October 25, 2007

Peter Hastings
AP1000 Reference Plant Licensing Lead
NuStart Energy Development, LLC
200 Exelon Way
M/S KSA 3-N
Kennett Square, PA 19348

SUBJECT: NRC AUDIT REPORT ON THE REVIEW OF DUKE ENERGY'S WILLIAM STATES LEE III NUCLEAR STATION AND TENNESSEE VALLEY AUTHORITY'S BELLEFONTE NUCLEAR PLANT COMBINED LICENSE APPLICATIONS

Dear Mr. Hastings:

On July 30 - August 3, 2007, U.S. Nuclear Regulatory Commission (NRC) staff audited the development programs for Duke Energy's William States Lee III Nuclear Station (Lee) and Tennessee Valley Authority's (TVA) Bellefonte Nuclear Plant (Bellefonte) combined license applications (COLA). This audit occurred at the Enercon Services Inc., facility in Mount Arlington, New Jersey. The enclosed audit report presents the details of these activities.

The NRC auditors reviewed the implementation of selected portions of the Duke Energy and TVA and their contractors' quality assurance programs related to the Lee and Bellefonte COLA development programs, respectively. The NRC staff also reviewed quality activities performed to support the development of the Lee and Bellefonte COLAs. During this audit, the NRC audit team identified several issues associated with the implementation of the Lee and Bellefonte COLA programs that should be addressed prior to submittal of these applications. These issues are described in the attached audit report as audit response requests (ARRs), and you are requested to respond to these ARRs before or as part of your COLA submittal.

In accordance with §2.390, "Public inspections, exemptions, requests for withholding," of the *Code of Federal Regulations*, 10 CFR 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 electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Document Access and Management System, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/

Stephen R. Monarque, Project Manager
Division of New Reactor Licensing
Office of New Reactors

Enclosure: As stated

cc: Gary W. Curtis
Tennessee Valley Authority
1101 Market Street,
LP 5A-C
Chattanooga, Tennessee 37402-2801

cc: Mailing Lists:

In accordance with §2.390, "Public inspections, exemptions, requests for withholding," of the *Code of Federal Regulations*, 10 CFR 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 electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Document Access and Management System, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/

Stephen R. Monarque, Project Manager
Division of New Reactor Licensing
Office of New Reactors

Enclosure: As stated

cc: Gary W. Curtis
Tennessee Valley Authority
1101 Market Street,
LP 5A-C
Chattanooga, Tennessee 37402-2801

cc: Mailing Lists:

Distribution:

Public	KHeck	JSebrosky
RidsNroDnrlNwe1	ARivera-Verona	
RidsNroLAKGoldstein	MConcepcion-Robles	
SMonarque	SCleavenger	
RidsOgcMailCenter	YMalave	
RidsAcrsAcnwMailCenter	PHeher	
RidsRgn2MailCenter	RJackson	
KWInsburg	SCoffin	
GGalletti	JPeralta	

ADAMS Accession No.: ML072950515

OFFICE	DNRL/NWE1:LA	DNRL/NWE1:PM	DNRL/NWE1:BC
NAME	KGoldstein	SMonarque	SCoffin
DATE	10/ /07	10/25/07	10/25/07

OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS

Audit Report Nos:	Tennessee Valley Authority's (TVA) Bellefonte Nuclear Plant (Bellefonte): PROJ0740-2007-002; Duke Energy's William States Lee III Nuclear Station (Lee): PROJ0742-2007-002
Organizations:	TVA and Duke Energy
Project Contacts:	Peter Hastings AP1000 Reference Plant Licensing Lead NuStart Energy Development, LLC (NuStart) 200 Exelon Way M/S KSA 3-N Kennett Square, PA 19348
Nuclear Industry:	Enercon Services, Inc. (Enercon) is contracted to supply the combined license applications (COLAs) to TVA for the Bellefonte plant and to Duke Energy for the Lee plant. Enercon Services, Inc. is an engineering, environmental, technical and management services firm providing a broad range of professional services to private and government sector clients throughout the United States.
Audit Dates:	July 30 - August 3, 2007
Auditors:	Greg S. Galletti, Lead Inspector, NRO/DCIP/CQVP Kenneth Heck, Inspector, NRO/DCIP/CQVP Aida Rivera-Verona, Inspector, NRO/DCIP/CQVB Milton Concepcion-Robles, Inspector, NRO/DCIP/CQVB Sabrina Cleavenger, Reactor Systems Engineer, NRO/DCIP/CQVB Yanely Malave, General Engineer, NRO/DCIP/CQVP Patrick Heher, General Engineer, NRO/DCIP/CQVB Rahsean Jackson, Construction Engineer, RII Steven Monarque, Project Manager, NRO/DNRL Stephanie Coffin, Branch Chief, NRO/DNRL
Branch Chief:	Juan Peralta, Chief Quality and Vendor Branch 1 Division of Construction Inspection & Operational Program Office of New Reactors

ENCLOSURE 1

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 combined license applications (COLAs) for the Bellefonte and Lee nuclear plants. The audit was conducted at the Enercon Service Inc. Facility in Mount Arlington, New Jersey. 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* (Appendix B),
- Part 21, "Reporting of Defects and Noncompliance," to Part 50 of Title 10 of the *Code of Federal Regulations* (Part 21),
- Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," and
- 10 CFR 50.9, "Completeness and accuracy of information."

During this audit, the Nuclear Regulatory Comission (NRC) audit team identified several issues associated with the implementation of the Bellefonte and Lee COLA development programs that should be addressed prior to completion of the applications. These issues are described in this report as audit response requests (ARR).

1.1 AUDIT RESPONSE REQUESTS

- ARR-001 was identified and is discussed in Section 3.2 of this report.
- ARR-002 was identified and is discussed in Section 3.7 of this report.
- ARR-003 was identified and is discussed in Section 3.12 of this report.
- ARR-004 was identified and is discussed in Section 3.14 of this report.

2.0 STATUS OF PREVIOUS AUDITS

There were no previous NRC audits in support of the review of the Bellefonte and Lee COLA development.

3.0 AUDIT OBSERVATIONS AND OTHER COMMENTS

3.1 QUALITY ASSURANCE PROGRAMS

a. <u>Audit Scope</u>

The NRC audit team reviewed the quality assurance (QA) program requirements and the implementation process for Bellefonte and Lee COLA activities. Specifically, the NRC audit team reviewed the QA program manuals that govern

the implementation of quality activities performed by NuStart, Duke Energy, and their contractors for Bellefonte and Lee COLA activities.

b. Observations

The NRC audit team reviewed the NuStart, Duke Energy, and their contractors' policies governing QA programs to assure those policies provided an adequate description of the implementation requirements consistent with the applicable requirements of 10 CFR Part 50, Appendix B.

(i) NuStart QA Program

The NuStart QA program provides the basis for the control and performance of safety-related and quality-related activities associated with the Bellefonte COLA activities. Controls, as currently stated in the program, are based on NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," for contract oversight, corrective action, document control, and record management.

(ii) Duke Energy QA Program

The Duke Energy quality assurance program provides the basis for the control and performance of safety-related and quality-related activities associated with the Lee COLA activities. Duke Energy implements the existing quality assurance program topical report for its operating units for the areas of contractor oversight, corrective action, document control, and record management for activities associated with the Lee COLA development.

(iii) Enercon QA Program Plan

Enercon was contracted by both NuStart and Duke Energy to prepare the Bellefonte and Lee COLAs. The Enercon QA program provides the basis for the control and performance of safety-related activities associated with the Bellefonte and Lee COLA preparation. Controls, as currently stated in the program, are in compliance with the requirements of 10 CFR Part 50, Appendix B and reflect the guidance in ANSI/ASME N45.2-1977, "Quality Assurance Program Requirements for Nuclear Facilities," and NQA-1-1983 for contract oversight, corrective action, document control, and record management.

(iv) MACTEC Engineering and Consulting QA Program

MACTEC was subcontracted by Enercon to provide geotechnical field investigation, laboratory testing, and engineering analysis associated with site characterization activities. Enercon qualified MACTEC QA program to the execution and delivery of geotechnical field investigation and laboratory testing provided by MACTEC. The general format of the

MACTEC Quality Assurance Manual (QAM) followed the criteria for QA outlined in 10 CFR Part 50, Appendix B and ASME NQA-1-1994. Engineering analysis by MACTEC is performed under Enercon's QA program.

(v) Risk Engineering, Inc. QA Program

Enercon subcontracted to Risk Engineering, Inc. (REI) to obtain computational and expert consulting services in performing probabilistic seismic hazard and sensitivity analyses for the Bellefonte and Lee sites. The audit team reviewed the REI QAM and Software Quality Assurance Plan (SQAP). These quality documents covered all activities related to REI's services that were important to safety as specified in the Enercon service contract.

(vi) William Lettis & Associates, Inc.

Services for geotechnical evaluation of the site and engineering analysis were provided by William Lettis and Associates (WLA) under a subcontract with Enercon. Because WLA did not possess a QA program that met the requirements of 10 CFR Part 50, Appendix B, WLA performed work in accordance with MACTEC QA program for any geotechnical field work and under Enercon's QA program for any engineering analyses.

c. Conclusions

The NRC audit team concluded that the QA programs described above appropriately provided an adequate description for the implementation of quality activities consistent with the requirements of 10 CFR Part 50, Appendix B to support the Bellefonte and Lee COLA development programs. The NRC audit team did not identify any issues in this area requiring additional action by the applicants prior to completion of the COLA.

3.2 DESIGN CONTROL PROCESS

a. Audit Scope

The NRC audit team reviewed the implementation of Enercon's design control process for the Bellefonte and Lee COLAs. Specifically, the NRC audit team reviewed the policies and procedures governing the implementation of Enercon's design control process, and reviewed selected draft completed portions of the COLAs that have been reviewed and accepted by NuStart and Duke, respectively.

b. Observations

The NRC audit team reviewed Enercon's policies and procedures governing the design process to assure those guidelines provided an adequate description of the process and its implementation consistent with the requirements of Criterion III, "Design Control," of 10 CFR Part 50, Appendix B.

b.1 Design Control Policy and Procedures

Enercon's QA program states, in part, that design activities are documented in Project Planning Documents and accomplished in accordance with procedures to assure that applicable design controls are accomplished.

NuStart Project Planning Document, PPD-001, Revision 3, "Combined Operating License Application," (PPD-001), provides the general program direction for preparation of the COLA submittal, and includes requirements for major QA controlled activities involved in the project, including design control. The document provides a description of design inputs, including site data and calculations, and identifies additional procedural guidance for the preparation, documentation, and retention of design documentation.

