March 25, 2008

Mr. John E. Price
UniStar Nuclear Energy, LLC
750 East Pratt Street
Baltimore, MD 21202

SUBJECT: UNISTAR NUCLEAR ENERGY, LLC - NRC AUDIT REPORT FOR THE CALVERT CLIFFS NUCLEAR POWER PLANT, UNIT 3 COMBINED LICENSE APPLICATION (PART 2) REVIEW

Dear Mr. Price:

On January 22-25, 2007, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an audit of the UniStar Nuclear Energy, LLC (UNE) Calvert Cliffs Nuclear Power Plant, Unit 3 (Calvert Cliffs) combined license application (COLA) development program at the Constellation Energy facility in Baltimore, Maryland. The enclosed audit report presents the details of that activity. The NRC auditors reviewed the implementation of selected portions of the UNE and its contractors' quality assurance programs related to the Calvert Cliffs COLA development program, and reviewed quality activities performed to support the Calvert Cliffs COLA development. During this audit, the NRC audit team did not identify any issues associated with the implementation of Calvert Cliffs COLA development program that should be addressed prior to completion of the application.

In accordance with Section 2.390, "Public inspections, exemptions, requests for withholding," of Title 10 of the *Code of Federal Regulations* Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter, and its enclosures will be made available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland, and via the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, http://www.nrc.gov/reading-rm/adams.html.

If you have any questions regarding this matter, please contact me at 301-415-4122 or via email at jxr7@nrc.gov.

Sincerely,

/RA/

John Rycyna, Project Manager
EPR Project Branch
Division of New Reactor Licensing
Office of New Reactors

Docket No. 52-016

Enclosure:
As stated

cc: see next page

If you have any questions regarding this matter, please contact me at 301-415-4122 or via email at jxr7@nrc.gov.

Sincerely,

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U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS

Audit Report No: PROJ0746-2008-001

Organization: UniStar Nuclear Energy, LLC

Applicant Contacts: John E. Price
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Baltimore, MD 21202

Nuclear Industry: Constellation Energy and EDF formed a new nuclear holding company, known as UniStar Nuclear Energy, LLC, (UNE), designed to develop, own and operate new U.S. and Canadian nuclear projects. UniStar Nuclear Energy, LLC is developing the combined license application (COLA) for the Calvert Cliffs Nuclear Power Plant, Unit 3 (Calvert Cliffs) for submittal to the NRC for review and approval.

Audit Dates: January 22 - 25, 2008

Auditors: Kerri A. Kavanagh, Lead Inspector, CQVP/DCIP/NRO
Jonathan Ortega, Inspector, CQVP/DCIP/NRO
Dori Votolato, Inspector, CQVP/DCIP/NRO
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John Rycyna, Project Manager, DNRL/NRO

Approved by: Juan Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection
& Operational Programs
Office of New Reactors

Enclosure

1.0 AUDIT SUMMARY

The purpose of this audit was to determine if quality activities were adequately established, documented, and implemented to support the development of the COLA for Calvert Cliffs.

The audit was conducted at the Constellation Energy facility in Baltimore, Maryland. The audit bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50,
- 10 CFR Part 21, "Reporting of Defects and Noncompliance,
- Regulatory Guide (RG) 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," and
- 10 CFR 50.9, "Completeness and accuracy of information."

2.0 STATUS OF PREVIOUS AUDITS

There were no previous NRC audits in support of the Calvert Cliffs COLA development.

3.0 AUDIT OBSERVATIONS AND OTHER COMMENTS

3.1 QUALITY ASSURANCE PROGRAMS

a. Audit Scope

The NRC audit team reviewed the quality assurance (QA) program requirements and the implementation process for Calvert Cliffs COLA activities to assure that the QA programs were consistent with the applicable requirements of Appendix B. Specifically, the NRC audit team reviewed the QA program manuals that govern the implementation of quality activities performed for Calvert Cliffs COLA activities by UNE, and its contractors.

b. Observations

UniStar Nuclear Energy Quality Assurance Program

The NRC audit team reviewed Revision 1 of the UniStar Nuclear Energy Topical Report Number UN-TR-06-001-A, "Quality Assurance Program Description UniStar Nuclear Energy QAPD," dated January 21, 2008, which documents the transition from UniStar Nuclear to UNE and provides changes to the generic management titles within the UNE organization. Revision 0 of UN-TR-06-001 was approved by the NRC by letter dated March 14, 2007. UN-TR-06-001-A describes the quality assurance plan (QAP) basis for siting, design, fabrication, construction (including pre-operational testing), operation

(including testing) maintenance and modification of the U.S. Evolutionary Power Reactor (EPR). The quality assurance program description (QAPD) is used in-part or entirely to develop and submit a COL application.

AREVA NP Quality Assurance Program

Design controls are established utilizing the existing AREVA NP Quality Management Manual (QMM), 56-5015885. The NRC audit team reviewed AREVA NP 56-9017592-002, "Quality Assurance Plan (QAP) for Design and Deployment of the US EPR," Revision 2, dated August 1, 2007, which is the applicable quality plan for all US EPR projects, and may be augmented by specific project quality plans. AREVA NP Project Plan, "U.S. EPR Combined Operating License Application #1 Support Project," Revision 2, dated September 28, 2007, details the plan to provide specific engineering and licensing documents that are sufficiently detailed and complete to form the basis of the COLA that will be submitted to the NRC by Constellation Energy for an EPR at the Calvert Cliffs site.

