The programmatic mission of a facility
- The particular characteristics of a facility
- The relative importance of radiological and non-radiological hazards
- Any other relevant factor"

The Assessment Team met with BNI Engineering Management and was briefed on a draft grading process that was developed as a result of the APC assessment. ORP has not performed a detailed review of the document to determine if it provides sufficient guidance on the application and grading of the QA Rule requirements.

BNI Procedure 24590-WTP-QAM-QA-06-001, "Quality Assurance Manual," provides a basic description of what a graded approach is but does not provide additional direction as to how grading decisions are made regarding all elements of the QA Rule as they relate to the nuclear program supporting nuclear facility construction. The primary focus of the grading guidance thus far has been in the area of procurement. As program improvements are being put in place to address the process of applying grading to

procurements of items and activities that are Q and CM, BNI should consider establishing guidance for the broader application of the QA Rule. (A-07-ESQ-RPPWTP-010-O01)

2. Findings and Observations

A-07-ESQ-RPPWTP-010-F01: BNI has not consistently demonstrated a process for evaluating CM items and activities for application of 10 CFR 830 Subpart A as required.

Requirements:

a. 10 CFR 830.120, "Scope," "This subpart establishes quality assurance requirements for contractors conducting activities, including providing items and services, that affect, or may affect, nuclear safety of DOE nuclear facilities."

b. 10 CFR 830.121(a), "Quality Assurance Program," states, "Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria of § 830.122."

c. 10 CFR 830.121(c)(1), "The QAP must describe how the quality assurance criteria of § 830.122 are satisfied."

d. 10 CFR 830.121(c)(4), "The QAP must describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122."

e. Office of General counsel; Ruling 1995-1; "Ruling concerning 10 CFR Parts 830 (Nuclear Safety Management) and 835 (Occupational Radiation Protection)," Section B.1 states in part that the requirements of Parts 830 and 835 cover all activities under DOE's auspices with the potential to cause radiological harm. Section B.1 further states: "Because all ionizing radiation has the potential to cause harm, the Department did not limit the application of the nuclear safety requirements in Parts 830 and 835."

f. EGS 00-03, Section 1, states in part, "specifically, this guidance reaffirms that quality assurance (QA) controls required by 10 CFR 830 are not in any way limited by language contained in SARs, TSRs, or technical specifications documents. The EGS provides illustrative examples of PAAA non-compliances in situations that did not directly involve safety systems or structures. They supported the conclusion that all work in nuclear facilities may have the potential to affect nuclear safety in a nuclear facility." The supplement goes on the state: "The argument that 10 CFR 830 only applies to safety equipment or systems that are specifically referenced in the SAR, TSR, or Technical Specifications has no basis in the text of the Rule."

g. EGS 99-01, "Enforcement of 10 CFR Part 830.120 for Facilities Below Hazard Category III," states in part: "The QA Rule applies in a graded approach to all DOE reactor and nonreactor nuclear facilities. Non reactor nuclear facilities are defined as those that conduct activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public..." It further states that this rule does not specify any minimum for such a hazard. The EGS also states that Standard 1027 provides guidance for determining whether a facility, activity, or area requires a Safety Analysis Report, but it does not provide a basis for exclusion from the provisions of the QA Rule.

h. DOE O 414.1B, "When the contractor conducts activities or provides items or services that affect or may affect the safety of Department of Energy, nuclear facilities, it must conduct work in accordance with the quality assurance (QA) requirements of 10 CFR 830 Subpart A."

Discussion:

Contrary to these requirements, BNI procedures did not specify processes for ensuring that CM items and activities were consistently evaluated for application of 10 CFR 830 Subpart A. Because the process for applying the QA Rule to CM items and activities was not specified in procedures, procurements for these activities did not consistently demonstrate applicable QA Rule elements were included in the procurement as required. The following examples led the Team to their conclusion that the QA Rule was not being properly evaluated.