Corporate Standard Procedure (CSP) 3.01 Revision 5, "Preparation and Control of Calculations" provides requirements and responsibilities for the preparation, design verification, approval, revision and control of calculations.

NuStart Project Procedure G-001 Revision 4, "COL Application First Draft/Annotated Outline Writer's Guide," (G-001), provides guidance to COLA preparers on: (1) achieving consistency on development of COL sections; (2) early understanding and identification of additional information inputs for the sections; (3) identifying potential challenges; (4) identifying the disposition of design control document (DCD) action items; (5) identifying NRC requirements and/or guidance; and (6) documenting the above.

Enercon Project Procedure G-002, Revision 6, "COL Application Preparation Instructions," (G-002), provides the guidance to COLA preparers on: (1) achieving consistency for the development of the application; (2) developing additional information inputs; (3) resolving potential challenges; (4) facilitating incorporation of DCD and early site permit (ESP) action item information; (5) assuring compliance with NRC regulations; and (6) documenting the above actions.

b.2 Implementation of Design Controls

The NRC audit team reviewed the Enercon's design control process, and the implementing procedures and policy guidelines governing the Enercon's design process applied to the Bellefonte and Lee projects. The NRC audit team verified that the guidance was consistent with the requirements for design control described in Criterion III of 10 CFR Part 50, Appendix B. The NRC audit team

verified that both G-001 and G-002 were being used in the development of draft COLA/Final Safety Analysis Report (FSAR) sections, as required. The NRC audit team verified that once a COLA/FSAR section was completed, proper internal and external reviews were performed.

The NRC audit team reviewed selected packages associated with the draft COLA/FSAR sections that were reviewed by the applicants. The NRC audit team review packages associated with (1) COL Action Items identified in the AP1000 DCD, (2) Departures from the DCD, and (3) Site-specific parameters calculations.

(i) COL Action Items:

The NRC audit team reviewed the work done by Enercon to address the COL action item identified in Section 15.7, "Radioactive Release" of the DCD Tier 1 Material. The NRC audit team verified that the work was performed consistent with the guidance provided in G-002.

As supporting information used for the development of Section 15.7, the NRC audit team reviewed the following calculation packages: (1) NuStart 001-FSAR-15.7- BCALC-002, Revision 0, "Postulated Liquid-Containing Tank Failure," and (2) NuStart 001-FSAR-15.7-BCALC-001, Revision 1, "Bellefonte FSAR Groundwater Velocity Calculation." The NRC audit team verified that the calculations were developed as required by CSP 3.01. The NRC audit team verified that the calculation packages included the calculation cover letter, the calculation revision status, the calculation design verification plan with a calculation design verification summary, the calculation design verification checklist and the calculation text section with the purpose, background, summary of results, references, assumptions, and design inputs.

The NRC audit team review a selected sample from the COL Action Items listed in Table 1.8-2 of the DCD Tier 2 Material. These packages included: (1) COL Item 3.7-4, "Reconciliation of Seismic Analyses of Nuclear Island Structures;" (2) COL Item 4.4-1, "Changes to Reference Reactor Design;" (3) COL Item 5.4-1, "Steam Generator Tube Integrity;" and (4) COL Item 19.59.10-3, "Internal Fire and Internal Flood Analyses." The NRC staff discussed these packages with Enercon staff, and for each COL item, the audit team verified that the associated package included the COLA text that addressed the COL action item. The NRC team verified that annotations were made in the right margin of the text for any statement of fact (SOF), open item (OI), or COL holder commitment (COM) that supported the information included in the COLA as required by G-002. The NRC audit team reviewed the associated SOF, OI, or COM for each of the packages. During the review of the packages and during conversations with Enercon staff, the NRC audit team noted that Enercon used regulatory and industry guidance available to include the proper amount of information needed for each of the COL action items. In addition, during the process of addressing the COL action items, Enercon

identified a few cases where additional information is needed based on as-procured equipment and/or as-built plant information. The NRC audit team noted that Enercon is designating those COL action items as commitments to be completed by the COL holder prior to fuel load.

The NRC audit team verified that design control requirements had been appropriately implemented consistent with the procedures for the development of COL Action Items. The NRC audit team did not identify any deficiencies in this area.

(ii) Departures from DCD:

The NRC audit team reviewed the process developed by the applicants for addressing potential departures from the Westinghouse AP-1000 DCD. Enercon Procedure G-002, describes design departures as a plant-specific deviation from design information in a standard design certification rule. As part of the development of the Bellefonte and Lee COLAs, a goal of the applicants was to have no safety-related departures from the Westinghouse AP-1000 certified design. During the design control review conducted by the NRC audit team, the applicant was requested to provide a comprehensive list of all known potential departures from the Westinghouse AP-1000 certified design under consideration for each respective COLA. The applicants identified approximately five potential departures, with only one potentially requiring system design modification for the Bellefonte plant service water system (SWS), which is a nonsafety-related auxiliary system. The remaining potential departures, which were common to both COLAs, were administrative in nature. The NRC audit team discussed the potential deviation regarding the Bellefonte SWS with the applicant and reviewed the preliminary COLA description in Section 9.2., “Water Systems,” which included changes to the standard text from the Westinghouse AP-1000 certified design document. The applicant noted that the detailed evaluation of the potential departure had not commenced at the time of the NRC audit.

The NRC audit team also reviewed the guidance developed by NuStart and Enercon to standardize the process for evaluation of potential departures and developing justifications for such departures. Although Enercon Procedure G-002 provides a description of the departure concept, the procedure lacks guidance on developing and documenting the justification of such departures. The applicant acknowledged this process weakness and stated that appropriate project management documents will be revised to address the issue. Therefore, as a result of this audit, the applicant is requested to provide a description of the actions taken to ensure that justifications for deviations from the certified design incorporated into the COLA are performed in accordance with appropriate project management documents and that such justifications are documented. This is identified as audit response request (ARR-001).

(iii) Site-specific parameters calculations:

The NRC audit team reviewed the work done by Enercon to compare the AP1000 DCD site parameters to Bellefonte site characteristics to verify that site characteristics are bounded. The NRC audit team selected three samples to verify that design control requirements had been appropriately implemented. The sample included: (1) site specific COL action item 2.5-2, “Safe Shutdown Earthquake (SSE);” (2) site specific COL action item 2.5-4, “Shear Wave Velocity;” and (3) site specific COL action item 2.4-2, “Flood Level.”

Enercon contracted William Lettis and Associates (WLA) to perform the SSE and shear wave velocity site specific information for the Bellefonte COLA. The NRC audit team discussed with the senior WLA engineer the process that WLA implemented under Enercon's QA program. The NRC audit team verified that calculations in this area were performed consistent with Enercon's procedures. The audit team did not find any deficiency in the work WLA performed in this area working under Enercon's QA program.

The NRC audit team reviewed and discussed with members of the Enercon staff the flood level information and calculations. Section 2.4.2 of the COLA for Bellefonte addresses the numbers and supporting information for this area. The NRC audit team noted that Enercon used a TVA calculation “Flood Reassessment for Effects of Dam Safety Modifications,” RIM number [B45-980326001], dated March 3, 1998, as input in this calculation. This calculation addresses the flood characteristics for all TVA facilities, including Bellefonte, based on the need to update the dam and river characteristics close to TVA facilities. The NRC audit team did not identify any deficiencies in the work performed in this area.

c. Conclusions

The NRC audit team concluded that, with the exception noted above, the design 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 its sub-suppliers’ procedures to support the Bellefonte and Lee COLA development programs. The NRC audit team did identify an issue requiring additional action by the applicant prior to completion of the COLA (ARR-001).

3.3 PROCUREMENT DOCUMENT CONTROL

a. Audit Scope

The NRC audit team reviewed Enercon's procedural controls for assuring that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in procurement documents. The scope of the evaluation included review of Enercon corporate procedures, specific requirements of contractor QA programs, purchase orders, quality vendor lists, quality and technical requirements, and other related documents. Although both Duke Energy and NuStart documentation were reviewed, the work breakdown structures and contracting arrangements for both projects are virtually identical. Since, the conclusions reached as to the effectiveness of procurement document controls for both contracts are the same, only the details of the Duke Energy procurement process are described in this section.

b. Observations

b.1 Policies and Procedures for Procurement Document Control

The NRC audit team reviewed Enercon's procedural controls for assuring that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in procurement documents. Controlling documents include corporate procedures CSP 2.04, "Preparation of a Certificate of Conformance," CSP 17.0, "Issuance of Project Deliverables," and applicable sections of the Enercon Quality Assurance Plan (QAP).

Section 4.0 of the QAP provides general and specific requirements for controlling procurement documents. Procurement documents are controlled to ensure that requirements, including the basis of acceptance of items or services, or fully and correctly specified. Technical and quality requirements may be detailed in the procurement document or in referenced documents, which are referenced by revision and applicable parts. Specific technical requirements include design specifications; design documents that identify and define essential characteristics, special processes, and instructions for shipping and handling.

Specific quality requirements include identification of: (1) inspections and tests; (2) designated hold points; (3) right of access to subcontractor facilities and records; (4) QA programs to be documented and applied by subcontractors that cover the applicable requirements of the Enercon QA program, including 10 CFR Part 21; (5) required records or other documentation and their retention periods; (6) types of non-conformance to be submitted to Enercon review/approval; and (7) provisions for extending procurement contract requirements to lower tier subcontractors.

b.2 Duke Energy Purchase Order

The Duke Energy purchase order associated with activities associated with the preparation of the COL application was prepared and processed in accordance with Duke Energy's QA program, which has been approved by the NRC for its licensed nuclear facilities. The NRC audit team reviewed the authorizing purchase order (PO) and agreement, dated December 29, 2005. Prior to contract authorization, Duke Energy evaluated and approved Enercon's QAP for the specific scope of activities contracted under the PO. Services procured under the contract are classified as "safety-related," which require these services to be provided under Enercon's Appendix B QA program; quality and technical requirements are to be invoked on their sub-contractors.

Quality requirements, similar to those identified in section 3.3(b.1) of this report were invoked. These requirements included issuance of a certificate of conformance upon contract completion, and attesting that contract activities and documents conform to the technical and quality requirements of the contract. The reporting requirements of 10 CFR Part 21 were imposed on activities conducted pursuant to the contract and extended to all sub-suppliers.

Quality and applicable technical requirements of the Duke Energy contract were extended through Enercon purchase documents to all sub-suppliers. Enercon performs quality surveillances and auditing of internal and sub-supplier activities and provides reports of these oversight activities to Duke Energy. Duke Energy retains access rights to subcontractor facilities and records for inspection.

b.3 MACTEC Purchase Order

The Enercon purchase order associated with contract activities for the preparation of the Lee COLA was authorized on February 1, 2006. Under the contract, MACTEC was charged to collect and analyze geotechnical and geophysical data as part of preparing section 2.5 of the FSAR. MACTEC was responsible for performing all drilling, data collection, and laboratory analysis of data in accordance with its QAP. The NRC audit team verified that MACTEC was maintained on Enercon's Qualified Vendors List and had been qualified as an Appendix B on January 11, 2006, on the basis of an audit conducted from December 14-16, 2005.

