DUKE ENERGY.

Leo Martin
General Manager
Nuclear Engineering

526 S. Church Street
Charlotte, NC 28202

980-373-9364
leo.martin@duke-energy.com

Serial: NPD-NRC-2017-005
February 16, 2017

10 CFR 50.55(f)(4)

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

LEVY NUCLEAR PLANT, UNITS 1 AND 2
COMBINED LICENSE NOS. NPF-99 AND NPF-100
DOCKET NOS. 52-029 AND 52-030

WILLIAM STATES LEE III NUCLEAR STATION, UNIT NOS. 1 AND 2
COMBINED LICENSE NOS. NPF-101 AND NPF-102
DOCKET NOS. 52-018 AND 52-019

SHEARON HARRIS NUCLEAR POWER PLANT, UNITS 2 AND 3
DOCKET NOS. 52-022 AND 52-023

SUBJECT: Submittal of Quality Assurance Program Description, Revision 0

References: 1. Letter from U.S. Nuclear Regulatory Commission (NRC) to Fadi Diya, dated April 1, 2016, "Callaway Plant, Unit 1 - Operating Quality Assurance Manual Revision 31, Change Notice 15-002 (CAC NO. MF6789)" (ML16089A167)

2. Letter from U.S. Nuclear Regulatory Commission to Arthur Zaremba, dated May 26, 2015, "Catawba Nuclear Station, Units 1 and 2; McGuire Nuclear Station, Units 1 and 2; and Oconee Nuclear Station Units 1, 2, and 3: Request For Change To Quality Assurance Topical Report (TAC Nos. MF5055, MF5056, MF5057, MF5058, MF5059, MF5060 and MF5061)" (ML15138A347)

Duke Energy is submitting a revised Quality Assurance Program Description (QAPD) for the Levy Nuclear Plant (LNP), Units 1 and 2, William States Lee III Nuclear Station (WLS), Units 1 and 2, and Shearon Harris Nuclear Power Plant (HAR), Units 2 and 3 in accordance with 10 CFR 50.55(f)(4)(i). The QAPD applies to 10 CFR 52 activities.

The Duke Energy QAPD (Enclosure 1) replaces the QAPD that was submitted with the three combined license applications (COLAs). This letter satisfies the 10 CFR 50.55(f)(4)(i) requirement to provide the Nuclear Regulatory Commission with an update of changes to the quality assurance program description that do not reduce commitments in the program description and, therefore, do not require NRC approval prior to implementation.

The changes made in this revision of the QAPD have been reviewed in accordance with 10 CFR 50.55(f)(4)(i) and 10 CFR 50.54(a)(3). The changes are not considered to be reductions of commitment as they involve organizational changes, administrative improvements and

TOID
D094
D093
D084
Q004
NRD

clarifications, spelling corrections, punctuation, editorial items, and the use of a quality assurance alternative approved by an NRC safety evaluation as allowed by 10 CFR 50.54(a)(3)(ii). The specific changes are described below.

- Part II, Section 1 Organization was updated to reflect organizational changes since the last update was submitted as part of the COLA.
- Part II, Section 7 was updated to use NEI 14-05A, Guidelines for the Use of Accreditation In Lieu Of Commercial Grade Surveys for Procurement Of Laboratory Calibration and Test Services, March 2015, for dedication of commercial grade calibration suppliers. The use of this process was approved for licensees in NRC Safety Evaluation to Union Electric Company, Callaway Plant (Reference 1).
- Part II, Section 17 was updated for management of electronic records to use the 2011 NIRMA standards as identified in NRC Safety Evaluation to Duke Energy Carolinas (Reference 2).

Enclosure 2 contains the changes identified above as redline strike-outs and blue insertions. Conforming changes, such as corrections to the organizational charts, made to be consistent with the revised organization, are not included in Enclosure 2.

Even though the review of the COLA is suspended, this revision applies to HAR, Unit Nos. 2 and 3 for any activities should COLA activities be resumed. As identified in the HAR Final Safety Analysis Report Chapter 17, the same QAPD was submitted for both the Levy and Harris COLAs and would become effective following issuance of the first license. This letter acknowledges that Duke Energy is now implementing the attached QAPD for any remaining activities supporting the HAR Units 2 and 3 COLA and this QAPD replaces in its entirety the QAPD included in the Harris COLA Part 11.

This letter does not make any regulatory commitments.

If you have any questions concerning this letter, or require additional information, please contact me or Erik Wagner at (704) 382-3949.

Sincerely,

Leo A. Martin
General Manager - Nuclear Engineering

Enclosure 1. Duke Energy Common Quality Assurance Program Description
Enclosure 2. Duke Energy Common Quality Assurance Program Description Mark Up Pages

cc: B. Hughes, USNRC Project Manager
Deputy Regional Administrator, Region II
U.S. NRC Resident Inspector, SHNPP Unit 1

Enclosure 1

Duke Energy Common Quality Assurance Program Description

(92 pages including cover page)

DUKE ENERGY QUALITY ASSURANCE TOPICAL REPORT FOR 10 CFR PART 52 LICENSES

DUKE-QAPD-002 -A-

Rev 0

DUKE ENERGY QUALITY ASSURANCE TOPICAL REPORT FOR 10 CFR PART 52 LICENSES

Document Owner	Regulatory Compliance/Licensing

Facilities	**William S Lee III Nuclear Station, Units 1 and 2** Docket Numbers 52-022 and 52-023 **Levy Nuclear Power Plants, Units 1 and 2** Docket Numbers 52-029 and 52-030

Prepared By	**Title** Nuclear QA Codes and Standards Consultant	**Date:** 11/16/16
	Print James R. Cassidy	
Reviewed By	**Title** Nuclear Plant Development Operational Readiness Manager	**Date:** 11/17/16
	Print Richard L. Browder	
Approved By	**Title** Director Nuclear Oversight Audit and Programs	**Date:** 11/17/16
	Print W. Scott Saunders	
Approved By	**Title** Chief Nuclear Officer	**Date:** 11/18/16
	Print J. William Pitesa	

Description of Change

Controlling DRR 02077115

Part II, Section 1 Organization updated to reflect organization changes since the document was frozen during licensing.

Part II, Section 7 updated to use NEI 14-05A. The use of this process was approved for licensees in NRC Safety Evaluation (ADAMS Accession Number ML16089A167) dated April 1, 2016 to Union Electric Company, Callaway Plant.

Part II, Section 17 updated for management of electronic records as identified in NRC Safety Evaluation dated May 26, 2015 to Duke Energy Carolinas (ADAMS Accession No. ML15138A347).

NOTE: Previous revisions of this document are files as NGGM-PM-0033, Duke Energy Quality Assurance Topical Report for 10 CFR Part 52 Licenses.

QUALITY ASSURANCE PROGRAM POLICY STATEMENT

Duke Energy Corporation (DEC) designs, procures, constructs, and operates its nuclear plants in a manner that ensures the health and safety of the public and workers. These activities are performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating Licenses, and applicable laws and regulations of the state and local governments.

The applicable Quality Assurance Program (QAP) is the Quality Assurance Program Description (QAPD) contained or referenced in each nuclear plant's Updated Final Safety Analysis Report (UFSAR) and the associated implementing documents. Together they provide for control of DEC activities that affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) and include all planned and systemic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAP may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The QAPD is the top-level policy document that establishes DEC's overall philosophy regarding achievement and assurance of quality. Implementing documents assign detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. Compliance with the QAP is mandatory for individuals involved directly or indirectly with its implementation.

DEC personnel have authority commensurate with their responsibility, including the authority to stop work that does not conform to established requirements. This stop work authority may be exercised in accordance with established nuclear system procedures.

PART I INTRODUCTION

SECTION 1 GENERAL

The Duke Energy Quality Assurance Topical Report for 10 CFR Part 52 Licenses is the Duke Energy Corporation Quality Assurance Program Description (QAPD) for all 10 CFR Part 52 Licenses. This is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for COL construction, pre-operations and operations activities conducted by or for Duke Energy Corporation. The QAPD describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements and recommendations of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I, II, and III, as specified in this document.

The Quality Assurance Program is defined by the NRC approved regulatory document that describes the QA elements, along with the associated implementing documents. Procedures and instructions that control Nuclear Development will be developed prior to commencement of those activities. As the overall controlling QAPD for design, construction, and operations, this document invokes QA requirements for controlling Duke Energy Corporation performed quality-affecting activities as well as providing controls for subcontractors addressed by Part II Sections 4 and 7, to perform their assigned quality affecting activities to their own QA Programs. Policies establish high level responsibilities and authority for carrying out important administrative functions which are outside the scope of the QAPD. Procedures establish practices for certain activities which are common to all Duke Energy Corporation organizations performing those activities so that the activity is controlled and carried out in a manner that meets QAPD requirements. Site or organization specific procedures establish detailed implementation requirements and methods, and may be used to implement policies or be unique to particular functions or work activities.

1.1 Scope/Applicability

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

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

ITAAC are those Inspections, Tests, Analyses and Acceptance Criteria the applicant must satisfy as determined by the commission in accordance with 10 CFR Part 52.

This QAPD was developed to address COL activities associated with William S. Lee Nuclear Station Units 1 and 2, Harris Nuclear Power Plant Units 2 and 3, Levy Nuclear Power Plant Units 1 and 2, and any future nuclear power units pursued by Duke Energy Corporation in accordance with 10 CFR Part 52. This QAPD / Quality Assurance Topical Report does not apply to any of the existing Duke Energy Corporation nuclear power plants.

Safety-related SSCs 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 Energy Corporation 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.

The definitions provided in ASME NQA-1-1994, Part 1, Section 1.4, apply to select terms as used in this document.

PART II QAPD DETAILS

SECTION 1 ORGANIZATION

This section describes the proposed Duke Energy Corporation organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes corporate support, off-site and on-site functions including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

Duke Energy Corporation management is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned.

The Duke Energy Corporation Nuclear Development organization is responsible for new nuclear plant licensing, engineering, procurement, construction, startup and operations development activities. There are several organizations within the Duke Energy Corporation that implement and support the QAPD. These organizations include, but are not limited to Nuclear Development, Nuclear Supply Chain and Nuclear Oversight.

Organization charts for various departments/locations are contained in Chapter 13 of the respective station's FSAR and describe organizational positions of the nuclear station and associated functions and responsibilities.

Design, engineering and environmental services are provided to the Duke Energy Corporation Nuclear Development organization by a contract that identifies the Engineer and Constructor and invokes the applicable quality program requirements described in this document to applicable contractors and subcontractors.

The organizations responsible for the implementation of the requirements of this Quality Assurance Program Description Topical Report for new nuclear generating plants are described below. There are two primary organizations responsible for implementation within the corporate structure based on the activity being performed. The responsibility for the licensing and development of new nuclear generating plants for Duke Energy is assigned to the Executive for Nuclear Development. The responsibility for construction of new nuclear plants is assigned to the Executive for Operations Support. The responsibility for the operation of the new nuclear generating plants is assigned to the Chief Nuclear Officer. Each of these individuals reports directly to the Chief Operating Officer.

