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December 11, 2008

Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Duke Energy Carolinas, LLC.
William States Lee III Nuclear Station - Docket Nos. 52-018 and 52-019
AP1000 Combined License Application for the William States Lee III Nuclear Station Units 1 and 2
Response to Request for Additional Information (RAI No. 811)
Ltr # WLG2008.12-13

Reference: Letter from Brian C. Anderson (NRC) to Peter Hastings (Duke Energy) *Request for Additional Information Letter No. 037 Related to SRP Section 17.5 for the William States Lee III Units 1 and 2 Combined License Application*, dated October 6, 2008.

This letter provides the Duke Energy response to the Nuclear Regulatory Commission's requests for additional information (RAIs) included in the referenced letter.

Responses to the NRC information requests described in the reference letter is addressed in separate enclosures, which also identify associated changes, when appropriate, that will be made in a future revision of the Final Safety Analysis Report for the Lee Nuclear Station.

If you have any questions or need any additional information, please contact Peter S. Hastings, Nuclear Plant Development Licensing Manager, at 980-373-7820.

Bryan J. Dolan
Vice President
Nuclear Plant Development

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NRO

Enclosures:

1) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-001
2) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-002
3) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-003
4) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-004
5) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-005
6) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-006
7) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-007
8) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-008
9) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-009
10) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-010
11) Duke Energy Response to Request for Additional Information Letter 037, RAI 17.05-011

AFFIDAVIT OF BRYAN J. DOLAN

Bryan J. Dolan, being duly sworn, states that he is Vice President, Nuclear Plant Development, Duke Energy Carolinas, LLC, that he is authorized on the part of said Company to sign and file with the U. S. Nuclear Regulatory Commission this supplement to the combined license application for the William States Lee III Nuclear Station and that all the matter and facts set forth herein are true and correct to the best of his knowledge.

Bryan J. Dolan

Bryan J. Dolan

Subscribed and sworn to me on December 11, 2008

Phoebe P. Elliott

Notary Public

My commission expires: June 26, 2011

SEAL

xc (w/o enclosures):

Luis Reyes, Regional Administrator, Region II
Loren Plisco, Deputy Regional Administrator, Region II
Stephanie Coffin, Branch Chief, DNRL

xc (w/enclosures):

Brian Hughes, Senior Project Manager, DNRL
Brian Anderson, Project Manager, DNRL

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-001

NRC RAI:

The Duke Quality Assurance (QA) Program Description (QAPD) Part I, Section 1.1 Scope/Applicability, states that the QAPD applies to COL/construction/pre-operation and/or operation activities. The "and/or" is not consistent with the scope of the QAPD as stated in QAPD Part I, Section 1 or Final Safety Analysis Report (FSAR) Table 13.4-201, which lists the QA program as a required operational program. Please address the inconsistent use of "and/or", since the QAPD applies to all of the stated activities.

Duke Energy Response:

The Nuclear Plant Development Quality Assurance Program Description (QAPD) Part I, Section 1.1 will be revised to replace "and/or" with "and".

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Associated Revisions to the Duke Energy Nuclear Plant Development QAPD:

COLA Part 11, QAPD Part I, Section 1.1

Attachment:

1) Revision to COLA Part 11, QAPD Part I, Section 1.1.

Lee Nuclear Station Response to Request for Additional Information (RAI)

Attachment 1 to RAI 17.05.001

Revision to COLA Part 11, QAPD Part I, Section 1.1

COLA Part 11, QAPD Part I, Section 1.1 will be revised as follows:

This QAPD applies to COL/construction/pre-operation and~~/or~~ operations activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

Designing	Testing	Operating	Repairing	Shipping
Construction	Pre-operational activities	Maintaining	Training	
Procuring	(including ITAAC)	Receiving	Decommission	
Fabricating	Licensing	Storing	Modifying	
Cleaning	Startup	Erecting	Inspecting	
Handling	Siting	Installing	Refueling	

Safety-related systems, structures, and components, under the control of the QAPD are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QAPD requirements for activities within their scope.

The policy of Duke is to assure a high degree of availability and reliability of its nuclear plants while ensuring the health and safety of its workers and the public. To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-002

NRC RAI:

The Duke Quality Assurance (QA) Program Description (QAPD) Part I, Section 1.1 Scope/Applicability, lists siting as an activity within the scope of the QAPD. Since the QAPD would not become effective until COL issuance, clarify how siting activities would be subject to its provisions.

Duke Energy Response:

Siting under the Nuclear Plant Development Quality Assurance Program Description (QAPD) would not be applicable to Lee Nuclear Station. The FSAR Section17.1 clarifies the timing for and applicability of the QAPD to activities for Lee Nuclear Station. However, during the preparation of the QAPD, "siting" was included to allow the QAPD to be used for potential future new plant development activities.

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Associated Revision to the Duke Energy Nuclear Plant Development QAPD:

Reference to siting and ESP activities are contained in the QAPD and, therefore, no COLA revisions have been identified associated with this response.

Attachments:

None

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-003

NRC RAI:

QAPD Part II, Section 1, Organization, describes the Duke organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The description is applicable to the construction/preoperation phase and also to the operations phase.

Every applicant for a combined license is required by the provisions of §52.79 to include in its FSAR a description of the QA applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operations. The QAPD must include a discussion of how the applicable requirements of Appendix B have been and will be satisfied, including a discussion of how the QA program will be implemented.

In accordance with the above, Section 1, Organization, of the QAPD should be structured to clearly delineate 1) how the QA program is implemented during the period of construction and testing and 2) how the QA program is implemented during the operations phase. The transition process during which the operational programs become effective should be described. Position descriptions, including roles, responsibilities, and lines of authority, should be included for applicable corporate and line positions that implement and verify elements of the QA program and the administrative controls described by N18.7, Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants.

Duke Energy Response:

The basic implementation of the QA Program is the same during construction and testing and operations. The activities being implemented differ. QAPD Part II, Section 1 describes the responsibilities for those activities. During the construction and testing phase, the executive responsible for Nuclear Plant Development (Part II, Section 1.4) reports to the Chief Nuclear Officer (CNO) and is responsible for the development of new facilities including all activities up to turnover to operations by providing engineering, licensing and document control support where applicable including primary responsibility for implementation of the QA Program. During operations, the executive responsible for Nuclear Operations (Part II, Section 1.3) reports to the CNO and has the primary responsibility for QA program implementation. However, the manager responsible for Quality Assurance and Oversight (Part II, Section 1.5) performs the independent oversight functions throughout all phases of QA Program implementation.

