

March 16, 2011

Peter S. Hastings, Licensing Manager
Nuclear Plant Development
Duke Energy Carolinas, LLC
526 South Church Street
Charlotte, NC 28202

SUBJECT: NRC INSPECTION REPORT NOS. 05200018/2011-201 AND
05200019/2011-201 AND NOTICE OF VIOLATION

Dear Mr. Hastings:

On January 24-28, 2011, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the headquarters offices of Duke Energy Carolinas, LLC (Duke), in Charlotte, North Carolina. The purpose of the NRC inspection was to verify that Duke effectively implemented quality assurance (QA) processes and procedures applied to activities related to the William States Lee III Nuclear Station (Lee) Units 1 and 2 combined license application. The inspection focused on assessing compliance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Processing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The enclosed report presents the results of this inspection. This NRC inspection report does not constitute an NRC endorsement of your overall QA or 10 CFR Part 21 programs.

Based on the results of this inspection, the NRC has determined that one violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because a review of Duke's QA topical report, as it pertains to activities related to the combined license application for Lee Units 1 and 2, found that certain program policies and implementation procedures were not in compliance with the applicable requirements of 10 CFR Part 21. The NRC evaluated this violation in accordance with the agency's Enforcement Policy, which is available on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements

Based on the results of this inspection, the NRC has also determined that one additional Severity Level IV violation of NRC requirements occurred. This violation is being treated as Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy. The NCV is described in the subject inspection report. If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Director, Office of New Reactors; and (2) the Director, Office of Enforcement.

In accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), which is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide, in detail, the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,
/RA/

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

Docket Nos.: 05200018 and 05200019

Enclosures:

1. Notice of Violation
2. Inspection Report Nos. 05200018/2011-201 and 05200019/2011-201 and Attachment

If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Sincerely,
/RA/

Juan Peralta, Chief
Quality and Vendor Branch 1
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Docket Nos.: 05200018 and 05200019

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2. Inspection Report Nos. 05200018/2011-201 and 05200019/2011-201 and Attachments

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NRO-002

OFFICE	NRO/DCIP/CQVA	E	NRO/DCIP/CQVA	E	NRO/DCIP/CQVA	E
NAME	RPatel		GGalletti (KAK for)		ABelen (KAK for)	
DATE	03/14/11		03/16/11		03/15/11	
OFFICE	NRO/DCIP/CQVA	E	NRO/DCIP/CQVA		NRO/DSER/RHEB	
NAME	PCoco (KAK for)		FTalbot		NTiruneh	
DATE	03/15/11		03/14/11		03/14/11	
OFFICE	NRO/DSER/RHEB	E	BC:NRO/DCIP/CQVA	E	BC: NRO/DCIP/CAEB (OT FOR	E
NAME	MMcBride (KAK for)		JPeralta (KAK for)		TFrye	
DATE	03/15/11		03/16/11		03/15/11	

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Duke Energy Carolinas, LLC
Lee Units 1 and 2
Charlotte, NC 28202

Docket Nos.: 05200018 and 05200019
Report No. 2011-201

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the headquarters offices of Duke Energy Carolinas, LLC, (Duke), in Charlotte, NC, on January 24–28, 2011, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is described below:

Title 10 of the *Code of Federal Regulations* (10 CFR) 21.21, “Notification of Failure to Comply or Existence of a Defect and Its Evaluation,” paragraph 21.21(a) requires, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable.

10 CFR 21.3, “Definitions” states, that “discovery” means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21(a). In addition, Section 21.3 states that an “evaluation,” means the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

10 CFR 21.21(a)(1) requires, in part, that deviations and failures to comply be evaluated within 60 days of discovery in order to identify a reportable defect or failure to comply that could create a substantial safety hazard were it to remain uncorrected.

10 CFR 21.21(a)(2) require, in part, that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(d)(5).

Contrary to the above, as of January 28, 2011, Duke procedural guidance NSD 229, “Evaluation and Reporting of Potential Defects and Noncompliance per 10 CFR Part 21” incorrectly defined “discovery” and “evaluation;” and did not use the terms “deviations” and “defect” consistently through the procedure. Additionally, Duke failed to evaluate a deviation or failures to comply associated with substantial safety hazards within 60 days of discovery and failed to submit an interim report to the NRC if an evaluation of an identified deviation or failure to comply cannot be completed within 60 days of discovery.

This issue has been identified as Violations 05200018/2011-201-01 and 05200019/2011 201-01.

This is a Severity Level IV violation (Section 6.5).

Pursuant to the provisions of 10 CFR 2.201, "Notice of Violation," Duke is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality and Vendor Branch 1, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation" 05200018/2011-201-01 and 05200019/2011-201-01, and should include (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> to the extent possible, it should not include any personal privacy or proprietary or safeguard information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If Safeguards Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated at Rockville, MD, this 16th day of March 2011

**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS
DIVISION OF CONSTRUCTION INSPECTION AND
OPERATIONAL PROGRAMS**

Docket Nos.: 05200018 and 05200019

Report Nos.: 05200018/2011-201 and 05200019/2011-201

Applicant: Duke Energy Carolinas, LLC.
526 South Church Street
Charlotte, NC 28202

Applicant Contact: Mr. Peter S. Hastings
Licensing Manager, Nuclear Plant Development
980-373-7820

Background: Duke Energy Carolinas LLC is pursuing a combined license (COL) for two new AP1000 units at the Williams State Lee III Nuclear Station site in Somervell County, NC.

Inspection Dates: January 24–28, 2011

Inspectors: Greg Galletti NRO/DCIP/CQVA, Team Leader
Raju Patel NRO/DCIP/CQVA, Assistant Team Leader
Paul Coco NRO/DCIP/CQVA
Aixa Belen-Ojeda NRO/DCIP/CQVA
Frank Talbot NRO/DCIP/CQVA
Mark McBride NRO/DSER/REB
Nebiyu Tiruneh NRO/DSER/REB

Project Managers: Brian Hughes NRO/DNRL/NWE1
Thomas Galletta NRO/DNRL/NWE1

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

EXECUTIVE SUMMARY

Duke Energy Carolinas LLC
Report Nos. 05200018/2011-201 and 05200019/2011-201

The U.S. Nuclear Regulatory Commission (NRC) inspection focused on quality assurance (QA) policies and procedures implemented to support the COL application (COLA) for William States Lee III Nuclear Station (Lee), Units 1 and 2, as described in NRC Inspection Manual Chapter 2502, "Construction Inspection Program: Pre-Combined License (Pre-COL) Phase," dated October 3, 2007. The purpose of this inspection was to verify that Duke Energy Carolinas LLC (Duke) had implemented an adequate QA program (QAP) that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." The inspection also verified that Duke had implemented a program under 10 CFR Part 21, "Reporting of Defects and Noncompliance," that meets NRC regulatory requirements.