Figure II.1-1 displays the relationships of the Duke Energy organizations described in and responsible for implementing the requirements of this QAPD. This division of responsibilities was made to allow the Chief Nuclear Officer and Nuclear Generation to remain focused on improving the performance of the operating fleet and minimize the distractions associated with the construction of new nuclear generating plants. Organizational control and responsibility for the newly constructed nuclear generating plant transfers to the Chief Nuclear Officer from the Executive for Operations Support following the completion of unit specific construction activities and prior to loading of fuel. This transition point allows for the continued support by the Nuclear Development organization, while the Operational Readiness (OR) organization transitions to the final structure typical of the operating fleet.

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting this QA Program. Figures II.1-1 and II.1-2, and II.1-3 show the organizational structures for corporate, the operations phase, and the construction phase, respectively. Figure II.1-2 shows a typical operating plant structure within Duke Energy Corporation. The detailed roles, responsibilities and organizational structure and reporting relationships for the operations phase organization is detailed in Chapter 13 of the respective plant's FSAR.

1.1 Duke Energy Corporation Corporate Organization

The Chairman, President and Chief Executive Officer has overall responsibility for Design, Construction, and Operation of generation and transmission facilities. The Chief Operating Officer reports to the Chairman, President and Chief Executive Officer and is responsible for: generation and transmission, including but not limited to the Duke nuclear operating fleet; new plant development and construction; and nuclear decommissioning activities. The Chief Operating Officer has overall authority and responsibility for the QA Program. Reporting to the Chief Operating Officer are the Chief Nuclear Officer (CNO), the executive for Nuclear Development, the executive for Operations Support, the executive for Supply Chain, the executive for Environmental Health and Safety, the executive for Transmission, and the executive for Fossil Hydro Generation. The interface between Duke Energy Nuclear (see section 1.2) and non-nuclear dedicated organizations providing support to nuclear is described in Section 1.3.

Also reporting to the Chairman, President and Chief Executive Officer are Group Executives responsible for providing support to Nuclear Generation and Nuclear Development for the following: electrical distribution; support for the emergency response communications; and Information Technology Services. The interface with organizations providing those activities are described in Section 1.3. As such, the attainment of quality rests with those assigned the responsibility of performing the activity. The verification of quality is assigned to qualified personnel independent of the responsibility for performance or direct supervision of the activity. The degree of independence varies commensurate with the activity's importance to safety.

1.2 Duke Energy Nuclear

Duke Energy Nuclear is responsible for: the nuclear operating fleet; new nuclear plant development and construction; and decommissioning activities. These activities are directed by the Chief Operating Officer.

Duke Energy Nuclear is comprised of Nuclear Generation, which is headed by the CNO having responsibility for Duke Energy Corporation operating nuclear stations; Nuclear Development, which is headed by executive for Nuclear Development whose responsibilities include activities associated with submittal, review, and approval of combined operating license for new nuclear plants, and the nuclear construction and decommissioning portions of Operations Support.

1.2.1 Nuclear Generation

Nuclear Generation has direct line responsibility for all Duke Energy Corporation operating nuclear stations. Nuclear Generation is responsible for achieving quality results during engineering, preoperational testing, operation, testing, maintenance and modification of the Corporation's nuclear stations and with complying with applicable codes, standards and NRC regulations. The functions of Nuclear Generation are directed by the CNO.

The CNO formulates, recommends, and carries out plans, policies, and programs related to the nuclear generation of electric power. The CNO is informed of significant problems or occurrences relating to safety and QA through established administrative procedures, and participates directly in their resolution, when necessary.

Nuclear Generation is organized into three divisions. The activities of each division are directed by an executive who reports to the CNO. The divisions are Nuclear Operations, Nuclear Corporate, and Nuclear Oversight.

The CNO has the organizational flexibility to reassign responsibilities for functions, within the limits specified in the following section, between the standard divisions to provide added focus on areas determined to need increased management attention. This flexibility includes both the ability to consolidate divisions or to identify new divisions. The actual organization in-place is defined in a controlled document containing the fleet operating model.

1.2.1.1 Nuclear Operations

The executive for Nuclear Operations reports to the CNO and is located in the NGO. This executive is responsible for the safe operation of the nuclear stations. Reporting to the CNO through this executive are the Site executives for the respective nuclear stations.

The organization structure for each site is controlled by the site's UFSAR, which may vary from the following generic description. Reporting to the site executive for each nuclear station is a Nuclear Plant Manager who is assigned the direct responsibility for the safe operation of the facility including operations, maintenance, work management, radiation protection, chemistry, and environmental services. Also reporting to the site executive is a site Engineering manager; a site Training manager; and an Organization Effectiveness manager, typically having responsibility for regulatory affairs, emergency preparedness, performance improvement, and procedures. Each site executive also has a Security manager assigned to provide services to the site. The qualification requirements for the Nuclear Plant personnel are in accordance with the provisions of ANSI N18.1 or ANS 3.1 as identified in each site's UFSAR and Technical Specifications. Figure II.1.2 shows a typical operating nuclear site organization.

1.2.1.2 Nuclear Corporate

The senior executive(s) reports to the CNO and is responsible for Corporate Governance and support functions to the Nuclear Sites in the following areas: Nuclear Engineering; Nuclear Regulatory Affairs; Nuclear Support Services; Nuclear Protective Services; Nuclear Operations; Nuclear Corporate Organizational Effectiveness; Nuclear Training; and Emergency Preparedness.

The organizational structure for these functions may vary based on near-term activities and the strategic importance of our fleet initiatives, in our continuing efforts to set and achieve industry-leading operational and outage performance. These functions are primarily off-site located in the Nuclear General Office (NGO).

1.2.1.2.1 Nuclear Engineering

Nuclear Engineering provides broad engineering leadership and technical support to the nuclear sites with emphasis on generic issues and consistent practices, providing expertise in safety assessment with technical support in the areas of risk assessment, radiological engineering, and safety analysis; fuel management with leadership and technical support in the areas of fuel supply, spent fuel management, reactor core mechanical and thermal hydraulic analysis; the fleet electrical and procurement engineering with technical support in the areas of procurement engineering, nuclear process systems, and electrical systems and analysis; and programs and components support in the areas of steam generator inspections and maintenance, engineering programs, component engineering, material failure analysis and materials science, equipment reliability, and ASME Code inspections and testing. Nuclear Engineering provides support to Site engineering for contracts, engineering and management related to fleet and nuclear site modification projects.

Nuclear Engineering provides record storage and document management services, technology planning, project control and technical support for information technology applications and systems such as equipment databases, applications, infrastructure, and plant process information systems.

1.2.1.2.2 Nuclear Regulatory Affairs

Nuclear regulatory affairs provides fleet support to and governance of the site regulatory affairs and licensing activities to help improve overall fleet performance.

1.2.1.2.3 Nuclear Support Services

Nuclear support services provides fleet support to the nuclear sites for laboratory, calibration, and select maintenance and refueling activities.

1.2.1.2.4 Nuclear Protective Services

Nuclear protective services provides access authorization support to the nuclear sites security organization. Nuclear protective services is responsible for governance of the site security functions, providing assistance to help improve overall fleet performance.

1.2.1.2.5 Nuclear Operations

Nuclear operations is responsible for governance of the nuclear site operating organizations, providing assistance to promote improvements to overall fleet performance.

1.2.1.2.6 Nuclear Corporate Organizational Effectiveness

Nuclear corporate organizational effectiveness is responsible for governance of the nuclear site performance improvement organizations, providing assistance to promote improvements to overall fleet performance through the corrective action and self-assessment programs. This group also supports implementation of the corrective action and self-assessment programs by the Nuclear Corporate Organization.

1.2.1.2.7 Nuclear Training

Nuclear training is responsible for governance of the nuclear site training organizations, providing assistance to promote improvements to overall fleet performance. This group also supports implementation of the training programs by the Nuclear Corporate Organization.

1.2.1.2.8 Emergency Preparedness

Emergency preparedness is responsible for governance of the nuclear site emergency response organizations, providing assistance to promote improvements to overall fleet performance.

1.2.1.3 Nuclear Oversight (NOS)

The executive for Nuclear Oversight (NOS) reports to the CNO and is located in the NGO. NOS consists of both site assigned and NGO located personnel. The executive for NOS is responsible for all matters related to the independent monitoring and auditing of activities performed by or in support of the development, deployment, and construction of new nuclear generating plants, decommissioning activities, and project management and construction activities not controlled by the CNO. In executing this responsibility, the executive for NOS reports to the Chief Operating Officer. The NOS executive has the authority and organizational freedom to: identify quality problems, initiate, recommend or provide solutions to quality problems through designated channels, verify the implementation of solutions to quality problems, and ensure cost and schedule do not influence decision making involving quality.

NOS provides oversight of the general office including Nuclear Development activities and all nuclear sites with QA program audits, performance assessments, vendor quality, supplier verification, and quality control activities. The NOS executive has the authority and organizational freedom to: identify quality problems, initiate, recommend or provide solutions to quality problems through designated channels, verify the implementation of solutions to quality problems, and ensure cost and schedule do not influence decision making involving quality.

The executive for NOS has unfettered access to corporate executive management to resolve any quality or nuclear safety related concerns that cannot be resolved satisfactorily at a lower management level.

The NOS executive is delegated primary ownership of the department QA program description (this document) and is responsible for day-to-day administration of the program and resolution of QA issues. If significant quality problems are identified, NOS personnel have the authority to stop work as discussed in Section 1.5 pending satisfactory resolution of the identified problem.

Also reporting to the executive for Nuclear Oversight is Employee Concerns, which investigates concerns identified through the Employee Concerns Programs to determine their validity and initiate corrective actions as appropriate. Employee Concerns also promotes the Safety Conscious Work Environment (SCWE) Program and is sensitive to SCWE concerns during investigations performed.

1.2.2 Nuclear Development

Nuclear 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, and operational readiness. The executive in charge of Nuclear Development reports directly to the Chief Operating Officer and is assisted by a support staff. Initially, Nuclear Development is responsible for construction planning and preparation. The responsibility for construction transitions to the executive for Site Construction at the start of construction activities when filled. Nuclear Development responsibilities include the establishment and execution of a contract or contracts for the engineering, procurement, construction, and startup activities of new nuclear plants. Organizational control and responsibility for newly constructed nuclear generating units transfers to the Chief Nuclear Officer following the completion of unit specific construction activities and prior to loading of fuel. Figure II.1.3 shows the Nuclear Development/Construction Organization. As a new nuclear plant approaches startup, the site organization transitions from the development / construction focused organization in Figure II.1.3 to the Operating Plant Site Organization shown in Figure II.1.2.

1.2.3 Site Construction

The executive for Site Construction reports to the Chief Operating Officer through the executive for Operation Support. This reporting relationship allows the Chief Nuclear Officer and Nuclear Generation to remain focused on improving the performance of the operating fleet and minimize the distractions associated with the construction of new nuclear generating plants. This position will be filled in support of the start of construction activities for a new nuclear plant. This position is responsible for the control and oversight of all construction activities associated with a new nuclear unit. Reporting to this position will be the manager for construction; manager for site engineering; and the site plant manager as shown on QAPD Figure II.1-3. This position will transfer responsibility for the constructed unit to the site executive reporting to the CNO at the completion of construction activities and prior to the loading of fuel in that unit. This position will retain responsibilities for other units under construction at a multi-unit site until construction activities for each unit are completed. This position is supported during these construction activities by other Duke Energy Nuclear organizations as needed.