Under the Professional Services Agreement, MACTEC was contracted to perform field activities associated with exploration and geotechnical data collection. This included the furnishing of drill rigs and specialized equipment; drilling operations; the collection, logging, and handling of samples; lab analyses; geophysical surveys; and support documentation. Under the contract, Enercon provided the geologist overseeing drill rig operations and performing logging of associated activities. The contract deliverable is a report, including certified boring logs and lab analyses with supporting technical documentation. Contractual quality requirements invoke 10 CFR Part 50 Appendix B, Part 21, and NRC regulatory guides associated with COL site and laboratory investigations. Task

authorizations and modifications to the technical scope of the contract to drill additional holes and provide for continuous water sampling were also reviewed.

b.4 WLA Purchase Order

The Enercon purchase order associated with contract activities for the preparation of the Lee COLA was authorized on January 1, 2006. Standard contract provisions for this professional services agreement were provided, with quality requirements identified in Exhibit A of the agreement, "Quality Assurance Requirements." Under the general provisions of the contract, WLA was charged with performing activities at the owner's site under the approved MACTEC QA program. All other QA activities were conducted in accordance with the Enercon QA program. MACTEC personnel, working closely with WLA, generated reports and drafts of section 2.5 of the FSAR, whose backup analysis and calculations were prepared in accordance with the Enercon QA program.

The QA requirements were invoked by the master Duke Energy purchase order. WLA activities at the owner's site were performed under the MACTEC QA program; all other activities were performed under the Enercon QA program. Applicable QA requirements were invoked through procurement documents on sub-suppliers.

Task authorizations associated with the work were reviewed; authorization was given for coordination of work activities associated with field exploration and geotechnical data. Subsequent authorization was given for field changes and transfer of work scope between WLA and MACTEC personnel. Separate authorization was given for technical coordination of specialty contractors, (i.e., MACTEC, University of Texas, and REI) who were charged with performing the probabilistic seismic hazard analysis and developing the design ground motion in compliance with regulatory requirements.

b.5 Subcontractors for Geological Technical Data

Specialty work performed by subcontractors at the owner's site was conducted in accordance with "MACTEC Master Subcontract Agreement with Subcontractors," dated February 8, 2004. This subcontract invoked standard contract provisions that imposed flow-down provisions from the Duke Energy subcontract on subcontractors performing safety-related activities associated with the preparation of the COLA. The agreement imposed the requirement that work be performed in accordance with the applicable portions of the owner's QA program and the MACTEC QA program. Specifically, applicable requirements were included for calibration of measurement and test equipment, software validation, personnel training and qualification, corrective actions, and documentation of work. Conformance to technical requirements specified by contract, witnessing of work, right of inspection, acceptance of work by MACTEC, and corrective actions in response to MACTEC identified deficiencies were included as contract requirements.

c. Conclusions

The NRC audit team concluded that the procurement document control process requirements have been appropriately translated into implementing procedures and, for those activities reviewed by the audit team, implemented as required by the applicants' and its sub-suppliers' procedures to support the Bellefonte and Lee COLA development programs. The NRC audit team did not identify any issues in this area requiring additional action by the applicants prior to completion of the COLA.

3.4 DOCUMENT CONTROL

a. Audit Scope

The NRC audit team reviewed the implementation of the NuStart, Duke Energy, and Enercon processes for document control for the Bellefonte and Lee COLA programs. Specifically, the NRC audit team reviewed policies and procedures governing their document control processes to verify the overall extent and effectiveness of their programs. The NRC audit team verified that the quality-related documents were developed, reviewed, approved, issued, used, and revised under an established program.

b. Observations

b.1 Policies and Procedures for Document Control

Enercon's QA program states, in part, that document control covers review for adequacy and issuance of documents, the revision and disposition of superseded documents, and required notification of affected organizations.

NuStart Project Procedure G-001 provides guidance to preparers on: (1) achieving consistency on development of COL sections, (2) early understanding and identification of additional information inputs for the sections, (3) identifying potential challenges, (4) identifying the disposition of DCD action items, (5) identifying NRC requirements and/or guidance and (6) documenting the above actions.

Enercon Project Procedure G-002 provides the guidance to preparers on (1) achieving consistency for the development of the application; (2) developing additional information inputs, (3) resolving potential challenges, (4) facilitating incorporation of DCD and ESP action item information, (5) assuring compliance with NRC regulations, and (6) documenting the above actions.

b.2 Implementation of Document Control Programs

The NRC audit team reviewed selected packages associated with the draft COLA/FSAR sections that were reviewed by the applicants. The NRC audit team reviewed packages associated with (1) COL Action Items identified in the AP1000

DCD, (2) Departures from the DCD, and (3) Site-specific parameters calculations. The NRC audit team reviewed these packages to verify that documents had been reviewed, approved, issued, and revised consistent with procedures.

The NRC audit team noted that the COLAs are developed in different stages with different revision numbers for each stage, where Revision A is the first draft of the individual sections of the COLA. Revision B is the second draft after resolution of all internal and external comments on each of the sections. Revision C is when the COLA sections are combined at a chapter level. Revision D is the COLA at chapter level after comment resolution by the applicants. Revision E is the final COLA ready to be submitted to NRC for review.

Enercon uses different electronic systems to track the development of the COLAs. Enercon uses the electronic system (eB) for NuStart AP1000 COLA development and reviews, and the electronic database management system (EDMS) is used for Duke Energy AP1000 COLA development and reviews. These systems track all design support information and provide interfaces of information between different sections. When information is updated, the change is automatically generated for all affected sections. In addition, when documents are prepared and are ready for comments, the documents are sent to the applicants for review via the respective electronic system. All comments from the applicants are entered on a comment resolution form for Enercon's review and proper disposition. The NRC audit team did not identify any concerns with the use of the electronic tracking systems.

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 audit team, implemented as required by the applicants' and its contractors' procedures to support the Bellefonte and Lee COLA development programs. 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 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

a. Audit Scope

The NRC audit team reviewed the implementation of the NuStart, Duke Energy, and Enercon processes for controlling purchased material, equipment and services for the Bellefonte and Lee COLA programs. Specifically, the NRC audit team reviewed the policies and procedures governing the process used to verify the quality of suppliers providing engineering services for Bellefonte and Lee COLAs design activities.

b. Observations

The NRC audit team reviewed the NuStart, Duke, and Enercon policies governing control of design engineering services and activities for the Bellefonte and Lee COLAs. These documents govern the implementation of quality activities performed for Bellefonte and Lee COLA design activities by NuStart, Duke, and Enercon.

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

Enercon's QA program states, in part, that for services procured by Enercon, acceptance would be accomplished by the review of documents produced, and may require verification of conformance to specifications by surveillance or audit of the activity.

Enercon Project Procedure G-002, Revision 6, "COL Application Preparation Instructions," provides the guidance to preparers on (1) achieving consistency for the development of the application; (2) developing additional information inputs, (3) resolving potential challenges, (4) facilitating incorporation of DCD and ESP action item information, (5) assuring compliance with NRC regulations, and (6) documenting the above actions.

NuStart Project Instruction PI-014, Revision 1, "NuStart COLA Review," provides guidance for performing reviews of COLA content and related documents.

b.2 Review of Activities

The NRC audit team reviewed the above program and implementing procedures governing the NuStart, Duke Energy, and Enercon control of purchased engineering services for the Bellefonte and Lee COLA programs. The NRC audit team verified that the guidance was consistent with the requirements for Control of Purchased Material, Equipment and Services as described in 10 CFR Part 50, Appendix B, Criterion VII. The NRC audit team verified that the Enercon process adequately specified the requirements for procurement of material, equipment and services, including the appropriate application of NuStart and Duke Energy invoked technical, engineering, and quality requirements on the POs, and for supplier audits for Approved Vendor List status.

As part of the implementation review, the NRC audit team verified that NuStart and Duke Energy had included appropriate level of quality requirements in the purchase orders, in addition to the quality requirements needed for sub-suppliers. The NRC audit team did not identify any deficiencies in this area.

The NRC audit team also reviewed the implementing procedures developed by NuStart and Duke Energy for the review and approval of COLA documents. As stated in PI-014, NuStart's and Duke's project managers use the electronic systems (eB and EDMS) during the different stages of the development of the

COLAs for review and comment. All comments are entered on a comment resolution form for Enercon's review and disposition. In addition, the PI-014 provides for additional review and approval by proper management when the final package is sent by Enercon. The NRC audit team did not identify any deficiency from NuStart or Duke Energy for the control of purchased material, equipment and services for the activities completed at the time of the audit.

The NRC audit team reviewed Enercon's control of purchased materials, equipments and services process, policy guidelines, and implementing procedures applied to the Bellefonte and Lee COLA projects. For the development of the Bellefonte and Lee COLAs, Enercon sub-contracted services for site-specific activities, including site characterization tests and calculations. Enercon uses implementing procedure G-002 to document the verification and acceptance of purchased services. The acceptance of contracted services will be documented when the final package is sent to each applicant/client. The audit team discussed with Enercon's QA manager this process for documentation. The audit team was able to verify through conversations with Enercon staff that proper review of documents produced by sub-contractors is performed before the documents are used.

The NRC audit team reviewed other quality records such as the Approved Vendor List information, Audit Reports, supplier responses to audit findings, and Enercon Corrective Action Request 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 material, equipment, and services process requirements, including the oversight of suppliers, have been appropriately translated into implementing procedures and, for those activities reviewed by the audit team, implemented as required by the applicants' and its contractors' procedures to support the Bellefonte and Lee COLA development programs. 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 TEST CONTROL

a. Audit Scope

The NRC audit team reviewed the implementation of QA measures related to test control associated with site characterization activities. Specifically, the NRC audit team reviewed procedures that described the controls implemented by contractors and suppliers 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

The NRC audit team reviewed the policies and procedures associated with test control, and conducted interviews with the project managers for NuStart and Duke Energy projects. The NRC audit team learned that test controls applicable to the Bellefonte and Duke Energy COLA activities were implemented by MACTEC and its subcontractors.

The NRC audit team reviewed MACTEC's QAM and procedures describing the requirements and responsibilities for the control of tests. The NRC audit team reviewed Section 11 of the MACTEC's QAM, which described the measures for controlling tests performed on materials or equipment and verifying test conformance to specified requirements. The audit team noted that measures were provided to ensure that (1) tests are conducted in accordance with written procedures or instructions; (2) procedures are reviewed and approved by responsible personnel; and (3) test results are documented and reviewed for accuracy and completeness.