Bechtel Quality Assurance Program

The NRC audit team reviewed Revision 4 of the Bechtel "US EPR-Constellation Project Bechtel Job Nos. 25140 and 25237 Quality Assurance Program Plan (QAPP)," dated July 31, 2007, which establishes the quality program interface between the Bechtel Nuclear Quality Assurance Manual (NQAM), Revision 4, AREVA NP, Inc., and Constellation Energy. The QAPP is based on the NQAM, and in most cases, such as QA program requirements, organization, design control and verification, and QA records, the QAPP simply refers to the NQAM. The QA program policies contained in the NQAM were designed to meet the requirements of Appendix B.

Schnabel Engineering Incorporated

Services for geotechnical field investigation, laboratory testing, and engineering analysis associated with site characterization activities of the Calvert Cliffs site were provided by Schnabel Engineering (Schnabel) under a subcontract with Bechtel. Because Schnabel did not possess a QA program that met the requirements of Appendix B, Schnabel performed work in accordance with Bechtel's QA program for the execution and delivery of geotechnical field investigation and laboratory testing.

Risk Engineering, Inc. Quality Assurance Program

Bechtel subcontracted to Risk Engineering, Inc. (REI) to obtain computational and expert consulting services in performing probabilistic seismic hazard and sensitivity analyses for the Calvert Cliffs site. The audit team reviewed the REI QA manual, Revision 8, dated November 15, 2006, and Software Quality Assurance Plan (SQAP), Revision 8, dated November 17, 2006. These quality documents covered all activities related to REI's services that were important to safety as specified in the Bechtel service contract.

William Lettis & Associates, Inc.

Services for geotechnical evaluation of the Calvert Cliffs site and engineering analysis were provided by William Lettis and Associates (WLA) under a subcontract with Bechtel. Because WLA did not possess a QA program that met the requirements of Appendix B, WLA performed work in accordance with Bechtel's QA program for any geotechnical field work and engineering analysis.

c. Conclusions

The NRC audit team concluded that the QA program requirements for quality activities to support the Calvert Cliffs COLA development program were consistent with the requirements of Appendix B. The NRC audit team also concluded that the applicant's and its contractors' QA program requirements were appropriately translated into implementing procedures to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the COLA.

3.2 DESIGN CONTROL PROCESS

a. Audit Scope

The NRC audit team reviewed the implementation of the UNE, AREVA NP, and Bechtel design control processes for the Calvert Cliffs COLA to assure that the design control processes were consistent with the requirements of Criterion III, "Design Control," of Appendix B. Specifically, the NRC audit team reviewed the policies and procedures governing the implementation of the UNE design control process, and reviewed selected draft completed portions of the Final Safety Analysis Report (FSAR), which were in various stages of review by UNE.

b. Observations

b.1 Design Control Policy and Procedures

UNE EG-AN-201, "Owners Acceptance," Revision 0, dated March 30, 2007 provides instruction for the review and approval of work products developed by UNE contractors for U.S. EPR COLAs.

UNE LS-AN-1091, "UniStar Writer's Guide for the Development of the Combined License Application," Revision 1, dated January 10, 2008, describes the methodology to identify the disposition of EPR Design Certification (DC) FSAR, combined license (COL) Action Items, and Open Items for the development of a new plant COLA.

Bechtel procedure 25237-000-3DP-G04G-00037, "Design Calculations," Revision 001, dated April 20, 2007, defines the requirements for preparing, checking, and approving design calculations. The procedure requires design calculations to include input data, assumptions, equations used for calculations, and a concise statement addressing the calculation results and conclusions.

AREVA NP Administrative Procedure (AP) 0405-01, "Design Control Process," Revision 1, dated March 23, 2007, defines the controlled, logical, systematic, comprehensive flow and hierarchy of design information in order to integrate and transform design inputs into design outputs. The procedure covers control of design development, design support measures, design configuration, and software design.

b.2 Implementation of Design Controls

The NRC audit team reviewed UNE, Bechtel, and AREVA NP design control processes, including the implementing procedures and policy guidelines, applied to the Calvert Cliffs project. The NRC audit team verified that the guidance was consistent with the requirements for design control described in Criterion III of Appendix B. The NRC audit team verified that both Bechtel procedure 25237-000-3DP-G04G-00037 and AREVA NP AP 0405-01 were being used in the development of draft FSAR sections, as required. The NRC audit team verified that reviews of draft FSAR sections submitted to UNE by its contractors were performed consistent with the UNE procedures.

The NRC audit team also reviewed selected packages associated with the draft COLA/FSAR sections that were in the process of being reviewed by UNE. The following design packages were reviewed:

- Bechtel 25237-000-30R-M21G-00001, Revision 0, "Desalination Study." This study was used as a basis for part of Section 9.2.11, "Raw Water System," of the FSAR.