The NRC based its inspection on the following regulatory requirements:

- 10 CFR Part 21
- Appendix B to 10 CFR Part 50

During this inspection, the NRC inspection team implemented Inspection Procedure 35017, "Quality Assurance Implementation Inspection," dated July 29, 2008, and Inspection Procedure 36100, "Inspection of 10 CFR Parts 21 and 50.55(e) Programs for Reporting Defects and Noncompliance," dated October 3, 2007.

10 CFR Part 21 Program

The NRC inspection team identified one violation of 10 CFR Part 21 requirements. Violations 05200018/2011-201-01 and 05200019/2011-201-01 were cited for Duke's failure to implement 10 CFR Part 21 requirements in following areas: (1) Procedural Guidance, (2) Definitions, and (3) Notification of Failure to Comply or Existence of a Defect and its Evaluation.

Design Control

The NRC inspection team concluded that the implementation of the Duke design control process is consistent with the regulatory requirements of Criterion III, "Design Control," of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the NRC inspection team also determined that Duke is effectively implementing its policies and associated procedures to support the COLA for Lee Units 1 and 2. No findings of significance were identified.

Procurement Document Control

The NRC inspection team concluded that the implementation of the Duke procurement control process is consistent with the regulatory requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50. Based on its review, the NRC inspection team determined that Duke is effectively implementing its policies and procedures to support the COLA for Lee Units 1 and 2. No findings of significance were identified.

Quality Assurance Records

The NRC inspection team concluded that the implementation of Duke's QA records is consistent with the regulatory requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the NRC inspection team determined that Duke is effectively implementing its policies and procedures to support the COLA for Lee Units 1 and 2. No findings of significance were identified.

Corrective Action

The NRC inspection team concluded that the implementation of Duke's corrective action is consistent with the regulatory requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the NRC inspection team determined that Duke is effectively implementing its policies and procedures to support the COLA for Lee Units 1 and 2. No findings of significance were identified.

Internal and External Audits

The NRC inspection team concluded that the implementation of Duke's external and internal audits is consistent with the regulatory requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team identified one non-cited violation (NCV) that resulted from Duke not complying with its procedure for qualifying lead auditors.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The NRC inspection team reviewed the implementation of the Duke 10 CFR Part 21 program in support of the COLA for Lee Units 1 and 2. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of the Duke process to verify compliance with the regulatory requirements of 10 CFR Part 21. The NRC inspection team also discussed this process with members of Duke's management and technical staff.

The NRC inspection team reviewed the following documents for this inspection area:

- Duke QA Topical Report Duke-1-A, "Quality Assurance Program," (QAP) Amendment 38, dated August 13, 2010
- Duke Nuclear Plant Development (NPD)-03, "Nuclear Plant Development Quality Assurance Plan," Revision 1, dated July 20, 2009
- Duke Nuclear System Directive (NSD) 202, "Reportability", Revision 10, dated November 28, 2006
- NSD 229, "Evaluation and Reporting of Potential Defects and Noncompliance Per 10 CFR Part 21," Revision 4, dated October 20, 2008
- NSD 205, "Postings Requirements," Revision 5, dated August 24, 2009
- Oconee 10 CFR Part 21 report dated July 22, 2008, for Duke Stock Code 127794, ABB part no. 709799T11, charging motors for 5HK switchgear breakers
- Problem Identification Program (PIP) O-00-01990, dated May 22, 2000
- PIP O-02-07236, dated December 19, 2002
- PIP G-09-00519, dated May 21, 2009.
- PIP G-10-00584, dated April 29, 2010
- PIP Serial No. G-09-00721 Category 4, for training request form related to need for 10 CFR Part 21 training, dated June 15, 2009

b. Observation and Findings

b.1. Policies and Procedures

NPD-03 provides guidance for the Nuclear Plant Development (NPD) Group to successfully comply with the Duke Energy quality assurance (QA) program and related procedures in the course of performing their required work for Lee Units 1 and 2 COLA project. This document places all new project development QA activities under the existing Duke's QA Topical Report Duke 1-A and Duke fleet procedures.

NSD 202 provides guidance to ensure proper and consistent reporting of station events or conditions under the provisions of 10 CFR 50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors"; 10 CFR 50.73, "Licensee Event Reporting System"; 10 CFR Part 21; and 10 CFR 50.9, "Completeness and Accuracy of Information." NSD 202.6 requires that 10 CFR Part 21 reporting be performed in accordance with NSD 229.

NSD 205 provides instructions for posting requirements of 10 CFR Part 19, "Notices, Instructions, and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection against Radiation"; and 10 CFR Part 21. NSD 205.4, "Implementation," states, in part, that if posting the regulations or procedures is not practical, in addition to posting the NRC form 3 and Section 206 of the Energy Reorganization Act of 1974, a notice may be posted that describes the regulations and procedures; and states where they may be examined. In addition, the notice will contain the name of the individual to whom the report of defects and noncompliance can be made.

NSD 229 provides guidance to comply with the requirements of 10 CFR Part 21. NSD 229 describes the method of evaluating if a potential defect or failure to comply associated with a basic component could create a substantial safety hazard were it remain uncorrected. This method includes identification, Phase I evaluation (identified as the discovery phase), Phase II evaluation, evaluation results, and reporting to the NRC. Also, this NSD identifies the responsibilities of different organizational groups; and the reporting and record keeping requirements associated with 10 CFR Part 21.

b.2. 10 CFR Part 21 Implementation

The NRC inspection team verified the implementation of Duke's Part 21 program as described in NSD 229 related to compliance with the regulations, posting, procurement, reporting, and record retention. As part of the verification of Duke's Part 21 procedure implementation, the NRC inspection team observed the following activities:

- Postings

The NRC inspection team observed that Duke had posted a notice on a conspicuous location within the building. The notice included a copy of Section 206 of the Energy Reorganization Act of 1974; a notice describing the regulations/procedures related to Part 21; and the name of the individual to whom reports may be made.

