Department of Energy
Washington, DC 20585

September 2, 2010

The Honorable Peter S. Winokur
Chairman
Defense Nuclear Facilities Safety Board
625 Indiana Avenue, N.W., Suite 700
Washington, DC 20004-2901

Dear Mr. Chairman:

Thank you for your May 5, 2010, letter regarding the Defense Nuclear Facilities Safety Board's (Board) review of the Quality Assurance (QA) aspects of the hydrogen in pipes and ancillary vessels experimental test program for the Waste Treatment and Immobilization Plant. QA is one of the cornerstones of the Office of Environmental Management's (EM) overall safety program. Since the development of the EM Quality Assurance Program (QAP) in November 2008, EM has been involved in an effort to continuously improve QA across all of our sites and projects. We take any concerns dealing with potential shortcomings in our QAP very seriously and respond accordingly to address the concerns.

Your letter requested that the Department of Energy provide a report that addresses the QA and safety concerns identified in the letter, including flow down of QA requirements to subcontractors and more rigorous application of consensus quality standards to contractor and subcontractor QA programs. The requested response is included in the Enclosure to this letter.

We look forward to continuing to work closely with the Board to ensure the EM QAP is maintained at a high level of excellence.

If you have any further questions, please contact me or Dr. Steven L. Krahn, Deputy Assistant Secretary for Safety and Security Program at (202) 586-5151.

Sincerely,

Inés R. Triay
Assistant Secretary for
Environmental Management

Enclosure

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SEPARATION

PAGE

DEFENSE NUCLEAR FACILITIES SAFETY BOARD
QUALITY ASSURANCE REPORT

The Department of Energy (DOE) Office of Environmental Management (EM) received from the Defense Nuclear Facilities Safety Board (Board) a letter dated May 5, 2010, expressing concerns regarding the quality assurance (QA) aspects of the hydrogen in pipes and ancillary vessels (HPAV) experimental test program. The Board identified two issues and made four specific requests for responses from DOE. DOE's response to the issues raised and the requests made in the Board's May 5, 2010, letter is set forth below.

Board Issue One:

"BNI did not impose the quality assurance requirements cited in Department of Energy (DOE) Order 414.1C, *Quality Assurance,* upon Dominion Engineering Incorporated (DEI), BNI's subcontractor for the HPAV test program. Consequently, DEI and its subcontractor did not use the DOE order's quality assurance requirements, including those related to safety software, for the HPAV test program. This challenges the reliability and usefulness of the data resulting from the test program in demonstrating the safety of this aspect of the HPAV design."

Response:

DOE imposes DOE O 414.1C on contractors by inclusion of the Contract Requirements Document (CRD) in the contract. DOE Orders apply only to contractors performing work directly for DOE and do not *automatically* extend to suppliers and subcontractors. The CRD for DOE O 414.1C incorporated into Bechtel National Inc.'s (BNI) contract with DOE states that the "contractor is responsible for flowing down the requirements of this CRD to subcontractors at any tier to the *extent necessary* to ensure the contractor's compliance with the requirements and safe performance of the work." [emphasis added]. Therefore, flow-down to suppliers and subcontractors is only required as it is necessary to ensure the contractor's compliance with the requirements of the CRD and performance of the work to the requisite levels of quality.

EM Headquarters (HQ) empowers and expects the several field offices to audit their contractors to ensure compliance with QA requirements, which includes requirements flow-down. Also, EM HQ reserves the right to itself, as part of its oversight role, to audit both the field office and the prime contractor to ascertain and ensure that QA requirements are passed down to lower tier contractors as applicable.

In addition to the CRD provision quoted above, DOE O 414.1C states at paragraph 3.b. (4) that, "Regardless of the performer of the work, the contractor with the CRD incorporated into its contract is responsible for compliance with the requirements of the CRD."

It is possible for contractors to ensure that suppliers and subcontractors comply with the requirements of DOE O 414.1C, *Quality Assurance*, without explicitly specifying DOE O 414.1C in subcontracts and purchase orders; for example, placing specific, applicable requirements from DOE O 414.1C in contractually binding technical specifications achieves this end. A contractor may also apply the necessary QA criteria for the subcontractor or require the subcontractor to perform under the contractor's QA Program (QAP), rather than requiring the subcontractor to develop a separate QAP compliant with EM QA rules and Orders (see the first paragraph of Attachment 2, *Contractor Requirements Document*, of reference 33).

BNI self-identified the lack of flow-down (September 16, 2009, Ref. 8) and was working with DEI to resolve the deficiency. A surveillance was conducted on May 20-21, 2010, (EM was an observer) to confirm resolution of this deficiency. BNI flows down the requirements of Nuclear Quality Assurance (NQA)-1 (including subpart 2.7) to DEI in the DEI subcontract and then stipulates the specific additional applicable requirements from DOE O 414.1C (e.g., safety software requirements) directly in the purchase order/subcontract exhibits or in specifications. Explicitly specifying the DOE Order in DEI's subcontract is not required to achieve the objective of the DOE Order (as discussed above).

As discussed in greater detail below, EM has determined that BNI has done the following:

- Identified the correct set of QA requirements to DEI (Note: BNI previously identified a gap in the flow-down of the appropriate software requirements to suppliers/subcontractors, including DEI. These software requirements are being applied to DEI at this time);

- Verified that DEI's QA program and implementation satisfy those requirements, with the exception of software quality requirements (this is discussed in greater detail below);

- Verified that DEI identified the correct QA program requirements to the DEI subcontractor, Southwest Research Institute (SwRI®); and

- Verified that SwRI®'s QA program and implementation satisfy those requirements. (Note: SwRI®is also an acceptable supplier for Nuclear Regulatory Commission-regulated nuclear power plants under the Nuclear Procurement Issues Committee).