Section 11 of MACTEC's quality assurance program description (QAPD) described the measures to control the tests of soil samples for use in preparation of information that was included in the COLA. MACTEC stated that tests are to be performed using acceptable industry standard methods such as American Society for Testing and Materials (ASTM). The NRC audit team noted that controls were in place to (1) designate the individual responsible for the activities conducted in the field; (2) ensure that testing criteria and requirements were followed; (3) evaluate exceptions to these criteria and requirements; (4) notify the client for consultation and permission before tests were conducted, and (5) document requirements for field and laboratory tests.

The NRC audit team reviewed Section 2 of the NuStart Bellefonte COL Project Geotechnical Work Plan, Revision 0, and dated April 17, 2006. This section contains the testing requirements associated with the field exploration activities. Controls require the use of procedures that include requirements, test conditions, and acceptance criteria in accordance with the MACTEC's QAM and implementing procedures.

b.2 Review of Test Control Activities

The NRC audit team reviewed a sample of testing procedures used for the collection of data. Below is a list of the procedures reviewed:

- Oyo P-S Suspension Seismic Velocity Logging
- Procedure for Using the Robertson Geologging Hi-Resolution Acoustic Televiewer (HiRAT)

- Standard Operating Procedure for Field Geophysical Surveys.

The NRC audit team confirmed that these procedures were based on ASTM standards for the particular tests.

The NRC staff also conducted a site visit during July 10-11, 2006, to observe COL pre-application subsurface investigation activities being conducted to obtain geotechnical/seismic data to support the Bellefonte COL application. As noted in the site visit report, the NRC staff confirmed that drilling operations were adequately being overseen by MACTEC or WLA geotechnical personnel. The NRC site visit report documented that the MACTEC activities were controlled by adequate procedures and standards with an appropriate level of supervisory and QA 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 applicant's and/or its sub-supplier's procedures to support the Bellefonte and Lee COLA development programs. 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 CONTROL OF MEASURING AND TEST EQUIPMENT

a. Audit Scope

The NRC audit team reviewed the implementation of QA measures associated with the control of measuring and test equipment (M&TE). Specifically, the NRC audit team reviewed procedures that described the controls implemented by contractors and suppliers to ensure that M&TE utilized in site characterization activities were adequately controlled.

b. Observations

b.1 Policies and Procedures for M&TE

The NRC audit team reviewed Section 12, "Control of Measuring and Test Equipment," of the Enercon QAM. This section describes the requirements and responsibilities for the control of M&TE. The NRC audit team noted that this section adequately defined the responsibilities for the maintenance, control, calibration, documentation, and identification of M&TE used in activities affecting quality. Controls require the use of calibrated tools, gages, instruments, and other M&TE used for laboratory or field testing activities. Additionally, this section requires that calibration be performed against known nationally recognized standards, and also provides controls for M&TE found out of calibration.

The NRC audit team confirmed that quality-related activities associated with M&TE were controlled by procedures and instructions developed in accordance with MACTEC's QAM.

b.2 Implementation of Sub-Supplier Programs for M&TE

The NRC audit team reviewed Section QS-12, "M&TE," of the MACTEC's QAM. This section invokes measures for the control of M&TE. Specifically, these measures include provisions for evaluating the measurement and test results obtained from equipment that is found to be out of calibration. Such equipment was not to be used until it had been repaired or re-calibrated and found acceptable for use. Any results determined to be invalid due to calibration errors were required to have a nonconformance written and processed as specified in the applicable portions of the MACTEC QAPD. M&TE equipment utilized was required to be listed on the test data sheet and meet the criteria as specified in the chosen test method. The NRC audit team verified that these controls were consistent with 10 CFR Part 50, Appendix B requirements.

The NRC audit team noted that MACTEC's QAPD, Quality Section QS-12, "M&TE," invoked additional measures for the control of measuring and test equipment. MACTEC also utilized its Geotechnical Work Plan to delineate requirements for calibration of instrumentation used for testing activities. Attachment 8 of the Geotechnical Work Plan required maintaining of calibration documentation of field and laboratory equipment.

With respect to the Duke/Lee COLA, the audit team reviewed several Enercon and MACTEC surveillance reports related to site investigation activities. The audit team reviewed Surveillance Report No. DUK-SURV-2006-02, conducted on April 10-12, 2006. This surveillance was conducted by Enercon to evaluate selected elements of the MACTEC's QA program including their implementation in the area of geotechnical subsurface investigations. The report identified a potential issue regarding the use of equipment and instruments calibrated by a vendor not implementing an 10 CFR Part 50, Appendix B QA program. This finding was entered in the Enercon's corrective action program and issued to MACTEC under corrective action request DUK010-CAR-01. To follow-up on this issue, the audit team reviewed surveillance report no. CS-8, conducted by MACTEC on April 13, 2006. This surveillance report verified the implementation of Geovision's controls for M&TE utilized during site characterization activities. The surveillance report highlighted a potential issue with the calibration of a piece of equipment. However, the surveillance report was not documented in accordance with the requirements of MACTEC's QA procedures. The audit team requested help from Enercon to understand the purpose of the surveillance report and the potential finding due to its lack of detail. After discussions with Enercon personnel, the audit team learned that the MACTEC QA individual conducting the surveillance on Geovision's activities was aware of the corrective action request by Enercon (DUK010-CAR-01), and conducted additional field observations of Geovision's activities when he observed a piece of equipment in use without a calibration record. Enercon personnel stated that a separate finding was not

initiated because this issue was already identified by Enercon in Surveillance Report No. DUK-SURV-2006-02. The audit team noted that DUK010-CAR-01 was closed on June 15, 2006, after Enercon verified that equipment used in the field was calibrated by a NVLAP accredited laboratory, and also confirmed that the piece of equipment in question was not required to be calibrated as described in ASTM Standard D 5777.

The audit team found that, although Enercon identified in its corrective action program the potential finding associated with the use of equipment without a calibration record, MACTEC's surveillance report CS-8 did not clearly describe the potential finding associated with the use of equipment with undetermined calibration status. In addition, the audit team could not find a nonconformance and corrective action report generated by MACTEC describing this potential deficiency. The audit team noted that this is not consistent with MACTEC's QA Project Document and associated procedures. Therefore, as a result of this audit, the applicant is requested to provide a description of the actions taken to ensure that surveillances conducted by suppliers and sub-suppliers are properly documented. This is identified as audit response request (ARR-002).

The NRC staff also conducted a site visit during July 10-11, 2006 to observe COL pre-application subsurface investigation activities being conducted to obtain geotechnical/seismic data to support the Bellefonte COL application. As noted in the site visit report, the NRC staff reviewed calibration records for some of the equipment used for the standard penetration tests. No deficiencies were found during the site visit. A similar site visit was also conducted on May 15-16, 2006, by the NRC for the Lee COL application to be submitted by Duke. Calibration records for this project were also reviewed by the NRC staff and were found to be adequate.

c. Conclusions

The NRC audit team concluded that, with the exception noted above, 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/or its sub-supplier to support the Bellefonte and Lee COLA development programs. However, the NRC audit team identified one issue in this area requiring additional action by the applicant prior to completion of the COLA (ARR-002).

3.8 HANDLING, STORAGE, AND SHIPPING

a. Audit Scope

The NRC audit team reviewed the implementation of Enercon's process for handling, storage, and shipping of soil samples for the Bellefonte and Lee COLA development. 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

(i) Enercon Services, Inc.

The NRC audit team reviewed Section 13 of Enercon's QAM, "Handling, Storage, and Shipping." It describes the responsibilities to control and protect materials and equipment consistent with 10 CFR Part 50, Appendix B requirements. The NRC audit team also reviewed Enercon's QA Project Planning Document (PPD) for the NuStart project and noted that quality-related activities associated with handling, storage, and shipping were controlled by procedures and instructions developed in accordance with MACTEC's QAM.

(ii) MACTEC Engineering and Consulting, Inc.

The NRC audit team reviewed Section 13 of MACTEC's QAM, Rev. 1, titled "Handling, Storage, and Shipping of Items and Samples." It established requirements for assuring that methods are used in the handling, storage, preservation, packaging, and shipping of samples. The NRC audit team also reviewed the controls for the handling, storage and shipping of items contained in MACTEC's QAPD. The QAPD stated that samples are to be identified, traceable to the origin and location, maintained in chain of custody, and stored in a locked facility with controlled access.

The NRC audit team reviewed MACTEC's "NuStart Bellefonte COL Project Geotechnical Work Plan," Revision 0, dated April 17, 2006. Attachment 7 of the Geotechnical Work Plan described the controls for the handling, shipping, and storage of soil samples. The NRC audit team noted that the controls required the use of ASTM standards for preserving and transporting soil samples.

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

The NRC audit team verified that instructions for: (1) marking and labeling packaging; (2) shipping and handling packaging; and (3) storing packaged items, were developed and used within an established program. The NRC audit team reviewed the following supporting documents and held "handling, storage, and shipping" related discussions with Enercon personnel. Documents reviewed included:

- MACTEC Engineering and Consulting Document - QAM, Quality Section QS-13, "Handling and Storage of Samples," Revision 0 (April 14, 2006)

- MACTEC Engineering and Consulting Document - Geotechnical Data Collection Plan for the Nustart/Enercon Combined Operating License Application, Revision 5 (April 17, 2007)

The NRC audit team also verified the controls implemented by two of MACTEC's subcontractors, University of Texas (UT) and Severn Trent Laboratories. The NRC audit team reviewed two audit reports of laboratory testing activities conducted by UT and Severn Trent Laboratories. The audit checklist utilized by MACTEC verified the use of procedures/instructions, adequate cleanliness, and control and preservation of samples. The NRC audit team noted that in both instances samples were adequately identified, traceable to the origin and location, maintained in chain of custody, and stored in a locked facility with controlled access. As detailed in both audit reports, the NRC audit team noted that controls for handling, storage, and shipping were found adequately implemented by UT and Severn Trent Laboratories.

The NRC staff also conducted a site visit during July 10-11, 2006, to observe COL pre-application subsurface investigation activities being conducted to obtain geotechnical/seismic data to support the Bellefonte COL application. As described in the site visit report, the NRC staff noted that jar samples were collected, and stored in accordance with ASTM D4220, "Standard Practices for Preserving and Transporting Soil Samples." Also, the NRC staff verified that field soil classification was performed in accordance with ASTM D2487, "Unified Soil Classification System."