- Part 21 Procedure

The NRC inspection team reviewed Duke's NSD 229, and discussed it with Duke's management and staff personnel responsible for development and maintenance of the procedure. The NRC inspection team noted that the definitions of deviation and defect were used interchangeably within the body of the procedure, and that the definitions for discovery and evaluation were inconsistent with the definitions contained in 10 CFR 21.3, "Definitions."

In addition, the NRC inspection team reviewed PIP G-09-00519 and PIP G-10-00584, which documents the discrepancy between the 10 CFR Part 21 language and NSD 229. PIP G-09-00519 is still open pending an update to NSD 229. Duke closed the PIP G-10-00584 on April 29, 2010. The NRC inspection team observed that one of the bases for the closure of PIP G-10-00584 was that the definitions were consistent with 10 CFR Part 21.3

regulations. As stated above, at the date of the inspection, two of the definitions in NSD 229 were not consistent with 10 CFR 21.3, "Definitions."

Based on the review of the Duke NSD 229 procedure and these two PIPs, the NRC inspection team determined that NSD 229 did not provide adequate guidance for the implementation of 10 CFR Part 21 program. Specifically, NSD 229 failed to (1) provide consistent use of the terms deviation and defect throughout the procedure; and (2) define discovery and evaluation consistently with the definitions contained in 10 CFR 21.3, "Definitions." This is identified as an example of Violations 05200018/2011-201-01 and 05200019/2011-201-01.

- 10 CFR Part 21 Report

The NRC inspection team learned that Duke had not performed any 10 CFR Part 21 evaluations or identified any potential 10 CFR Part 21 deviations or failures requiring evaluation for Lee Units 1 and 2. However, the NRC team requested an example of 10 CFR Part 21 report from other facility under their purview to verify Duke's implementation of the program. Duke provided the NRC inspection team with the Oconee 10 CFR Part 21 report dated July 22, 2008, and PIP O-02-07236 associated to the report. The Oconee 10 CFR Part 21 report documents the identification, evaluation, and reporting of defective charging motors for 5HK (4,160 volt) switchgear breakers.

The NRC inspection team reviewed PIP O-02-07236 and interviewed Duke's staff responsible for the screening process to understand the evaluation of deviations. During the review of PIP O-02-07236, and the interview with Duke's staff, the NRC inspection team noted that Duke had first identified and documented the deviation in May 22, 2000, under PIP O-00-01990. PIP O-00-01990 was closed based on stating that there was no apparent cause of the deviation and to return the basic components to the vendor for evaluation. As result of a self-assessment audit of 10 CFR Part 21 program, Duke reevaluated and documented this deviation on December 19, 2002, in PIP O-02-07236. Duke completed the Phase I evaluation (discovery) on April 4, 2008; initiated the Phase II evaluation (Part 21 evaluation) on April 29, 2008; and completed the Phase II evaluation on June 23, 2008, eight years after the first identification and documentation of the deviation in PIP O-00-01990. Based on this review, the NRC inspection team determined that Duke failed to: (1) effectively implement its Part 21 procedure to perform an evaluation of a deviation within 60 days of discovery, as required by 10 CFR 21.21(a)(1); and (2) submit an interim report to the NRC if an evaluation of an identified deviation or failure to comply cannot be completed within 60 days of discovery, as required by 10 CFR 21.21(a)(2). This issue is identified as an example of Violations 05200018/2011-201-01 and 05200019/2011-201-01.

- Purchase Orders

The NRC inspection team noted that Duke procurement process imposes the requirements of 10 CFR Part 21 into all purchase orders (POs) for nuclear safety-related materials, items, and services. The NRC inspection team reviewed a sample of Duke POs and verified that Duke had implemented its 10 CFR Part 21 program in a manner consistent with the requirements described in 10 CFR 21.31, "Procurements Documents," for basic components.

- Records Retention

The NRC inspection team noted that Duke did have a formalized process for specifying the retention period of evaluations, notifications sent to purchasers, and records of purchasers of basic components. The NRC inspection team reviewed Duke's records associated with the Oconee 10 CFR Part 21 report and determined that Duke had implemented its 10 CFR Part 21 program in a manner consistent with the requirements in 10 CFR 21.51 for basic components.

- c. Conclusions

The NRC inspection team issued Violations 05200018/2011-201-01 and 05200019/2011-201-01 for Duke's failure to implement 10 CFR Part 21 requirements. The NRC team concluded that: Duke failed to (1) provide consistent use of the terms deviation and defect throughout the NSD 229 procedure; (2) define discovery and evaluation consistently with the definitions contained in 10 CFR 21.3, "Definitions;" (3) evaluate a deviation or failures to comply associated with substantial safety hazards within 60 days of discovery; and (4) failed to submit an interim report to the NRC if an evaluation of an identified deviation or failure to comply cannot be completed within 60 days of discovery.

2. Design Control

- a. Inspection Scope

The NRC inspection team reviewed the implementation of the Duke design control process in support of the COLA for Lee Units 1 and 2. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of Duke's design control process to verify compliance with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed the following documents for this inspection area:

- Section 17.3.2.2, "Design Control," of Duke-1-A, "Quality Assurance Program"
- Duke Topical Report, Duke-2, "Quality Assurance Program Description (QAPD), Nuclear Plant Development QAPD," Revision 3, December 17, 2010
- Duke PIP Serial No. G-10-00778 Site Characterization
Duke PIP Serial No. G-09-01211 Site Characterization
- NPD-03
- ENERCON Services, Inc (ENERCON), "Quality Assurance Program," Revision 9, dated April 13, 2004
- ENERCON CSP No. 3.02, "Control of Computer Software," Revision 5, dated June 7, 1998
- ENERCON CSP No. 7.01, "Commercial Grade Dedication," Revision 2, dated March 24, 2008