As a result of the reviews described below, the SwRI® HPAV test program data is reliable and useful (Ref. 10). Joint audits of DEI by both EM and BNI have concluded the DEI analysis of the data from the SwRI® HPAV test program using software is at an acceptable level of risk for use. However, DEI currently is restricted from issuing any calculations using developed software until the proper requirements are in place and is restricted from further software development or revision until BNI verifies the implementation of the NQA-1 Part II, Subpart 2.7, and the applicable DOE O 414.1C

software requirements (Ref. 10). Prior to May 22, 2010 (when these restrictions were accepted by DEI), DEI's QA Manual (QAM), DEI-002, *Quality Assurance Manual for Safety-Related Nuclear Work,* used 10 C.F.R. Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" as its basis. Although implementing the requirements of 10 C.F.R. Part 50 results in a robust QA program, this is not the underlying regulation in DOE O 414.1C. However, using 10 C.F.R. Part 50 allowed the SwRI® QAP to be developed using a sound regulatory framework.

On May 13, 2010, the DEI subcontract was revised to update the *Q Datasheet of ANSI/ASME, Quality Assurance Program Requirements NQA-1* (hereafter, "Q Datasheet"), to address the BNI identified gap in the flow-down of software requirements discussed later in this section. Also, a design analysis specification is being flowed down to DEI to apply the appropriate DOE O 414.1C safety software requirements.

Verification of Compliance and Implementation of the DEI QA Program

BNI has been contracting with DEI since early 2006 and has performed five audits and one surveillance of DEI activities to ensure DEI compliance with the identified QA requirements and implementation of the DEI QA program. The scope of the initial subcontract was associated with design analysis only. When the HPAV testing scope was added to the subcontract, BNI Supplier Qualification performed an audit of DEI in February 2008, with a subsequent audit in March 2009, to assess the DEI program for this scope of work. BNI Supplier Qualification also completed a surveillance of DEI in September 2009 to perform a limited scope audit, based on the re-location of the DEI facility, and reviewed the progress of the resolution of open Supplier Corrective Action Reports (SCARS, Refs. 1-5) resulting from the previous audits. In addition, a May 8, 2009, audit (Ref. 4) identified some SCARs, all related to adequacy of DEI documentation. None of these SCARs are related to the flow-down of requirements from BNI to DEI. These audits document DEI's acceptable compliance with the required QA requirements and implementation of DEI's QAP.

Verification of Compliance and Implementation of the SwRI® QA Program

DEI qualified SwRI® to perform the work scope through qualification audits. The DEI QA Manager and Principal Officer also performed an assessment to verify SwRI® compliance to identified QA requirements and implementation of the SwRI® QAP. To confirm SwRI® qualification and add confidence to the data collection activity, BNI also performed an audit of SwRI®. The BNI audit activity occurred July 15-16, 2008 (Ref. 6). This audit was observed by a representative of the Office of River Protection (ORP) QA office and evaluated the SwRI® QAP and implementation for each NQA-1 requirement specified by DEI. There were no programmatic or implementation deficiencies noted, although several areas of interest dealing primarily with records were identified. SwRI® was given two weeks to perform the corrective actions and a subsequent audit (Ref. 7) of SwRI® was performed on July 29-31, 2008. No deficiencies in the program or implementation were identified.

These audit activities document SwRI®'s compliance with the required QA requirements and implementation of the SwRI® QAP.

BNI Identified a Gap in Flow-down of Safety Software Requirements for Design and Safety Analysis Related Procurements and Subcontracts

On April 15, 2008, the effective date of 24590-WTP-QAM-QA-06-001, *Quality Assurance Manual*, Revision 2b, the BNI QA program was revised to implement American Society of Mechanical Engineers (ASME) NQA-1-2000 and DOE O 414.1C. At that time, BNI believed that the application of ASME NQA-1-2000 sufficiently addressed the applicable requirements of DOE O 414.1C for suppliers/subcontractors because NQA-1-2000 added the requirements of Subpart 2.7 for software quality assurance (SQA). However, Subpart 2.7 requirements were not flowed down for software used in design analysis as a result of a note on the Q Datasheets that limited the scope of Subpart 2.7 to software procurement. Discussions with individuals involved in the development of the BNI supplier QA program requirements prior to the addition of DOE O 414.1C indicate that NQA-1 requirements 3 and 11 and Supplemental Requirements 3S-1 and 11S-2 were selected in lieu of Subpart 2.7 to satisfy the minimum requirement basis for a graded approach to the flow-down of requirements for software used in design and analysis. This application of the graded approach has remained on the Q Datasheet until the recent revision to address the identified gap.

In late September 2009, BNI identified that implementation of the revised BNI QAM in April 2008 did not result in appropriate flow-down of SQA requirements to suppliers/subcontractors performing design or safety analysis. Specifically, BNI did not flow-down NQA-1 2000 Part II, Subpart 2.7, contrary to the suggested guidance of DOE G 414.1-4 and did not provide a justified alternative approach when the supplier/subcontractor scope of work included the use of software to perform safety-related design and analysis. Also, the necessary safety software requirements from DOE O 414.1C were not applied to suppliers and subcontractors when the scope of work included the use of software to perform safety-related design and analysis.

This condition is documented in the BNI corrective action program system (Ref. 8) as a Project Issues Evaluation Report (PIER) and is in the process of being corrected at this time.