- Bechtel 25237-000T7C-GAMC-00309 contained the PJM Generator Interconnection Q48 Calvert Cliffs 1640 MW Impact Study. The draft FSAR Section 8.2, "Offsite Power System," also denoted two open items that needed to be addressed by UNE prior to COLA submittal.

- AREVA NP engineering information record (EIR), 51-9059213-001, "Technical Input to COLA FSAR Section 8.4, "Station Blackout," for CCNPP Unit 3." This EIR provided preliminary design information for Section 8.4 of the FSAR.

- AREVA NP design requirements document, 115-9003669-001, "Circulating Water (PA) System." This design requirements document provided the preliminary design information for Section 10.4.5, "Circulating Water System," of the FSAR.

- AREVA NP EIR 51-9060831-000, "Offsite Dose Calculation Manual (ODCM)." The ODCM will be provided in Part 11 of the Calvert Cliffs application.

- AREVA NP Calculation Summary Sheet, 32-9050900-001, "Calvert Cliffs Site Control Room Dose Evaluation for a DBA LOCA." This design package provided design input for Section 6.2.6, "Containment Leakage," of the FSAR.

c. Conclusions

The NRC audit team concluded that the design control process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, were implemented as required by the applicant's and its contractors' procedures to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues requiring additional action by the applicant prior to completion of the COLA.

3.3 DOCUMENT CONTROL

a. Audit Scope

The NRC audit team reviewed the implementation of the UNE, AREVA NP, and Bechtel processes of document control for the Calvert Cliffs COLA development program to assure that the processes were consistent with the requirements of Criterion VI, "Document Control," of Appendix B. Specifically, the NRC audit team verified that quality-related documents were developed, reviewed, approved, issued, used, and revised under an established program and verified the overall extent and effectiveness of their programs.

b. Observations

b.1 Policies and Procedures for Document Control

UNE QAPD Section F, Document Control, states, in part, that procedures are established which control the preparation, issuance and changes of documents that specify quality requirements or prescribe activities affecting quality.

UNE Procedure RM-AN-102, Revision 1, implements the UNE document control policy and provides detailed requirements for procedure format, development, approval, revision, and distribution of approved procedures and instructions.

AREVA NP QAP-56-9017592-002 states, in part, that the document control program defines the system of controls for the preparation, review, approval, revision, distribution, and use of documents that prescribe activities affecting quality.

Policy Number Q-6.2 of the Bechtel NQAM establishes the policy and identifies requirements and responsibilities for the control of documents used in the activities affecting quality within Bechtel's scope of work.

b.2 Implementation of Document Control Programs

The NRC audit team reviewed the design packages described in Section 3.2 of this audit report to verify that the documents had been reviewed, approved, issued, and revised consistent with AREVA NP and Bechtel procedures. The NRC audit team also observed that UNE currently used "Documentum" electronic system for document control. The NRC audit team confirmed that "Documentum" tracks all design support information and provides the interface for information between different sections/groups in UNE. Full

access to each of the systems and full control of documents within the system is limited to a small number of personnel, including UNE higher management, UNE document control and UNE QA personnel. All other UNE personnel are restricted to “read-only” access.

The NRC audit team also verified that “Documentum” maintains proper identification of complete controlled documents. In addition, the NRC audit team verified that the system provided adequate control and interface between UNE sections/groups.

c. Conclusions

The NRC audit team concluded that the document control process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant’s and its contractor’s procedures to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the COLA.

3.4 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

a. Audit Scope

The NRC audit team reviewed the implementation of the UNE and Bechtel process of controlling purchased material, equipment and services for the Calvert Cliffs COLA development program to assure that the processes were consistent with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B. Specifically, the NRC audit team reviewed the policies and procedures governing the process to verify the quality of suppliers providing engineering services for Calvert Cliffs COLA development activities.

b. Observations

b.1 Policies and Procedures for Control of Purchased Material, Equipment and Services

Bechtel NQAM states, in part, that Bechtel selects suppliers who have or who can demonstrate the ability to furnish services that comply with the requirements of Bechtel’s services procurement documents. The NQAM further states, in part, that prior to any selection of a supplier of services, the supplier must meet the following technical and quality requirements:

- A determination by Bechtel Engineering that the source is responsive to the technical requirements of a particular specification.

- A determination by Bechtel Engineering and Bechtel Quality Services that the supplier’s QA program is capable of meeting specified requirements.

Policy number Q-7.1 of the Bechtel NQAM provides the actual guidance to complete the above elements while UNE Procedure SC-AN-176, “Procurement of Contracted

Materials, Equipment, and Services," Revision 1, dated January 11, 2008, provides additional guidance for the applicant.

b.2 Review of Activities

The NRC audit team reviewed Bechtel's control of purchased materials, equipment, and services process, policy guidelines, and implementing procedures applied to the Calvert Cliffs COLA development project. The NRC audit team verified that the Bechtel processes adequately specified that requirements for procurement of purchased material, equipment, and services invoke technical, engineering, and quality requirements on the purchase orders. The NRC audit team verified that Bechtel had included an appropriate level of quality requirements in the purchase orders, in addition to the quality requirements needed for subcontractors. The NRC audit team did not identify any deficiencies in this area.