- ENERCON CSP No. 7.02, “Control of Purchased Items and Services,” Revision 0, dated December 12, 2006
- ENERCON PO No. 191-01-S to Pacific Engineering and Analysis, Inc (PEA), “Annex Building and Turbine Building Foundation Input Response Spectra (FIRS) (Revision 0) and FIRS for Lee Unit 1 North West Corner (Revision 1),” dated August 4, 2010
- PEA Software Dedication Plan, Revision 0, dated January 4, 2008
- ENERCON Calculation Package DUK010-FSAR-2.5.2-CALC-010, “Lee Unit 1 Nuclear Island Northwest Corner Site Response Sensitivity Analysis for Horizontal Motions,” Revision 0, dated February 3, 2010
- ENERCON Calculation Package DUK010-FSAR-2.5.2-CALC-011, “Calculation of Location-Specific Foundation Input Response Spectra (FIRS) for Seismic Category II Structures,” Revision 1, dated August 13, 2010
- ENERCON Calculation Package DUK010-FSAR-2.5.2-CALC-012, “Calculation of Location-Specific Foundation Input Response Spectra (FIRS) for Lee Unit 1 Northwest Corner,” Revision 0, dated August 6, 2010
- ENERCON Calculation Package DUK010-FSAR-2.4-CALC-016, “Groundwater Velocity Calculation,” Revision 5
- ENERCON CAR DUK010-CAR-14, “Corrective Action Resolution—ENERCON CSP No. 16.01,” Revision 6, Attachment B, dated October 15, 2009
- ENERCON Project Report DUK010-PR-015, “Well Construction logs,”
- MACTEC Packer Test Report, Attachment B, “Geotechnical Boring Logs,” Revision 2, dated January 11, 2011

b. Observation and Findings

b.1. Policies and Procedures

Section 17.3.2.2, “Design Control,” of the QAP establishes procedures and instructions for the implementation and assurance of design control for QA items. These procedures and instructions ensure the design is performed in accordance with approved criteria. The NRC inspection team reviewed the Duke QAP, Lee COLA Units 1 and 2 QAPD, NSD 301, and engineering directive manuals (EDMs) for engineering drawings, engineering calculations and analyses, engineering design change control, and other documents related to design control and verification.

The QAPD requires that the Lee COLA final safety analysis report (FSAR) documents are based on the AP1000 (AP1000 passive pressurized-water reactor (PWR)) design certification. It further requires that the Lee COLA design, engineering, and construction activities, including majority of the environmental services for the new project will be performed by contractors in accordance with their approved QA programs.

NPD-03 states that Duke performs its work in accordance with its QAP to ensure proper implementation of the QA Plan. Training and familiarization with NPD procedures and NSDs

support the performance of quality work. Duke staff performs assessments to confirm compliance with NPD procedures and NSDs. If there is inconsistent performance the Duke staff identifies problems in its corrective action program. The NPD Training Program Review Committee has the responsibility to review all NSD/EDM changes for any impact on the NPD.

b.2. Implementation of Design Controls

Duke has contracted with Westinghouse Electric Company (WEC) and ENERCON to develop the Lee COLA project, which includes site-specific design activities and the conduct of seismic, environmental, and site characteristic activities, but Duke retains overall responsibility for the design and development of the Lee COLA. As a primary contractor of Duke, ENERCON is responsible for overall COLA project management and development. Site-specific design activities associated with the development of the COLA for Lee Units 1 and 2 consist of design documents and calculations prepared by ENERCON and reviewed and approved by Duke. ENERCON has subcontracted design control activities with FWLA, PEA, and MACTEC to provide seismic service work for the COLA for Lee Units 1 and 2. These contractors perform engineering services to complete FSAR Section 2.5 for geotechnical and seismic work activities for the COLA for Lee Units 1 and 2.

The NRC inspection team reviewed the ENERCON QAP and corporate standard procedures (CSP) related to design control, design verification, and the design change control process. Section 3.0 of CSP No. 3.02 applies to projects where the scope involves the use of safety-related applications. This section states that software that has been previously developed by ENERCON or other companies may be used in safety-related activities, provided the requirements in Section 3.0 are met. ENERCON ensures the accuracy and applicability of the software. The software is maintained under the ENERCON or company-approved QAP.

ENERCON CSP 3.02 requires software requirement specifications and software verification and validation records (SVVRs). CSP 3.02 also requires software configuration management for computer run use, error resolution, and initiation of corrective action reports (CARs) for tracking errors in computer runs. It further states that the Project Manager is responsible for documenting his or her evaluation of the potential impact of errors for the project. The procedure invokes the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 for reports of errors to be documented in notification review form.

The NRC inspection team reviewed ENERCON PO No 191-01-S related to calculations completed by ENERCON's contractor, PEA. The NRC inspection team selected a sample of three design calculation packages that established the design-basis input to the Lee COLA. Each design calculation package consists of purpose, scope, assumptions, design basis, codes and standards, reference standards, design methodology, design calculations, drawings, and computer verification data.

The NRC team reviewed the following design calculation packages:

- Calculation Package DUK010-FSAR-2.5.2-CALC-010

This calculation package documents the results of horizontal design response spectra developed as a site response sensitivity evaluation of the localized rock properties beneath the Lee Unit 1 northwest corner and to demonstrate the adequacy of FIRS A1 at the northwest corner of Lee Unit 1. The analysis results presented in this calculation package will be used to support Duke's response to the NRC Request for Additional Information

Letter 076 (RAI 02.05.02-049). ENERCON used RASCALS and FRACTILE, as well as other software, to perform the design calculations. This calculation was used as input to FSAR Chapter 2.

- Calculation Package DUK010-FSAR-2.5.2-CALC-011

This calculation package documents the methodology and results for location-specific FIRS used to develop probabilistic ground motions, as well as hazard-consistent, strain-compatible properties (HCSCP) and spectrally matched design time histories for seismic Category II structures, including annex and turbine building structures, for Lee Units 1 and 2. ENERCON used SIGCOMB, HCSCP, RASCALS, and FRACTILE, as well as other software, to perform the design calculations. This calculation was used as input to FSAR Chapter 2.

- Calculation Package DUK010-FSAR-2.5.2-CALC-012

This calculation documents the methodology and results for location-specific FIRS used to develop probabilistic ground motions, as well as HCSCP and design time histories for the northwest corner of Lee Unit 1. ENERCON used RASCALS and FRACTILE, as well as other software, to perform the design calculations. This calculation was used as input to FSAR Chapter 2.

The NRC inspection team verified that each calculation package contained the design bases, assumptions, and methodology used to develop the calculations, results, and conclusions. The NRC inspection team noted that the samples it reviewed were consistent with the procedural guidance contained in the procedures of ENERCON and its contractors. No findings of significance were identified.

b.3 Computer Software Control

The NRC inspection team reviewed ENERCON's programs and policies associated with the control of computer programs used for design analysis activities including example calculations and sample test cases for a number of applications. The NRC inspection team reviewed the following computer programs:

- RANPAR Version 2.2

The NRC inspection team reviewed the ENERCON "Computer Program Certification Report for RANPAR Version 2.2," Revision 0, issued March 2008. RANPAR Version 2.2 is a proprietary computer code developed by PEA and is part of a computer suite called RASCAL SET Version 1.0, Revision 00. The program suite is used to estimate the effects of the dynamic response of site-specific materials on reference rock outcrop ground motions.