1.2.4 Nuclear Decommissioning

The executive for Nuclear Decommissioning reports to the Chief Operating Officer through the executive for Operation Support. This reporting relationship allows the Chief Nuclear Officer and Nuclear Generation to remain focused on improving the performance of the operating fleet and minimizes the distractions associated with defining and executing the decommissioning strategy for Crystal River Unit 3 to meet required regulations and obligations.

1.3 Department Interfaces

Quality related activities performed by departments other than Duke Energy Nuclear are identified by and conducted in accordance with controls identified in approved departmental interface agreements. The following are generic descriptions of those other corporate departments and the services they provide. These generic organizations are referred to, as appropriate, within this document; however, approved departmental interface agreements establish and define the applicability of the Quality Assurance Program to the services they provide.

1.3.1 Corporate Communications

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

1.3.2 Environmental Services

Environmental, Health and Safety provides environmental and laboratory support services.

1.3.3 Nuclear Finance

Nuclear Finance provides support for the nuclear sites in the areas of financial planning.

1.3.4 Customer Operations

Customer Operations provides electrical transmission, distribution, and switchyard engineering, as well as providing electrical maintenance and testing support.

1.3.5 Information Technology

Information Technology provides a variety of services and technical support to Nuclear Generation for information technology applications and systems such as equipment databases, applications, infrastructure, and plant process information systems. They are also responsible for the development and maintenance of selected information technology services and support, including electronic document management, some of which support QA related activities.

1.3.6 Supply Chain

Nuclear Supply Chain provides procurement services to Duke energy Nuclear. Nuclear Supply Chain also provides storage, inventory control, and receipt inspection/testing for Nuclear Generation.

1.4 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.

1.5 Authority to Stop Work

Quality assurance and inspection personnel have the authority, and the responsibility, to stop work in progress which is not being done in accordance with the Quality Assurance Program requirements, approved procedures or where safety, nuclear safety or System, Structure and Component (SSC) integrity may be jeopardized. This extends to off-site work performed by suppliers furnishing safety-related materials and services to Duke Energy Corporation.

1.6 Quality Assurance Organization Independence

Independence shall be maintained between the organization or organizations performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

1.7 NQA-1-1994 Commitment

In establishing its organizational structure, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

Figure II.1-1

Duke Energy Nuclear Corporate Organization

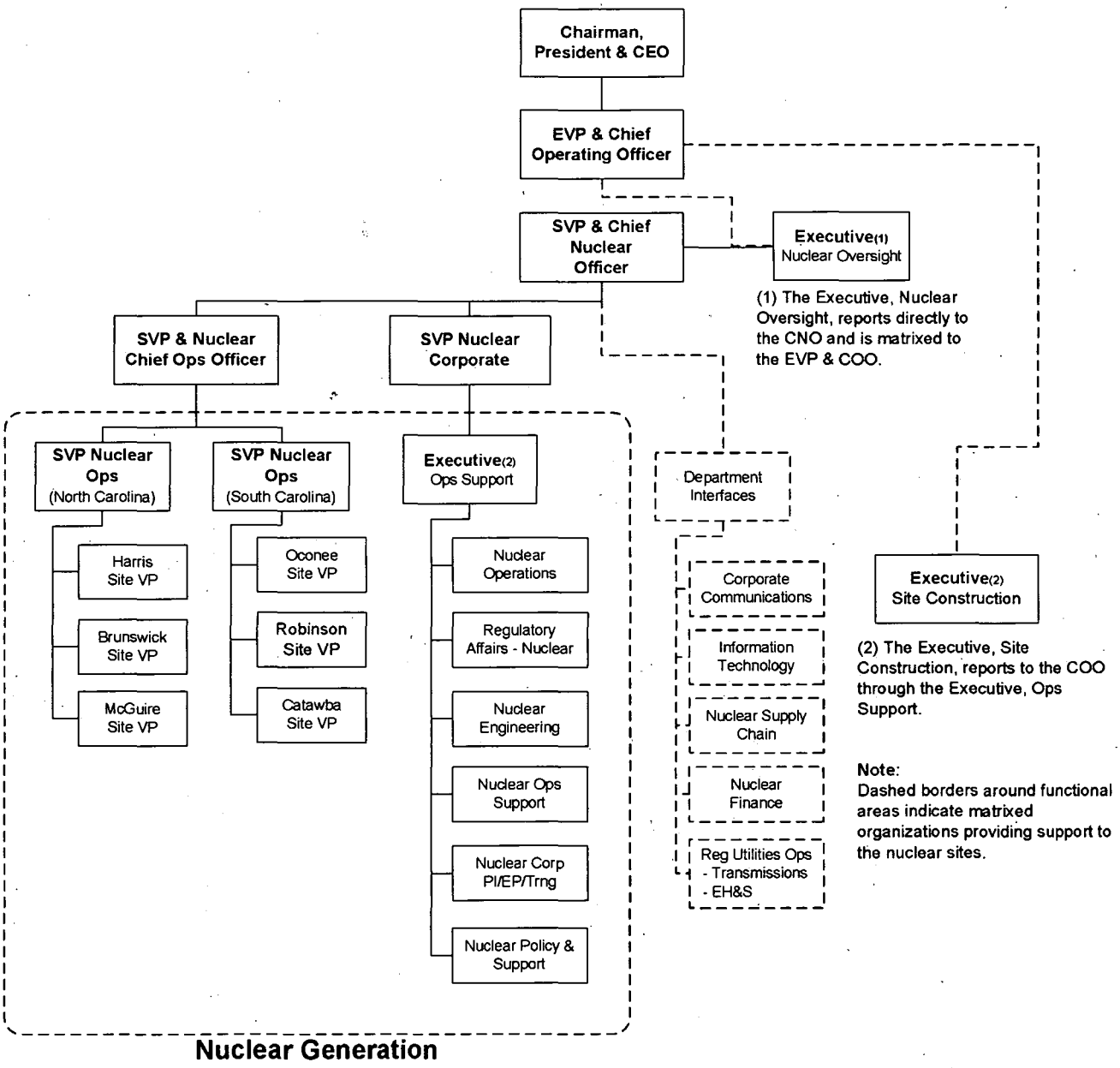
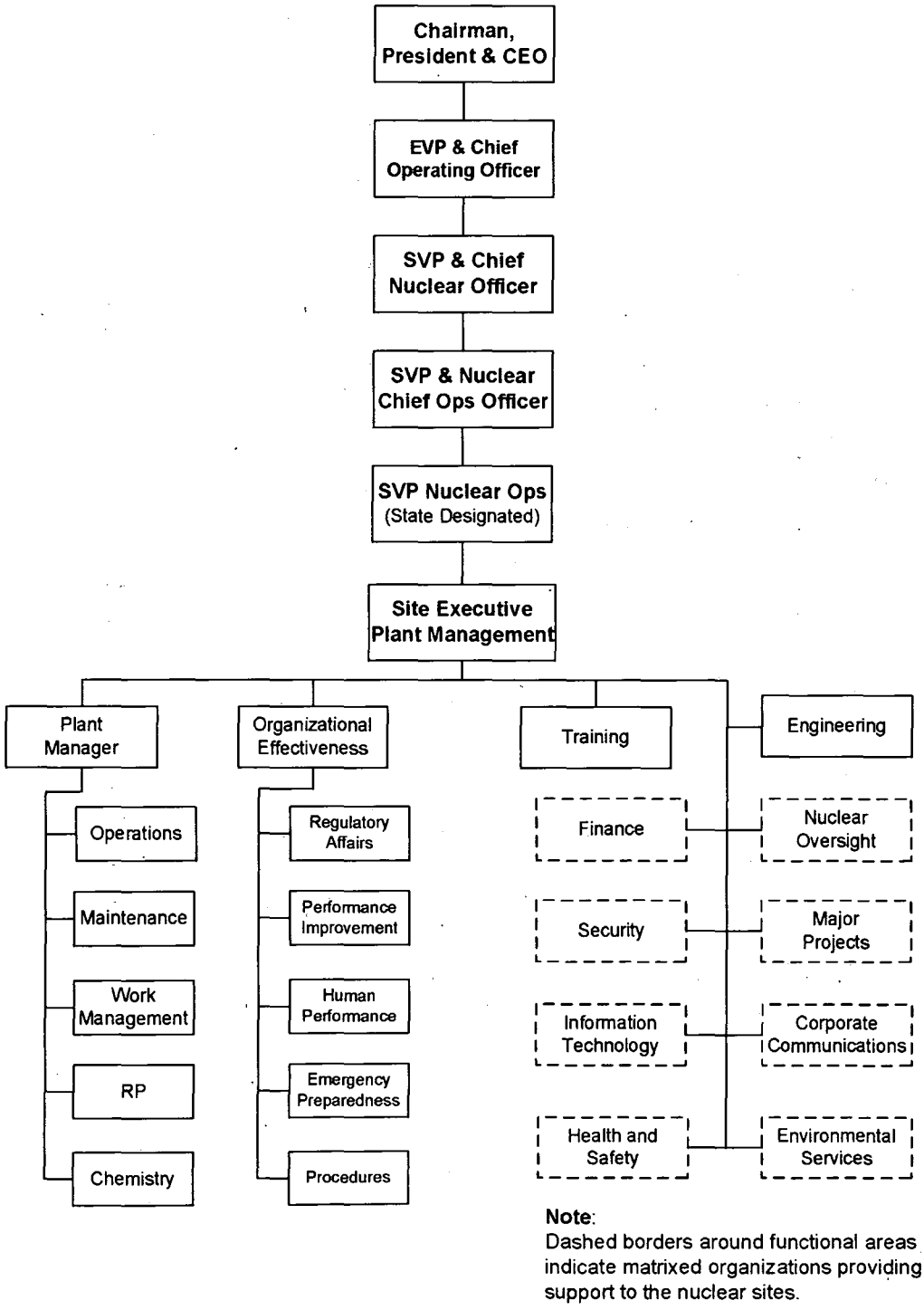