The NRC audit team verified that the UNE and Bechtel contractors described in Section 3.1 of this audit report were listed on the respective Approved Supplier List (ASL). The NRC audit team reviewed other quality records such as the ASL information, audit reports, supplier responses to audit findings, and Bechtel corrective action forms related to audit findings. The NRC audit team did not identify any deficiencies in this area.

c. Conclusions

The NRC audit team concluded that the control of purchased material, equipment, and services process requirements, including the oversight of suppliers, have been appropriately translated into implementing procedures. The NRC audit team also concluded that those activities reviewed by the NRC audit team were implemented as required by the applicant's and its contractor's procedures to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the COLA.

3.5 TEST CONTROL

a. Audit Scope

The NRC audit team reviewed the implementation of QA controls related to test control associated with site characterization activities to assure that the controls were consistent with the requirements of Criterion XI, "Test Control," of Appendix B. Specifically, the NRC audit team reviewed procedures that described the controls implemented by contractors and subcontractors to ensure that testing related to COLA activities, such as site boring evaluations, were adequately identified and controlled.

b. Observations

b.1 Policies and Procedures for Test Control

Bechtel Power Corporation

The NRC audit team reviewed the Bechtel NQAM and procedures describing the requirements and responsibilities for the control of tests. Policy Number Q-5.1 of the Bechtel NQAM describes the requirements for instructions, procedures, and drawings and Policy Number Q-6.1 describes the policy, manual, and procedure control. Additionally, Bechtel document 25237-103-GQP-GAP-00001-000, "Quality Plan (QP) for Subsurface Investigation for CCNPP Site," Revision 0, dated April 14, 2006, lists procedures for testing of cone penetrometer, downhole geophysical logging, and suspension P-S velocity logging as subject to the requirements for control of special processes. The NRC audit team confirmed that these controls were consistent with Appendix B requirements.

Schnabel Engineering, Inc.

The NRC audit team reviewed Schnabel procedures describing the requirements and responsibilities for the control of tests. Schnabel procedures were reviewed and accepted by Bechtel QA personnel before work was to proceed. The NRC audit team reviewed Schnabel Procedure, G06-CC, "Test Control," Revision 1, dated July 5, 2006, which establishes and defines the measures for controlling tests performed on materials and verifying test conformance to specified requirements. The NRC audit team noted that measures were provided to ensure that: (1) tests are conducted in accordance with written procedures; (2) test plans are developed and approved prior to testing; and (3) test results are documented and conformance with acceptance criteria will be evaluated.

Risk Engineering, Inc.

The REI QAM and SQAP describe the overall process for conducting safety-related calculations and establish software testing requirements that were applied to the Calvert Cliffs project. Appendix A to the SQAP describes the testing controls implemented by REI to ensure that the particular software program used complied with the software design requirements and that it returned the results in a correct and accurate manner.

b.2 Review of Test Control Procedures

The NRC audit team reviewed a sample of testing procedures used by Schnabel and its subcontractors for site characterization activities, including drilling, collection of data, and chain of custody of soil samples. Below is a partial list of the technical procedures reviewed:

- Drilling and Sampling, Revision 2, June 6, 2006
- Cone Penetrometer Test, Revision 1, June 2, 2006
- Fugro RCTS Testing Procedures Houston Geotechnical Laboratory, Revision 3, June 12, 2007

- Classification and Logging of Samples, Revision 0, dated April 14, 2006

The NRC audit team confirmed that these procedures were based on American Society for Testing and Materials (ASTM) standards for the particular tests, as required by the Bechtel NQAM Policy Number 9.1.3.1.

The NRC audit team reviewed a sample of test reports produced by Schnabel and its subcontractors. The sample included the following reports: Specific Gravity; Natural Density; Mechanical Analysis; Unconfined Compression Test; and, Geotechnical Subsurface Investigation Data Report.

The reports were completed and reviewed as required by the applicable test procedures. The NRC audit team also verified the controls implemented by Schnabel through the review of a Nonconformance and Corrective Action Report (NCAR) which identified multiple examples of deficiencies concerning laboratory records. Schnabel implemented corrective actions to correct the deficiencies in accordance with the applicable procedures. The NRC audit team determined that controls had been implemented for test control and reports.

The NRC audit team also reviewed documents used by REI to perform testing on software. The NRC audit team reviewed REI's verification and validation plan (VVP) generated during the testing of one of the software codes utilized for data analysis in support of the COLA. This document described the tasks used to verify and validate the software. The NRC audit team noted that the VVP included provisions for test requirements and assumptions, test acceptance criteria, and handling of test deviations, as required by the SQAP.

The NRC staff conducted a site visit on June 12-13, 2006, to observe COL pre-application subsurface investigation activities being conducted by Schnabel and its subcontractors at the Calvert Cliffs site. The NRC site visit report documented that the Schnabel activities were controlled by adequate procedures and standards with an appropriate level of supervisory oversight.

c. Conclusions

The NRC audit team concluded that the test control process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicants and/or its subcontractors procedures to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the COLA.