To address this issue, the flow-down of NQA-1 Part II, Subpart 2.7 requirements for design analysis is being accomplished utilizing a revised NQA-1 Quality Assurance Requirements Datasheet (Ref. 9). The new datasheet was added to the DEI subcontract scope on May 13, 2010. This action upgraded the ASME NQA-1 2000 requirements to include Part II, Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*. The flow-down of the applicable DOE O 414.1C Safety Software Requirements is being accomplished using a design analysis specification. These are the current QA requirements for the DEI subcontract.

As noted above, BNI conducted a supplier surveillance (Ref. 10) of DEI on May 21-22, 2010. The surveillance team evaluated the adequacy, implementation, and effectiveness of the DEI QA Program as it pertains to software quality. The surveillance activity was observed by EM HQ staff with expertise in SQA. This assessment concluded that the scope of work and work activities performed by SwRI® to date did not call for the use of safety software; therefore, these requirements should not be applicable to SwRI®. However, the audit results indicate that the DEI QAP did not fully implement the NQA-1 2000 Part I; Part II, Subpart 2.7; and DOE O 414.1C software quality requirements. Although several gaps were identified, none of them impacted the technical performance of any deliverables as of the date of the audit. The surveillance found the following gaps:

- DEI calculation C-6916-00-09, did not contain the required information in accordance with DEI Procedure, DEI-QAP-2, "Control of Analysis," section 1.12 (Ref. 11).
- DEI did not implement the contractual requirements flowed down from BNI (Ref. 12), which imposed NQA-1-2000 requirements for *Design Control*, Section 800, *Software Design Control* (Ref. 13).
- DEI software Commercial Grade Dedication reports (i.e., verification and validation reports) did not provide objective evidence of the range of inputs for use and the Functional Requirements to IGOR.IPF software code, CS-6916-00-01, and did not address performance requirements. This SCAR condition was described as being in noncompliance with NQA-1-2000, Requirement 3, "Design Control," Section 401, "Use of Computer Programs," subparagraph (a).

In the case of the Quantitative Risk Analysis (QRA) software, DEI is in early development of this software, and the software will be in compliance with NQA-1 Part II, Subpart 2.7 and DOE O 414.1C requirements prior to its use in full production.

BNI placed the following restrictions on DEI as a result of the identified gaps: DEI is restricted from providing calculations using developed software (e.g., CS-6916-00-01 Rev. 3, QRA, etc.) until NQA-1 (2000) Requirement 3, Section 800, "Software Design Control," Part II, Subpart 2.7, and applicable DOE O 414.1C software requirements are developed, implemented, and verified by BNI Supplier Qualification. Additionally, DEI is restricted from modifying any developed software and QRA-related computer programs until approved by BNI Supplier Qualification. EM and ORP will continue to monitor these corrective actions.

Board Issue Two:

"BNI bases its quality assurance program requirements for the procurement of all categories of supplies and services on the ASME standard for nuclear quality assurance (NQA-1-2000). The Board supports the use of NQA-1-2000 for the WTP project; however, BNI did not properly implement the quality assurance requirements of NQA-1-2000, Part I, for the HPAV test program. Specifically, NQA-1-2000, Part I, consists of 18 requirements; 15 of these contain detailed requirements in addition to a basic initial introductory-level expectation paragraph. Implementation of the detailed requirements is

necessary to ensure full compliance with the NQA-1 standard. BNI has only required its subcontractors to meet the basic paragraph for each of the applicable Part I requirements (Paragraph 100, *Basic),* which does not provide the rigor necessary to ensure quality work."

The Board also observed:

> "The Board believes this approach is (1) inconsistent with the intent of the ASME NQA-1 Code and Standards Committee, (2) fails to meet the requirements established in DOE Order 414.1C, and (3) produces a flawed quality assurance program. An initial discussion with NQA-1 code committee members confirmed that invoking only the basic introductory-level expectation for requirements of the standard is not consistent with the intent of the standard.
>
> Further, the Board is concerned that the practice of only invoking Paragraph 100, *Basic*, is being applied to other DOE-Office of Environmental Management (DOE-EM) projects."

Response:

EM notes that NQA-1 permits "judicious application of the entire standard or portions of the standard," as noted in the Foreword to NQA-1-2000. In addition, the Foreword to NQA-1-2000 encourages organizations using the standard to select the portions of the standard, based on their applicability, to use in a graded approach, based on the work scope. EM understands that using a graded approach means that implementing the NQA-1 requirements can be done with varying degrees of rigor, depending on conditions, as described in 10 C.F.R. Part 830, *Nuclear Safety Management*. Several criteria to be used in applying the graded approach are listed in the definition of the term, "graded approach" in that regulation.

As such, appropriate application of the standard requires thoughtful consideration and selection of the requirement elements that are appropriate to the work scope[1]. The content of the BNI Q Datasheets represents the results of the selection of applicable requirements based on supplier/subcontractor scope. This datasheet is implemented using 24590-WTP-PD-MGT-0001, *WTP Graded Approach* (Ref. 15).

Additionally, EM disagrees that "BNI has only required its subcontractors to meet the basic paragraph for each of the applicable Part I requirements." As discussed below (see section "Identification of Quality Assurance Requirements contained in the DEI

[1] The EM QA Corporate Board created a focus area to develop a model for requirements flow-down and use of the graded approach. The focus area report (Ref. 32) provided two important concepts. First, the graded approach is the application process for administrative controls. It is a process by which the level of analysis, extent of documentation, and degree of rigor of process control are applied commensurate with their significance, importance to safety, life cycle state of a facility or work, or programmatic mission. The second concept is the graded approach does not allow for a requirement to be waived, but rather allows for varying levels of managerial controls to be applied to provide adequate assurance, commensurate with risk, that the requirement is being met.