The response to RAI 17.05-004 provides descriptions of how the QA program is implemented during the construction and testing phases and during the operations phase, as well as the transition process. The response to RAI 17.05-004 also provides additional information on the QA Program responsibilities, implementation and administrative controls.

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Associated Revision to the Duke Energy Nuclear Plant Development QAPD:

Revisions to clarify QAPD Part II, Section 1 are discussed with the response to RAI 17.05-004.

Attachments:

None

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-004

NRC RAI:

Organization (QAPD Part I, Section 1)

FSAR Section 17.5 states that the QAPD is maintained as a separate document; whereas QAPD Part II, Section 1 states that organization charts for various departments/locations are contained in chapter 13 of the FSARs of the respective station. NEI 06-14A, "Quality Assurance Program Description," referenced by FSAR Section 17.5, includes charts typical of the construction/preoperation phase.

Because the QAPD is a stand-alone document, periodically submitted for NRC review, it should include organization charts for the construction/preoperation phase and the operations phase. These charts should depict the flow of responsibilities from corporate positions responsible for quality-related programs to and including positions responsible for implementing and verifying elements of these programs. Generic position titles, descriptive of position functions and supplemented by descriptive text, may be used.

The QAPD describes the functions and responsibilities associated with the quality assurance requirements of Appendix B, Criteria I, Organization, Criteria II, Quality Assurance, and the administrative requirements described by American National Standard Institute (ANSI) N18.7. All positions associated with the establishment, implementation, and verification of quality-related activities should be shown on the organization charts and described in the QAPD. For the operations phase, the level of detail to be included should include roles, responsibilities, and lines of authority for the positions necessary to implement the requirements of N18.7. Comparable detail should be provided for the construction/preoperation phase.

The following clarifications are requested, specific to the submitted QAPD, Section 1:

Section 1, Organization – It is stated that design, engineering and environmental services are provided by a contract that identifies the Engineer and Constructor. Please clarify whether these services are provided by a single contract, as suggested in the text, and also the method for determining the "applicable" requirements of the QA program.

Section 1.1, Corporate Organization – It is stated that "The verification of quality is assigned to qualified personnel independent of the responsibility for performance or direct supervision of the activities. The degree of independence varies commensurate with the activity's importance to safety." Please describe the method for determining an activity's "importance to safety."

Section 1.2, Group Executive & Chief Nuclear Officer, Nuclear Generation – It is stated that this position is responsible for providing "technical support to the plants" and establishing and

managing the contract for the development of new nuclear generation." Section 1.1 also assigns responsibility for "technical support" to the President of US Franchised Electric Gas and responsibility for "procurement" to the Chief Financial Officer. Please clarify the distinction between the technical support and contract responsibilities of the CNO and the positions described in Section 1.1.

Section 1.3, Nuclear Operations – This section describes the responsibilities of the "executive responsible for Nuclear Operations". Is this position filled during the construction/preoperation phase? If it is, please differentiate between responsibilities during this phase and the operations phase.

Section 1.4, Nuclear Plant Development – Management of engineering, construction, and procurement contractors and subcontractors is assigned to the "executive responsible for Nuclear Plant Development." Since no quality assurance responsibilities are assigned to this position, please clarify how QA program implementation and verification is conducted during the construction/preoperation phase, with particular detail provided with respect to activities performed by contractors and subcontracts.

Section 1.5, Quality Assurance and Oversight – Is the position of the "manager responsible for quality assurance and oversight" a corporate position or a plant position? The reporting relationships incumbent with this position are not described. Please clarify the oversight responsibilities of this position, including those associated with implementation of the independent review function, described in Section 2.7. Section 1.5 states that the "manager for quality assurance and oversight" is responsible for "making periodic reports on the effectiveness" of the quality assurance program. To whom are these reports distributed and for what purpose?

Section 1.6, Support and Shared Services - Clearly identify the positions and responsibilities for the "executives responsible for support and shared services." To whom do these executives report? Clarify the position(s) responsible for implementing the programs for "maintenance and testing services," which are noted as elements of the quality program, but which are not assigned to position(s).

Section 1.8, Authority to Stop Work – Reference is made to "approved procedures." If this reference pertains to the Duke procedural controls described in Section 5, identify them as such. If these are other than procedures developed and controlled by Duke, describe the process for approving these procedures.

Section 1.9, QA Organizational Independence – What is the functional definition of "checking" and how does it differs from "verification." Since it is stated that design activities are not checked, provided clarification of how the adequacy of design activities is assured.

Duke Energy Response:

Duke Energy will add organization charts to the QAPD consistent with the detail in the current Duke Energy Carolinas Topical Report Quality Assurance Program and with the content shown in the NEI 06-14A example "Organization charts," including a figure typical of the construction/preoperation phase.

To ensure that the Organization description in QAPD aligns with those organization charts, Part II, Sections 1.1 through 1.7 will be revised as shown in Attachment 1.

The following information is provided in response to the specific clarifications requested.

Section 1, Organization: Refer to FSAR Chapter 13 for details about the contract/contractors specific to the Lee Station. The number of contracts is not appropriate information for the QAPD, which is applicable to multiple plants and details about each individual plant such as this may vary. Chapter 13 of the FSAR provides the information requested, which for the Lee Station is shown as a single Engineering, Procurement, and Construction contract. The "applicable" (flowdown) requirements are developed following QAPD Part II, Sections 4 and 7.

Section 1.1, Corporate Organization: The intent of the statement in Section 1.1 is that QA Program functions associated with safety-related activities are performed independently, whereas activities that have no safety significance do not require independent QA Program treatment.

Section 1.2, Group Executive & Chief Nuclear Officer, Nuclear Generation: Section 1.1 identifies the reporting relationships for the functions/organizations of Duke Energy that support the nuclear facilities. Section 1.1 indicates that the Chief Nuclear Officer (CNO) is the corporate executive with overall authority and responsibility for directing the establishment and implementation of the nuclear policies, goals, and objectives of the QA Program to attain safe, reliable, and efficient operation of nuclear plants. In addition, as shown in Figure 1, the CNO maintains the ultimate responsibility for support activities, including procurement and other technical support provided to Nuclear Generation by the other identified organizations. The support generally described in Section 1.1 for organization elements outside Nuclear Generation was further detailed in Section 1.6.

Section 1.3, Nuclear Operations: Yes, during the construction/pre-operation phase a Site Executive will be named for the Lee Station and responsibilities for the Lee Station will transition from the Nuclear Plant Development Executive to that position. See FSAR Chapter 13 for additional information on the responsibilities, which include testing and startup activities.