The NRC audit team concluded that the organizations, assigned with the responsibility of proper and appropriate handling, storage, and shipping of materials for the Bellefonte and Lee projects had adequate handling, storage, and shipping procedures in place.

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 applicants' and/or its sub-suppliers' procedures to support the Bellefonte and Lee COLA development programs. The NRC audit team did not identify any issues in this area requiring additional action by the applicant prior to completion of the COLA.

3.9 CORRECTIVE ACTIONS

a. Audit Scope

The NRC audit team reviewed Enercon's corrective action process associated with the preparation of the NuStart and Duke Energy COLAs. Specifically, the NRC audit team reviewed the policies and controlling procedures associated with the projects, and reviewed the status of all corrective actions which are

predominately identified through the audits and surveillances described in the Project Plans for the COLA projects.

b. Observations

b.1 Policies and Procedures for Corrective Actions

Enercon corporate procedure CSP 16.0 prescribes controls to ensure correction of conditions adverse to quality of safety-related items or services within Enercon or at a subcontractor facility. Responsibility for determining the significance of a condition or event, initiation of actions to correct adverse conditions, and determination of recurrence controls are the responsibility of the QA Manager. Both the Project Manager and the QA Manager are responsible for determining whether a reported adverse condition is reportable under 10 CFR Part 21. Verification of the adequacy and completion of corrective actions are the responsibility of the QA Manager, the Project QA Engineer, and the Lead Auditor responsible for a particular audit.

Documentation of corrective action(s) include: (1) description of the identified deficiency; (2) cause analysis; (3) immediate actions taken to correct the deficiency; and (4) recurrence control, if applicable. Upon verification that immediate actions and applicable recurrence controls have been completed, the Corrective Action Report may be closed out. The report and any associated documents are retained in the project files as a quality record.

b.2 Corrective Action Status

The NRC audit team reviewed Enercon's corrective action status report, dated July 27, 2007. Several files for completed and in-process corrective actions were reviewed. None of the corrective action reports identified deficiencies as significant or reportable under 10 CFR Part 21. The NRC Audit team determined these Corrective Action Reports (CARs) were adequately addressed; the 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.

As of the date of the status report, all CARs had been closed or were in the process of closure verification by the QA organization, with exception of two audit findings issued (MTAR-CAR-13. MTAR-CAR-15), associated with deficiencies in subcontractor training and qualifications. The adequacy of corrective actions taken to resolve these findings, had not yet been evaluated by Enercon QA because the response from the sub-supplier was received by Enercon approximately a week prior to the NRC audit. Additionally, the NRC audit team reviewed two corrective action requests, issued just prior to the NRC audit, that did not appear on the corrective action status report. These deficiencies, identified during an audit of subcontractor Burns & Roe Associates, were associated with preparation of calculation packages and software verification for the COLAs (BNR-CAR-01 and -02). These calculation package issues were administrative in nature. Based on review of the audit report and documented

description of the adverse conditions, the NRC audit team concluded that the proposed corrective actions to correct the administrative issues and to ensure software verification is completed prior to release of the information to the applicant was adequate to address the issues.

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 audit team, implemented as required by the applicants' and/or its sub-supplier's procedures to support the Bellefonte and Lee COLA development programs. The NRC audit team did not identify any issues requiring additional action by the applicants prior to completion of the COLAs.

3.10 QA RECORDS

a. Audit Scope

The NRC audit team reviewed QA program record controls to verify that the QA program provides for the preparation of sufficient records to furnish documentary evidence of activities affecting quality. 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. In addition, the audit team verified that the procedures and policies were developed to adequately implement the requirements for record retention and to ensure adequate configuration control was applied to quality records.

b. Observations

b.1 Policies and Procedures for QA Records

The NuStart and Duke Energy QAMs, state that sufficient records, such as corrective action documentation, reports of reviews, audits, assessments, qualifications of personnel, and procedures will be maintained to furnish evidence of activities affecting quality.

Section 17.0 of Enercon's QAM, Revision 9, prescribes requirements for QA records that furnish documentary evidence regarding the quality of safety related items, or the performance of activities affecting the quality of such items.

CSP 17.03, Revision 1, "Quality Assurance Records", of Enercon's "Corporate Quality Assurance Program Manual" prescribes the activities required for the collection, storage, and maintenance of QA records associated with the design, manufacture, construction, and operational phase activities of nuclear power plants. It provides generic record retention requirements between Enercon and its clients. In addition to the generic requirements given in CSP 17.03, specific record retention requirements are provided in the "Project Planning Document and Project Instructions" for both NuStart and Duke Energy.

Section 2.2, “Procedure 2: Quality Assurance Records,” of Risk Engineering's QAM, specifies the requirements for filing and retention of QA records, for both the NuStart and Duke Energy projects.

Section 17, “Quality Assurance Records,” of MACTEC's QAM, establishes measures for the collection, storage, retention, retrieval, and maintenance of records that furnish documentary evidence of quality, for both the NuStart and Duke Energy projects.

b.2 Review of QA Records

The NRC audit team reviewed sample records of Enercon to verify that the procedures related to QA record control are being adequately implemented. The sample included records for: (1) the Project Planning Document, including Project Instructions for both, NuStart and Duke Energy; (2) Audits Reports and Surveillances for MACTEC and Risk Engineering; and (3) Enercon's Training Records. The NRC audit team also spoke with Enercon's QA Manager to discuss their process for collection, storage, and maintenance of QA records. The NRC audit team visited Enercon's record room to verify that their implementation of the filling system, maintenance, and security associated with their storage facility was done in accordance with their procedures. The NRC audit team did not identify any deficiencies in this area.

The NRC audit team reviewed sample records of NuStart to verify that the procedures related to QA record control are being adequately implemented. The NRC audit team noted that NuStart PI-009, “Quality Assurance Plan,” NuStart PI-010, “Corrective Action Process,” and NuStart PI-011, “Audit and Assessment Process,” did not have signatures of approval. The audit team discussed this issue with the applicant and learned that NuStart PI-009, NuStart PI-010, and NuStart PI-011, that are used for quality-related activities, were reviewed and approved using an electronic database. Additionally, NuStart PI-001, “NuStart Energy Organization Plan,” which describes procedure development process requirements did not provide explicit guidance for written approval by the NuStart President or the QA Lead for quality-related documents in accordance with the NuStart QAM. This issue was identified by TVA during a previous audit of the NuStart COLA development program. In response, NuStart opened a CAR, (CAR-07-005), dated July 26, 2007. The NRC audit team reviewed the actions identified in the CAR to correct the problem. Specifically, the CAR states that NuStart will add the appropriate endorsement process to NuStart PI-001 for quality-related documents. At the time of the NRC audit, those corrective actions had not yet been implemented.

The NRC audit team also reviewed Duke Energy's Nuclear System Directive 208, “Problem Investigation Process (PIP),” and Duke Energy's Nuclear System Directive 229, “Evaluation and Reporting of Potential Defects and Noncompliance Per 10 CFR Part 21”, to verify that these procedures were adequately reviewed

and approved in accordance with the program requirements. The NRC audit team did not identify any deficiencies in this area.

c. Conclusions

The NRC audit team concluded that 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 applicants' and/or its sub-suppliers' procedures to support the COLA development program. The NRC audit team did not identify any issues requiring additional action by the applicant prior to completion of the Bellefonte and Lee COLAs.

3.11 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. Audit findings reported by the audits were reviewed for any adverse significance they may have on the results of the COLAs. Corrective actions to resolve deficiencies identified by the findings and observations were reviewed for adequacy and timely resolution.

The audits of the Enercon QA program by the Nuclear Procurement Issues Committee and Enercon's internal audit consisted of project activities at the Mount Arlington office that are applicable to both the NuStart and Lee COLAs. For meteorological activities conducted by the Enercon Oklahoma City office and projects tasks contracted to sub-suppliers, surveillances specific to the Lee COL application were reviewed. However, controlling procedures, project personnel, and sub-suppliers activities of both projects are very similar and the conclusions reached with regard to the Duke Energy contract can reasonably be applied to the NuStart contract.

b. Observations

b.1 Audit Policies and Procedures

Section 18.0 of the Enercon QAP describes the audit program for determining the effectiveness of the Enercon program in implementing quality requirements consistent with Appendix B to 10 CFR Part 50. Section 18.9 also describes the requirements for qualifications of auditors, qualification and certification of lead auditors, audit planning and performance, and audit reporting, notifications and closeout.

CSP 17.0 establishes the requirement and defines the responsibilities and methodology for the performance and documentation of surveillance activities involving safety related items or services. Surveillances are conducted for the purpose of verifying that Enercon personnel and subcontractors are performing

activities in accordance with applicable codes, standards, and procurement documents.

CSP 18.0 establishes the method used to review and approve commercial grade services, such as the sample analyses conducted by the Argonne National Laboratory.

Project plans summarize and translate client procurement requirements and Enercon policies and procedures into a controlling document for implementing safety-related activities. The Project Plan specifies applicable corporate standards and procedures, and industry and regulatory documents that govern activities to be conducted in accordance with Appendix B to 10 CFR Part 50.

Section 7.0 of the Project Plan establishes the audit/inspection schedule and frequencies for project activities.

b.2 Review of Audit Activities

(i) Internal and External Audit Activities

The NRC audit team selected a representative sample of the audits associated with the activities performed during the preparation of the Bellefonte and Lee COL applications. Both external and internal audits were reviewed including: (1) a NUPIC audit of the Enercon Services offices at Tulsa, Oklahoma and Mount Arlington, New Jersey conducted from March 6-16, 2006, related to implementation of the Enercon QA Program; (2) an internal audit of COL project-related activities at the Mount Arlington office from June 4-7, 2007, to verify the effective implementation of the Enercon QA program and implementing procedures; and (3) an internal audit at Enercon's Oklahoma office of activities related to the Duke Energy Lee site to verify that investigation at the Cherokee COL site was being conducted in accordance with the Duke Energy purchase order.

The NRC audit team noted that these audits identified a number of issues including: (1) deficiencies in document control requirements; (2) deficiencies in corrective action requirements; and (3) deficiencies in training requirements. Several of these deficiencies were administrative in nature, and did not materially affect the quality of the COLA applications. The NRC audit team reviewed the corrective action files for these findings and found the resolution and timeliness of the corrective actions to be in accordance with the COLA development program requirements. The NRC audit team confirmed that all findings had been closed at the time of the NRC audit.