- Two Operations Engineers and one System Engineer responsible for the Laser Ablation and waste analysis activity said they considered that prototype work that was being done to a proven technology and/or process did not have to be done to the QA Rule, QA Order, NQA-1, or QARD. Part of the rationale was that the procurement and testing of the equipment and glove box process flow using actual tank waste was being performed in the 222-S Laboratory and was screened as a non-safety item and activity and therefore was CM. It was also considered that as long as the hold point in the installation work was followed, NQA-1 would be applied at the appropriate time prior to installation of the actual process glove box on the WTP hot cell. The Assessment Team notes that the above discussion is consistent with BNI procedures as discussed below.

- BNI Procedure 24590-WTP-GPG-M-036, "Determining Quality and Seismic Classification of Sub-Components, Assemblies, Sub-Assemblies, and Parts," does not provide guidance for evaluation and application of the QA Rule to CM items and activities. The procedure states in Section 2.2.3, "CM are items and activities that are not Q. This includes both APC and Non-ITS. CM items are commercially available without any special or extraordinary requirements and may be procured from suppliers available to the general public (e.g., catalog sales or 'over the counter')." While this may be true for a subset of items and activities within the CM category,

procurement of items must still meet QA Rule requirements if the item or activity affects or may affect the nuclear safety of a nuclear facility.

- BNI Procedure 24590-WTP-3DP-G06B-00010, "Specifying Supplier Quality Assurance Program Requirements," Figure 1, does not provide guidance for evaluation and application of the QA Rule to CM items and activities. The procedure provides guidance for the designation of Quality Level as it relates to ITS, APC, and Immobilized High-Level Waste type activities. The break down determines if CM or Q requirements will be applied to an item or activity. QA requirements for CM items and activities are further discussed in this procedure where it states that generally, no quality requirements need to be identified for CM procurements beyond the procurement general conditions.

- The Assessment Team did not identify a reference in BNI procedures that established QA Rule applicability consistent with the requirements of § 830.120, Subpart A and the guidance of Office of General Counsel; Ruling 1995-1, EGS-99-01 and EGS-00-03 discussed above as they relate to CM items and activities.

A-07-ESQ-RPPWTP-010-F02: BNI did not apply NQA-1-1989, "Quality Assurance Requirements for Nuclear Facilities," standard for implementing QA requirements for nuclear activities, other than for safety related items, as required by DOE O 414.1B and the ORP/BNI Contract.

Requirements:

a. DOE O 414.1B, "General Quality Requirements," 2.a(2) states, "Use the appropriate national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used. Appropriate standards include the following:

   - ASME NQA-1-2000, "Quality Assurance Requirements for Nuclear Facility Applications" (for nuclear-related activities)

   - ANSI/ISO/ASQ Q 9001-2000, 'Quality Management System: Requirements' (for non-nuclear activities)"

b. The DOE/BNI Contract, Standard 7, (3)(v), specifies the use of NQA-1 (1989 Revision) as the standard for nuclear facility construction or nuclear safety-related work.

c. 10 CFR 830.120, "Scope," "This subpart establishes quality assurance requirements for contractors conducting activities, including providing items and services, that affect, or may affect, nuclear safety of DOE nuclear facilities."

d. 10 CFR 830.121(a), "Quality Assurance Program," states, "Contractors conducting activities, including providing items or services, that affect, or may

affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria of § 830.122."

e. 10 CFR 830.121(c)(1), "The QAP must describe how the quality assurance criteria of § 830.122 are satisfied."

f. 10 CFR 830.121(c)(4), "The QAP must describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122."

g. 10 CFR 830.122(e)(1), Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.

h. 10 CFR 830.122(f)(4), Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.

i. 10 CFR 830,122(f)(5), Verify or validate work before approval and implementation of the design.

j. 10 CFR 830. 122(g)(2), Evaluate and select prospective suppliers on the basis of specified criteria.

k. DOE O 414.1B, "When the contractor conducts activities or provides items or services that affect or may affect the safety of Department of Energy, nuclear facilities, it must conduct work in accordance with the quality assurance (QA) requirements of 10 CFR 830 Subpart A."