Section 1.4, Nuclear Plant Development: As was indicated in Section 1.4, this position is responsible for the development of new facilities including licensing, site layout, design review, development of engineering, procurement, and construction contracts, training program development, and procedure development, by providing engineering, licensing and document control support where applicable. This position is responsible for managing and providing technical oversight for the engineering and procurement contractors and subcontractors. Nuclear Plant Development responsibilities include the establishment and execution of a contract or contracts for the engineering, procurement, construction, and startup activities of new nuclear plants up to the transition point when a Site Executive is named to assume those responsibilities for the specific plant. Those activities include implementation of the QA Program. QA Oversight is the responsibility of Quality Assurance and Oversight organization for all phases.

Section 1.5, Quality Assurance and Oversight: This is a corporate position with direct access to the CNO. The reporting relationships will be shown in the organization charts to be added. This position has responsibilities and authority to provide independent oversight of activities

subject to the QAPD. The reports are distributed to the management of the organization being evaluated for their review and response.

Section 1.6, Support and Shared Services: As indicated in Part II, Section 1.1, these executives report to the CEO. The revised Organization description along with the Organization Charts better depict these responsibilities and relationships.

Section 1.8, Authority to Stop Work: Section 1.8 as referenced in this RAI is standard content from NEI 06-14A. The SER issued for that document on April 25, 2007 approved this content as worded. The procedures identified are governed by QAPD Part II, Section 5 or by a contractor's QAP.

Section 1.9, QA Organizational Independence: Section 1.9 as referenced in this RAI is standard content from NEI 06-14A. The SER issued for that document on April 25, 2007 approved this content as worded. The content was added during the review of NEI 06-14 by the NRC in response to an RAI. This section addresses implementation of SRP Section 17.5, paragraph II.A.4. The adequacy of design activities is addressed in Section 3 of the QAPD.

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Associated Revisions to the Duke Energy Nuclear Plant Development QAPD:

QAPD Part II, Section 1.1 through 1.7 will be revised with the text in Attachment 1. Additionally, organization charts shown in Attachment 1 will be added. Those are consistent with the detail in the current Duke Energy Carolinas Topical Report Quality Assurance Program and with the content shown in the NEI 06-14A example "Organization Charts."

The changes provided in Attachment 1 and the associated conforming changes to the QAPD will be incorporated in a future revision.

Attachment:

1) COLA Part 11, QAPD Part II, Section 1.1 through 1.7 and associated Organization Charts.

Lee Nuclear Station Response to Request for Additional Information (RAI)

Attachment 1 to RAI 17.05.004

Revision to COLA Part 11, QAPD Part II, Section 1

COLA Part 11, QAPD Part II, Section 1.1 through 1.7 will be revised by replacing those sections with the following:

1.1 Duke Corporate Organization

The Chairman, President, and Chief Executive Officer (CEO) has overall responsibility for design, construction, and operation of generation and transmission facilities. The CEO reports to the Duke Board of Directors with respect to all matters. The QAP Policy Statement issued by the CEO establishes mandatory expectations for all organizations and personnel to comply with the QAPD and its implementing documents while performing quality affecting activities covered by the QAP. Thus, the attainment of quality rests with those assigned responsibility for performing an activity.

Reporting to the CEO is the President and Chief Operating Officer (COO) of US Franchised Electric and Gas who is responsible for electrical transmission, distribution, laboratory services, and switchyard maintenance and technical support; the Chief Strategy and Policy Officer who supports emergency response communications; and the Chief Administrative Officer who is responsible for Information Technology Services, purchasing activities, and corporate document control and record management activities. Various services that support nuclear generation are provided by these mentioned branches of the corporate organization.

Also reporting to the CEO is the Chief Nuclear Officer (CNO) who is the corporate executive delegated overall authority and responsibility for directing the establishment and implementation of the nuclear policies, goals, and objectives of the QAP to attain safe, reliable, and efficient operation of nuclear plants.

Figure 1 shows the overall Corporate Organization.

1.2 Nuclear Generation

As directed by the CNO, the Nuclear Generation Department has direct line responsibility for all nuclear plant operations. Nuclear Generation is responsible for achieving quality results during design, construction, preoperational testing, operation, testing, maintenance, and modification of the plants and for complying with applicable codes, standards and NRC regulations. The CNO is also responsible for establishing and managing new nuclear plant development.

The CNO is informed of significant problems or occurrences relating to safety and QA through established administrative procedures, and participates directly in their resolution, as necessary.

1.2.1 Operating Plant Site Organization

As shown in Figure 2, each plant has a Site Vice President who reports to the Senior Vice President of Nuclear Operations, who in turn reports to the CNO. The Site Vice President has the responsibility for overall plant nuclear safety as established by Technical Specifications. The Site VP is also responsible for the administration, implementation, and assessment of the QAP as it applies to plant operation. The Site Vice President directs the activities of the plant through five major suborganizations: 1) Station Management, 2) Safety Assurance, 3) Engineering, 4) Site Services, and 5) Training.

1. **Station Management** consists of five primary groups: a) Operations, b) Maintenance, c) Work Control, d) Radiation Protection, and e) Chemistry. Each group's activities are

directed by a superintendent or senior manager who reports to the Station Manager. Reporting to the Site Vice President is a Station Manager who is assigned the direct responsibility for operating the station in a safe, reliable, and efficient manner; and is responsible for protection of the station staff and the general public from radiation exposure and any other consequences of an accident at the station and bears the responsibility for compliance with the facility operating license. In addition, the Station Manager or his designee shall approve, prior to implementation, each proposed test, experiment, or modification to SSCs that affect nuclear safety.

a. **Operations** directs the actual day-to-day operation of the station.

b. **Maintenance** directs the maintenance of mechanical equipment, electrical equipment, instrumentation, controls, and computers.

c. **Work Control** facilitates operational and outage activities through coordination, development, and shift and outage management of a timely and effective integrated station schedule.

d. **Radiation Protection** directs the radiation protection program. The duties include the training of personnel in equipment use, control of personnel radiation exposure, continuous determination of plant radiological status, surveillance of radioactive waste disposal operations, conduct of radiological environmental monitoring, and records maintenance.

e. **Chemistry** directs activities to meet overall chemistry and radiochemistry requirements, with special emphasis on primary and secondary system water chemistry.

2. **Safety Assurance** directs activities in environmental health and safety, regulatory compliance, emergency planning, and security.

3. **Engineering** directs activities in the following engineering areas: reactor, component, systems, mechanical, electrical, civil, computer, and modifications. Functions include design and coordination of plant modifications, design basis documentation and design reviews, plant process information systems, and support of maintenance, operating, and surveillance activities.