(ii) Oversight of Sub-suppliers

Enercon performed a series of audits and surveillances of their contracted sub-suppliers which had performed COLA development activities. The NRC audit team reviewed the audit and surveillance reports prepared by Enercon for the following activities: (1) an audit of MACTEC from December 14-15, 2006, to qualify MACTEC as a safety-related supplier, as well as, a surveillance of MACTEC activities from March 14-17, 2006, to review quality documents and work plans/instructions, drilling records, and personnel qualifications/training for operations; (2) an audit of REI from March 7-9, 2006, to review the implementation of the REI QA program; (3) a commercial grade survey of activities performed by Argonne National Laboratory associated with sample analyses performed for the COL sites; (4) a surveillance of WLA from April 24-25, 2007, to verify that WLA was implementing the requirements of the Enercon QA program, corporate standards, and associated project instructions for preparing the required engineering analyses; (5) a surveillance of Burns & Roe (B&R) Enterprise from July 17-19, 2007, to assess the B&R implementation of the Enercon QA program, corporate procedures, and Project Planning Documents for performing the required the analysis activities for the NuStart and Duke Energy COLAs.

The NRC audit team noted that these audits and surveillances identified a number of issues including: (1) lack of detailed Enercon quality procedures for controlling sub-suppliers working at remote locations; and (2) observations related to calculation packages and software verification prepared by B&R. The NRC audit team reviewed the corrective action files for these findings and found the resolution and timeliness of the corrective actions to be adequate and in accordance with the COLA development program requirements. The NRC audit team confirmed that, with the exception of two findings regarding calculation packages and software verification which were ongoing at the time of the NRC audit, all other findings had been closed at the time of the NRC audit.

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 sub-suppliers. Audits, surveillances, and surveys conducted by the applicants and Enercon 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.

3.12 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. Specifically, the NRC audit team verified that the applicant, Duke Energy, NuStart, and associated vendors adequately implemented and maintained personnel training and qualification processes.

b. Observations

b.1 Policies and Procedures for Training and Qualification of Personnel

NuStart's PPD, NuStart-001, Revision 5, provides the overall requirements for qualification, training, and certification of personnel whose activities affect quality of safety-related Structures, Systems, and Components. It also provides a list of applicable Enercon CSPs contained in Enercon's Corporate QA Program Manual, Revision 9.

Enercon's Corporate QA Program Manual, Revision 9, prescribes the activities required for providing QA indoctrination and training of personnel at the initiation of a project, as well as measures for update training, and for orientation of new personnel during the project's duration. The manual also states that the program shall include control mechanisms to ensure that competent personnel are assigned for each activity commensurate with its type and importance.

The MACTEC QAM, Revision 1 establishes the requirements and procedures for the development, implementation, and maintenance of programs for personnel training and qualification. The manual ensures that personnel selected to perform and/or manage activities affecting quality are appropriately trained and qualified.

MACTEC's Procedure of Qualification of Personnel, QAP 20-1, describes the requirements for the qualification of personnel to perform inspections, examinations, and testing at nuclear power plants, or on materials destined for use at these plants. Specifically, this procedure describes the criteria used to determine initial qualification of personnel, certification of qualifications, physical requirements, and program for periodic performance evaluation.

b.2 Review of Training Activities and Records

Enercon's Corporate QA Program Manual, Revision 9, contains CSP 2.03, QA Training Requirements, Rev. 3, which describes the QA indoctrination of project personnel performing safety-related activities. The manual states that, "The Project Manager, or designee, shall schedule, conduct, and document the training of project personnel in quality assured activities." This allows the project

manager to decide what training is applicable to specific personnel, without further explicit guidance provided in the COLA development program documentation. However, the audit team noted that there was no specific documented qualification requirements captured in this standard procedure or any other guidance within the training program. The audit team held discussions with NuStart and Duke project managers to confirm that training for each individual working on the project is task-specific and based solely on the project manager's discretion. While the NRC audit team did not find any specific examples of training deficiencies for individuals assigned to the project, the lack of documented criteria describing how the training curriculum or explicit qualification is determined was noted as a programmatic weakness by the NRC audit team. Therefore, as a result of this audit, the applicant(s) is requested to provide a justification for the training and qualification practices used for the COLA development, and describe how the training and qualification for personnel assigned to the COLA development were determined to be adequate. This is identified as audit response request (ARR-003).

b.3 Training and Qualification Records

The NRC audit team reviewed a sample of training and qualification records for Enercon and its suppliers to verify that individuals were properly qualified and indoctrinated to perform safety-related work. The NRC audit team also verified that the maintenance and storage of records was in accordance with project procedures. The records reviewed included QA briefing agendas checklists, resumes, projected procedure update memos, and personnel attendance certifications.

The NRC audit team reviewed several CARs related to training and qualification drafted as a result of an internal audit (MTAR-AUD-06) conducted on June 4-7, 2006, at the Enercon office in Mount Arlington, NJ. PDD NuStart-001, Rev. 4, Section II states in part: "Sub-Contractor Leads are responsible for reviewing qualification of personnel performing QA tasks for them. Sub-contractor leads will document this review by memo to the Enercon Project manager. This memo will also provide resumes and related tasks assignments to Enercon PM for technical staff accountable to the Sub-contractor lead."

The audit noted that, contrary to this requirement, no memo confirming this review was sent to the Enercon PM resulting in corrective action report MTAR CAR-15. The corrective action associated with this CAR required an email be sent to all relevant sub-contractors requesting the information needed. The PM will also ensure that contractor qualification requirements are called out in procurement documents for new subcontractors and will reference this requirement during training sessions as well. This CAR was closed by the QA manager on July 27, 2007. A similar CAR (CAR MTAR-CAR-13) was drafted under the Duke project related to the same issue, but has not been approved at the time of the NRC audit.

c. Conclusions

The NRC audit team concluded that, with the exception identified above, the training process requirements reviewed by the NRC audit team were implemented as applicable by the applicant and its sub-suppliers. The NRC audit team did identify an issue in this area requiring additional action by the applicant prior to completion of the COLAs (ARR-003).

3.13 10 CFR Part 21 IMPLEMENTATION

a. Audit Scope

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

b. Observations

b.1 Contractual Imposition of Part 21 Requirements

The procurement documents associated with the preparation of the COLAs for both NuStart and Duke Energy impose explicit Part 21 requirements on the primary contractor Enercon and its sub-suppliers. The contracts classify the procured services associated with the COL application as “nuclear safety related and impose standard terms and conditions for the quality program to be applied to this class.”

Section 4.2.5 of Duke Energy’s project planning document, DUK-01, typical for both COLAs, states the applicable contractual requirements as follows: “Procurement of all safety related services shall be in accordance with the Enercon QA Program. All services important to safety shall be supplied under Enercon’s approved QA program or shall be procured from sub-suppliers whose QA program has been acceptably audited and evaluated as being effectively implemented by Enercon. Procurement documents to sub-suppliers must impose applicable QA requirements, including Part 21.”

Procurement documents were reviewed by the NRC audit team and found to impose the above conditions on the COL application services provided by Enercon. In addition to the above contractual requirements, the applicant procurement documents impose right of access conditions to contractor and subcontractor facilities and records for inspection. Also imposed are provisions for identification and disposition for nonconformances in accordance with Enercon’s QA program.

Sub-supplier procurement documents for those sub-suppliers identified in Section 3 of this report were also reviewed and found to impose the applicable requirements of the applicant contractual agreements.

b.2 Enercon Program for Evaluating Defects and Noncompliances

The requirements, responsibilities, and methodology for evaluating defects and noncompliances in accordance with the requirements of Part 21 are established in Enercon CSP 16.02. This procedure requires evaluation and reporting to the NRC noncompliances related to a basic component or service when:

(i) an item or result of a service has been offered to a client, who has placed the item or result of a service in a status where use is permitted.

(ii) an item or result of service has been rejected by a client and returned without use, but the similar items or services have been offered to other clients.

(iii) a subcontractor has offered an item or result of service to Enercon for acceptance, the item or result of service has been rejected, and Enercon has contractually agreed to perform Part 21 evaluations rather than the subcontractor.

Assignment of responsibilities for reporting, evaluating, and documenting potential 10 CFR 21 defects and noncompliances were evaluated and found to be consistent with Part 21 requirements. The NRC audit team also reviewed the processes for identifying potentially reportable problems through design review, audit reports, corrective action reports, client or subcontractor feedback, or other methods. Reporting and record keeping requirements were also reviewed and found to be consistent with regulatory requirements. Based on its review of CSP 16.02, the audit team determined that Enercon's Part 21 program met the applicable regulatory requirements, including the timeliness requirements for evaluation and reporting.

CSP 16.02 acknowledges that the services of design, inspection, test or consultation associated with a basic component are within the scope of Part 21. It further recognizes that Enercon's obligations to comply with Part 21 extend beyond completion of the contracted services.

The NRC audit team observed that postings requirements of Section 21.6 of Part 21, were met and that a notice was placed in a conspicuous place at the Mount Arlington office. Nonconformances and corrective actions are processed through the Enercon corrective action program, as discussed in section 3.9 of this report. A sample of CARs issued in 2006 and 2007 were reviewed to determine whether Enercon personnel had considered the evaluation for potential reportability of defects and failures to comply. The audit team found Enercon had determined that none of the deficiencies had reached the threshold of

"substantial safety hazard"; the audit team found this determination to be adequate and in accordance with CSP 16.02.

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 and/or its sub-supplier's procedures to support the Bellefonte and Lee COLA development programs. The NRC audit team did not identify any issues requiring additional action by the applicant prior to completion of the COLA.

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

a. Audit Scope

Upon receipt of a COLA, the NRC staff will perform a review of the application to determine its acceptability for docketing. The acceptability review will ensure that the COLA addresses the information provided in RG 1.206. The NRC audit team reviewed selected parts of the draft COLA, FSAR, for both Lee and Bellefonte and compared those drafts with the guidance contained in RG 1.206. The NRC audit team discussed with the applicants and their contractor the results of the NRC audit team's review of the FSAR, including the differences relating to the completion for both applications.

b. Observations

b.1. Policies and Procedures

The NRC audit team used the following chapters of Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants," June 2007, for its review. Part I: Standard Format and Content of Combined License Applications: C.I.2.1, "Geography and Demography," C.I.2.2, "Nearby Industrial, Transportation, and Military Facilities," C.I.3.5.1.6, "Aircraft Hazards," C.I.5, "Reactor Coolant and Connecting Systems," and C.I.13, "Conduct of Operations." In addition, the NRC audit team used NUREG-0800, "Standard Review Plan," (SRP) Chapter 3.9.6, "Functional Design, Qualification, and Inservice Testing Programs for Pumps, Valves, and Dynamic Restraints," and Chapter 6.2.6, "Containment Leakage Testing."

b.2. Audit Activities

The NRC audit team performed a review of the applicants' method for revising each FSAR Section and discussed the review process with members of the applicants' COLA development staff. On this basis, the audit team gained a better understanding of the COLA development process. Specifically, FSAR Sections marked as Revision A had been written by the contractor and were

being reviewed by either NuStart or Duke Energy. After the contractor had incorporated comments to Revision A, FSAR Sections, these FSAR Sections were then changed to Revision B. Revision C was developed when a group of particular FSAR Sections were combined to form a specific FSAR chapter. Technical and acceptance reviews were also conducted at the Revision C level. Once the contractor had incorporated comments to a chapter marked as Revision C, this chapter was then marked as Revision D. Once the FSAR chapters had been completed and all technical comments addressed, the combined chapters were considered to be at the Revision E level, which is the final COLA package.