l. 24590-WTP-3PS-G000-T0001, Revision 0, "Supplier Quality Assurance Program Requirements," Section 3.1, "At the time of bid proposal, the Supplier shall submit an uncontrolled copy of their Quality Assurance Program Document(s) which defines the program they will follow to meet this specification. With the documents(s), the Supplier shall submit a facsimile of the Supplier Quality Assurance Program Requirements Data Sheet, or applicable portion of the material requisition or technical specification, on which the 'Supplier Document and Paragraph References' shall be identified by listing document identity numbers and applicable paragraphs which satisfy the criteria imposed."

m. 24590-WTP-3PS-G000-T0001, Revision 0, "Supplier Quality Assurance Program Requirements," Section 3.2, "At the time of Purchase Order, Contract, Subcontract, or other written agreement, the Supplier shall submit an uncontrolled copy of their Quality Assurance Program Document they will follow to meet this specification. With the documents(s), the Supplier shall submit a facsimile of the Supplier Quality Assurance Program Requirements Data Sheet, or applicable portion of the material requisition or technical specification, on which the "Supplier Document and

Paragraph References: shall be identified by listing document identity numbers and applicable paragraphs which satisfy the criteria imposed."

n. 24590-CM-MRA-AELE-00009, Revision 0, "Material Requisition," Section 2.4.4, Paragraph 1, "Refer to the attached Supplier Quality Assurance Program Requirements Specification, 24590-WTP-3PS-G000-T0001 for general requirements."

Discussion:

Application of NQA-1

Contrary to these requirements, BNI procedures do not specify the appropriate consensus standard for items and activities that affect or may affect nuclear safety within a nuclear facility. Because the appropriate consensus standard was not selected, criteria was not established to ensure that the standard was applied using a graded approach. The following examples led the Team to their conclusions that NQA-1 was not consistently applied as the standard for nuclear facility construction other than nuclear safety-related work.

- The responsible Operations and Project Engineers for the Inductively Coupled Plasma/Atomic Emission Spectroscopy with Laser Ablation procurement considered that the Supplier QA Program Requirements Data sheet for Commercial Procurements and the resultant ISO 9001 certification letter from the vendor was sufficient to ensure an appropriate level of quality. The assessment team noted that the procurement met the criteria of affecting nuclear safety and was classified as a CM procurement.

- There was no documented process for applying NQA-1 consensus standard to nuclear related procurements other than those that are deemed safety related and identified as Q procurements.

- BNI had not performed an evaluation at the program level to determine that an ISO 9001 certified program meets NQA-1 requirements. This evaluation is necessary to support the blanket use of the Supplier QA Program Requirements Data sheet for Commercial Procurements that support nuclear applications. A similar evaluation could have been performed for this specific procurement with any additional QA requirements necessary for the procurement to meet the level of NQA-1 determined through the grading process provided to the vendor in the procurement specifications.

- The DOE/BNI Contract, Standard 7, (3) provides specific direction on the application of the QA Rule, DOE QA Order, OCRWM program requirements, and consensus standards. The contract further states that the Contractor's documentation shall be submitted to DOE for review and approval. Section (3)(iv) and (3)(v) provide direction on non-QARD programs and expect that work will be done in accordance with DOE O 414.1B. In Section (3)(v) the contract specified the use of NQA-1 (1989

Revision) as the standard for nuclear facility construction or nuclear safety-related work.

As such, the use of ISO 9001 as the consensus standard for nuclear activities that are performed in accordance with DOE O 414.1B without a link to NQA-1 is not in accordance with the BNI contract. Additionally, the BNI procedures provided to DOE for review and approval do not include the use of ISO 9001 as being appropriate for nuclear activities.