Figure II.1-2

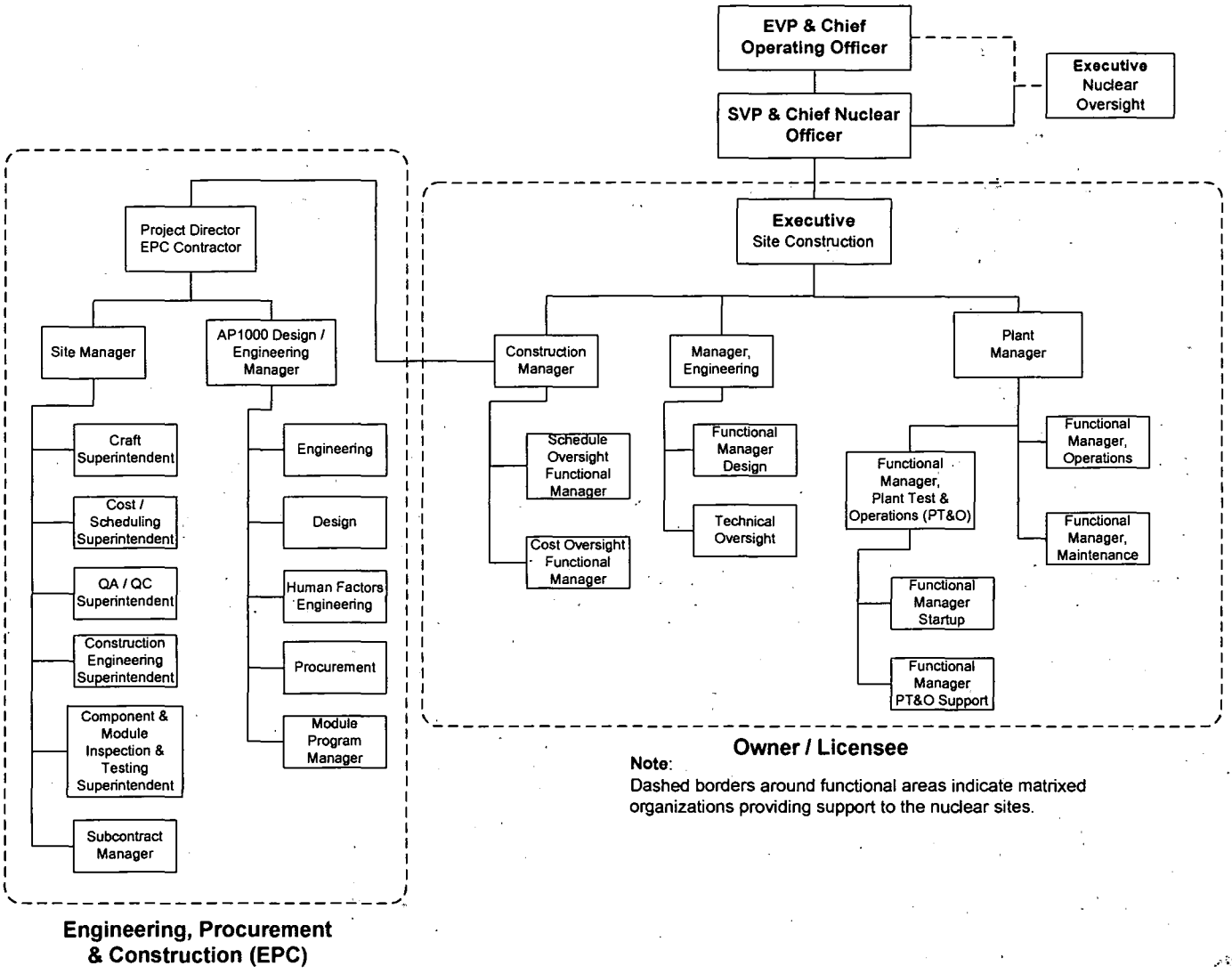
Typical Operating Plant Site Organization



Note:
Dashed borders around functional areas indicate matrixed organizations providing support to the nuclear sites.

Figure II.1-3

Nuclear Development/Construction Organization



Note:
Dashed borders around functional areas indicate matrixed organizations providing support to the nuclear sites.

SECTION 2 QUALITY ASSURANCE PROGRAM

Duke Energy Corporation has established the necessary measures and governing procedures to implement the QAP as described in the QAPD. Duke Energy Corporation is committed to implementing the QAP in all aspects of work that are important to the safety of the nuclear plants as described and to the extent delineated in this QAPD. Further, Duke Energy Corporation ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. Senior management is regularly apprised of audit results evaluating the adequacy of implementation of the QAPD through the audit functions described in Part II, Section 18.

The objective of the QAPD is to assure that Duke Energy Corporation's nuclear generating plants are designed constructed and operated in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as further described in this document. The QAPD applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (SSCs) associated with the design (excluding Design Certification activities), fabrication, construction and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations. Examples of COL program safety-related activities include, but are not limited to, site specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis. A list or system that identifies SSCs and activities to which this program applies is maintained at the appropriate facility. The Design Certification Document is used as the basis for this list. Cost and scheduling functions do not prevent proper implementation of the QAPD.

As described in Part III of the QAPD, specific program controls are applied to non-safety-related SSCs, for which 10 CFR 50, Appendix B, is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided that the supplier or principle contractor has been approved as a supplier in accordance with the QAPD. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principle contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

For the COL applications, the QAPD applies to those Nuclear Development and Duke Energy Corporation activities that can affect either directly or indirectly the safety related site characteristics or analysis of those characteristics. In addition, the QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

New nuclear plant construction will be the responsibility of Duke Energy Corporation's Nuclear Development organization. Detailed engineering specifications and construction procedures will be developed to implement the QAPD and Contractor QA programs prior to commencement of construction activities. Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs include impacts of construction to existing facilities and, for construction of new plants, the interface between non-safety-related and safety-related SSCs and the placement of seismically designed backfill.

In general, the program requirements specified herein are detailed in implementing procedures that are either Duke Energy Corporation implementing procedures, or supplier implementing procedures governed by a supplier quality assurance program.

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early. Audits schedules are based on the month in which the audit starts.

2.1 Responsibilities

Personnel who work directly or indirectly for Duke Energy Corporation are responsible for achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Part I, Section 1.1. Duke Energy Corporation personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAPD are performed as directed by documented instructions, procedures and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. The Vice President Nuclear Oversight is responsible to verify that processes and procedures comply with QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2 Delegation of Work

Duke Energy Corporation retains and exercises the responsibility for the scope and implementation of an effective QAPD. Positions identified in Part II, Section 1, may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the level appropriate for its nature and effect, and with any necessary technical advice or review.

2.3 Site-specific Safety-Related Design Basis Activities

Site-specific safety-related design basis activities are defined as those activities, including sampling, testing, data collection and supporting engineering calculations and reports that will be used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied to these activities.

2.4 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program, or portions thereof, assesses the adequacy of that part of the program for which they are responsible to assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. However, the period for assessing QA programs during the operations phase may be extended to once every two years.

2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a), as appropriate. Nuclear Oversight is responsible to ensure proposed changes to the QAPD are evaluated and that such changes do not degrade previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the COL application development process. New revisions to the document will be reviewed, at a minimum, by Nuclear Oversight and approved by an executive for Nuclear Oversight, and the Chief Nuclear Officer.

Regulations require that the Final Safety Analysis Report (FSAR) include, among other things, the managerial and administrative controls to be used to assure safe operation, including a discussion of how the applicable requirements of Appendix B will be satisfied. In order to comply with this requirement, the FSAR references this QAPD and as a result, the requirements of 10 CFR 50.54(a), are satisfied by and apply to the QAPD.

2.6 Personnel Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end Duke Energy Corporation establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained. Plant and support staff minimum qualification requirements are as delineated in the unit Technical Specifications. Other qualification requirements may be established but will not reduce those required by Technical Specifications. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable Duke Energy Corporation procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed. Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training that implement a systematic approach to training. Records of personnel training and qualification are maintained.The minimum qualifications of the corporate manager Audits and Programs and Manager Site Nuclear Oversight at the new nuclear generating plants are that each holds an engineering or related science degree and has a minimum of four years of related experience including two years of nuclear power plant experience, one year of supervisory or management experience, and one year of the experience is in performing quality verification activities.

Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of the individuals responsible for planning, implementing and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.7 NQA-1-1994 Commitment / Exceptions

- In establishing qualification and training programs, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3 and 2S-4, with the following clarifications and exceptions:
  - NQA-1-1994, Supplement 2S-1
    - Supplement 2S-1 will include use of the guidance provided in Appendix 2A-1 the same as if it were part of the Supplement. Either or both of the following two alternatives may be applied to the implementation of this Supplement and Appendix:
      - (1) In lieu of being certified as Level I, II, or III in accordance with NQA-1-1994, personnel that perform independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.
      - (2) A qualified engineer may be used to plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purpose of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, civil) and has a minimum of five years engineering work experience with at least two years of this experience related to nuclear facilities.

- NQA-1-1994, Supplement 2S-2

  - In lieu of Supplement 2S-2, for qualification of nondestructive examination personnel, Duke Energy Corporation will follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME Boiler and Pressure Vessel Code approved by the NRC for use at Duke Energy Corporation sites.

- NQA-1-1994, Supplement 2S-3

  - The requirement that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years is replaced by the following, "The prospective lead auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by Duke Energy Corporation, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification."

SECTION 3 DESIGN CONTROL

Duke Energy Corporation has established and implements a process to control the design, design changes and temporary modifications (e.g. temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. The design process includes provisions to control design inputs, outputs, changes, interfaces, records and organizational interfaces within Duke Energy Corporation and with suppliers. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification. Design change processes and the division of responsibilities for design-related activities are detailed in Duke Energy Corporation and supplier procedures. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the Duke Energy Corporation design organization or by other organizations so authorized by Duke Energy Corporation.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements.

3.1 Design Verification

Duke Energy Corporation design processes provide for design verification to ensure that items and activities subject to the provisions of the QAPD are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.

Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. This includes design inputs, design outputs, and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for item's intended use.

Duke Energy Corporation normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, manufacture, or construction. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

3.2 Design Records

Duke Energy Corporation maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses and computer programs) and the sources of input that support the final output.

Plant design drawings reflect the properly reviewed and approved configuration of the plant.

3.3 Computer Application and Digital Equipment Software

The QAPD governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated non-safety-related applications. Duke Energy Corporation and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto is documented and approved by authorized personnel. The QAPD is also applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAPD requirements such as QA records.

3.4 Setpoint Control

Instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. As a minimum, these written instructions shall:

(1) Identify responsibilities and processes for reviewing, approving, and revising setpoints and setpoint changes originally supplied by the Design Certification Holder, the A/E, and the plant's technical staff.

(2) Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.

(3) Provide for documentation of setpoints, including those determined operationally.

(4) Provide for access to necessary setpoint information for personnel who write or revise plant procedures, operate or maintain plant equipment, develop or revise design documents, or develop or revise accident analyses.

3.5 NQA-1-1994 Commitment

In establishing its program for design control and verification, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 3, and Supplement 3S-1, the subsurface investigations requirements in Subpart 2.20, and the standards for computer software contained in Subpart 2.7.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

Duke Energy Corporation has established the necessary measures and governing procedures to assure that purchased items and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.

- Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating, and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under Duke Energy Corporation's approved QA program).

Reviews of procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.1 NQA-1-1994 Commitment / Exceptions

In establishing controls for procurement, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 4S-1

  - Section 2.3 of this Supplement 4S-1 includes a requirement that procurement documents require suppliers to have a documented QAP that implements NQA-1-1994, Part 1. In lieu of this requirement, Duke Energy Corporation may require suppliers to have a documented supplier QAP that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of the procurement.

  - With regard to service performed by a supplier, Duke Energy Corporation procurement documents may allow the supplier to work under the Duke Energy Corporation QAP, including implementing procedures, in lieu of the supplier having its own QAP.

  - Section 3 of this supplement 4S-1 requires procurement documents to be reviewed prior to bid or award of contract. The quality assurance review of procurement documents is satisfied through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to bid or award of contract. Procurement document changes (e.g., scope, technical or quality requirements) will also receive the quality assurance review.

  - Procurement documents for Commercial Grade Items that will be procured by Duke Energy Corporation for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated.

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Duke Energy Corporation has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAPD as described in the QAPD. Such documents are prepared and controlled according to Part II, Section 6. In addition, means are provided to disseminate to the staff instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1 Procedure Adherence

Duke Energy Corporation's policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, Section 6. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require: (1) the written procedure to be present and followed step-by-step while the task is being performed, (2) the user to have committed the procedure steps to memory, (3) verification of completion of significant steps, by initials or signatures or use of check-off lists. Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

In cases of emergency, personnel are authorized to depart from approved procedures when necessary to prevent injury to personnel or damage to the plant. Such departures are recorded describing the prevailing conditions and reasons for the action taken.