Subcontract for Analysis and Testing Work Scope"), some requirements were specified in full, only the basic requirements were imposed in other cases, and some requirements were not applicable.

Identification of QA Requirements contained in the DEI Subcontract for Analysis and Testing Work Scope

On April 10, 2008, the subcontract 24590-QL-SRA-W000-00125 was awarded to DEI and BNI elected to impose NQA-1 2000 requirements in this subcontract as the project was within days of implementing NQA-1 2000 and DOE O 414.1C (April 15, 2008). As the 2000 *Q Datasheet* was not available at the time of award, an older form was used. The Q Datasheet is a tool used to provide consistent selection and application of quality requirements (Ref. 34) and specifies that a subcontractor scope of "Engineering Design and/or Service Supplier" and "Laboratory/Material Analysis Service Supplier" was required to address the full set of ASME NQA-1 2000 requirements for Part I Requirements 3, 4, 8, 9, 10, 11, 12 and basic requirements for Part I Requirements 1, 2, 5, 6, 7, 13, 14, 15, 16, 17, and 18. BNI applied the graded approach in identifying the appropriate quality requirements for the scope of work (see response to Board Issue Two for details on the application of the graded approach).

In the DEI subcontract with SwRI®, DEI specified the following NQA-1 2000 requirements as applicable to the SwRI® scope (Laboratory/Material Analysis Service Supplier) through DEI specification S-6916-00-02, *Specification for HPAV Gaseous Deflagration, Detonation and Deflagration-to-Detonation Transition (DDT) Test Program*: NQA-1 2000 Part I Basic requirements 1, 2, 4, 5, 6, 7, 13, 14, 15, 16, 17, 18 and full requirements 8, 9, 10, 11, 12. These requirements are consistent with the requirements BNI flowed down to DEI and are appropriate for the scope of work in the DEI contract to SwRI®.

Table 1. QA Requirements Flow-down from BNI to DEI and from DEI to SwRI®

	From BNI to DEI		From DEI to SwRI®	
Requirement	**Basic**	**Full**	**Basic**	**Full**
1.	X		X	
2.	X		X	
3.		X		
4.		X	X	
5. *	X		X	
6.	X		X	
7.	X		X	
8.		X		X
9.		X		X
10.		X		X
11.		X		X
12.		X		X
13.	X		X	
14. *	X		X	
15.	X		X	
16. *	X		X	
17.	X		X	
18.	X		X	
Sub Part 2.7				

*Requirements 5, 14, and 16 contain only a single paragraph (100).

The shaded rows in the table illustrate the differences in QA requirements as they were passed down from contractor to subcontractor. Differences show up in NQA-1 Requirements 3 (full requirement passed from BNI to DEI but neither basic nor full requirement passed from DEI to SwRI®), and 4 (full requirement passed from BNI to DEI but only the basic requirement passed from DEI to SwRI®). Neither party invoked Subpart 2.7 on SQA.

NQA-1 Requirement 3 describes the steps for a design control program. Requirement 4 describes a procurement document control program. This analysis suggests that DEI dropped inclusion of Requirement 3, *Design Control*, and reduced Requirement 4, *Procurement Document Control*, from the full requirement to the basic requirement.

Requirement Flow-down and Graded Approach:

BNI takes a graded approach to the implementation of NQA-1 for the Waste Treatment Plant (WTP). The implementation of NQA-1 requirements by BNI is provided as follows:

- BNI has been directed, by contract, to implement the ASME NQA-1-2000 edition of the standard for the construction of the facility.
- BNI assesses the content of ASME NQA-1-2000 for requirements applicable to its work scope.

- A QAM is prepared to incorporate the applicable NQA-1 requirements. In a limited number of cases, NQA-1 language is modified for use in the EM environment. (Although outside the scope of this question, BNI also complies with Quality Assurance Requirements Document (QARD) Revision 20 for High Level Waste Acceptance Impacting items and services).

- The QAM is issued by BNI for ORP review and approval. When approved by ORP, the QAM is issued for use.

- Project procedures are prepared and issued to implement QAM requirements.

- In the case of procurement and subcontracting processes, project procedures identify the applicable ASME NQA-1-2000 requirements to flow-down to supplier/subcontractor scope types.

The Graded Approach program description (Ref. 15) describes this process in more detail.

BNI procedures (Ref. 16) provide QA Requirements Datasheets to specify the ASME NQA-1 requirements imposed on a supplier/subcontractor's QA program. NQA-1 requirements are designated on the Q Datasheets as either "Basic" or "Full" based on the supplier/subcontractor scope of work, risk, and task complexity. The Q Datasheets address 11 different supplier/subcontractor scope types. Suppliers are also required to flow-down the applicable requirements to each of their sub-tier suppliers. BNI audits supplier/subcontractor QA programs and implementation to ensure conformance with applicable requirements. Although three different versions (Ref. 17–19) of the Q datasheet have been used, the NQA-1 requirements have been flowed down and remain the same, with the exception of the addition of Part II, Subpart 2.7, as discussed previously.

Three versions of the Q Datasheet have been applied to DEI within the duration of the subcontract.

- Subcontract Award April 10, 2008 - The BNI *Q Datasheet of ANSI/ASME NQA-1 (1989) Quality Assurance Program Requirements* (BNI Form 24590-G06B-F0008, Revision 7) was provided in Exhibit J of the DEI subcontract.