Use of ISO 9001

Contrary to the above requirements, the BNI Material Requisition for Inductively Coupled Plasma Atomic Emission Spectrometer with Laser Ablation accepted a certification for an ISO-9001 Quality Management System as sufficient evidence that the Seller had an adequate QA program to meet all requirements from the procurement. 24590-CM-MRA-AELE-00009, Revision 0, "Material Requisition," Section 2.4.4, Paragraph 4 states "the completed datasheet shall be included after purchase, per Section 3.2 of the General Specification for Supplier QA Requirements along with a copy of the Supplier's QA program Manual and any QA program Certificate (e.g. ISO 9001:2000) merited, in accordance with Supplier Engineering Document Requirements form G-321-E, Category 6.0. If the Supplier has been independently certified as an ISO 9001 Supplier and the items and/or services are covered entirely by ISO 9001, evidence of ISO 9001 certification is adequate in lieu of the QA program."

During discussions with engineering and QA personnel it was identified that the QA program manual was not reviewed prior to awarding the contract as required. The award was based on the fact that the prospective Supplier had an ISO 9001 independently certified program. This is non-compliant to BNI's Supplier QA program requirements, Paragraph 3.1 to evaluate the prospective Supplier's QAM and implementation matrix showing where and how requirements will be met. By not performing that level of review, BNI has no assurance that the Seller's ISO program will meet DOE O 414.1B and QA Rule requirements. The fact that BNI did not follow their implementing procedure in non-compliant to the QA Rule.

T0002, Section 1.4.2, states, "The Seller shall establish and implement a QA program that conforms to the requirements specified on the applicable Supplier Quality Assurance Program Requirements Data Sheet for Commercial Procurements." This section also references 24590-WTP-3PS-G000-T0001, "General Specification for Supplier Quality Assurance Program Requirements" for further details. BNI's acceptance of a certification of ISO 9001 program only establishes that an ISO program is in place. Without looking at how that ISO program is implemented through the Seller's QA program and implementing procedures, BNI is not able to determine if the program is properly implemented and covers this procurement entirely.

The Assessment Team also noted that the Material Requisition (MR), Section 2.4.4, fourth paragraph regarding the completed data sheet after purchase, states "if the Supplier has been independently certified as an ISO 9001 Supplier and the items and/or services are covered entirely by ISO 9001, evidence of ISO 9001 certification is adequate in lieu of the QA program." BNI was not able to provide objective evidence that an evaluation/gap analysis had been performed to determine if the ISO 9001 program entirely covered the procurement requirements and the underlying DOE O 414.1B and NQA-1 program requirements. The Assessment Team performed a spot check comparison of ISO 9001 to DOE O 414.1B and NQA-1 for the five quality areas identified by the procurement specification as being applicable to this procurement. The following issues were identified.

- DOE O 414.1B, Criterion 6(d), "verify/validate the adequacy of design products using individuals or groups other than those who performed the work." Criterion 6(e) "Verify/validate work before approval and implementation of the design."

  ISO-9001, Paragraph 7.3.6, "Design and development validation," "Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product..." Based on a comparison of the above requirements, ISO-9001 does not meet Criterion 6(d) and 6(e) QA Order requirements.

- ASME NQA-1-2004, Subpart 4.3, provided a guide to be used for modification of an ISO 9001-2000 Quality Program to meet NQA-1-2000 requirements. According to the Guide, an ISO 9001 based program does not meet NQA-1 requirements. While it is recognized that BNI has yet to implement NQA-1-2000, ISO 9001 would not be a good fit for a procurement of this type. The five quality areas discussed on the Supplier QA Program Requirements Datasheet for this commercial procurement, (documents and records, work processes, design, procurement, and inspection and acceptance testing) would require upgrading to meet NQA-1 requirements as discussed in the NQA-1 Guide and in Finding F02.

T0002, Section 1.4.1 states "All of the equipment provided under this specification, shall be built to CM (Commercial Grade) Quality Requirements. The Safety Classification for the equipment is Non-ITS." BNI procedures do not define "commercial grade quality requirements" nor were "commercial grade quality requirements" passed down to the vendor through this procurement.