Bellefonte

The NRC audit team reviewed draft FSAR, Chapter 13, "Conduct of Operations," Revision C for Bellefonte Nuclear Plant against RG 1.206, C.I.13 Conduct of Operations. The NRC audit team found that the applicant's FSAR Chapter 13 appeared consistent with the guidance contained in this RG. As part of its review of Chapter 13, the NRC audit team also reviewed the Bellefonte COL Emergency Plan (Draft), dated July 19, 2007, against the guidance in RG 1.206, C.I.13.3, "Emergency Planning." The NRC audit team found that the applicant's Emergency Plan appeared consistent with the guidance in RG 1.206. In addition, the NRC audit team reviewed draft FSAR Table 13.4-1, specifically the scope of programs included and the implementation milestones identified, and found that the milestones appear to be consistent with RG 1.206 guidance. Where RG 1.206 provided no specific guidance, the draft FSAR Table provided specific implementation milestones which is appropriate. The NRC audit team also reviewed the draft containment leakage rate and motor-operated valve testing programs, described in FSAR Table 13.4-1, and found that these program descriptions appeared to be consistent with SRP, Chapters 6.2.6, "Containment Leakage Testing," and 3.9.6, "Functional Design, Qualification, and Inservice Testing Programs for Pumps, Valves, and Dynamic Restraints." Additionally, the NRC audit team discussed the purpose of Appendix 13A of the COLA application, created to clearly distinguish between the historical (i.e., pre-COL issuance) and operational phases, with the potential applicant. On the basis of this review, the NRC audit team suggested that the purpose of this appendix be clarified in the COL application.

Lee

The NRC audit team reviewed draft FSAR, Chapter 13, "Conduct of Operations," Revision A of the Lee COLA against RG 1.206, C.I.13 Conduct of Operations, and found that the applicant's FSAR Chapter 13 appeared to be consistent with the guidance contained in this RG, with the exception of the applicant's Emergency Plan. Specifically, the Lee draft Emergency Planning, Revision B description had not been completed at the time of the NRC audit, and as a result, the audit team was unable to determine if it followed the guidance in RG 1.206. The NRC audit team also reviewed the containment leakage rate and motor-operated valve testing programs, described in FSAR Table 13.4-1, and

found that the motor-operated valve testing program appeared to be consistent with SRP, Chapter 3.9.6, "Functional Design, Qualification, and Inservice Testing Programs for Pumps, Valves, and Dynamic Restraints." However, the NRC audit team was unable to determine if the containment leakage rate program description followed SRP 6.2.6 because the program description had not been completed at the time of the NRC audit.

The NRC audit team reviewed draft FSAR, Section 3.5.1.6, "Aircraft Hazards," Revision C for Bellefonte Nuclear Plant against RG 1.206, C.I.3.51.6, "Aircraft Hazards." The audit team found that the applicant's FSAR Section 3.5.1.6 appeared consistent with the guidance contained in this RG. However, when the audit team reviewed this same FSAR Section of the Lee COLA, the audit team noted that the FSAR, Section 3.5.1.6, "Aircraft Hazards," Revision B description had not been completed at the time of the NRC audit and thus could not determine if it followed the guidance in RG 1.206, C.I.3.5.1.6.

The NRC audit team reviewed draft FSAR, Section 2.1, "Geography and Demography," Revision B for both Bellefonte and Lee COLAs against RG 1.206, C.I.2.1, "Geography and Demography," and found that these sections appeared consistent with the guidance in RG 1.206. In addition, the NRC audit team reviewed draft FSAR, Section 2.2, "Identification of Potential Hazards in Site Vicinity," Revisions A and B for the Bellefonte and Lee COLAs, and found that Section 2.2 for both of these applications appeared consistent with the guidance in RG 1.206, C.I.2.2, "Nearby Industrial, Transportation, and Military Facilities," with one exception related to Section 2.2.3 "Evaluation of Potential Accidents," of the Lee COLA. Specifically, the NRC audit team found that FSAR, Section C.I.2.2.3, "Evaluation of Potential Accidents," Revision A for Bellefonte Nuclear Plant was under review by the applicant, however, FSAR, Section 2.2.3, "Evaluation of Potential Accidents," for the Lee COLA had not been written at the time of the NRC Audit.

The NRC audit team reviewed Chapter 5, "Reactor Coolant and Connecting Systems" of the AP1000 DCD Revision 16 and NuStart's Topical Report, "Reactor Vessel Material Surveillance Program Description." The audit team found the applicant's topical report appeared to be consistent with the guidance in RG 1.206. The audit team also reviewed Chapters 3.10, 3.11 and Appendix 3D of the AP1000 DCD Revision 16 and NuStart Topical Report, "Equipment Qualification Program Description." RG 1.206, C.I.3.10 and C.I.3.11 discuss the need for the COL applicant to document successful completion of qualification tests and/or analyses and qualification status for each type of equipment. The audit team did not identify any discussion of such qualification test results in either the DCD or the topical report. As a result, the applicant should include information regarding the qualification testing of each type of equipment in the NuStart COLA. The information provided should be consistent with the guidance contained in RG 1.206, C.I.3.10 and C.I.3.11.

With respect to the draft FSAR Chapter 14, "Initial Test Program," the NRC audit team reviewed the internal review process applied to the development of

individual sections within the chapter. The Bellefonte and Lee COLAs used Westinghouse's AP1000 DCD Revision 16 to identify COL items. The applicants also used the SRP and RG 1.206 to help ensure the entire scope was identified and addressed. The applicant has a tracking system to identify areas of change such as AP1000 technical reports that are under revision based on NRC staff Requests for Additional Information and therefore may result in the need for an FSAR revision. The NRC audit team observed the use of the "left hand margin annotations" that all AP1000 COL applicants will use. These annotations are meant to assist the NRC staff in identifying standard and plant-specific responses to COL action items, standard and plant-specific supplemental information, and standard and plant-specific deviations from the DCD. These annotations should help the NRC staff in its review although specific training and familiarization with the annotations and their meanings would be useful. The NRC audit team noted that exceptions to the SRP and/or RG 1.206 should be clearly and explicitly identified in the COLA. The applicant also has a tracking system for licensing commitments; however, it was not clear to the NRC audit team how these licensing commitments would be conveyed to the NRC staff in the COLA. Therefore the NRC staff is requesting that prior to or as part of the COLA submittal, the applicant provide a description of how these licensing commitments will be conveyed to the NRC Staff in the COLA. This is identified as audit response request (ARR-04).

At the time of this review, the audit team found the FSAR Sections and Chapters for Bellefonte COLA to be approximately 80 percent complete and the FSAR Sections and Chapters for the Lee COLA to be approximately 40 percent complete. Because Bellefonte is the "reference" plant for the AP1000 COLA, the applicants and contractor plan to complete the Bellefonte application and then use it as a template to facilitate the completion of the Lee COLA. The NRC staff will be reviewing these COLAs relative to their conformance to the SRP and RG 1.206 as part of the acceptance review process.

c. Conclusions

The audit team concluded that, with the exception identified above, the FSAR Sections and Chapters of the Bellefonte and Lee COLAs reviewed appear to be consistent with the guidance in RG 1.206 as well as the SRP. The NRC audit team did identify an issue in this area requiring additional action by the applicant prior to completion of the COLA (ARR-004).

4.0 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on July 30, 2007, the NRC audit team discussed the scope of the audit, outlined the areas to be reviewed, and established interfaces with TVA, Duke Energy, and its sub-supplier's staffs and management involved in the Bellefonte and Lee COLAs development. In the exit meeting on August 2, 2007, the NRC audit team discussed the audit activities conducted during the audit, and identified issues associated with the COLAs development with representatives of TVA, Duke Energy, and its sub-supplier's management and staff.

PARTIAL LIST OF PERSONS CONTACTED

Name	Position	Organization
J. Mancinelli*	Project Manager	Enercon Services
D. Masiero*	Design Manager	Enercon Services
R. Ladesic*	QA Manager	Enercon Services
P. Hastings*	Licensing Manager	Duke Energy/NuStart
G. Salamon*	COLA Licensing Manager	Enercon Services
J. Cassidy*	NuStart QA Lead	Duke Energy/NuStart
B. Falk*	Project Manager	Enercon Services
F. Redwanz**	FSAR Lead	Enercon Services
R. Grumbir*	Project Manager	NuStart
G. Curtis*	Sr. Project Manager	TVA
D. Boland**	QA Records Administrator	Enercon Services
B. Evans***	Vice President, New Plant Services	Enercon Services
D. Whitson***	Client Services Manager	Enercon Services
T. Graham***	Technical Specialist	Enercon Services
M. Ohara***	Admin Assistant	Enercon Services
C. Palmer	Senior Engineer	Enercon Services
I. Nelson	Civil/Structural Engineer	Enercon Services
A. Breitwieser	Mechanical Engineer	Enercon Services
J. Young	Senior Engineer	William Lettis and Associates
B. Goldwin	Lead Contact	William Lettis and Associates
J. Adamson	Section 2.5 Author	Enercon Services
B. Morgan	Project Manager	Duke Energy