4. **Site Services** directs activities associated with tools management, facilities management, and equipment and distribution.

5. **Training** directs implementation and oversight of the training programs for site personnel. Functions include analysis, design, development, implementation, and evaluation of training and qualifications programs that support personnel performing plant work.

1.2.2 General Office Organization

The General Office is organized into four divisions. The activities of each division are directed by a vice president who reports to the CNO. The four divisions are: 1) Nuclear Operations, 2) Nuclear Plant Development, 3) Nuclear Engineering, and 4) Nuclear Fleet Performance, Oversight and Strategy.

1. **Nuclear Operations** consists of two primary groups: a) Plant Support and b) Major Projects. Each group's activities are directed by a vice president reporting to the Senior Vice President, Nuclear Operations who also provides management oversight to the nuclear stations.

a. **Plant Support** is divided into five subgroups: 1) Nuclear Technical Services, 2) Nuclear Supply Chain, 3) Licensing and Regulatory Compliance, 4) Fleet Outage Support, and 5) Plant Services that support the nuclear sites. Each subgroup's activities are directed by a senior manager who reports to the group vice president.

1) **Nuclear Technical Services** provides chemistry, radiation protection, metallurgy, laboratory services, materials, aging management, specialized plant engineering support, calibration services, steam generator maintenance, QC and NDE inspector training and certification, inspection procedure management, and special projects support.

2) **Nuclear Supply Chain** provides procurement engineering, procurement, storage, inventory control, and receipt inspection/testing support.

3) **Licensing and Regulatory Compliance** provides regulatory issues and industry affairs support.

4) **Fleet Outage Management** provides refueling outage planning coordination support.

5) **Plant Services** provides Fitness for Duty and Nuclear Access Program implementation support.

b. **Major Projects** manages contracts, engineering, and overall management for major projects.

2. **Nuclear Plant Development** is responsible for development of the licensing actions needed in support of new nuclear site development. Responsibilities also include engineering oversight of contractors, site layout, staffing and program development. The executive in charge of nuclear plant development is assisted by a support staff and reports directly to the CNO. Nuclear Plant Development responsibilities include the establishment and execution of a contract or contracts for the engineering, procurement, construction, and startup activities of new nuclear plants up to the transition point when a Site Executive is named to assume those responsibilities. Figure 3 shows the Nuclear Plant Development/Construction Organization. As a new nuclear plant development approaches startup, the site organization transitions from the development focused organization in Figure 3 to the Operating Plant Site Organization shown in Figure 2.

3. **Nuclear Engineering** provides station support for probabilistic risk analysis, safety analysis, nuclear design, core mechanical and thermal hydraulic analysis, fuel management, and radiological engineering.

4. **Nuclear Fleet Performance, Oversight, and Strategy** consists of two primary groups: a) Independent Nuclear Oversight (INOS) and b) Nuclear Performance and Strategy. Each group's activities are directed by a senior manager who reports to the division vice president.

a. **INOS** provides QA oversight of corporate and supplier organizations that are involved in nuclear safety-related activities. Oversight is provided by four functional groups: Audit, Inspection, Procurement Quality, and Performance. Audits are conducted to verify effective implementation and compliance with QAPD criteria and NRC regulations. Inspections (both QC and NDE) are conducted to ensure compliance with applicable codes and standards. Procurement Quality performs audits and surveillances of supplier products and services to ensure compliance with the supplier's quality program and Duke's procurement requirements. Performance conducts assessments of plant operation and support activities based

on their nuclear safety risk-significance with a focus on performance improvement. All four groups identify and communicate adverse quality conditions for timely resolution and advise line and corporate management on the overall quality and safety of plant operations.

The INOS manager is delegated primary ownership of the department QAP and is responsible for day-to-day administration of the program and resolution of QA issues. The INOS manager has immediate access to the CNO to communicate significant QAP concerns and issues. Within the INOS group, a QA single point of contact (QA SPOC) provides the first point of reference for QAP issues, clarifications, and interpretations. Duties also include ownership of the QAPD, interpretation of QAP details and commitments, review and acceptance of proposed QAPD changes, response to management, regulator, and industry inquiries with regard to QAP implementation, and review of department policy documents to maintain their alignment with the QAP.

b. **Nuclear Performance and Strategy** provides performance improvement program oversight that identifies gaps to excellence, conducts operating experience assessments, administers the corrective action program, monitors other lower level performance trends and issues, and provides oversight for document control and record management activities.

1.3 U. S. Franchised Electric and Gas

1.3.1 Power Delivery

Power Delivery provides electrical transmission, distribution and switchyard engineering, maintenance, and testing support.

1.3.2 Engineering and Technical Services

Engineering and Technical Services provides environmental and laboratory support services and relay engineering and switchyard maintenance support.

1.4 Corporate Administration

1.4.1 Enterprise Business Services

Enterprise Business Services provides a variety of services and technical support for critical information technology applications and systems such as equipment databases, applications, and infrastructure. This organization is also responsible for the development and maintenance of selected information technology services and support, including electronic document management, some of which support QA Condition activities.

1.4.2 Enterprise Operations Services

Enterprise Operations Services provides record storage and document management services.

1.4.3 Supply Chain

Supply Chain provides overall corporate procurement services.

1.5 Strategy, Policy, and Regulatory Activities

1.5.1 Corporate Communications

Corporate Communications provides support for the nuclear site's emergency response organization.

1.6 Department Interfaces

Departmental interfaces are identified in QAP manuals. Quality related activities performed by departments other than Nuclear Generation are identified by and conducted in accordance with approved departmental interface agreements.

1.7 Agents and Contractors

Duke may contract various activities such as engineering, procurement, and construction. These contracts will identify QAP requirements that are applicable to the contractors and their subcontractors, consistent with the requirements of Part II, Sections 4 and 7.