The Assessment Team notes that 24590-WTP-GPG-M-036, "Determining Quality and Seismic Classification of Sub-Components, Assemblies, Sub-Assemblies, and Parts," Section 2.2.3, states that CM are items and activities that are not Q. This includes both APC and Non-ITS. CM items are commercially available without any special or extraordinary requirements and may be procured from suppliers available to the general public (e.g., catalog sales or "over the counter"). While this may be true for a subset of

items and activities within the CM category, procurement of items must still meet rule requirements if the item or activity meets the QA Rule definitions of non-reactor nuclear facility and hazards. The procedure goes on to state "However, when additional requirements apply (e.g., welding, or measuring and test equipment), these are to be defined in a specification or MR Technical Notes." While these activities represent some inspection activity, they do not cover the suite of quality requirements that must be met to be compliant to NQA-1 and the QA Rule. This issue is discussed in more detail in Finding A-07-ESQ-RPPWTP-010-F01.

A-07-ESQ-RPPWTP-010-O01: The Assessment Team's review of BNI's implementing procedures for application of a graded approach to all elements of the QA program did not identify processes for grading the QA Rule implementation for other areas of rule applicability besides procurement.

Discussion:

BNI Procedure 24590-WTP-QAM-QA-06-001, "Quality Assurance Manual," provides a basic description of what a graded approach is but does not provide additional direction as to how grading decisions are to be made regarding all elements of the QA Rule as they relate to the nuclear program supporting nuclear facility construction. The primary focus of the grading guidance thus far has been in the area of procurement. As program improvements are being put in place to address the process of applying grading to procurements of items and activities that are Q and CM, BNI should consider establishing guidance for the broader application of the QA Rule.

A-07-ESQ-RPPWTP-010-O02: BNI procedures for R&D nuclear related activities do not establish guidance for application of a graded approach to QA implementation differently than for standard nuclear related items and activities procurements as allowed by NQA-1-2000, Subpart 4.2.

Discussion:

DOE O 414.1B indicates that DOE contractors are required to develop a QA Program that "Uses appropriate national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used." When the Assessment Team discussed the Laser Ablation procurement with BNI staff and management, BNI indicated that for R&D projects the application of QA requirements was different than for normal WTP project work. However, the Assessment Team was not able to identify where the BNI QAM allowed this latitude, nor could the Assessment Team find any QA criteria (based on a consensus standard) in the QAM to cover the differences in the application of QA to R&D.

NQA-1-1989 did not provide specific guidance for a graded application of QA to R&D activities. However, NQA-1-2000, Subpart 4.2 did provide guidance for applying QA to R&D activities. The Assessment Team recognizes that NQA-1-2000 was not specified in the BNI contract, but felt the Standard would be beneficial in assessing BNI's

understanding of applying NQA-1 to R&D activities that fall under the QA Rule such as the Laser Ablation procurement. The NQA-1 Guide stated that R&D projects include two types of activities: 1) science activities; and 2) support activities (procurement, maintenance facility operations, calibration of M&TE, etc.)

- Science Activities:

  The Guide states that for applying QA to the science activities "A graded approach based on importance and significance of the activity is key to successful application of the NQA-1 Standard to R&D."

- Support Activities:

  The Guide states, "Support activities are those which are conventional and secondary in nature to the advancement of knowledge or development of technology." The Guide indicated that for support activities, the application of QA and the graded approach was established "with regard to safety considerations, cost, schedule, and programmatic mission, e.g., importance of data accuracy." The Guide also stated for support activities "The graded approach methods of implementation and documentation are formally defined."

The Guide further makes it clear that grader latitude is allowed for the "science activities," and that this latitude is based on importance and significance of the activity, but for the "support activities" QA is applied the same as other QA activities (based on safety considerations, cost, schedule, and programmatic mission considerations, etc.).

The Assessment Team found that BNI's understanding, as discussed with BNI staff and management, did not match the NQA-1 guidance. The Assessment Team ran out of time and was not able to locate procedures that discussed the application of QA requirements to R&D science and support activities nor how the Graded Approach was formally defined for use with R&D.