3.6 CONTROL OF MEASURING AND TEST EQUIPMENT

a. Audit Scope

The NRC audit team reviewed the implementation of QA controls associated with the control of measuring and test equipment (M&TE) to assure that the controls were consistent with the requirements of Criterion XII, "Control of Measuring and Test

Equipment," of Appendix B. Specifically, the NRC audit team reviewed procedures that described the controls implemented by the Bechtel contractors to assure that M&TE utilized in site characterization activities were adequately controlled.

b. Observations

b.1 Policies and Procedures for M&TE

Bechtel Power Corporation

Policy Number 12.1 of the Bechtel NQAM defines responsibilities for the maintenance, control, calibration, documentation, and identification of M&TE used in activities affecting quality. In addition, the Bechtel QAPP for Subsurface Investigation for the Calvert Cliffs site requires that M&TE activities associated with the preparation of the COLA are to be performed in accordance with the Bechtel NQAM with no additional modifications.

Schnabel Engineering, Inc.

Control of M&TE used by Schnabel Engineering for the Calvert Cliffs project was controlled by the Bechtel NQAM. Schnabel Procedure G04-CC, “Control of Measuring and Test Equipment,” Revision 0, dated April 11, 2006, describes the requirements and methods for control and calibration of M&TE. The NRC audit team noted that M&TE equipment utilized and its calibration status was required to be listed on the test reports.

b.2 Implementation of Programs for M&TE

The NRC audit team reviewed sample records of Schnabel and its subcontractors to verify that procedures related to M&TE were implemented. The sample of documents reviewed by the NRC audit team included:

- calibration records for equipment of equipment utilized in the RCTS testing,
- calibration records for equipment used in moisture content and unit weight,
- calibration records of scales and thermometers.

The NRC audit team also reviewed a sample of test data sheets and noted that the equipment utilized was identified on the test record. During the site visit conducted on June 12-13, 2006, the NRC staff reviewed calibration records of equipment used for the P-S suspension logging. The NRC audit team did not identify any issue requiring additional action by the applicant prior to completion of the COLA.

c. Conclusions

The NRC audit team concluded that the M&TE requirements have been appropriately translated into procedures and for those activities reviewed by the NRC audit team, have been properly implemented as required by the applicant and its contractors to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the COLA.

3.7 HANDLING, STORAGE, AND SHIPPING

a. Audit Scope

The NRC audit team reviewed implementation of the Bechtel and its subcontractor's processes of handling, storage, and shipping for the Calvert Cliffs COLA development to assure that the processes were consistent with the requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B. Specifically, the NRC audit team reviewed policies and procedures governing these processes to verify the overall extent and effectiveness of their programs.

b. Observations

b.1 Policies and Procedures for Handling, Storage, and Shipping

Bechtel Power Corporation

Policy number Q-13.1 of the Bechtel NQAM describes the responsibilities for housekeeping and for control and protection of materials, components, and equipment during handling, storage, and shipping. The NRC audit team noted that these controls were consistent with Appendix B requirements.

Schnabel Engineering, Inc.

The Schnabel procedure T10-00, "Handling and Storage of Samples," Revision 0, dated April 14, 2006, contains additional controls for the handling and storage of soil and rock samples. Samples are to be stored in an on-site warehouse until approval by the owner's representative. The NRC audit team noted that Schnabel required the use of ASTM D4220, "Standard Practices for Preserving and Transporting Soil Samples," to control and preserve, transport, and handle the samples.

b.2 Implementation of Sub-Supplier Programs for Handling, Storage, and Shipping

The NRC audit team verified the controls implemented by Schnabel through review of two NCARs which identified deficiencies concerning shipment and storage of soil samples. Schnabel implemented corrective actions to correct the deficiencies in accordance with the applicable procedures. The NRC audit team determined that controls had been implemented for handling and storage of soil samples.

The NRC staff also observed during the site visit conducted on June 12-13, 2006, that disturbed samples were properly logged and labeled and undisturbed samples were properly stored and sealed in accordance with ASTM D4220.

c. Conclusions

The NRC audit team concluded that handling, storage, and shipping requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's and its contractor's procedures to support the Calvert Cliffs COLA development program. The

NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the COLA.

3.8 CORRECTIVE ACTIONS

a. Audit Scope

The NRC audit team reviewed the corrective action process associated with the preparation of the Calvert Cliffs COLA to assure that the process was consistent with the requirements of Criterion XVI, "Corrective Action," of Appendix B. Specifically, the NRC audit team reviewed the UNE policies and controlling procedures associated with the project, and reviewed the status of all corrective actions, which are predominately identified through the audits and surveillances.

b. Observations

b.1 Policies and Procedures for Corrective Actions

UNE Procedure CA-AN-101, “Corrective Action,” Revision 0, dated March 31, 2007, provides the requirements of the Corrective Action Process (CAP) for UNE. The procedure establishes the program for identification, investigation, reporting, tracking, and resolution of adverse conditions associated with the programs and processes established and implemented by UNE. Adverse conditions are categorized into four levels ranging from adverse condition (Level 1) to a condition that does not require correction, but rather, can be enhanced, improved, or made more efficient (Level 4).