- RASCAL Version 5.5

The NRC inspection team reviewed the ENERCON "Computer Program Certification Report for RASCAL Version 5.5," Revision 0, issued April 2008. RASCAL Version 5.5 is a proprietary computer program developed by PEA and is part of a computer suite called RASCAL SET Version 1.0, Revision 00. The program suite is used to estimate the effects of the dynamic response of site-specific materials on reference rock outcrop ground motions.

- FRACTILE Version 2.0

The NRC inspection team reviewed the ENERCON “Computer Program Certification Report for FRACTILE Version 2.0,” Revision 0, issued April 2008. FRACTILE Version 2.0 is a proprietary computer program developed by PEA and is part of a computer suite called SOILHAZ SET Version 1.0, Revision 00. The program suite is used to compute a soil hazard curve from a rock hazard curve and associated amplification factors to calculate the uniform hazard spectra on soil and the uniform reliability spectrum.

The NRC inspection team reviewed and evaluated a sample test case problem results and for each code and reviewed the test results against the results published in the final calculations and conformed the results were consistent with the code output values. No findings of significance were identified

b.4. Ground Water Flow and Transport Evaluation

The NRC inspection team reviewed Duke’s methodology for data collection and the approaches used for developing site characteristics related to ground water flow and radionuclide transport at the Lee site. The NRC inspection team discussion with the Duke staff included the following items:

- methods used by Duke to estimate maximum post construction ground water levels
- methods and data used to produce estimates of hydraulic conductivity of various subsurface units, including, in particular how older Cherokee-era (ca. 1973) data were incorporated into estimates, and what QA procedures were used while obtaining and analyzing the data
- description of the process followed to determine site characteristics important to ground water flow and radionuclide transport
- description of the well logging, pumping test, slug test, sampling and analyses, and quality assurance procedures
- design of the synthetic layer membrane underneath the nuclear island and its effects on ground water movement

The NRC inspection team also interviewed Duke’s subject matter experts (SMEs) to clarify the estimation of postconstruction maximum ground water levels and of the hydraulic properties of subsurface materials. The Duke SMEs briefly described the timeline of the Lee COLA FSAR revisions and the changes in hydraulic conductivity values that were documented in the subsequent revisions. The NRC inspection team discussed with Duke’s SMEs the methodology for estimating site characteristics such as hydraulic conductivity and ground water flow velocity and focused on the various tests and statistical derivations employed in the estimation of these characteristics, while reviewing the following documents:

- Duke PIP Serial No. G-10-00778 that documents actions taken by Duke in relation to the estimation of site characteristics
- Duke PIP Serial No. G-09-01211 that documents action taken by Duke in relation to the estimation of site characteristics
- ENERCON CAR No. DUK010-CAR-14 that addresses the inconsistencies between certain calculation packages and FSAR drawings and project boring logs regarding relative locations of materials important to ground water flow

- ENERCON Calculation Package DUK010-FSAR-2.4-CALC-016, “Groundwater Velocity Calculation,” Revision 5
- ENERCON Project Report DUK010-PR-015 that documents well construction logs and detailed descriptions of wells, tests data, and other important information

The NRC inspection team discussed with Duke’s SMEs the design and hydraulic performance of the waterproofing membrane. No findings of significance were identified.

c. Conclusions

The NRC inspection team concluded that the implementation of the Duke design control process is consistent with the regulatory requirements of Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50. Based on the sample of design documents reviewed, the NRC inspection team also determined that Duke and its contractors are effectively implementing policies and associated procedures to support the COLA for Lee Units 1 and 2. No findings of significance were identified.

4. Procurement Document Control

a. Inspection Scope

The NRC inspection team reviewed the implementation of the Duke procurement document control process in support of the COLA for Lee Units 1 and 2. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of the Duke procurement control process to verify compliance with Criterion IV, “Procurement Document Control,” of Appendix B to 10 CFR Part 50 and inspected a representative sample of procurement records. In addition, the NRC inspection team discussed the procurement control program with members of the Duke management and technical staff.

The NRC inspection team reviewed the following documents for this inspection area:

- Section 17.3.2.4, “Procurement Control,” of the Duke-1-A
- NSD 302, “Nuclear Procurement Program,” Revision 12, dated July 15, 2009
- Duke QA Plan-07-009, “Nuclear Quality Assurance & Oversight, Supplier Quality Assurance Plan, Restriction on Westinghouse Sub-Suppliers,” dated May 17, 2007
- Nuclear Policy Manual Chapter 13, “Supply Chain Interface Agreement,” Revision 1, dated June 14, 2010
- Approved Supplier List (ASL)—Supplier Classifications for 10 CFR Part 50, Appendix B/N45.2
- Contract No. 00089824, WEC, dated May 22, 2007
- Service Contract No. 000120083, WEC, dated June 11, 2009
- Service Contract No. 00021094, ENERCON, dated December 29, 2005

- Technical Requirements Document Specification (TRDS) WLR-4000.55-03-0001, Revision 0, dated May 17, 2007
- TRDS WLR-4000.55-03-0002, Revision 0, dated May 7, 2009
- ENERCON Letter, RPL09-09, “ENERCON Audit Report of William Lettis & Associates, Inc (WLA),”—Qualification Audit (WLA-AUD-01), dated April 16, 2009
- ENERCON CAR WLA-CAR-06, Verification and Closeout, dated July 15, 2009
- ENERCON CAR WLA-CAR-07, Verification and Closeout, dated September 10, 2009
- ENERCON CAR WLA-CAR-08, Verification and Closeout, dated July 15, 2009
- WLA Quality Assurance Manual, Revision 4, dated October 30, 2009

b. Observations and Findings

b.1. Policies and Procedures

Section 17.3.2.4, “Procurement Control,” of the QAP establishes requirements and assigns responsibilities for the control of procurement documents, including purchase authorizations and POs for safety-related items or services purchased from approved suppliers.