5.2 Procedure Content

The established measures address the applicable content of procedures as described in the introduction to Part II of NQA-1-1994. In addition, procedures governing tests, inspections, operational activities and maintenance will include as applicable, initial conditions and prerequisites for the performance of the activity.

5.3 NQA-1-1994 Commitment

In establishing procedural controls, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 5.

SECTION 6 DOCUMENT CONTROL

Duke Energy Corporation has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control systems (including electronic systems used to make documents available) are documented and provide for the following:

(a) identification of documents to be controlled and their specified distribution;

(b) a method to identify the correct document (including revision) to be used and control of superseded documents;

(c) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;

(d) review of documents for adequacy, completeness, and correctness prior to approval and issuance;

(e) a method for providing feedback from users to continually improve procedures and work instructions; and

(f) coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

(a) drawings such as design, construction, installation, and as-built drawings;

(b) engineering calculations;

(c) design specifications;

(d) purchase orders and related documents;

(e) vendor-supplied documents;

(f) audit, surveillance, and quality verification/inspection procedures;

(g) inspection and test reports;

(h) instructions and procedures for activities covered by the QAPD including design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing;

(i) technical specifications; and,

(j) nonconformance reports and corrective action reports

During the operational phase, where temporary procedures are used, they shall include a designation of the period of time during which it is acceptable to use them.

6.1 Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. During the construction phase, procedures for design, construction, and installation are also reviewed by Nuclear Oversight organization or a contractor quality assurance organization, as assigned by contract, to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence.

During the operations phase, documents affecting the configuration or operation of the station as described in the SAR are screened to identify those that require review by the IRB prior to implementation as described in Part V, Section 2.2.

To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed, and updated as necessary, based on the following conditions:

(a) following any modification to a system;

(b) following an unusual incident, such as an accident, significant operator error, or
equipment malfunction;

(c) when procedure discrepancies are found;

(d) prior to use if not used in the previous two years; or

(e) results of QA audits are conducted in accordance with Part II, Section 18.1.

Prior to issuance or use, documents including revisions thereto, are approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval. Where temporary procedure changes are necessary during the operations phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures. Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a classification shall be clearly delineated in implementing procedures.

6.3 NQA-1-1994 Commitment

In establishing provisions for document control, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Duke Energy Corporation has established the necessary measures and governing procedures to control the procurement of items and services to assure conformance with specified requirements. Such control provides for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services.

7.1 Acceptance of Item or Service

Duke Energy Corporation establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication and construction activities. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.

- Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of, or changes the methods or controls for, activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. Duke Energy Corporation may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet Duke Energy Corporation requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

7.2 NQA-1-1994 Commitment/Exceptions

In establishing procurement verification controls, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 7S-1

  - Duke Energy Corporation considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to Duke Energy Corporation plants are not required to be evaluated or audited.

- For the procurement of commercial grade calibration and/or testing services, Duke Energy Corporation uses NEI 14-05A, Revision 0, "Guidelines For The Use Of Accreditation In Lieu Of Commercial Grade Surveys For Procurement Of Laboratory Calibration And Test Services." The use of this process was approved for licensees in NRC Safety Evaluation (ADAMS Accession Number ML16089A167) dated April 1, 2016 to Union Electric Company, Callaway Plant. As identified in NEI 14-05A, commercial grade calibration or testing services may be procured from commercial laboratories based on the laboratory's accreditation to ISO/IEC-17025 by an Accreditation Body (AB) which is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) without performing commercial grade surveys provided all of the following are met:

  - A documented review of the supplier's accreditation is performed and includes a verification of the following:

    - The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."

    - For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

- For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.

- The purchase documents require that:
  - The service must be provided in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation.
  - As found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance. (for calibration services only)
  - The equipment/standards used to perform the calibration must be identified in the certificate of calibration. (for calibration services only)
  - The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
  - Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
- It is validated, at receipt inspection, that the laboratory's documentation certifies that
  - The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 program, and has been performed within their scope of accreditation, and
  - The purchase order's requirements are met.

- For Section 8.1, Duke Energy Corporation considers documents that may be stored in approved electronic media under Duke Energy Corporation or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to Duke Energy Corporation to support operations. The Duke Energy Corporation records management system will provide for timely retrieval of necessary records.

- In lieu of the requirements of Section 10, Commercial Grade Items, controls for commercial grade items and services are established in Duke Energy Corporation documents using 10 CFR 21 and the guidance of EPRI NP-5652 as discussed in Generic Letter 89-02 and Generic Letter 91-05.

  - For commercial grade items, special quality verification requirements are established and described in Duke Energy Corporation documents to provide the necessary assurance an item will perform satisfactorily in service. The Duke Energy Corporation documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

  - Duke Energy Corporation will also use other appropriate approved regulatory means and controls to support Duke Energy Corporation commercial grade dedication activities Duke Energy Corporation will assume 10 CFR 21 reporting responsibility for all items that Duke Energy Corporation dedicates as safety-related.

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Duke Energy Corporation has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. The identification of items is maintained throughout fabrication, erection, installation and use so that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so as not to affect the function or quality of the item.

8.1 NQA-1-1994 Commitment

In establishing provisions for identification and control of items, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

SECTION 9 CONTROL OF SPECIAL PROCESSES

Duke Energy Corporation has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

9.1 NQA-1-1994 Commitment

In establishing measures for the control of special processes, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 9 and Supplement 9S-1.

SECTION 10 INSPECTION

Duke Energy Corporation has established the necessary measures and governing procedures to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspection may also be applied to items, services and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction, installation, and operations activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are documented.

10.1 Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality: (1) at the source of supplied items or services, (2) in-process during fabrication at a supplier's facility or at a Company facility, (3) for final acceptance of fabricated and/or installed items during construction, (4) upon receipt of items for a facility, as well as (5) during maintenance, modification, in-service, and operating activities.

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and includes qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as: rejection, acceptance, and re-inspection results; and the person(s) performing the inspection.

Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

10.2 Inspector Qualification

Duke Energy Corporation has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in Part II, Section 2. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

10.3 NQA-1-1994 Commitments/Exceptions

In establishing inspection requirements, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 10, Supplement 10S-1 and Subpart 2.4, with the following clarification. In addition, Duke Energy Corporation commits to compliance with the requirements of Subparts 2.5 and 2.8 for establishing appropriate inspection requirements.

- Subpart 2.4 commits Duke Energy Corporation to IEEE 336-1985. IEEE 336-1985 refers to IEEE 498-1985. Both IEEE 336 -1985 and IEEE 498-1985 use the definition of "Safety Systems" from IEEE 603-1980. Duke Energy Corporation commits to the definition of Safety Systems in IEEE 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.

- An additional exception to Subpart 2.4 is addressed in Part II, Section 12.

- Where inspections at the operating facility are performed by persons within the same organization (e.g. Maintenance group), Duke Energy Corporation takes exception to the requirements of NQA-1-1994, Supplement 10S-1, Section 3.1, the inspectors report to Nuclear Oversight organization while performing those inspections.

SECTION 11 TEST CONTROL

Duke Energy Corporation has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant as a whole is satisfactory. These programs include criteria for determining when testing is required, such as proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, in-service tests, and operational tests (such as surveillance tests required by Plant Technical Specifications), to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions to establish and adjust test schedules and to maintain status for periodic or recurring tests. Tests are performed according to applicable procedures that include, consistent with the effect on safety: (1) instructions and prerequisites to perform the test, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

The initial start-up test program is planned and scheduled to permit safe fuel loading and start-up; to increase power in safe increments; and to perform major testing at specified power levels. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted will be prescribed. The scope of the testing demonstrates, insofar as practicable, that the plant is capable of withstanding the design transients and accidents. For new facility construction, the suitability of facility operating procedures is checked to the maximum extent possible during the pre-operational and initial start-up test programs.

Tests are performed and results documented in accordance with applicable technical and regulatory requirements including those described in the Technical Specifications and SAR. Test programs ensure appropriate retention of test data in accordance with the records requirements of the QAPD. Personnel that perform or evaluate tests are qualified in accordance with the requirements established in Part II, Section 2.

11.1 NQA-1-1994 Commitment

In establishing provisions for testing, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 11 and Supplement 11S-1.

11.2 NQA-1-1994 Commitment for Computer Program Testing

Duke Energy Corporation establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained and configuration control maintained. To this end Duke Energy Corporation commits to compliance with the requirements of NQA-1-1994, Supplement 11S-2, and Subpart 2.7 to establish the appropriate provisions.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

Duke Energy Corporation has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment. The suppliers of commercial-grade calibration services are controlled as described in Part II, Section 7.

12.1 Installed Instrument and Control Devices

For the operations phase of the facilities, Duke Energy Corporation has established and implements procedures for the calibration and adjustment of instrument and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure the facility is operated within design and technical requirements. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device.

12.2 NQA-1-1994 Commitment/Exceptions

In establishing provisions for control of measuring and test equipment, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 12 and Supplement 12S-1 with the following clarification and exception:

- The out of calibration conditions described in paragraph 3.2 of Supplement 12S-1 refers to when the M&TE is found out of the required accuracy limits (i.e. out of tolerance) during calibration.

- Measuring and test equipment are not required to be marked with the calibration status where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-1994, Subpart 2.4, Section 7.2.1 (ANSI/IEEE Std. 336-1985).

SECTION 13 HANDLING, STORAGE, AND SHIPPING

Duke Energy Corporation has established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration. These provisions include specific procedures, when required to maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling and storage to identify, maintain, and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and temperature levels) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment are used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained.

Operators of special handling and lifting equipment are experienced or trained in the use of the equipment. During the operational phase, Duke Energy Corporation establishes and implements controls over hoisting, rigging and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. Where required, Duke Energy Corporation complies with applicable hoisting, rigging and transportation regulations and codes.

13.1 Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems and components within the plant. This includes control of cleanliness of facilities and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, protection of equipment, radioactive contamination control and storage of solid radioactive waste. Housekeeping practices help assure that only proper materials, equipment, processes and procedures are used and that the quality of items is not degraded. Necessary procedures or work instructions, such as for electrical bus and control center cleaning, cleaning of control consoles, and radioactive decontamination are developed and used.

13.2 NQA-1-1994 Commitment/Exceptions

In establishing provisions for handling, storage and shipping, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 13 and Supplement 13S-1. Duke Energy Corporation also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-1994, Subpart 2.1, Subpart 2.2, and Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions:

NQA-1-1994, Subpart 2.1

- Subpart 2.1, Section 3.1 and 3.2 establish criteria for classifying items into cleanness classes and requirements for each class. Instead of using the cleanness level system of Subpart 2.1, Duke Energy Corporation may establish cleanness requirements on a case by case basis, consistent with the other provisions of Subpart 2.1. Duke Energy Corporation establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure. [NOTE: Optional clarification/alternative to QA requirements that only applies to operation programs.]

NQA-1-1994, Subpart 2.2

- Subpart 2.2, Section 2.2 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, Duke Energy Corporation may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function. [NOTE: Optional clarification/alternative to QA requirements that only applies to operational programs.]

- Subpart 2.2, section 6.6, "Storage Records:" This section requires written records be
prepared containing information on personnel access. As an alternative to this
requirement, Duke Energy Corporation documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.