UNE Procedure CA-AN-101-1001, “Trending,” Revision 0, dated January 11, 2008, provides general instructions for applying trend codes consistently and for identifying trends, analyzing issues, and communicating trend results. The purpose of the trending program is to identify performance shortfalls at an early stage and implement corrective actions to preclude significant events.

b.2 Corrective Action Status

The NRC audit team reviewed corrective action listing for UNE. Five corrective action reports out of the 26 completed and in-process corrective actions were reviewed by the NRC audit team. The NRC audit team reviewed the following UNE condition reports:

CR 2007-01 – a few UNE procedures were not approved and issued under the UNE quality program;

CR 2007-09 – two requests for information (RFIs) regarding the exclusion area boundary for a particular site contained conflicting information;

CR 2007-10 – through the RFI process, technical information was forwarded to a contractor that was used as design inputs;

CR 2007-18 – purchase order was issued for safety-related work that did not invoke the necessary QA program requirements and conditions for vendor approval; and

CR 2007-21 – several RFI responses provided FSAR narratives as responses to RFI requests. An FSAR narrative is considered an output document rather than a source document, and therefore this type of response is considered inappropriate.

None of the corrective action reports identified deficiencies as significant or reportable under 10 CFR Part 21. At the time of the audit, all corrective action reports had been closed or were in the response process in accordance with the applicable procedures. The NRC audit team determined that these corrective action reports were found to adequately document the issues; corrective actions were determined to appropriately address the identified conditions; and closure and verification were adequately documented.

c. Conclusions

The NRC audit team concluded that the requirements for corrective actions have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues requiring additional action by the applicant prior to completion of the COLAs.

3.9 QUALITY ASSURANCE RECORDS

a. Audit Scope

The NRC audit team reviewed implementation of the UNE controls of QA records for the Calvert Cliffs COLA development program to assure that the controls were consistent with the requirements of Criterion XVII, "Quality Assurance Records," of Appendix B. Specifically, the NRC audit team verified that the QA program provides for the administration, identification, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records.

b. Observations

b.1 Policies and Procedures for Quality Assurance Records

The UNE QAPD, Section Q, Records, establishes the necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable. UNE Corporate Procedure RM-AN-101, "Records Management," Revision 2, dated January 18, 2008, defines the requirements for preparation, transfer, storage, retention, and disposition of records. RM-AN-101 describes how records are identified, prepared, collected, authenticated, controlled, stored, preserved, retrieved and disposed.

b.2 Review of Quality Assurance Records

The NRC audit team reviewed the implementation of the UNE controls of QA records for the Calvert Cliffs COLA development program. UNE maintains a dual storage location for the QA and non-QA hard copy records. Records are stored in the Baltimore Pratt Street building and in the Baltimore Candler Street building. The standard controlled environment at these storage locations provides reasonable protection from natural disasters such as wind, floods or fire, infestation of insects, mold, or rodents, and temperature and humidity. The NRC audit team verified that UNE records management program is effectively implemented in accordance to the UNE policy and procedures and is consistent with the requirements of Appendix B.

c. Conclusions

The NRC audit team concluded that the QA record control requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues requiring additional action by the applicant prior to completion of the Calvert Cliffs COLA.

3.10 AUDITS

a. Audit Scope

The NRC audit team reviewed a representative sample of audits conducted by the applicant and its contractors to determine the effectiveness of the audit process and timely completion of audits and to assure that the audit programs were consistent with the requirements of Criterion XVIII, "Audits," of Appendix B. Audit findings reported by the audits were reviewed for any adverse significance they may have on the results of the COLA. Corrective actions to resolve deficiencies identified by the findings and observations were reviewed for reasonableness and timely resolution.

b. Observations

The UNE program for external audits and surveillances is established in Section R, Audits, of the UNE QAPD. UNE procedure, QA-AN-201, "Supplier Audit and Qualification Program," Revision 01, dated October 18, 2007, provides the methods and controls for the evaluation, qualification, periodic assessment, and maintenance of QA Level 1 and QA Level 2 contractors providing items and services to UNE. UNE conducts external surveillances and audits to verify adequacy of a contractor's QA program. Audit results are documented and reviewed by the applicant's responsible management. In addition, where corrective action measures are required, the NRC audit team verified that UNE had completed an adequate follow-up inspection, review, or audit.

The AREVA NP program for QA is established in Section 3.1.18 of the AREVA NP QAP. AREVA NP Procedure 1719-21, "Quality Assurance Audits of Internal Activities," Revision 21, dated January 28, 2005, establishes the methods to be used in preparing for and conducting QA audits of internal activities, including field activities. Procedure

1721-01, “Quality Engineering Surveillance of Engineering Activities,” Revision 5, dated November 16, 2007, establishes the methods to be used in preparing for and conducting QA surveillances of internal engineering activities under the AREVA NP QA program.