NSD 302 supplements the requirements of the Duke QAP by providing specific guidance on the purchase, receipt, and storage of materials and the procurement and receipt of services for the Nuclear Generation Department and is Duke’s primary procurement document control procedure. In addition to NSD 302, the NRC inspection team reviewed several CSDs and EDMs and determined that these directives adequately covered the QA, PO scope of work, technical requirement specifications for POs, adequacy of the COLA and supplier QAP, control of the qualified supplier list, control of the supply chain, review and approval of POs for safety-related structures, systems, and components (SSCs) and commercial-grade dedication of SSCs, control of changes to POs, procurement engineering services, commodity requisition, component QA category identification, procurement and receipt inspection, detection of nonconformance or fraudulent items, and disposition of nonconformance reports and 10 CFR Part 21 reports.

b. 2 Duke and ENERCON Approved Supplier List (ASL)

The NRC inspection team reviewed Duke’s ASL, consisting of suppliers for both the existing operating fleet and for Lee Units 1 and 2. The NRC inspection team confirmed that the suppliers performing work for Duke with respect to the COLA for Lee Units 1 and 2 were appropriately on the Duke ASL and their scope of supply was documented and consistent with their contracted activities with Duke. No findings of significance were identified.

b. 3 Contract Review

The NRC inspection team reviewed several contracts between Duke and their sub-suppliers as part of the evaluation of the implementation of procurement control. Specifically, the NRC inspection team reviewed the following contracts:

Duke Service Contract No. 00089824 to WEC for engineering services related to site characterization work including fill material evaluation and ground water system qualification.

Duke Service Contract No. 000120083 to WEC for engineering services related to site characterization work including performance of analyses related to granular fill material and review calculations related lateral earth pressures.

Duke Service Contract No. 00021094 to ENERCON for the development of design documents needed to complete FSAR Section 2.5 for the COLA for Lee Units 1 and 2.

The NRC inspection team confirmed that each contract contained the relevant technical and quality assurance requirements, including reference to pertinent industry and NRC guidance documents, necessary to perform the activities as defined in the referenced TRDS for each contract, and that contract deliverables were clearly described. No findings of significance were identified.

c. Conclusions

The NRC inspection team concluded that the implementation of the Duke procurement control process are consistent with the regulatory requirements of Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50 and has been implemented in accordance with the applicable Duke and contractor policies and procedures to support the COLA for Lee Units 1 and 2. No findings of significance were identified.

5. Corrective Action Program

a. Inspection Scope

The NRC inspection team reviewed the implementation of the Duke corrective action program in support of the COLA for Lee Units 1 and 2. Specifically, the NRC inspection team reviewed the policies and procedures governing the implementation of the Duke corrective action process to verify compliance with Criterion XVI, "Corrective Actions," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the corrective action program with members of the Duke management and technical staff.

The NRC inspection team reviewed the following documents for this inspection area:

- Section 17.3.2.13, "Corrective Actions," of the DUKE 1-A
- NSD 208, "Problem Investigation Program," Revision 32, dated July 29, 2010
- NSD 212, "Cause Analysis," Revision 18, dated December 8, 2010
- NSD 223, "PIP Trending Program," Revision 6, dated July 2, 2007
- NSD 125, "Performance Improvement," Revision 3, dated March 1, 2010
- PIPs G-10-01299, G-09-01168, G-09-00793, G-09-00792, G-09-00392, G-08-01072, G-08-00136, G-08-00943, G-08-00704

- Duke NPD PIP Trend Reports: NPD-4000.01-05-2010-1Q, NPD-4000.01-05-2009-2Q, NPD-4000.01-05-2010-3Q, NPD-4000.01-05-2010-2Q, NPD-4000.01-05-2010-4Q
- Duke letter WLG2009-03-06 for Lee Units 1 and 2, 10 CFR 50.46 Annual Report, dated March 6, 2009

b. Observations and Findings

b.1. Policies and Procedures

Section 17.3.2.13, "Corrective Action," of the QAP describes the controls and corrective measures prescribed to ensure that conditions adverse to quality are promptly identified, controlled, and reported to responsible management. NSD 208 supplements the requirements of the QAP by providing specific guidance for the identification and resolution of issues entered in the PIP Database, which is the electronic tool used at the nuclear sites and the general office. The procedure also includes provisions to identify conditions adverse to quality and conditions not adverse to quality. The issues identified as conditions adverse to quality are part of Duke's corrective action program.

NSD 212 establishes the process for conducting a cause analysis as part of problem investigation and resolution, in accordance with the requirements of NSD 208. NSD 223 provides guidance to identify trends on low-level issues to prevent significant events or problems and to ensure the general office management team is well aware of trends in its area of responsibility.

NSD 125 provides guidance on performance improvement activities that identify gaps to achieving excellence and on making the necessary improvements to address the identified gaps.

b.2. Implementation of Corrective Action Program

The NRC inspection team reviewed a sample of PIPs, including open and closed PIPs and those associated with Duke's performance of audits, and a sample of trending analysis reports. The NRC inspection team interviewed the responsible Duke staff and management as part of its evaluation of the corrective action program. Through the review of these documents and interviews, the NRC inspection team confirmed that all actions identified in these PIPs had been completed in a timely manner, consistent with the requirements of Duke's corrective action program and determined that Duke's policies and implementing procedures provided the necessary guidance to adequately document, evaluate, correct, report, and verify the resolution of conditions adverse to quality.

c. Conclusions

The NRC inspection team concluded that the Duke corrective action program requirements were consistent with the regulatory requirements of Criterion XVI "Corrective Actions," of Appendix B to 10 CFR Part 50. Based on the sample reviewed, the NRC inspection team also determined that Duke adequately implemented the QAP and implementing procedures. No findings of significance were identified.

6. Quality Assurance Records

a. Inspection Scope

The NRC inspection team reviewed the implementation of the Duke QA records program in support of the COLA for Lee Units 1 and 2. Specifically, the NRC inspection team reviewed the policies and procedures governing the Duke records process to verify compliance with Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team discussed the records program with members of the Duke management and technical staff.

The NRC inspection team reviewed the following documents for this inspection area:

- Section 17.3.2.15, "Records," of the Duke -1-A
- NSD 701, "Records Management," Revision 8, dated April 1, 2010
- NPD-06, "Document Control and Records Management Guidance Document," Revision 1, dated September 30, 2009
- Information Services and Compliance (ISPG) 001, "Guidance Document for Retention Rules and File Plan," Revision 00, dated April 7, 2009

b. Observations and Findings

b.1. Policies and Procedures

Section 17.3.2.15, "Records," of the QAP describes measures and governing procedures that have been established to ensure that records of items and activities affecting quality are identifiable and retrievable. The provisions of such procedures establish the scope of the records retention program and include requirements for records administration, receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

The NRC inspection team reviewed Duke's administrative procedures pertaining to the QA records program. NSD 701 establishes guidance for the creation, authentication, storage, maintenance, and life cycle management of all record types generated by or for the Nuclear Generation Department. It specifically included provisions to ensure that records are available when needed for the intended businesses in the Nuclear Electronic Document Library and destruction at the end of the applicable retention period.