- Subpart 2.2, section 7.1 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging and transporting of items for the nuclear power plants during construction.

NQA-1-1994, Subpart 2.3

- Subpart 2.3, Section 2.3 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, Duke Energy Corporation bases its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions which, in the case of maintenance or modification work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. [**NOTE**: Optional clarification/alternative to QA requirements that only applies to operational programs.]

NQA-1-1994, Subpart 3.2

- Subpart 3.2, Appendix 2.1: Only Section 3 precautions are being committed to in accordance with RG 1.37. In addition, a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

Duke Energy Corporation has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications and status tracking.

Administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. Review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

14.1 NQA-1-1994 Commitment

In establishing measures for control of inspection, test and operating status, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 14.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Duke Energy Corporation has established the necessary measures and governing procedures to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with Duke Energy Corporation procedures, regulatory requirements, and industry standards.

15.1 Interface with the Reporting Program

Duke Energy Corporation has appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55(e) and/or 10 CFR 21 during COL design and construction and 10 CFR 21 during operations.

15.2 NQA-1-1994 Commitment

In establishing measures for nonconforming materials, parts, or components, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 15, and Supplement 15S-1.

SECTION 16 CORRECTIVE ACTION

Duke Energy Corporation has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. Duke Energy Corporation procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. Duke Energy Corporation procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, Duke Energy Corporation documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, Duke Energy Corporation may delegate specific responsibilities for corrective actions but Duke Energy Corporation maintains responsibility for the effectiveness of corrective action measures.

16.1 Interface with the Reporting Program

Duke Energy Corporation has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55(e) and or 10 CFR 21 during the COL design and construction, and 10 CFR 21 during operations.

16.2 NQA-1-1994 Commitment

In establishing provisions for corrective action, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 16.

SECTION 17 QUALITY ASSURANCE RECORDS

Duke Energy Corporation has the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for Duke Energy Corporation and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

17.1 Record Retention

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, startup, operations, maintenance, modification, decommissioning, and audits and their retention times are defined in appropriate procedures. The records and retention times are based on Regulatory Position C.2 and Table 1, of Regulatory Guide 1.28, Revision 3 for design, construction, and initial startup. Retention times for operations phase records are based on construction records that are similar in nature. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2 Electronic Records

The Duke Energy program for storage of records on microfilm, dual storage or in electronic format meets the preservation requirement for the retention of QA Records.

As identified in NRC Safety Evaluation dated May 26, 2015 to Duke Energy Carolinas (ADAMS Accession No. ML15138A347), for management of electronic records, the appropriate controls on quality are summarized as follows:

a) The Electronic Records Management (eRM) system does not allow deletion or modification of records. (NOTE: Authorized deletion of records per the Record Retention Rules is controlled.)

b) The eRM system provides redundancy (i.e., system backup, dual storage, etc.).

c) The legibility of each record is verified prior to acceptance into the eRM system.

d) The media used by the eRM system is maintained to ensure the records are acceptably copied onto a new media before the manufacturer's certified useful life of the media is exceeded. This includes verification of the records so copied.

e) Periodic random inspections of records are performed to verify that there has been no degradation of record quality.

f) If the eRM system in use is to be replaced by new system, the records stored on the old system are acceptably converted into the new system before the old system is taken out of service. This includes verification of the records so copied.

To implement those controls, Duke Energy Corporation uses the following Nuclear Information and Records Management Association (NIRMA) standards:

- NIRMA TG 11-2011 "Authentication of Records and Media"
- NIRMA TG 15-2011, "Management of Electronic Records,"
- NIRMA TG 16-2011, "Software Quality Assurance Documentation and Records"
- NIRMA TG 21-2011, "Required Records Protection, Disaster Recovery and Business Continuation"

There is no requirement to convert records stored on media including hardcopy, microfilm, compact disk recordable (CD-R), and magnetic media including videotape, computer tape, and optical disks to on-line electronic records. Those records may be maintained in their current form as long as retrieval technology and media life support the continued use of the media. If records stored on one media are to be converted to a new media, the records stored on the old system's media are acceptably converted into the new system before the old system is taken out of service. This includes verification of the records so copied are complete and accurate in the new system.

17.3 NQA-1-1994 Commitment/Exceptions

In establishing provisions for records, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 17S-1
  - Supplement 17S-1, Section 4.2(b) requires records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. For hard-copy records maintained by Duke Energy Corporation, the records are suitably stored in steel file cabinets or on shelving in containers, except that methods other than binders, folders or envelopes may be used to organize the records for storage.

SECTION 18 AUDITS

Duke Energy Corporation has established the necessary measures and governing procedures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.1 Performance of Audits

Internal audits of selected aspects of licensing, design, construction phase and operating activities are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. During the early portions of the new nuclear plant development activities, audits will focus on areas including, but not limited to, site investigation, procurement, and corrective action. Functional areas of an organization's QA program for auditing include, at a minimum verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of operating staff, corrective actions, and observation of performance of operating, refueling, maintenance and modification activities, including associated record keeping.

The audits are scheduled on a formal preplanned audit schedule. The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the Nuclear Oversight corporate manager responsible for Audits and Programs.

Duke Energy Corporation is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures (by representative sampling), and to determine if they are meaningful and comply with the overall QAPD. External audits determine the adequacy of supplier and contractor quality assurance program.

The results of each audit are reported in writing to the Chief Nuclear Officer, or designee, as appropriate. Additional internal distribution is made to other concerned management levels in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

Audits of suppliers of safety-related components and/or services are conducted as described in Part II, Section 7.1.

18.2 Internal Audits

Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter.

Internal audits of activities, conducted after placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area within a period of two years. Internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the above two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any functional area changes in responsibility, resources, or management. However, the internal audit frequency should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency should be rescinded and an audit scheduled as soon as practicable.

During the operations phase audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are completed within a period of two years. These audits will include, as a minimum, activities in the following areas:

(1) The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions including administrative controls.

The performance, training, and qualifications of the facility staff.

(2) The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B.

(3) The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit is conducted utilizing either a qualified offsite licensed fire protection engineer or an outside qualified fire protection consultant.

(4) Other activities and documents considered appropriate by Nuclear Development, Nuclear Operations, or the CNO.

Audits may also be used to meet the periodic review requirements of the code for the Security, Emergency Preparedness, and Radiological Protection programs within the provisions of the applicable code.

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by the QAPD; corrective actions taken following abnormal occurrences; and, observation of the performance of construction, fabrication, operating, refueling, maintenance and modification activities including associated record keeping.

18.3 NQA-1-1994 Commitment

In establishing the independent audit program, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

PART III NON-SAFETY-RELATED SSC QUALITY CONTROL

SECTION 1 Nonsafety-Related SSCs - Significant Contributors to Plant Safety

Specific program controls are applied to non-safety related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the non-safety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for non-safety-related SSCs.

1.1 Organization

The verification activities described in this part may be performed by the Duke Energy Corporation line organization. The QA organization described in Part II is not required to perform these functions.

1.2 QA Program

Duke Energy Corporation QA requirements for non-safety-related SSCs are established in the QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QA program is not required.

1.3 Design Control

Duke Energy Corporation has design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

1.4 Procurement Document Control

Procurement documents for items and services obtained by or for Duke Energy Corporation include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

1.5 Instructions, Procedures, and Drawings

Duke Energy Corporation provides documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed provides an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

1.6 Document Control

Duke Energy Corporation controls the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

1.7 Control of Purchased Items and Services

Duke Energy Corporation employs measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

1.8 Identification and Control of Purchased Items

Duke Energy Corporation employs measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf life restrictions for the items.

1.9 Control of Special Processes

Duke Energy Corporation employs process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10 Inspection

Duke Energy Corporation uses documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

1.11 Test Control

Duke Energy Corporation employs measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

1.12 Control of Measuring and Test Equipment (M&TE)

Duke Energy Corporation employs measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

1.13 Handling, Storage, and Shipping

Duke Energy Corporation employs measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

1.14 Inspection, Test, and Operating Status

Duke Energy Corporation employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

1.15 Control of Nonconforming Items

Duke Energy Corporation employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.16 Corrective Action

Duke Energy Corporation employs measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

1.17 Records

Duke Energy Corporation employs measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

1.18 Audits

Duke Energy Corporation employs measures for line management to periodically review and document the adequacy of the process, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).

SECTION 2 Non-safety-Related SSCs Credited for Regulatory Events

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety related.

- Duke Energy Corporation implements quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants" as identified in FSAR Chapter 1.

- Duke Energy Corporation implements the quality requirements for ATWS equipment in accordance with Part III, Section 1.

- Duke Energy Corporation implements quality requirements for SBO equipment in accordance with Part III, Section 1. Regulatory Guide 1.155, is not applicable for the AP1000 design in accordance with the certified design as shown in DCD Appendix 1A. Regulatory Guide 1.155 relates to the availability of safety related functions supported by AC power. Since AC power is not required to support the availability of safety-related functions, the guidance is not applicable.

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards which have been selected to supplement and support the Duke Energy Corporation QAPD. Duke Energy Corporation complies with these standards to the extent described or referenced. Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein.

Regulatory Guides:

Regulatory Guide 1.8, Rev. 3, May 2000 - Qualification and Training of Personnel for Nuclear Power Plants

Regulatory Guide 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel.

Duke Energy Corporation identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

Regulatory Guide 1.26, Revision 4, March 2007 - Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26 defines classification of systems and components.

Duke Energy Corporation identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

Regulatory Guide 1.28, Rev. 3, August 1985 - Quality Assurance Program Requirements (Design and Construction)

Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants.

Duke Energy Corporation identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

Regulatory Guide 1.29, Revision 4, March 2007 - Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

Duke Energy Corporation identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA

Regulatory Guide 1.33, Rev. 2, February 1978 - Quality Assurance Program Requirements (Operations)

Regulatory Guide 1.33 describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants.

Duke Energy Corporation identifies conformance and exceptions for the applicable regulatory position guidance provided in the regulatory guide in the following paragraphs:

- This Regulatory Guide endorses ANSI N18.7-1976/ANS-3.2 for complying with the quality assurance program requirements for the operation phase of nuclear power plants, subject to five regulatory positions. Attachment 4 to NEI 06-14, Rev. 9 provides a comparison of QA requirements established within NQA-1-1994 and the template to provide an alternate method of meeting 10 CFR 50, Appendix B during the operational phase in lieu of committing to the requirements of ANSI N18.7-1976/ANS-3.2.
- Regulatory Position C.1 addresses "Typical Procedures for Pressurized Water Reactors and Boiling Water Reactors." QAPD Part II, Sections 5 and 6, and Part V, Section 3 address requirements for procedures consistent with requirements addressed in SRP 17.5 section II.F and ANSI N18.7-1976.
- In meeting the intent of Regulatory Position C.2, Duke's commitment to Regulatory Guides governing QA is specified in Part II, IV, and V.
- Regulatory Position C.3 identifies a position related to Independent Review. The QAPD provides an alternative for this position by addressing Independent Review requirements specifically in Part V, Section 2.2 consistent with SRP 17.5 Section II.W rather than referencing ANSI N18.7. Item 2.2 c. specifically relates to the concern of this regulatory position.