- May 8, 2009 - The DEI subcontract was updated to include Revision 9 of the Q Datasheet. This revision was completed to replace the NQA-1 1989 Q Datasheet with the current NQA-1 2000 Q Datasheet.

- May 13, 2010 – The DEI subcontract was updated to include Revision 11 of the Q Datasheet. This revision was completed to add the NQA-1 2000 Part II, Subpart 2.7 software quality requirements to the subcontract.

The WTP regulatory basis for the selection of applicable NQA-1-2000 requirements is developed pursuant to the BNI Contract, Statement of Work, Section C.6, Standard 7, Section (e)(3)(i), which requires that:

> QA for radiological, nuclear, and process safety shall be conducted in accordance with 10 C.F.R. Part 830, Subpart A and DOE O 414.1C.

Title 10 C.F.R. § 830.7, *Graded Approach,* states that:

> 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. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements.

The BNI Contract also identifies ASME NQA-1-2000 as the primary QA reference document. ASME NQA-1-2000, Appendix 2A-2, *Non-Mandatory Guidance on Quality Assurance Programs,* Section 502, *Graded Approach,* states:

> Items and services may require varying degrees of control and verification to ensure compliance with requirements.

ASME NQA-1-2000, Appendix 2A-2, Section 502 also provides a series of grading factors for use in making grading decisions. These factors are used by BNI Engineering in, *Quality Designation and Grading* (Ref. 20).

BNI is complying with the ORP-approved document *WTP Graded Approach,* (Ref. 15), which states in Section 11.7, NQA-1 Compliance:

> In accordance with the BNI Contract and QAM, and following a graded approach, BNI design and procurement activities comply with applicable NQA-1-2000 requirements. NQA-1 compliance is achieved either by literal application as the quality standard for supplier quality assurance programs, or BNI will specify applicable NQA-1 requirements directly in procurement package documents. The quality assurance requirements of ASME NQA-1-2000 specification have been considered during development of the Supplier Quality Assurance Program Requirements Datasheets for a material or service requisition or subcontract as defined in *Specifying Supplier Quality Assurance Program Requirements* (Ref. 16).

The foregoing addressed the two issues mentioned on page 1 of the Board's May 5, 2010, letter. The four specific requests are addressed below.

1. ***Delineate DOE-EM's policy regarding the application of consensus quality assurance standards in quality assurance programs for WTP and across DOE-EM.***[2]

EM issued its QAP, EM-QA-001[3], in October 2008. The EM QAP serves as the QA roadmap to ensure that the EM mission gets accomplished safely, correctly, and efficiently. The objective of the QAP is to provide consistent QA implementation across EM while allowing both for grading based on importance to the EM mission and safety, and for site-specific requirements to be addressed (e.g., DOE/RW-0333P, *Quality Assurance Requirements and Description*; Environmental Protection Agency requirements; state permit requirements; etc.). The graded approach is used to determine the applicability of the QAP and Quality Assurance Implementation Plan (QIP) requirements to any activity and the extent of rigor in applying these requirements. Each QA criterion is stated as an expectation for management of work, performance of work, and assessment of work. As such, rigorous QA controls for any high-risk activity within EM might include: identifying required and/or appropriate standards; establishing a work plan to prescribe work; assigning responsibilities; specifying personnel, qualification and training provisions; developing and implementing work control processes and procedures, including configuration control; implementing procurement process control; instituting verification and validation of items or services performed or procured; and performing assessments to verify adequacy of performance and to identify and implement improvement opportunities when performance is unsatisfactory. Less rigorous or routine controls may be considered when appropriate levels of analysis, documentation, and planned actions allow.

Some of the implementation requirements and characteristics for the EM QAP follow:

- The EM QAP meets and implements the governing DOE and EM-specific QA requirements. These include DOE O 414.1C, *Quality Assurance*; 10 C.F.R. Part 830, Subpart A; *Quality Assurance Requirements*[4]; ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications* (with addenda through 2007); and EM Management Expectations.

- Each Field organization (including ORP which has direct responsibility for the WTP), is required to prepare a QAP. The field organizations are permitted to either adopt the EM QAP or prepare their own. In either case, the QAPs must be based on the EM QAP requirements, including the required consensus quality standard NQA-1, for acceptance by the local site office (for contractor QAPs) or EM HQ (for site office QAPs). A variance from the requirement to base the site

[2] Note: DOE's response is limited to information pertaining to EM "defense nuclear facilities."
[3] Internet available at: http://www.em.doe.gov/pdfs/EM-HQ%20QAPP%20(Final)%2005-2008.pdf
[4] Per 10 C.F.R. Part 830, quality assurance requirements apply to all "DOE nuclear facilities."

QAP on NQA-1-2004 is the Waste Isolation Pilot Plant near Carlsbad, New Mexico. Their QAP is based on NQA-1-1989 by regulation (Ref. 36).

- Their SQA is based on NQA-2 (1990) Addenda 2.7. DOE O 414.1C contains the provision that "In the case of a conflict between this Order and any QA regulation, the regulation prevails."

- Using a graded approach, each HQ and Field organization is required to prepare a QIP, identifying procedures and documents that directly implement the applicable requirements of the QAP. The QIP demonstrates how the QAP requirements are being implemented. Appendix G of the EM QAP presents an acceptable template for preparation of a site-specific QIP.