NPD-06 provides guidance for the preparation and submittal of documents and records to Document Control and Records Management. This procedure also provides guidance to those individuals who have the ultimate responsibility within NPD.

ISPG-001 provides guidance on using and submitting changes to the Nuclear Generation Department record retention rules and Nuclear File Plan, in accordance with the Enterprise Records Management Policy and NSD 701. The Information Services and Compliance Group are responsible for notifying and assisting each department with modifications related to records retention requirements.

b.2. Implementation of QA records

The NRC inspection team reviewed a sample of several records, including forms, tables, and logs used for identification, receipt control, processing, corrections, retention, and safekeeping for all documented records. During this review, the NRC inspection team verified that Duke had implemented a QA records system that provided adequate measures for the identification, classification, validation, and distribution controls of records. In addition, the NRC inspection team interviewed responsible Duke staff and management as part of its evaluation of the Duke QA records program. The NRC inspection team noted that Duke's policies and implementing procedures provided the necessary guidance for the administration, identification, receipt, storage, preservation, safekeeping, and disposition of all records.

c. Conclusions

The NRC inspection team concluded that the Duke QA records program requirements were consistent with the regulatory requirements of Criterion XVII, "Quality Assurance Records," of Appendix B to 10 CFR Part 50. Based on the QA records reviewed, the NRC inspection team also determined that Duke adequately implemented the QAP and implementing procedures. No findings of significance were identified.

7. Internal and External Audits

a. Inspection Scope

The NRC inspection team reviewed the implementation of the Duke external and internal audit processes in support of the COLA for Lee Units 1 and 2. Specifically, the NRC inspection team reviewed a representative sample of audits and the policies and procedures governing the implementation of Duke's processes to verify compliance with Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed the following documents for this inspection area:

- Section 17.3.3, "Self Assessment," of Duke -1-A
- NSD 606, "Quality Assurance Project Oversight," Revision 0, dated October 28, 2009
- INOP-240, "Conduct of Audits," Revision 4, dated August 1, 2010
- INOP-520, "QA Supplier Audits," Revision 1, dated March 11, 2010
- INOP-530, "Auditor Training, Qualification, and Certification," Revision 1, dated May 10, 2010
- INOP-220, "Audit Section Training and Auditor Certification," Revision 2, dated November 29, 2010
- GO-09-15(NPA)(LN)(COLA), the evaluation form documenting Duke's internal audit of "QA Program Used in the Development of Duke Energy COLA," conducted April 16 through May 02, 2009

- GO-09-23(INOS)(LEE)(NGO), the evaluation form documenting Duke’s internal audit of “Applicable Criteria of 10 CFR 50, Appendix B, for Lee Units 1 and 2 COLA,” conducted July 13–27, 2009
- VA08037 NUPIC 20094 ENERCON Audit, conducted October 6–16, 2008
- VA09106 NUPIC 20521 WEC Audit, conducted July 27–31, 2009

b. Observations and Findings

b.1. Policies and Procedures

Section 17.3.3, “Self Assessment,” of the QAP provides the basis for the control and performance of safety-related and quality-related activities associated with Duke’s operational fleet of nuclear power plants. NPD-03 provides the necessary guidance to successfully implement and manage the QA requirements for the development of the COLA for Lee Units 1 and 2 in accordance with the QAP.

NSD 606 provides guidance for oversight and applies to QA condition projects, contracts, or POs having significant risk or when work is performed, all or in part, under a supplier’s QAP. It defines the process and structure for developing independent oversight plans to ensure contract requirements are met. The level of oversight applied to these projects is dependent on the risk significance or complexity of the project and is determined by the Independent Nuclear Oversight (INOS) audit team, with concurrence from Nuclear Generation Department management.

INOP-240 provides guidance for the preparation, conduct, reporting, and closeout of audits performed by INOS to meet the requirements of the QAP and management expectations.

INOP-220 establishes training expectations and provides requirements for the qualification and training of personnel identified as auditors and lead auditors. Compliance is mandatory for all audit and assessment activities that must comply with Appendix B to 10 CFR Part 50.

INOP-520 describes the methodology used by procurement quality staff for preparing, performing, documenting, and communicating supplier audits. It also provides guidance in documenting audit reviews to take credit for evaluating third-party audits, such as Nuclear Procurement Issues Committee (NUPIC) audits.

INOP-530 describes the procedure for providing training, qualification, and certification for personnel performing supplier audits, surveys, or surveillances.

b.2. Review of Audit Activities

b.2.1. Duke Internal Audits

The NRC inspection team reviewed a sample of internal audit reports to verify that Duke performed audits in accordance with program requirements. For each of the audits reviewed, the NRC inspection team confirmed that the reports identified audit findings and corrective actions associated with these findings. The NRC inspection team noted that corrective actions were taken promptly to respond to any identified findings, and the reports contained an adequate level of objective evidence to support closing the condition. The NRC inspection team also verified that Duke had prepared and approved the audit plan

identifying the audit scope and focus and the applicable criteria before the initiation of the audit or surveillance activity.

b.2.2. Duke External Audit

- ENERCON

The NRC inspection team reviewed Duke's evaluation of NUPIC Audit Report No. 20094 of ENERCON's QAP, dated October 6–16, 2008, at Kennesaw, GA, and Mt. Arlington, NJ. Duke auditors led the audit. The scope of the audit included a review of the effectiveness of the ENERCON QAP for control of activities as they relate to the supply of engineering services. The NUPIC audit resulted in four findings and one observation that ENERCON addressed. All findings and observations were determined not to have any impact on the services provided by ENERCON in support of the Lee Unit 1 and 2 COLA. Duke reviewed the corrective actions implemented by ENERCON and found them to be satisfactory, as documented in an audit closure letter from ENERCON to Duke. Duke reviewed this audit closure letter, found that it adequately addressed the audit findings, and subsequently accepted the NUPIC audit report.

- WEC

The NRC inspection team reviewed Duke's evaluation of NUPIC Audit Report No. 20521 of WEC, dated July 27–30, 2009, at Monroeville, PA. The Tennessee Valley Authority led the NUPIC audit team, which included one member from Duke's QA organization. Duke, in accordance with INOP-520, adequately evaluated the audit report for acceptance. The scope of the audit included a review of the effectiveness of the WEC QAP pertaining to POs relating to the design and construction of the AP1000 PWR. The NUPIC audit resulted in nine findings that currently remain open. All findings and observations were determined not to have any impact on the services provided by WEC in support of the Lee Unit 1 and 2 COLA.