- In meeting the intent of Regulatory Position C.4, Duke describes the internal audit function, scheduling and frequency in Part II, Section 18. The audit scheduling process takes into consideration the need for increased auditing in areas that indicate ineffective performance.
- Regulatory Position C.5 identifies concerns of the NRC with the usage of the verbs "should" and "shall" in ANSI N18.7-1976. The QAPD provides an alternative to this position by providing adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA standard NQA-1994, as supplemented by the QAPD provisions in NEI 06-14, Rev. 8.

Regulatory Guide 1.37, Revision 1, March 2007 – Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants.

Regulatory Guide 1.37 provides guidance on specifying water quality and precautions related to the use of alkaline cleaning solutions and chelating agents.

Duke Energy Corporation identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

Regulatory Guide 1.54, Revision 1, July 2000 – Service Level I, II and III Protective Coatings Applied to Nuclear Power Plants.

Regulatory Guide 1.54 provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides, and for wear protection.

Duke Energy Corporation identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1, Appendix 1AA.

Standards:

ASME NQA-1-1994 Edition, Quality Assurance Requirements for Nuclear Facility Applications

Duke Energy Corporation commits to NQA-1-1994, Parts I, II, and III as described in Parts II and V of this document.

Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)

Duke Energy Corporation commits to NIRMA TGs as described in Part II, Section 17.

PART V ADDITIONAL QUALITY ASSURANCE AND ADMINISTRATIVE CONTROLS FOR THE PLANT OPERATIONAL PHASE

Duke includes the requirements of Part V that follow when establishing the necessary measures and governing procedures for the operations phase of the plant.

SECTION 1 DEFINITIONS

Duke uses the definitions of terms as provided in Section 4 of the Introduction of NQA-1-1994 in interpreting the requirements of NQA-1-1994 and the other standards to which the QAPD commits. In addition, definitions are provided for the following terms not covered in NQA-1-1994:

Administrative Controls: Rules, orders, instructions, procedures, policies, practices and designations of authority and responsibility.

Experiments: Performance of plant operations carried out under controlled conditions in order to establish characteristics or values not previously known.

Independent Review: Review completed by personnel not having direct responsibility for the work function under review regardless of whether they operate as a part of an organizational unit or as individual staff members (see review).

Nuclear Power Plant: Any plant using a nuclear reactor to produce electric power, process steam or space heating.

On-site Operating Organization: on-site personnel concerned with the operation, maintenance and certain technical services.

Operating Activities: Work functions associated with normal operation and maintenance of the plant, and technical services routinely assigned to the on-site operating organization.

Operational Phase: That period of time during which the principal activity is associated with normal operation of the plant. This phase of plant life is considered to begin formally with commencement of initial fuel loading, and ends with plant decommissioning.

Review: A deliberately critical examination, including observation of plant operation, evaluation of assessment results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions.

Supervision: Direction of personnel activities or monitoring of plant functions by an individual responsible and accountable for the activities they direct or monitor.

Surveillance Testing: Periodic testing to verify that safety related structures, systems, and components continue to function or are in a state of readiness to perform their functions.

System: An integral part of nuclear power plant comprising components which may be operated or used as a separate entity to perform a specific function.

SECTION 2 REVIEW OF ACTIVITIES AFFECTING SAFE PLANT OPERATION

2.1 Onsite Operating Organization Review

The Duke onsite organization employs reviews, both periodic and as situations demand, to evaluate plant operations and plan future activities. The important elements of the reviews are documented and subjects of potential concern for the independent review described below are brought to the attention of the Nuclear Station Manager. The reviews are part of the normal duties of plant supervisory personnel in order to provide timely and continuing monitoring of operating activities in order to assist the Nuclear Station Manager in keeping abreast of general plant conditions and to verify that day-to-day operations are conducted safely in accordance with the established administrative controls. The Nuclear Station Manager ensures the timely referral of the applicable matters discussed in the reviews to appropriate management and independent reviewers.

2.2 Independent Review

Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading. The independent review function performs the following:

a. Reviews proposed changes to the facility as described in the safety analysis report (SAR). The independent review function also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.

b. Reviews proposed tests and experiments not described in the SAR prior to implementation. Verifies the determination of whether changes to proposed tests and experiments not described in the SAR require a technical specification change or license amendment.

c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.

d. Reviews violations, deviations, and events that are required to be reported to the NRC. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

e. Reviews any matter related to nuclear safety that is requested by the Site Vice-President, Site Director, Plant Manager, or any independent review program member.

f. Reviews corrective actions for significant conditions adverse to quality.

g. Reviews internal audit reports.

h. Reviews the adequacy of the internal audit program every 24 months.

Independent Review Body (IRB)

A group may function as an Independent Review Body (IRB). In discharging its review responsibilities, the IRB keeps safety considerations paramount when opposed to cost or schedule considerations. One or more organizational units may collectively perform this function.

1. IRB reviews are supplemented as follows:

    a. A qualified person, independent of the preparer, reviews proposed changes in the procedures as described in the SAR prior to implementation of the change to determine if a technical specification change or NRC approval is required.

    b. Audits of selected changes in the procedures described in the SAR are performed to verify that procedure reviews and revision controls are effectively implemented.

    c. Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.

2. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed. This review is intended to support management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.

    a. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities. The IRB supervisor or chairman has a minimum six (6) years combined managerial and technical support experience. The members of the IRB should have a minimum of five years of experience in their own area of responsibility as applicable to the activities being reviewed (i.e., a minimum of five years of experience in one of the twelve areas listed below:

        (1) Nuclear power plant operations

        (2) Nuclear engineering

        (3) Chemistry and radiochemistry

        (4) Metallurgy

        (5) Nondestructive testing

        (6) Instrumentation and control

        (7) Radiological safety

        (8) Mechanical engineering

        (9) Electrical engineering

        (10) Administrative control and quality assurance practices

        (11) Training

        (12) Emergency plans and related procedures and equipment.

    b. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.

    c. Results of the review are documented and reported to responsible management.

d. Management periodically consider issues they determine warrant special attention, such as deficient plant programs, declining performance trends, employee concerns, or other issues related to safe plant operations and determine what issues warrant the review.

e. Management determines the scheduling and scope of review and the composition of the team performing the review.

SECTION 3 OPERATIONAL PHASE PROCEDURES

The following is a description of the various types of procedures used by Duke to govern the design, operation, and maintenance of its nuclear generating plants. Duke follows the guidance of Appendix A to Regulatory Guide 1.33 in identifying the types of activities that should have procedures or instructions to control the activity. Each procedure shall be sufficiently detailed for a qualified individual to perform the required function without direct supervision, but need not provide a complete description of the system or plant process.

3.1 Format and Content

Procedure format and content may vary from one location to the other. However, procedures include the following elements as appropriate to the purpose or task to be described.

- **Title/Status**

  Each procedure is given a title descriptive of the work or subject it addresses, and includes a revision number and/or date and an approval status.

- **Purpose/Statement of Applicability/Scope**

  The purpose for which the procedure is intended is clearly stated (if not clear from the title). The systems, structures, components, processes or conditions to which the procedure applies are also clearly described.

  - **References**

    Applicable references, including reference to appropriate Technical Specifications, are required. References are included within the body of the procedure when the sequence of steps requires other tasks to be performed (according to the reference) prior to or concurrent with a particular step.

  - **Prerequisites/Initial Conditions**

    Prerequisites/initial conditions identify those independent actions or procedures that must be accomplished and plant conditions which must exist prior to performing the procedure. A prerequisite applicable to only a specific portion of a procedure is so identified.

  - **Precautions**

    Precautions alert the user to those important measures to be used to protect equipment and personnel, including the public, or to avoid an abnormal or emergency situation during performance of the procedure. Cautionary notes applicable to specific steps are included in the main body of the procedure and are identified as such.

  - **Limitations and actions**

    Limitations on the parameters being controlled and appropriate corrective measures to return the parameter to the normal control band are specified.

  - **Main body**

    The main body of the procedure contains the step-by-step instructions in the degree of detail necessary for performing the required function or task.

- **Acceptance criteria**

  The acceptance criteria provide the quantitative or qualitative criteria against which the success or failure (as of a test-type activity) of the step or action would be judged.

- **Checklists**

  Complex procedures utilize checklists which may be included as part of the procedure or appended to it.

3.2 Procedure Types

Administrative Control Procedures

These include administrative procedures, directives, policies, standards, and similar documents that control the programmatic aspects of facility activities. These administrative documents ensure that the requirements of regulatory and license commitments are implemented. Several levels of administrative controls are applied ranging from those affecting the entire Company to those prepared at the implementing group level. These documents establish responsibilities, interfaces, and standard methods (rules of practice) for implementing programs. In addition to the administrative controls described throughout this QAPD, instructions governing the following activities are provided:

- **Operating Orders/Procedures**

  Instructions of general and continuing applicability to the conduct of business to the plant staff are provided. Examples where these are applied include, but are not limited to, job turnover and relief, designation of confines of control room, definition of duties of operators and others, transmittal of operating data to management, filing of charts, limitations on access to certain areas and equipment, shipping and receiving instructions. Provisions are made for periodic review and updating of these documents, where appropriate.

- **Special Orders**

  Management instructions, which have short-term applicability and require dissemination, are issued to encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters. Provisions are made for periodic review, updating, and cancellation of these documents, where appropriate.

- **Plant Security and Visitor Control**

  Procedures or instructions are developed to supplement features and physical barriers designed to control access to the plant and, as appropriate, to vital areas within the plant. Information concerning specific design features and administrative provisions of the plant security program is confidential and thus accorded limited distribution. The security and visitor control procedures consider, for example, physical provisions, such as: fences and lighting; lock controls for doors, gates and compartments containing sensitive equipment; and provisions for traffic and access control. Administrative provisions, such as: visitor sign-in and sign-out procedures; escorts and badges for visitors; emphasis on inspection, observation and challenging of strangers by operating crews; and a program of pre- employment screening for potential employees are also considered.

- **Temporary Procedures**

  Temporary procedures may be used to direct operations during testing, refueling, maintenance, and modifications to provide guidance in unusual situations not within the scope of the normal procedures. These procedures ensure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures or has been modified or extended in such a manner that portions of existing procedures do not apply. Temporary Procedures include designation of the period of time during which they may be used and are subject to the procedure review process as applicable.

Engineering Procedures

These documents provide instructions for the preparation of engineering documents, engineering analysis, and implementation of engineering programs. This includes activities such as designs; calculations; fabrication, equipment, construction, and installation specifications; drawings; analysis and topical reports; and testing plans or procedures. They include appropriate references to industry codes and standards, design inputs, and technical requirements.

Installation Procedures

These documents provide instructions for the installation of components generally related to new construction and certain modification activities. They include appropriate reference to industry standards, installation specifications, design drawings, and supplier and technical manuals for the performance of activities. These documents include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection and test instructions subject to the requirements for test and inspection procedures below.

System Procedures

These documents contain instructions for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation, and other instructions appropriate for operations of systems related to the safety of the plant. Actions to correct off-normal conditions are invoked following an operator observation or an annunciator alarm indicating a condition which, if not corrected, could degenerate into a condition requiring action under an emergency procedure. Separate procedures may be developed for correcting off-normal conditions for those events where system complexity may lead to operator uncertainty. Appropriate procedures will also be developed for the fire protection program.