The Bechtel program for QA audits is established in Policy Number Q-18.1 of the NQAM. This policy applies to audits conducted by the Quality Services Department of activities performed by Bechtel personnel, subcontractors, and design consultants. The Bechtel program for QA supplier surveillances and audits is established in Policy Number Q-7.2 of the NQAM. This policy applies to surveillance of supplier work when the surveillance requirement is identified in the procurement documents.

b.2 Review of Audit Activities

b.2.1 UniStar Nuclear Energy Project Audits and Surveillances

The NRC audit team reviewed the above program and the implementing procedures that govern the UNE QA audit and surveillance process. The NRC audit team verified that UNE guidance was consistent with the requirements for audits as described in Criterion XVIII of Appendix B to 10 CFR Part 50. As part of the implementation review, the NRC audit team verified UNE conducted and documented supplier audits and surveillances and that any issues identified were entered in the corrective action program and followed-up in a timely manner.

b.2.2 AREVA Audits and Surveillances

The NRC audit team reviewed the AREVA NP program and the implementing procedures for the audit and surveillance processes. The NRC audit team verified that AREVA NP conducted and documented internal audits and surveillances and that any issues identified were entered into the corrective action program and followed-up in a timely manner.

b.2.3 Bechtel Internal Audits

The NRC audit team reviewed the Bechtel program and the implementing procedures that govern their QA audit process. The NRC audit team verified that Bechtel conducted and documented internal audits and that any issues identified were entered in the corrective action program and followed-up in a timely manner.

b.2.4 Bechtel Oversight of Subcontractors

The NRC audit team reviewed the Bechtel program and the implementing procedures that govern their oversight of subcontractors and surveillance process. The NRC audit team verified the Bechtel conducted and documented supplier surveillances and that any issues identified were entered in the corrective action program and followed-up in a timely manner.

c. Conclusions

The NRC audit team concluded that the audit process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as applicable by the applicant and its contractors. Audits, surveillances, and surveys conducted by UNE, AREVA NP, and Bechtel were satisfactory and resolution of identified deficiencies were adequately documented, tracked, and resolved in a timely manner. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the COLA.

3.11 TRAINING AND QUALIFICATION

a. Audit Scope

The NRC audit team reviewed the QA program to verify that it provided for the indoctrination and training of personnel performing activities affecting quality to assure that proficiency was achieved and maintained to assure that the programs were consistent with the requirements of Criterion II, "Quality Assurance Program," of Appendix B. Specifically, the NRC audit team verified that UNE, AREVA NP, Bechtel, and associated vendors adequately implemented and maintained personnel training and qualification processes.

b. Observations

b.1 Policies and Procedures for Training and Qualification

The UNE QAPD provides the overall requirements for qualification, training, and certification of personnel whose activities may affect the quality of structures, systems, components and activities at UNE. UNE Procedure QA-AN-501, “Quality Assurance Indoctrination,” Revision 1, dated October 18, 2007, states, in part, that the procedure provides for a QA indoctrination and training program for UNE employees performing work involving QA Level 1 and QA Level 2 activities.

Policy Number Q-1.3 of the Bechtel NQAM prescribes the controls and responsibilities for the indoctrination and training of personnel performing activities affecting quality. Bechtel Procedure 3DP-G05G-00034, “Quality Indoctrination/Orientation and Training,” Revision 2, dated February 28, 2005, provides quality indoctrination/orientation and training requirements to ensure engineers are familiar with the Bechtel NQAM, procedures that govern the specific tasks they are expected to accomplish, and to maintain training records.

AREVA NP QAP 56-9017592-002 states, in part, that indoctrination and training requirements are provided to all personnel engaged in activities covered by AREVA NP’s QAP. AREVA NP AP 1702-22, “Employee Training,” Revision 27, dated December 17, 2007, defines the actions and responsibilities for planning, scheduling, executing, ad documenting personnel training.

Schnabel Engineering Inc. Procedure G02-CC, "Quality Program Training," Revision 0, dated April 10, 2006, identifies required training for Schnabel Engineering, Inc., and subcontractor personnel, and the implementation and documentation of the training required to support the Calvert Cliffs COLA Project.

Section 2.3 of the REI QA Manual provides qualification requirements of personnel involved in safety-related activities. The QA Manual also states that REI personnel working on QA-related work must attend QA training before performing QA-related activities and job responsibilities and authorities.

b.2 Review of Training Activities and Records

The NRC audit team reviewed a sample of training and qualification records for UNE, AREVA NP, Bechtel, Schnabel Engineering, REI, and WLA. The NRC audit team verified that individuals were properly qualified and indoctrinated to perform safety-related work. Records reviewed included training record forms, checklists, and attendance sheets. All training was documented in the appropriate training record forms in accordance with procedures. No issues were identified.

c. Conclusions

The NRC audit team concluded that the training process requirements reviewed by the NRC audit team were implemented as applicable by UNE and its contractors. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the Calvert Cliffs COLA.

3.12 10 CFR PART 21 IMPLEMENTATION

a. Audit Scope

The NRC audit team reviewed the process for implementing 10 CFR Part 21 regulations for reporting defects and noncompliances. The review included contractual provisions imposed by UNE concerning Part 21 reporting, policy and procedures, and imposition of Part 21 requirements on sub-suppliers.

b. Observations

Section P, "Corrective Action," of the UNE QAPD states that significant conditions adverse to quality shall be evaluated for reportability to the NRC (when required) in accordance with 10 CFR Part 21 and reported, when warranted. In addition, UNE procedure LS-AN-201, "Implementation of 10 CFR Part 21 and 10 CFR 50.55(e) During Construction," Revision 1, dated December 20, 2007, describes the requirements for conducting the evaluations, reports, notification, postings, procurement, and records for compliance with 10 CFR Part 21.