- The EM HQ oversight and review of local site office QAPs/QIPs is performed consistent with the *Protocol for EM-HQ Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)* dated February 2010. This document is based on the requirements of NQA-1 (Ref. 34), DOE Order 414.1C (Ref. 33), and 10 C.F.R. Part 830. The EM HQ review and approval of site-specific QAP/QIP consists of two distinct phases.

  Phase 1 is focused on the *Approval for Implementation of QAP/QIP*. Phase 2 is focused on the *Verification and Validation (V&V) of QAP/QIP* implementation.

- Phase 1 review consists of a programmatic review of the submitted QAP/QIP. The Phase 1 review addresses the following key areas: format and content, applicability and scope, and the reasonableness of the graded approach.

- The Phase 2 review consists of an onsite review of program implementation and addresses the following key areas: adequacy of implementing procedures and processes; and maturity and effectiveness of program implementation. In addition, the Phase 2 onsite review process focuses on the following:

  - Status of issues identified as part of the Phase 1 programmatic review of the QAP/QIPs. The expectation is that by the time an onsite visit is scheduled, the site has fully addressed these issues.

  - High priority and cross-cutting QA issues such as the Commercial Grade Dedication, Code of Record, Suspect/Counterfeit Items, Procurement, and flow-down of QA requirements to subcontractors and vendors.

The lines of inquiry (LOIs) and protocol for the Phase 2 review are organized consistent with the ten program criteria listed in the EM Corporate QAP. Each

criterion is based on the requirements of DOE O 414.1C; 10 CFR 830, Subpart A; NQA-1-2004; and EM Management Expectations.

2. ***Describe DOE-EM's approach to ensuring that the quality assurance requirements of DOE Order 414.1C are flowed down to DOE-EM's contractors and their subcontractors (e.g., BNI and its subcontractors for WTP).***

   - The requirements contained within the EM QAP apply to EM HQ, EM Field/Project Offices, and are used to oversee EM contractors (as applicable to the work being performed by each entity). Each organization will have an organization-specific QIP describing how the applicable requirements of the QAP are implemented and/or flowed down to lower-tier organizations. (Note: this process does not alter a contractor's legal obligation to comply with 10 C.F.R. Part 830, or other regulations affecting QA[5].)

   - The Contracting Officer incorporates the CRD and NQA-1 into the contract per the DOE Acquisition Regulation (DEAR) Clause 970.5204–2, *Laws, regulations, and DOE directives* (Laws Clause), and DOE O 414.1C.

   - The DOE expectations relative to flow-down are stated in the CRD for DOE O 414.1C: "Regardless of the performer of the work, the contractor is responsible for complying with the requirements of the Contractor Requirements Document (CRD). The contractor is responsible for flowing down the requirements of this CRD to subcontractors at any tier to the *extent necessary* to ensure the contractor's compliance with the requirements and the safe performance of work." [emphasis added]. Paragraph 3.b (2) of the QA Order requires the CRD to be included in the contracts of all Departmental work: "This CRD must be included in contracts that require or involve responsibility for work or operations at DOE sites or facilities. This includes work that may take place outside the physical boundaries of a DOE facility, such as design or analysis services."

   - The DOE's definition of "contractor," as stated in DOE O 251.1C *Departmental Directives Program* does not include subcontractors; the language in 3.b of DOE O 414.1C is directed to and instructs *DOE Elements only*—and the requirements in the CRD pertain to the contractors. See para. 3.b.(1) "Except for the exclusions in paragraph 3c, the Contractor Requirements Document (CRD), Attachment 2, sets forth requirements of this Order that will apply to contractors whose contracts include the CRD." The CRD is not required to be included in all subcontracts. It is the responsibility of the prime contractor to determine what requirements from the CRD need to be flowed down to each particular subcontractor in order to ensure that contractor's compliance with the requirements of the CRD (Ref. 33, see Attachment 2, *Contractor Requirements Document*, Section 2.a(3)).

[5] See Section 3.0 APPLICABILITY, EM Corporate QAP, EM-QA-001.

- The DOE-EM approach to ensuring QA requirements of DOE Order 414.1C are appropriately flowed down rests on the following key principles:

  - The EM QAP requires HQ and each Field organization, and their respective prime contractors, to develop a QIP for EM review and approval. EM uses a two-phase approach to verify and validate effectiveness of approved QIPs. The LOIs and expectations used have been documented in *Protocol for EM-HQ Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*, dated February 2010 (see footnote 4).

  - In review and approval of the site-specific QAP/QIPs, the associated LOIs focus on the proposed approach (graded strategy, risk and complexity of work scope, etc.) to ensure all applicable requirements and expectations of DOE O 414.1C, *Quality Assurance*; 10 C.F.R. Part 830, Subpart A; *Quality Assurance Requirements*; ASME NQA-1-2004 (with addenda through 2007), *Quality Assurance Requirements for Nuclear Facility Applications (QA)*; and EM management expectations are addressed.

  - EM QA audits and oversight (both Field and HQ) are based on contract-specific terms and conditions (including List B under the Laws Clause) and the specifications outlined in approved site/contract-specific QIPs.

  - The requirements of the QAP are applied in a graded fashion commensurate with the type of work being performed and the importance of the work in contributing to safe completion of the EM mission. As stated explicitly in the QAP, "EM expects applicable requirements will be passed down to subcontractors."[6] As such, the EM expectation is for all work to be executed in conformance with the approved contractor QIP. This is regardless of whether the prime contractor's employees, subcontractors, vendors, or consultants actually do the work.