Figure 1 -- Duke Corporate Organization

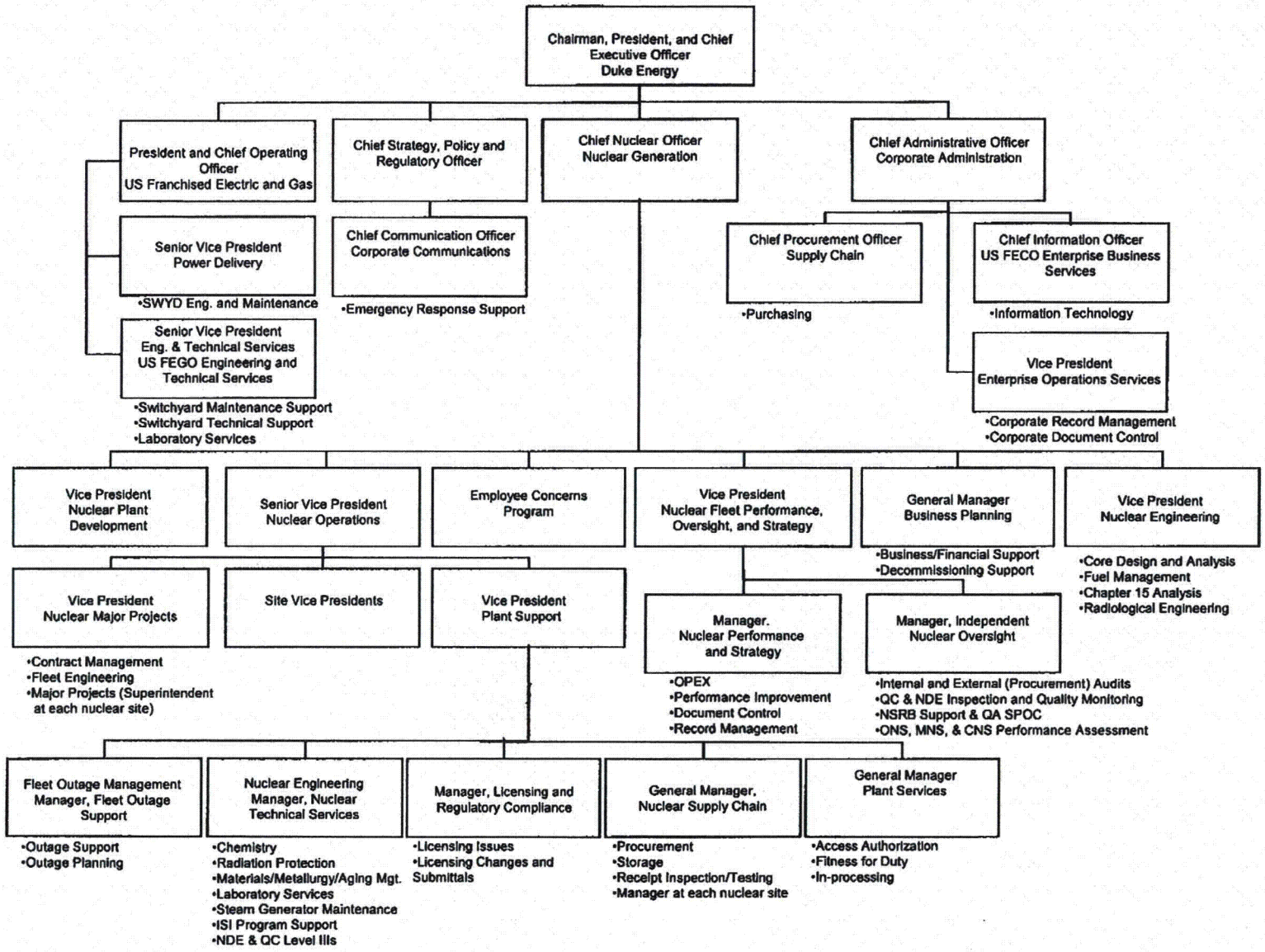


Figure 2 -- Operating Plant Site Organization

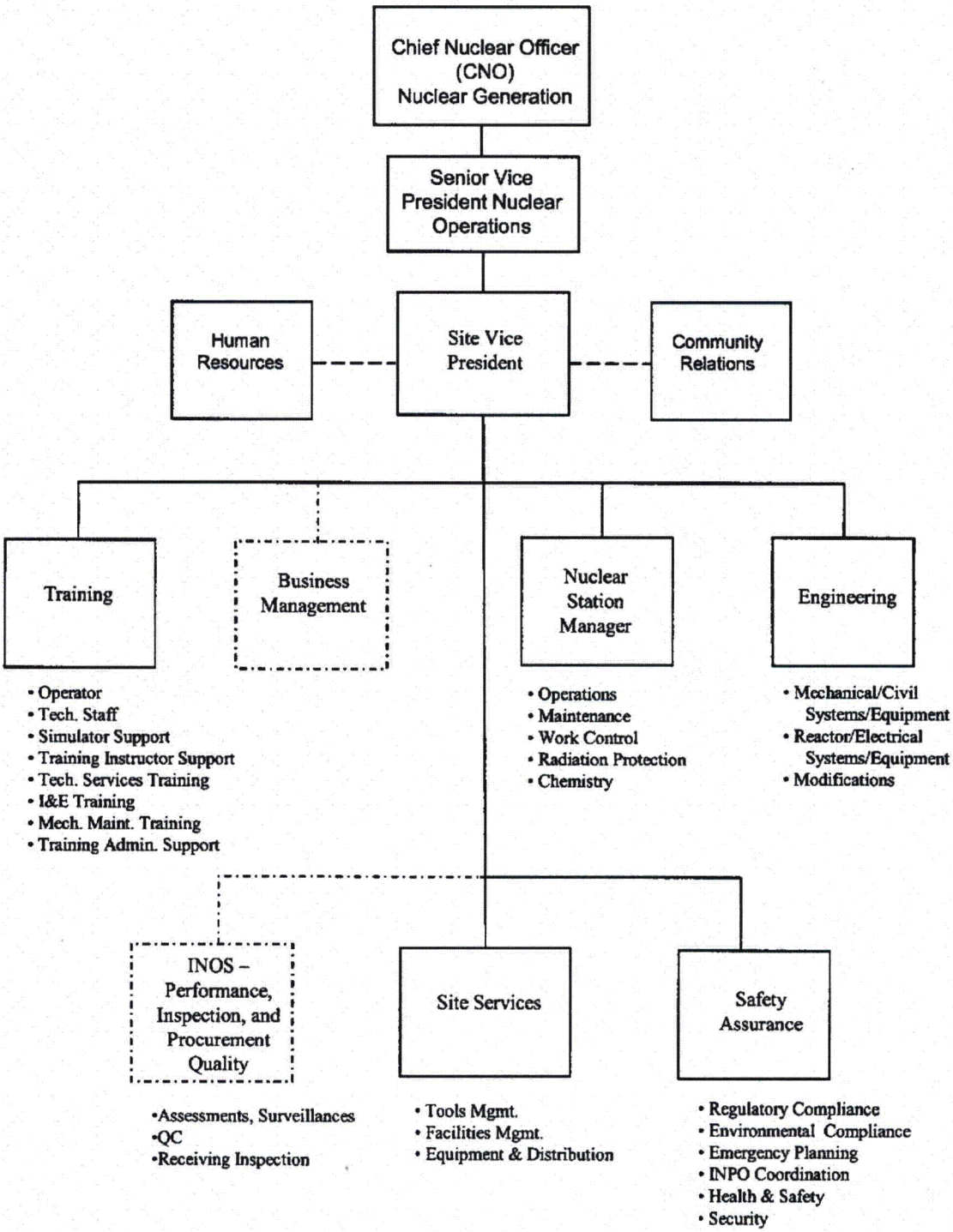
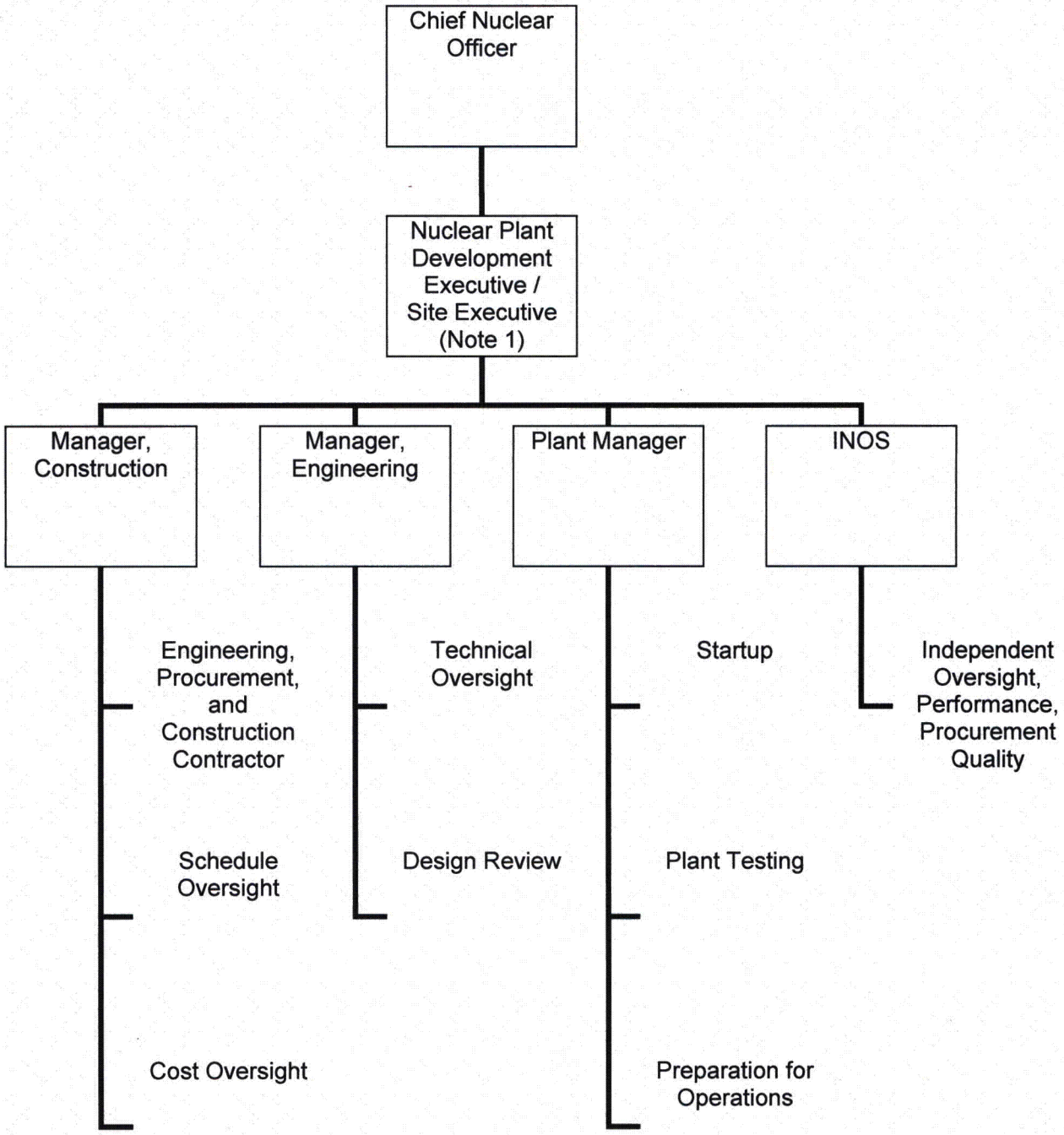


Figure 3 -- Nuclear Plant Development/Construction Organization

Note 1: Initially, Nuclear Plant Development described in QAPD Part II, Section 1.2.2, enumerated paragraph 2, is responsible for construction planning and preparation. The responsibility for construction oversight transitions to the Site Executive when that position is filled.



Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-005

NRC RAI:

Safety Related Systems, Structures, Components (SSCs) (QAPD Part I, Section 2)
The Duke Quality Assurance (QA) Program Description (QAPD) Part I, Section 2, states that the QAPD applies to those quality-related activities that involve the functions of safety-related activities of structures, systems, and components (SSCs) as described in the COL Final Safety Analysis Report. The staff notes that Appendix B to 10 CFR Part 50 requires, in part, that Part 52 applicants include in the FSAR a description of the quality assurance [program] applied to the design, and to be applied to the fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations. Please revise the language in this section to conform to this requirement.

Also, the current language in this section seems to indicate that safety-related SSCs are described in the FSAR. Please identify the corresponding FSAR section. Otherwise, please clarify the purpose of this text and/or modify it accordingly.

Duke Energy Response:

It appears that this NRC RAI 17.05-005 was intended to reference Duke Energy Nuclear Plant Development Quality Assurance Program Description (QAPD) Part II, Section 2 since there is no Section 2 in Part I of the QAPD. The RAI appears to be related to the standard language in the first two paragraphs of QAPD Part II, Section 2.

The QAPD is based on NEI 06-14, "Quality Assurance Program Description," which was approved by the NRC in Reference 203, FSAR Section 17.5. NRC has issued a similar RAI to NEI. This RAI will be answered by NEI. If NEI identifies any changes to the standard text, Duke Energy will review that change and update the QAPD if found to be appropriate.

Regulatory Guide 1.206 provides the detailed format and content of the FSAR, including the descriptions of the SSCs. Safety-related SSCs are described in the DCD, which is incorporated by reference in the Westinghouse Design Certification Document Rev. 16. However, "SSC" requirements were included in QAPD Part II, Section 2, to allow the QAPD to be used for potential future new plant development activities.