In addition, the NRC inspection team reviewed the qualification records for a sample of Duke's auditors and lead auditors. The NRC inspection team confirmed that all requirements for auditors and lead auditors had been satisfied and that all lead auditors, with one exception, had properly maintained their qualifications in accordance with the requirements of INOP-220. Upon review of Duke's lead auditor qualifications records, the NRC inspection team noted that one lead auditor had left Duke's organization for employment with an associated approved subsupplier. The lead auditor in question worked for the subsupplier for a period longer than 2 years and then returned to the Duke organization as a lead auditor, as documented in the qualification record. INOP-530, Section 5.7, "Termination of Audit Personnel Certification," Subsection 5.7.1, states, in part, that "lead auditor's and auditor's certification shall be terminated for any of the following reasons: a.) Separation from the company." INOP-530, Section 5.8, "Reinstating Terminated Audit Personnel Certification," Subsection 5.8.2, states, in part, the following:

Lead Auditor certifications terminated for a period of 2 years or more shall be recertified by completing the following:

- a. Retraining in accordance with paragraph 5.1.
- b. Examination in accordance with sub-paragraph 5.5.2.

- c. Participation as an acting Lead Auditor in at least one nuclear audit within the year prior to reinstating the terminated certification.

The NRC inspection team noted that Duke did not comply with the provision of Subsection 5.8.2 for the requalification of the lead auditor in question. It was also later confirmed, through an interview with a lead QA specialist, that none of the provisions of Subsection 5.8.2 were met to reinstate the terminated qualifications of the lead auditor in question. The finding was determined to be a violation because Duke did not comply with its procedure for qualifying lead auditors. This violation is classified as a Non-Cited Violation (NCV) in accordance with Section 2.3.2 of the NRC Enforcement Policy because the violation did not result in any safety consequences, it was promptly entered into Duke's corrective action program (PIP Serial No. G-11-00140), in which Duke committed to correct the violation within reasonable period of time, the violation was not repetitive of inadequate corrective action, and was not willful. Based on a review of Duke's documentation of this issue under its corrective action program, the NRC inspection team considers this NCV as closed.

- c. Conclusions

The NRC inspection team concluded that the implementation of the Duke external and internal audit processes is consistent with the regulatory requirements of Criterion VII, Control of Purchased Material, Equipment, and Services, and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The NRC inspection team identified one non-cited violation (NCV) that resulted from Duke not complying with its procedure for qualifying lead auditors.

- 7. Entrance and Exit Meetings

On January 24, 2011, the NRC inspection team presented the inspection scope during an entrance meeting with Mr. Peter S. Hastings, Nuclear Plant Development Licensing Manager, and other Duke and ENERCON personnel. On January 28, 2011, the NRC inspection team presented the inspection results during an exit meeting with Mr. Ron Jones, Senior Vice President, Nuclear Development, and other Duke and ENERCON personnel.

ATTACHMENT 1

1. PERSONS CONTACTED

Jerry Standridge	NPD Compliance Lead, Duke
Jeff Thomas	Fleet Licensing Manager, Duke
Jim Thornton	NRC Team Lead Contact, Duke
John Thrasher	Senior Engineering Manager, Duke
Kent Alter	Regulatory Compliance Manager, Duke
Norman Simms	Senior Licensing Engineer, Duke
Donna Scott	Document Control, Duke
Robert Morgan	Regulatory Compliance Manager, Duke
Luellen B. Jones	Engineer, Duke
Randy Todd	Oconee Regulatory Compliance Manager, Duke
Ken Rice	Nuclear Supply Chain, Duke
Mark Coren	Internal Nuclear QA Oversight, Duke
Jim Cassidy	Internal Nuclear QA Oversight, Duke
Julie A. Kuykendall	Document Control, Duke
Christopher Sweet	Project Manager, Duke
John Illingworth	Technical Specialist, ENERCON
Jeff Laughlin	Hydrology, ENERCON
John Cesare	Licensing, ENERCON
David Hargett	Hydrology, Hargett Resources, Inc

2. INSPECTION PROCEDURES USED

Inspection Procedure 35017, "Quality Assurance Implementation Inspection," dated July 29, 2008

Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Noncompliance," dated October 3, 2007

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

The NRC had not performed any previous implementation inspections of the quality assurance program governing the COLA for Lee Units 1 and 2.

The following items were found during this inspection:

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
05200018/2011-201-01	Open	NOV	10 CFR Part 21
05200019/2011-201-01	Open	NOV	10 CFR Part 21

ATTACHMENT 2

William States Lee III Nuclear Power Station, Units 1 and 2, Quality Assurance Implementation Inspection

Entrance and Exit Meeting Attendance

List of Attendees: (1) Entrance Meeting January 24, 2011, and (2) Exit Meeting on January 28, 2011

<u>(1)</u>	<u>(2)</u>		
X	X	Greg Galletti	NRC Inspection Team Leader
X	X	Raju Patel	NRC Inspection Assistant Team Leader
X	X	Paul Coco	NRC Inspection Team
X	X	Frank Talbot	NRC Inspection Team
X	X	Aixa Belen-Ojeda	NRC Inspection Team
X	X	Mark McBride	NRC Technical Specialist
X	X	Nebiyu Tiruneh	NRC Technical Specialist
X	X	Brian Hughes	NRC Project Manager
X	X	Thomas Galletta	NRC Project Manager
X	X	Peter Hastings	Duke
X	X	Allison Young	Duke
X	X	Robert Morgan	Duke
X	X	Jim Thorton	Duke
X	X	Jerry Standridge	Duke
X		John Thrasher	Duke
X		Randy Newton	Duke
X	X	Norman Simms	Duke
X	X	John Illingworth	Duke
X		Tony Jakson	Duke
	X	Tom Welch	Duke
X	X	Christopher Sweet	Duke
X	X	Phoebe Elliott	Duke
X	X	Vickie Prenatt	Duke
	X	Greg Kent	Duke
	X	Michael Flanigan	Duke
	X	Sandra Francis	Duke
	X	Lenny Azzarello	Duke
	X	Byan Dolan	Duke
X	X	Tom Scavowie	ENERCON
X	X	John Illingworth	ENERCON
X	X	John Cessre	ENERCON

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cc:

(Revised 06/23/2010)

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