  - It is the prime contractor's responsibility to determine which aspects of an approved QIP (which includes DOE O 414.1C and NQA-1-2004 with addenda through 2007) apply to the work scope that is assigned to a subcontractor. Regardless of whether the work is performed by the prime contractor or subcontractor, EM holds the prime contractor accountable for work performance.

  - EM oversight also evaluates execution of the work performed by subcontractors to ensure that it is consistent with the requirements and expectations outlined in the prime contractor's approved QIP.

  - With respect to the WTP (and other major EM design/construction projects), the immediate day-to-day oversight responsibility for the quality of any work

[6] See Section 3.0 APPLICABILITY, EM Corporate QAP, EM-QA-001

performed under EM contracts, including work performed by any subcontractor, vendors, or consultants, rests with the assigned Federal Project Director (FPD), the Integrated Project Team (IPT), and the local Field/Site Federal personnel. EM HQ performs assessments of the effectiveness and adequacy of the oversight activities conducted by the FPD, IPT, and local EM Field/Site office personnel. EM HQ works to stay apprised of the performance of subcontractors and coordinates these efforts with its Field Offices and prime contractors to determine the adequacy and efficiency of the subcontractors.

3. ***Provide an assessment of the flow-down of requirements and proper application of consensus standards in contractor quality assurance programs for DOE-EM design and construction activities to determine the state of compliance with the requirements of DOE Order 414.1C.***

- EM has established an annual Integrated Safety Management System (ISMS) and QA Effectiveness Review and an Annual Declaration. This declaration includes a summary of the results of each Field organization's annual effectiveness review and the status of ISMS and QA implementation. These annual reviews encourage the necessary adjustments to promote continuous improvement. The declarations address specific criteria, one of which is evidence of flow-down of requirements; they address evidence of flow-down of DOE O 414.1C not only from DOE Field organizations to the contractors but also to the subcontractors as well. The Field organizations have been requested to provide a description of the method of oversight and how proper implementation of these requirements is ensured as part of the declaration for calendar year 2010 (Ref. 35).

- EM's recently initiated Construction Project Reviews are also designed to assist in evaluating that EM's capital projects conform with QA requirements throughout the design, construction, and commissioning phase. To ensure a technically rigorous process, DOE EM, in conjunction with the Chief of Nuclear Safety, Office of the Under Secretary, has developed and issued a Standard Review Plan (SRP, Ref. 23). The technical basis and foundation for the SRP are centered on project expectations and requirements defined in DOE O 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Assets*, DOE-STD-1189-2008, *Integration of Safety into the Design Process,* and EM's internal business management practices. It also leverages the best practices and lessons learned from the Office of Engineering and Construction Management, Office of Science, National Nuclear Security Administration, EM Headquarters (HQ) and Field reviews, existing project review guides and protocols, and consensus standards.

- The SRP serves as the corporate framework designed to formalize the DOE and EM institutional processes and requirements associated with the review of project activities in support of Critical Decision approvals. The SRP is designed to improve project performance, including quality, by strengthening and formalizing

the technical basis for evaluating the readiness of EM capital and major operating projects. It is modeled after similar principles used extensively and successfully by the Nuclear Regulatory Commission for evaluating U.S. commercial nuclear industry licensed activities.

- The SRP is a series of standalone Review Modules (RMs) and Topical Reports, which provide a set of core performance objectives and criteria in addressing specific project review areas tailored to each Critical Decision phase. The Second Edition of the SRP, issued in March 2010, consists of 28 review modules and Topical Reports. Each RM or Topical Report addresses specific disciplines grouped by: Project Management; Engineering and Design; Safety; Environment; Security; and QA. There are three QA-related modules. These are: 1) Quality Assurance for Critical Decision Reviews; 2) Protocol for EM Review/Field Self Assessment of Site Specific QAP/QIP; and 3) Facility SQA for Capital Project Critical Decisions Reviews[7]. All three of these SRP modules, related to QA, address flow-down of requirements.

- The Office of Standards and Quality Assurance (EM-23) has the responsibility of ensuring the implementation of the EM QAP. This responsibility is fulfilled by EM-23 through the assessments of EM projects, field offices, and contractors. After reviewing the 47 audits performed from the year 2007 to date, difficulties in flow-down appear to occur primarily at the subcontractor level. EM has recently increased the frequency of subcontractor audits and are including LOIs specific to the flow-down of QA requirements to subcontractors.

A survey of these audits and other reviews was performed to quantify the assertions in the preceding paragraph. On completion, this initial audit was subjected to a peer review. The peer review team had two major observations: first, the LOIs among the audits reviewed were inconsistent, so that a direct comparison of one audit with another is difficult; and second, including Construction Project Reviews in the data set was inappropriate as these high-level assessments do not normally include detailed inquiries regarding flow-down. Because of these two observations, the audit methodology was changed to the following general steps:

1. Select a data set of audits;
2. Review the LOIs of each audit;
3. Select audits with LOIs concerning QA requirements of interest as a subset for analysis; and
4. Extract LOIs regarding QA requirements flow-down for consideration.

This survey provided the following results. Of the 47 documented assessments performed by EM HQ, 14 assessments mentioned flow-down of QA requirements. This subset of 14 contained a total of 183 comments or observations, 81 of which were related to QA requirements. It should be noted that audit scope frequently is

[7] Please see http://www.em.doe.gov/Pages/StandardReviewPlanModules.aspx.

greater than just examining QA requirements. For example, one recent vendor audit focused on welding issues. While the question of QA requirements flow-down would certainly be discussed in such an audit, it is not the primary focal point of the LOIs and may not be formally documented in the audit plan. The results of this survey were determined to be inconclusive due to sample size. The data set only included HQ (EM-23 and Office of Project Management) sponsored audits. EM agrees to conduct a survey specifically designed to examine the issue of QA requirements flow-down with a larger population of field-sponsored audits and report the results to the Board in March 2011.