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Attachments:

None

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-006

NRC RAI:

QAPD Part II, Section 2 – Reference is made to ESP applications in Section 2 and other places in the QAPD. Please clarify how the QAPD applies to ESP activities or remove these references from the QAPD.

Duke Energy Response:

Since Duke did not execute an ESP for the Lee Nuclear Station, ESP requirements in the Duke Energy Nuclear Plant Development Quality Assurance Program Description (QAPD) do not apply to Lee site. FSAR Section 17.1 clarifies the timing for and applicability of the QAPD to activities for Lee. "ESP" requirements were included in the QAPD to allow the QAPD to be used for potential future new plant development activities.

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Attachments:

None

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-007

NRC RAI:

Section 2.3 of NEI 06-14A states that the QAPD in the COL application will be annotated to identify site-specific design basis activities. Section 2.3 of the Lee QAPD states that this information will be maintained in a project planning document. Please clarify the intent of this statement which seems to refer to the development of the COL application rather than to the design, construction, or operational phases of the Lee Nuclear Station. Are the annotated outlines intended to be submitted as part of the application?

Duke Energy Response:

Duke notes that the NRC has issued a similar RAI to NEI and NEI has agreed to respond to the RAI. Section 1 of the SER issued for NEI 06-14 identifies the treatment of bracketed text as follows: "The QAPD template contains bracketed text that the applicants will modify with specific information as necessary for each ESP or COL application. The staff will review and approve the bracketed text included in the QAPD template with the ESP and COL application to determine the acceptability of the QAPD submitted by the applicant." QAPD Section 2.3, which is bracketed text in the QAPD Template, addresses identification of QA Controls for ESP and COL application development.

The Duke wording of Section 2.3 is intended to address the activities that would apply to any future ESP or COL application development. QAPD Section 2.3 is not intended to be a commitment for the applicants to develop or submit annotated outlines for their COL application and annotated outlines are not discussed in the QAPD.

Since Duke did not execute an ESP for Lee Nuclear Station and the COL application preparation was not performed under the QAPD, this requirement would not be applicable to Lee. FSAR Section 17.1 clarifies the timing for and applicability of the QAPD to activities for Lee. "ESP" requirements were included in the QAPD to allow the QAPD to be used for potential future new plant development activities. This section of the QAPD will be revised for clarity as shown in Attachment 1.

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Associated Revision to the Duke Energy Nuclear Plant Development QAPD:

QAPD Part II, Section 2.3

Attachments:

1) Revision to QAPD Part II, Section 2.3

Lee Nuclear Station Response to Request for Additional Information (RAI)

Attachment 1 to RAI 17.05-007

Revision to COLA Part 11, QAPD Part II, Section 2.3

COLA Part 11, QAPD Part II, Section 2.3, first sentence, will be revised as follows:

2.3 ~~Identification of~~ Site Specific Safety-Related Design Basis Activities

For Nuclear Plant Development, ~~S~~site safety-related design basis activities are defined as those activities, including sampling, testing, data collection and supporting engineering calculations and reports that are used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied.

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-008

NRC RAI:

FSAR Section 17.1 states that the Duke Energy Quality Assurance (QA) program and the Westinghouse Electric Company Quality Management System establish the QA requirements for design activities until the Duke QAPD becomes effective. In order to plan NRC inspections of these activities, please clarify the expected scope, locations, and schedules for design activities to be conducted by Duke/Westinghouse from the date of docketing until issuance of the COL.

Duke Energy Response:

Please note that by letter dated February 6, 2008 (Reference 1), Duke Energy Carolinas provided a clarification to Section 17.1 of the FSAR. Enclosure 1 of that letter revised information referenced above to remove the reference to Westinghouse Electric Company Quality Management System (DCD Section 17.6 Reference 9) and reads as follows: "The Duke Energy Quality Assurance (QA) Program defines the QA program requirements for design and construction activities. These program requirements remain in effect until such time as the Duke Energy Quality Assurance Program Description (QAPD) discussed in Section 17.5 becomes effective."

As identified in FSAR Section 17.1 "Construction activities at Lee are not planned before the COL is issued." If, prior to the COL issuance, Duke Energy enters into contracts for safety-related design work, Duke Energy will notify NRC of the schedule for those activities when it becomes available.

Westinghouse Electric Company (WEC) activities associated with the AP1000 are the responsibility of WEC and the scope and schedule for those activities would be addressed as appropriate as part of the AP1000 design certification process.

Standard Plant Design Certification activities and design finalization activities are in progress and are the responsibility of WEC.

Site Characterization activities have been completed and were the responsibility of the COL Applicant. Activities supporting the development of various FSAR Sections were performed under the QA Program, including Geology, Meteorological, Habitability Systems, and others.

These activities were performed to support the COL application development for Duke Energy under Duke Energy QA Program oversight.

<u>Site-Specific Design Finalization</u> – Detailed design for the site-specific SSCs is the responsibility of Duke Energy. This activity is in progress by various contractors under Duke oversight.

Engineering, Procurement, and Construction (EPC) – These activities will be conducted by WEC and Shaw Nuclear (SN) to be determined in the future. Once an EPC contract is signed with WEC and SN, the Duke QA Program will include flow down requirements to cover those activities that are specific to the Lee Nuclear Station.

Operation – The operational QA Program (as documented in the QAPD) will not be implemented prior to issuance of the COL. For additional information, please see the response to RAI 17.05-009 in this letter.

Reference:

1) Bryan Dolan (Duke Energy Carolinas), letter to R. William Borchardt (NRC), Title: William States Lee III Nuclear Station – Project 742 - Part 2, Final Safety Analysis Report, Chapter 17 – Clarification of Quality Assurance Plan Responsibilities, February 6, 2008, Accession Number ML080390506.

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Attachments:

None

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-009

NRC RAI:

FSAR Section 17.1 states that the Duke NPD QAPD will become effective at COL issuance. FSAR Table 13.4-201, Operational Programs Required by NRC Regulations, states that the QA Program – Operation will be implemented 30 days prior to initial fuel loading. Please confirm when the Duke NPD QAPD will become effective and clarify the variance between these statements.

Duke Energy Response:

As identified in FSAR Section 17.1, "The Duke Energy Quality Assurance Program Description (QAPD) discussed in Section 17.5 begins at COL issuance, and establishes the QA program requirements for the remaining portion of the design and construction phases."