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

6.0 REFERENCES

1. Duke Energy Carolinas Topical Report, DUKE-1-A, Revision 34, “Quality Assurance Program” Duke Energy's Nuclear System Directive 208, “Problem Investigation Process (PIP)”
2. Duke Energy's Nuclear System Directive 229, “Evaluation and Reporting of Potential Defects and Noncompliance Per 10 CFR Part 21”
3. Enercon’s Corporate Quality Assurance Program Manual, revision 9.
4. Enercon Corporate Standard Procedure CSP 2.03 Revision 3, “QA Training Requirements”
5. Enercon Corporate Standard Procedure CSP 2.04, “Preparation of a Certificate of Conformance”
6. Enercon Corporate Standard Procedure CSP 3.01 Revision 5, “Preparation and Control of Calculations”
7. Enercon Corporate Standard Procedure CSP 16.02, “Evaluating and Reporting of 10 CFR 21 Defects and Noncompliances”, Revision 5, dated April 13, 2004
8. Enercon Corporate Standard Procedure CSP 17.0, “Issuance of Project Deliverables”
9. Enercon Corporate Standard Procedure CSP 17.03, Revision 1, “Quality Assurance Records”
10. Enercon surveillance report no. DUK-SURV-2006-02 of MACTEC, dated April 10-12, 2006
11. MACTEC, “Quality Assurance Manual MACTEC Engineering and Consulting,” Revision 1, dated June 17, 2005.
12. MACTEC Engineering and Consulting Document - QAM, Section QS-8, Identification and Control of Items and Samples, Revision 1, dated June 17, 2005.
13. MACTEC Engineering and Consulting Document - QAM, Quality Section QS-13, “Handling and Storage of Samples,” Revision 0, dated April 14, 2006.
14. MACTEC, 5050-06-0496, “Quality Assurance Project Document,” Revision 2, dated February 21, 2007.
15. MACTEC Master Subcontract Agreement with Subcontractors,” dated February 8, 2004.
16. MACTEC Surveillance Report No.CS-8, dated April 13, 2006
17. MACTEC’s “NuStart Bellefonte COL Project Geotechnical Work Plan,” Revision 0, dated April 17, 2006.
18. MACTEC Quality Assurance Procedure – Audit Procedure QAP 18-1, Revision 0, dated October 12, 2006.
19. MACTEC’s Procedure of Qualification of Personnel, QAP 20-1
20. MACTEC Engineering and Consulting Document - Geotechnical Data Collection Plan for the Nustart/Enercon Combined Operating License Application, Revision 5, dated April 17, 2007.
21. MACTEC Employee Training Records.
22. NuStart’s Project Planning Document (PPD), NuStart-001, Revision 5
23. NuStart Project Procedure G-001 Revision 4, “COL Application First Draft/Annotated Outline Writer's Guide”
24. NuStart Project Procedure G-002, Revision 6, “COL Application Preparation Instructions”
25. NuStart001-FSAR-15.7- BCALC-002, Revision 0, “Postulated Liquid-Containing Tank Failure,”
26. NuStart001-FSAR-15.7-BCALC-001, Revision 1, “Bellefonte FSAR Groundwater Velocity Calculation.”
27. NuStart Bellefonte COL Project Geotechnical Work Plan, Revision 0, dated April 17, 2006

28. NuStart Quality Assurance Manual
29. NuStart Project Instruction PI-001, “NuStart Energy Organization Plan”
30. NuStart Project Instruction PI-009, “Quality Assurance Plan”
31. NuStart Project Instruction PI-010, “Corrective Action Process”
32. NuStart Project Instruction PI-011, “Audit and Assessment Process” Risk Engineering, Inc. (REI), “Quality Assurance Manual,” Revision 8.
33. Risk Engineering, Inc. (REI), “Software Quality Assurance Plan,” (SQAP)
34. Tennessee Valley Authority Quality Assurance Manual,”
35. US NRC Regulatory Guide 1.206, “Combined License Applications for Nuclear Power Plants,” June 2007
36. US NRC NUREG-0800, “Standard Review Plan,” (SRP)

COL Duke Energy - Lee Mailing List

cc:

Mr. Henry B. Barron
Group Vice President
Nuclear Generation and Chief Nuclear Officer
Duke Power
P.O. Box 1006 - ECO7H
Charlotte, NC 28201-1006

Ms. Michele Boyd
Legislative Director
Energy Program
Public Citizens Critical Mass Energy
and Environmental Program
215 Pennsylvania Avenue, SE
Washington, DC 20003

W. Craig Conklin, Director
Chemical and Nuclear Preparedness &
Protection Division (CNPPD)
Office of Infrastructure Protection
Department of Homeland Security
Washington, DC 20528

Mr. Marvin Fertel
Senior Vice President
and Chief Nuclear Officer
Nuclear Energy Institute
1776 I Street, NW
Suite 400
Washington, DC 20006-3708

Mr. Peter Hastings
NuStart Energy Development, LLC
c/o Duke Energy
EC05R / PO Box 1006
Charlotte, NC 28201-1006

Vanessa E. Quinn, Acting Director
Technological Hazards Division
National Preparedness Directorate
Federal Emergency Management Agency
500 C Street, NW
Washington, DC 20472

Email

APH@NEI.org (Adrian Heymer)
amonroe@scana.com (Amy Monroe)
awc@nei.org (Anne W. Cottingham)
bennettS2@bv.com (Steve A. Bennett)
BrinkmCB@westinghouse.com (Charles Brinkman)
chris.maslak@ge.com (Chris Maslak)
crpierce@southernco.com (Chuck Pierce)
CumminWE@Westinghouse.com (Edward W. Cummins)
cwaltman@roe.com (C. Waltman)
david.lewis@pillsburylaw.com (David Lewis)
dlochbaum@UCSUSA.org (David Lochbaum)
frankq@hursttech.com (Frank Quinn)
greshaja@westinghouse.com (James Gresham)
gzinke@entergy.com (George Alan Zinke)
jgutierrez@morganlewis.com (Jay M. Gutierrez)
jim.riccio@wdc.greenpeace.org (James Riccio)
JJNesrsta@cpsenergy.com (James J. Nesrsta)
john.o'neil@pillsburylaw.com (John O'Neil)
Joseph.savage@ge.com (Joseph Savage)
Joseph_Hegner@dom.com (Joseph Hegner)
KSutton@morganlewis.com (Kathryn M. Sutton)
kwaugh@impact-net.org (Kenneth O. Waugh)
lynchs@gao.gov (Sarah Lynch - Meeting Notices Only)
MaddenG@BV.com (George Madden)
Margaret.Bennet@dom.com (Margaret Bennet)
maria.webb@pillsburylaw.com (Maria Webb)
mark.beaumont@wsms.com (Mark Beaumont)
matias.travieso-diaz@pillsburylaw.com (Matias Travieso-Diaz)
media@nei.org (Scott Peterson)
mike_moran@fpl.com (Mike Moran)
murawski@newsobserver.com (John Murawski)
nirsnet@nirs.org (Michael Mariotte)
patriciaL.campbell@ge.com (Patricia L. Campbell)
paul.gaukler@pillsburylaw.com (Paul Gaukler)
Paul@beyondnuclear.org (Paul Gunter)
phinnen@entergy.com (Paul Hinnenkamp)
pshastings@duke-energy.com (Peter Hastings)
RJB@NEI.org (Russell Bell)
RKTemple@cpsenergy.com (R.K. Temple)
robert.kitchen@pgnmail.com (Robert Kitchen)
roberta.swain@ge.com (Roberta Swain)
ronald.hagen@eia.doe.gov (Ronald Hagen)
sandra.sloan@areva.com (Sandra Sloan)
sfrantz@morganlewis.com (Stephen P. Frantz)
Tansel.Selekler@nuclear.energy.gov (Tansel Selekler)

VictorB@bv.com (Bill Victor)
waraksre@westinghouse.com (Rosemarie E. Waraks)

COL NuStart Energy - Bellefonte Mailing List

cc:

Ms. Michele Boyd
Legislative Director
Energy Program
Public Citizens Critical Mass Energy
and Environmental Program
215 Pennsylvania Avenue, SE
Washington, DC 20003

W. Craig Conklin, Director
Chemical and Nuclear Preparedness &
Protection Division (CNPPD)
Office of Infrastructure Protection
Department of Homeland Security
Washington, DC 20528

Mr. Marvin Fertel
Senior Vice President
and Chief Nuclear Officer
Nuclear Energy Institute
1776 I Street, NW
Suite 400
Washington, DC 20006-3708

Mr. Ronald Kinney
South Carolina DHEC
2600 Bull Street
Columbia, SC 29201

Vanessa E. Quinn, Acting Director
Technological Hazards Division
National Preparedness Directorate
Federal Emergency Management Agency
500 C Street, NW
Washington, DC 20472

Email

APAGLIA@Scana.com (Al Paglia)
APH@NEI.org (Adrian Heymer)
awc@nei.org (Anne W. Cottingham)
bennettS2@bv.com (Steve A. Bennett)
BrinkmCB@westinghouse.com (Charles Brinkman)
chris.maslak@ge.com (Chris Maslak)
cristina.Ionescu@pgnmail.com (Christina Ionescu)
CumminWE@Westinghouse.com (Edward W. Cummins)
cwaltman@roe.com (C. Waltman)
david.lewis@pillsburylaw.com (David Lewis)
dlochbaum@UCSUSA.org (David Lochbaum)
frankq@hursttech.com (Frank Quinn)
garry.miller@pgnmail.com (Garry D. Miller)
GovePA@BV.com (Patrick Gove)
greshaja@westinghouse.com (James Gresham)
gwcurtis2@tva.gov (G. W. Curtis)
gzinke@entergy.com (George Alan Zinke)
jgutierrez@morganlewis.com (Jay M. Gutierrez)
jim.riccio@wdc.greenpeace.org (James Riccio)
JJNesrsta@cpsenergy.com (James J. Nesrsta)
john.o'neil@pillsburylaw.com (John O'Neil)
Joseph.savage@ge.com (Joseph Savage)
Joseph_Hegner@dom.com (Joseph Hegner)
KSutton@morganlewis.com (Kathryn M. Sutton)
kwaugh@impact-net.org (Kenneth O. Waugh)
lynchs@gao.gov (Sarah Lynch - Meeting Notices Only)
MaddenG@BV.com (George Madden)
Margaret.Bennet@dom.com (Margaret Bennet)
maria.webb@pillsburylaw.com (Maria Webb)
mark.beaumont@wsms.com (Mark Beaumont)
matias.travieso-diaz@pillsburylaw.com (Matias Travieso-Diaz)
media@nei.org (Scott Peterson)
mgiles@entergy.com (M. Giles)
mike_moran@fpl.com (Mike Moran)
nirsnet@nirs.org (Michael Mariotte)
patriciaL.campbell@ge.com (Patricia L. Campbell)
paul.gaukler@pillsburylaw.com (Paul Gaukler)
Paul@beyondnuclear.org (Paul Gunter)
phinnen@entergy.com (Paul Hinnenkamp)
pshastings@duke-energy.com (Peter Hastings)
rclary@scana.com (Ronald Clary)
RJB@NEI.org (Russell Bell)
RKTemple@cpsenergy.com (R.K. Temple)
roberta.swain@ge.com (Roberta Swain)
ronald.hagen@eia.doe.gov (Ronald Hagen)
sandra.sloan@areva.com (Sandra Sloan)

SauerB@BV.com (Robert C. Sauer)
sfrantz@morganlewis.com (Stephen P. Frantz)
tom.miller@hq.doe.gov (Tom Miller)
VictorB@bv.com (Bill Victor)
waraksre@westinghouse.com (Rosemarie E. Waraks)