4. ***Describe actions taken by DOE EM to correct any noted deficiencies.***

Among the lessons learned from EM's QA implementation experience over the past two years, and observed from other parts of DOE and the private sector, is that there are several important factors and characteristics that need to exist and function for QA to be truly embraced and embedded in EM's work culture. Towards this end, EM has embarked on the following:

- Developed and issued its QAP in 2008 to provide explicit and clear identification and communication of its QA requirements and expectations. The QAP promotes consistent QA implementation across EM while allowing both for grading based on importance to the EM mission and safety, and for site-specific requirements to be addressed.

- The issuance of the QAP was followed by a series of corporate QA assist visits to work closely with EM field elements to identify and address programmatic weaknesses.

- The assist visits were augmented by development of performance objective/expectations, and LOIs to provide further clarity of EM's QA expectations, including expectations regarding requirements flow-down (i.e., SRP Review Modules such as the *EM Protocol for Review/Field Self-Assessment of Site-Specific QAP/QIP*)[8].

- To formalize approval of site-specific QAPs/QIPs, EM HQ instituted a two-phase review process using consistent criteria based on requirements and expectations of the EM QAP, including a formalized peer review.

- The insights and lessons learned from reviews, assessments, and assist visits have also resulted in the development of focused outreach and awareness to expand and strengthen EM's QA capacity and capability. For example, EM HQ,

[8] EM Protocol for Review/Field Self-Assessment of Site-Specific QAP/QIP, dated February 2010.

in conjunction with the Chief of Nuclear Safety and EM Field Offices, has sponsored a series of basic QA training, NQA-1 Lead Auditor, Commercial Grade Dedication, and train-the-trainer courses. The expectation is that the EM Field elements and contractors will leverage the developed content to augment and expand their indigenous QA capacity and capability.

- Where deficiencies or weaknesses are found, corrective and preventive actions are taken.

Another factor that impacts the effectiveness of QA implementation is the degree to which the corporate decision-making framework offers a sense of regulatory stability, technical soundness, and predictability. To strengthen technical rigor and consistency in quality throughout the Critical Decision process, EM in collaboration with the Chief of Nuclear Safety, Office of the Under Secretary, has developed EM SRP, including several review modules on QA (http://www.em.doe.gov/Pages/StandardReviewPlanModules.aspx).

EM HQ is pursuing, concurrently, several initiatives and approaches to address noted QA deficiencies. Examples include:

- Foremost among these initiatives is the EM QA Corporate Board. The Corporate Board provides the management structure to integrate the independently managed Federal and contractor QAPs into a single corporate entity. The Board serves as a consensus-building body to facilitate institutionalization of a QA Management System across the EM-Complex. The Board will ensure that major QA decisions and recommendations incorporate and promote the use of the best practices and commonly accepted standards in nuclear industry. (The Board has formed specific focus areas to work on Commercial Grade Dedication, Suspect/ Counterfeit Items, graded approach as well as requirements flow-down.)

- EM has initiated a methodical approach to verify and validate site-specific QAPs/QIPs consistent with the *Protocol for EM HQ Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*, dated February 2010. As discussed previously, the site offices are currently engaged in performing Phase 2 self-assessments to validate the implementation of the site-specific QAP/QIPs. The Phase 2 reviews are being conducted using the *Protocol for EM Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs),* which includes the statement that the Phase 2 onsite review process will include:

> High priority and cross-cutting QA issues such as the adequacy of QA oversight associated with the American Recovery and Reinvestment Act projects, Commercial Grade Dedication (CGD), Code of Record,

> Suspect/Counterfeit Items (S/CI), Procurement, and flow down to subcontractors and Venders.

In order to further emphasize flow-down in the Phase 2 reviews, The Office of Safety and Security Program, EM-20, issued a memorandum to the field offices in August 2010. This memorandum asks each site to provide a heightened awareness and emphasis on the flow-down of requirements during the Phase 2 self-assessments. The Phase 2 reviews are scheduled to be completed by the end of December 2010. Once received, EM HQ will review the results of the reviews and compile the flow-down information into a single report. That report will be made available to the Board for review in March 2011.

- EM has also included the discussion of flow-down to contractors, subcontractors, and vendors as part of the 2010 Annual Integrated Safety Management System and Quality Assurance Review Criteria and Declaration Guidance. The guidance was provided to the field offices on July 1, 2010, and includes the following criteria:

> Discuss how DOE assures that contractual requirements, including ISM and QA, are being applied for all work levels including prime contractors, subcontractors, and vendors. As part of the QA discussion, specifically address the flow-down of requirements from EM Corporate Quality Assurance Program, EM-QA-001; and the effectiveness of the suspect/counterfeit item programs including how DOE assures suspect/counterfeit items are not introduced in safety related equipment.

The declarations are due by the end of December 2010. Once received, EM HQ will review the results of the annual declarations and compile the information into a single report. That report will be made available to the Board for review in March 2011.

- As discussed in the response to question number 3, EM HQ has conducted a review of the HQ assessments with regards to flow-down. Since the results of that review were inconclusive due to small sample size, EM has expanded the review to specifically include site office assessments of contractors, sub-contractors and vendors. This review is ongoing and the results will be compiled with the results from the annual QA declarations and Phase 2 reviews into a single report. That report will be made available to the Board for review in March 2011.

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