The NRC audit team verified that UNE procurement documents associated with the preparation of the Calvert Cliffs COLA project impose explicit 10 CFR Part 21 requirements on the primary contractor, Bechtel, and its subcontractors. A selection of procurement documents was reviewed and each contained a statement regarding the

applicability of the provisions of 10 CFR Part 21 and the name of the management position within UNE to notify of potential deviations.

The NRC audit team observed that posting requirements of 10 CFR Part 21, Section 21.6, were met and that notices were placed in a conspicuous place located in the UNE offices. The NRC audit team noted that UNE had not yet had reason to use its Part 21 program.

c. Conclusions

The NRC audit team concluded that the Part 21 requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the audit team, implemented as required by the applicant's procedures to support the Calvert Cliffs COLA development program. The NRC audit team did not identify any issues requiring additional action by the applicant prior to completion of the COLA.

3.13 CONSISTENCY WITH REGULATORY GUIDE 1.206, "COMBINED LICENSE APPLICATIONS FOR NUCLEAR POWER PLANTS," JUNE 2007

a. Audit Scope

The NRC audit team reviewed selected parts of the draft COLA, specifically the COL items, to assure that the COLA provided sufficient information to address these items. The NRC audit team compared the draft FSAR with the guidance contained in RG 1.206, Section C, Part I, "Standard Format and Content of Combined License Applications for Nuclear Power Plants - Light-Water Reactor Edition."

b. Observations

The NRC audit team reviewed the COL items in draft FSAR Chapters 3, 5, 6, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, and 19. There are no COL items in Chapters 4, 7, and 15. The NRC audit team identified five COL items that were not identified in the draft FSAR and were not on the UNE COL tracking system. These COL items were added to the UNE tracking system and the draft FSAR was modified to identify the previously missing COL information during the audit consistent with UNE procedures. During discussions with the UNE staff, it was identified that one of the COL items was missing from the associated chapter of the EPR design certification (DC) FSAR. Therefore, when the chapter author compared the COLA FSAR chapter to the EPR Design Control Document (DCD), the COL item was not there to be included.

The NRC audit team identified that the response to COL item 8.4-2 was incorrect. Specifically, the response identified that based on a review of FSAR Section 2.3, no hurricanes had ever occurred at the Calvert Cliffs site. However, FSAR Section 2.3, Revision 0, identifies that hurricanes had occurred at the Calvert Cliff site. Contrary to the requirements of UNE LS-AN-1091, "UniStar Writer's Guide for the Development of the Combined License Application," Revision 1, dated January 10, 2008, review of the technical input for this COL item by UNE failed to identify this error. During the audit,

UNE opened Condition Report 2008-2 to address this failure consistent with UNE procedures.

c. Conclusions

The NRC audit team concluded that the draft Calvert Cliffs FSAR chapters reviewed are consistent with the format and content prescribed in RG 1.206 and will support NRC staff review in accordance with the SRP. The NRC audit team did not identify any issue related to RG 1.206 compliance that requires correction prior to COLA submittal.

4.0 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on January 22, 2008, the NRC audit team discussed the scope of the audit, outlined the areas to be reviewed, and established interfaces with UNE, and its sub-supplier's staff and management involved in the Calvert Cliffs COLA development. In the exit meeting on January 25, 2008, the NRC audit team discussed the audit activities conducted during the audit with representatives of UNE and its sub-supplier's management and staff.

5.0 PARTIAL LIST OF PERSONS CONTACTED

Name	Position	Organization
Ian J. Kalin	Procurement Engineer	UniStar Nuclear Energy***
Gerry van Noordennen	Regulatory Consultant	UniStar Nuclear Energy*
Raj Jolly	Project QA Manager	Bechtel*
Ken Conti	AREVA QA Manager	AREVA NP*
Martin Owens	AREVA PM COLA	AREVA NP*
David Murphy	Bechtel PE	Bechtel*
John Traynor	Director Q&PI	UniStar Nuclear Energy*
R M Krich	Sr. VP Regulatory Affairs	UniStar Nuclear Energy*
Ray Schiele	PM	UniStar Nuclear Energy*
Warren Dorman	QA Contractor	UniStar Nuclear Energy*
John Slack	Contractor	UniStar Nuclear Energy*
Dan Green	Consultant	UniStar Nuclear Energy*
John Price	Consultant	UniStar Nuclear Energy*
George Vanderheyden	President/CEO	UniStar Nuclear Energy***
Mike Milbradt	Manager PM	UniStar Nuclear Energy*
Steve Meyer	Supervisor Engineer - QA	Ameren UE**
Shawn Hughes	Sr. VP Project Management	UniStar Nuclear Energy**
Eric de Fraguier	Sr. VP Procurement Eng.	UniStar Nuclear Energy**

* Attended entrance and exit meeting
** Attended exit meeting
*** Attended entrance meeting