FSAR Table 13.4-201, Item 16. QA Program - Operation identifies an implementation milestone for operational programs, of 30 days prior to scheduled date for initial loading of fuel. This implementation milestone recognizes that portions of the QAPD are specific to operations activities. Examples of these operations related requirements are described in QAPD Part II Section 2.7, "Independent Review", Section 3.4, "Setpoint Control", and Section 6.1, "Review and Approval of Documents". Implementation of the QAPD will begin upon its approval which is expected to be at COL issuance for applicable portions of the program; however as indicated in Table 13.4-201, full implementation of operations related requirements is not expected until 30 days prior to fuel load.

Associated Revision to the Lee Nuclear Station Final Safety Analysis Report:

FSAR Section 17.1

Attachments:

1) Revision to COLA Part 2, FSAR Chapter 17, Section 17.1

Lee Nuclear Station Response to Request for Additional Information (RAI)

Attachment 1 to RAI 17.05-009

Revision to COLA Part 2, FSAR Chapter 17, Section 17.1

COLA Part 2, FSAR Chapter 17, Section 17.1, (*), will be revised as follows:

17.1 QUALITY ASSURANCE DURING THE DESIGN AND CONSTRUCTION PHASES

This section of the referenced DCD is incorporated by reference with the following departures and/or supplements.

Replace the information in DCD Section 17.1 with the following information.

Duke Energy Carolinas (Duke) is responsible for the establishment and execution of quality assurance program requirements during the design, construction, and operations phases of Lee Nuclear Station Units 1 and 2. Duke may delegate, and has delegated to others, as discussed below, the work of establishing and executing the quality assurance program, or any parts thereof, but retains responsibility for the quality assurance program.

The Duke Energy Quality Assurance (QA) Program defines the QA program requirements for design and construction activities. These program requirements remain in effect until such time as the Quality Assurance Program Description (QAPD) discussed in Section 17.5 becomes effective.

Duke Energy contracted with Enercon Services, Inc. to develop the Lee Nuclear Station Combined License (COL) application, including site characterization activities. The process of collection, review and analysis of specific data for site characterization was performed under the Enercon Quality Assurance program and is described in the Enercon Quality Assurance Project Planning Document (Reference 201). Duke Energy maintains oversight under its existing 10 CFR Part 50, Appendix B program, as described in "Duke Energy Carolinas Topical Report Quality Assurance program" (Reference 202). Duke Energy oversight is provided through its review and approval of the Enercon QA Plan, by conducting QA audits and surveillances of Enercon activities, and by direct participation in COL development activities. This includes providing site specific applicant input and review of COL application content, signing the COL application as applicant at submittal, and working directly with Enercon and contractors to respond to NRC requests for additional information.

Implementation of the applicable portions of ~~The~~the "Quality Assurance Program Description" QAPD discussed in Section 17.5 begins at COL issuance. The program establishes the QA program requirements for the remaining portion of the design and construction phases and for operations; full implementation of the operations related requirements will be no later than as indicated in Table 13.4-201.

* FSAR text as amended by Reference 1, Bryan Dolan (Duke Energy Carolinas), letter to R. William Borchardt (NRC), Title: William States Lee III Nuclear Station – Project 742 - Part 2, Final Safety Analysis Report, Chapter 17 – Clarification of Quality Assurance Plan Responsibilities, February 6, 2008, Accession Number ML080390506.

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-010

NRC RAI:

Evaluation of Current QA Program against the SRP (FSAR Section 17.1)
FSAR Section 17.1 states that the existing Duke Energy QA program is used to provide oversight of contractors that have been delegated the responsibility of design activities prior to COL issuance. FSAR Table 1.9-202, Conformance with SRP Acceptance Criteria, states that the FSAR Position is acceptable with regards to SRP 17.1.

Pursuant to 10 CFR 52.79(a)(41), COL applicants must provide an evaluation of the facility against the SRP revision in effect 6 months before the docket date of the application. Where differences exist, the applicant's evaluation must discuss how the proposed alternative provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. Regulatory Guide (RG) 1.206, Section C.I.17.5.3, states that COL applicants may use an existing QAPD that the NRC has approved for current use for either or both phases of its QAPD submittal, provided that the applicant identifies and justifies alternatives to, or differences from, the SRP in effect 6 months prior to the docket date of the application. Pursuant to 10 CFR 52.79(a)(41), please provide an evaluation of the existing Duke Energy QA program against the acceptance criteria in SRP 17.5.

Duke Energy Response:

A comparison was performed between the acceptance criteria for SRP 17.5 against the Duke Energy Carolinas Topical Report, Quality Assurance Program, Amendment 35. The comparison result indicates that the Quality Assurance Program conforms to the Acceptance Criteria of SRP 17.5. The comparison is consistent with the evaluations of other SRPs and is appropriately reflected in COLA FSAR, Table 1.9-202 as "Acceptable" for SRP 17.5.

Associated Revisions to the Lee Nuclear Station Final Safety Analysis Report:

None

Attachments:

None

Lee Nuclear Station Response to Request for Additional Information (RAI)

RAI Letter No. 037

NRC Technical Review Branch: Quality & Vendor Branch 1

Reference NRC RAI Number(s): 17.05-011

NRC RAI:

FSAR Section 17.5 states, without reference, that the QAPD is maintained as a separate document. Appendix B to 10 CFR Part 50 states that every applicant for a combined license under 10 CFR Part 52 is required by the provisions of 10 CFR 52.79 to include in its FSAR a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of SSCs of the facility and to the managerial and administrative controls to be used to assure safe operation. Please clarify why the FSAR does not either include or incorporate the QAPD by reference.

Duke Energy Response:

FSAR Section 17.5 is revised as shown in Attachment 1 to identify that the QAPD is included as Part 11 of the Lee COL application and is incorporated by reference.

Associated Revision to the Lee Nuclear Station Final Safety Analysis Report:

COLA Part 2, FSAR Section 17.5

Attachment:

1) Revision to COLA Part 2, FSAR Section 17.5

Lee Nuclear Station Response to Request for Additional Information (RAI)

Attachment 1 to RAI 17.05-011

Revision to COLA Part 2, FSAR Section 17.5

COLA Part 2, FSAR Section 17.5 will be revised as follows:

The Quality Assurance Program in place during the design, construction, and operations phases is described in the in the "Nuclear Plant Development Quality Assurance Program Description (QAPD)", which is maintained as a separate document. The QAPD is included in the Lee COL application as Part 11 and is incorporated by reference. This QAPD is based on NEI 06-14, "Quality Assurance Program Description," which was approved by the NRC in Reference 203.

Table 13.4-201 provides milestones for operational quality assurance program implementation.

The Quality Assurance Program in place prior to implementation of the QAPD is described in Section 17.1.