Start-up Procedures

These documents contain instructions for starting the reactor from cold or hot conditions and establishing power operation. This includes documented determination that prerequisites have been met, including confirmation that necessary instruments are operable and properly set; valves are properly aligned, necessary system procedures, tests and calibrations have been completed; and required approvals have been obtained.

Shutdown Procedures

These documents contain guidance for operations during controlled shutdown and following reactor trips, including instructions for establishing or maintaining hot shutdown/standby or cold shutdown conditions, as applicable. The major steps involved in shutting down the plant are specified, including instructions for such actions as monitoring and controlling reactivity, load reduction and cooldown rates, sequence for activating or deactivating equipment, requirements for prompt analysis for causes of reactor trips or abnormal conditions requiring unplanned controlled shutdowns, and provisions for decay heat removal.

Power Operation and Load Changing Procedures

These documents contain instructions for steady-state power operation and load changing. These type documents include, as examples, provisions for use of control rods, chemical shim, coolant flow control, or any other system available for short-term or long-term control of reactivity, making deliberate load changes, responding to unanticipated load changes, and adjusting operating parameters.

Process Monitoring Procedures

These documents contain instructions for monitoring performance of plant systems to assure that core thermal margins and coolant quality are maintained in acceptable status at all times, that integrity of fission product barriers is maintained, and that engineered safety features and emergency equipment are in a state of readiness to keep the plant in a safe condition if needed. Maximum and minimum limits for process parameters are appropriately identified. Operating procedures address the appropriate nature and frequency of this monitoring.

Fuel Handling Procedures

These documents contain instructions for core alterations, accountability of fuel and partial or complete refueling operations that include, for example, continuous monitoring of neutron flux throughout core loading, periodic data recording, audible annunciation of abnormal flux increases, and evaluation of core neutron multiplication to verify safety of loading increments. Procedures are also provided for receipt and inspection of new fuel, and for fuel movements in the spent fuel storage areas. Fuel handling procedures include prerequisites to verify the status of systems required for fuel handling and movement; inspection of replacement fuel and control rods; designation of proper tools, proper conditions for spent fuel movement, proper conditions for fuel cask loading and movement; and status of interlocks, reactor trip circuits and mode switches. These procedures provide requirements for refueling, including proper sequence, orientation and seating of fuel and components, rules for minimum operable instrumentation, actions for response to fuel damage, verification of shutdown margin, communications between the control room and the fuel handling station, independent verification of fuel and component locations, criteria for stopping fuel movements, and documentation of final fuel and component serial numbers (or other unique identifiers) and locations.

Maintenance Procedures

These documents contain instructions in sufficient detail to permit maintenance work to be performed correctly and safely, and include provisions, such as hold or witness points, for conducting and recording results of required inspections or tests. These documents may include applicable inspection or test instructions subject to the requirements for test and inspection procedures below. Appropriate referencing to other procedures, standards, specifications, or supplier manuals is provided. When not provided through other documents, instructions for equipment removal and return to service, and applicable radiation protection measures (such as protective clothing and radiation monitoring) will be included. Additional maintenance procedure requirements are addressed in NQA-1-1994, Subpart 2.18, Section 2.2, Procedures.

Radiation Control Procedures

These documents contain instructions for implementation of the radiation control program requirements necessary to meet regulatory commitments, including acquisition of data and use of equipment to perform necessary radiation surveys, measurements and evaluations for the assessment and control of radiation hazards. These procedures provide requirements for monitoring both external and internal exposures of employees, utilizing accepted techniques; routine radiation surveys of work areas; effluent and environmental monitoring in the vicinity of the plant; radiation monitoring of maintenance and special work activities, and for maintaining records demonstrating the adequacy of measures taken to control radiation exposures to employees and others.

Calibration and Test Procedures

These documents contain instructions for periodic calibration and testing of instrumentation and control systems, and for periodic calibration of measuring and test equipment used in activities affecting the quality of these systems. These documents provide for meeting surveillance requirements and for assuring measurement accuracy adequate to keep safety-related parameters within operational and safety limits.

Chemical and Radiochemical Control Procedures

These documents contain instructions for chemical and radiochemical control activities and include: the nature and frequency of sampling and analyses; instructions for maintaining coolant quality within prescribed limits; and limitations on concentrations of agents that could cause corrosive attack, foul heat transfer surfaces, or become sources of radiation hazards due to activation. These documents also provide for the control, treatment and management of radioactive wastes, and control of radioactive calibration sources.

Emergency Operating Procedures

These documents contain instructions for response to potential emergencies so that a trained operator will know in advance the expected course of events that will identify an emergency and the immediate actions that are taken in response. Format and content of emergency procedures are based on NUREG and Owner's Group(s) guidance that identify potential emergency conditions and require such procedures to include, as appropriate, a title, symptoms to aid in identification of the nature of the emergency, automatic actions to be expected from protective systems, immediate operator actions for operation of controls or confirmation of automatic actions, and subsequent operator actions to return the reactor to a normal condition or provide for a safe extended shutdown period under abnormal or emergency conditions.

Emergency Plan Implementing Procedures

These documents contain instructions for activating the Emergency Response Organization and facilities, protective action levels, organizing emergency response actions, establishing necessary communications with local, state and federal agencies, and for periodically testing the procedures, communications and alarm systems to assure they function properly. Format and content of such procedures are such that requirements of each facility's NRC approved Emergency Plan are met.

Test and Inspection Procedures

These documents provide the necessary measures to assure quality is achieved and maintained for the nuclear facilities. The instructions for tests and inspections may be included within other procedures, such as installation and maintenance procedures, but will contain the objectives, acceptance criteria, prerequisites for performing the test or inspection, limiting conditions, and appropriate instructions for performing the test or inspection, as applicable. These procedures also specify any special equipment or calibrations required to conduct the test or inspection and provide for appropriate documentation and evaluation by responsible authority to assure test or inspection requirements have been satisfied. Where necessary, hold or witness points are identified within the procedures and require appropriate approval for the work to continue beyond the designated point. These procedures provide for recording the date, identification of those performing the test or inspection, as-found condition, corrective actions performed (if any), and as-left condition, as appropriate for the subject test or inspection.

SECTION 4 CONTROL OF SYSTEMS AND EQUIPMENT IN THE OPERATIONAL PHASE

Permission to release systems and equipment for maintenance or modification is controlled by designated operating personnel and documented. Measures, such as installation of tags or locks and releasing stored energy, are used to ensure personnel and equipment safety. When entry into a closed system is required, Duke has established control measures to prevent entry of extraneous material and to assure that foreign material is removed before the system is reclosed.

Administrative procedures require the designated operating personnel to verify that the system or equipment can be released and determine the length of time it may be out of service. In making this determination, attention is given to the potentially degraded degree of protection where one subsystem of a redundant safety system is not available for service. Conditions to be considered in preparing equipment for maintenance include, for example: shutdown margin; method of emergency core cooling; establishment of a path for decay heat removal; temperature and pressure of the system; valves between work and hazardous material; venting, draining and flushing; entry into closed vessels; hazardous atmospheres; handling hazardous materials; and electrical hazards.

When systems or equipment are ready to be returned to service, designated operating personnel control placing the items in service and document its functional acceptability. Attention is given to restoration of normal conditions, such as removal of jumpers or signals used in maintenance or testing, or actions such as returning valves, breakers or switches to proper start-up or operating positions from "test" or "manual" positions. Where necessary, the equipment placed into service receives additional surveillance during the run-in period.

Independent verifications, where appropriate, are used to ensure that the necessary measures have been implemented correctly. The minimum requirements and standards for using independent verification are established in company documents.

SECTION 5 PLANT MAINTENANCE

Duke establishes controls for the maintenance or modification of items and equipment subject to this QAPD to ensure quality at least equivalent to that specified in original design bases and requirements, such that safety-related structures, systems and components are maintained in a manner that assures their ability to perform their intended safety function(s). Maintenance activities (both corrective and preventive) are scheduled and planned so as not to unnecessarily compromise the safety of the plant.

In establishing controls for plant maintenance, Duke commits to compliance with NQA-1-1994, Subpart 2.18, with the following clarifications:

- Where Subpart 2.18 refers to the requirements of ANS-3.2, it shall be interpreted to mean the applicable standards and requirements established within the Duke Energy Carolinas QAPD
- Section 2.3 requires cleanliness during maintenance to be in accordance with Subpart 2.1. The commitment to Subpart 2.1 is described in the Duke Energy Carolinas QAPD, Part II, Section 13.2.

Enclosure 2

Duke Energy Common Quality Assurance Program Description
Mark Up Pages

(19 pages including cover page)

PART II QAPD DETAILS

SECTION 1 ORGANIZATION

This section describes the proposed Duke Energy Corporation organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes corporate support, off-site and on-site functions including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

Duke Energy Corporation management is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned.

The Duke Energy Corporation Nuclear Development organization is responsible for new nuclear plant licensing, engineering, procurement, construction, startup and operations development activities. There are several organizations within the Duke Energy Corporation that implement and support the QAPD. These organizations include, but are not limited to Nuclear Development, Nuclear Supply Chain and Nuclear Oversight.

Organization charts for various departments/locations are contained in Chapter 13 of the respective station's FSAR and describe organizational positions of the nuclear station and associated functions and responsibilities.

Design, engineering and environmental services are provided to the Duke Energy Corporation Nuclear Development organization by a contract that identifies the Engineer and Constructor and invokes the applicable quality program requirements described in this document to applicable contractors and subcontractors.

The organizations responsible for the implementation of the requirements of this Quality Assurance Program Description Topical Report for new nuclear generating plants are described below. There are two primary organizations responsible for implementation within the corporate structure based on the activity being performed. The responsibility for the licensing and development of new nuclear generating plants for Duke Energy is assigned to the ~~Vice President of~~ Executive for Nuclear Development. The responsibility for construction of new nuclear plants is assigned to the ~~Vice President Site Construction~~Executive for Operations Support. The responsibility for the operation of the new nuclear generating plants is assigned to the Chief Nuclear Officer. Each of these individuals reports directly to the ~~President of Duke Energy Nuclear~~Chief Operating Officer.

Figure II.1-1 displays the relationships of the Duke Energy organizations described in and responsible for implementing the requirements of this QAPD. This division of responsibilities was made to allow the Chief Nuclear Officer and Nuclear Generation to remain focused on improving the performance of the operating fleet and minimize the distractions associated with the construction of new nuclear generating plants. Organizational control and responsibility for the newly constructed nuclear generating plant transfers to the Chief Nuclear Officer from the ~~Vice President Site Construction~~Executive for Operations Support following the completion of unit specific construction activities and prior to loading of fuel. This transition point allows for the continued support by the Nuclear Development organization, while the Operational Readiness (OR) organization transitions to the final structure typical of the operating fleet.

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting this QA Program. Figures II.1-1 and II.1-2, and II.1-3 show the organizational structures for corporate, the operations phase, and the construction phase, respectively. Figure II.1-2 shows a typical operating plant structure within Duke Energy Corporation. The detailed roles, responsibilities and organizational structure and reporting relationships for the operations phase organization is detailed in Chapter 13 of the respective plant's FSAR.

1.1 Duke Energy Corporation Corporate Organization

The Chairman, President and Chief Executive Officer has overall responsibility for Design, Construction, and Operation of generation and transmission facilities. The ~~President of Duke Energy Nuclear~~ Chief Operating Officer reports to the Chairman, President and Chief Executive Officer and is responsible for: ~~the~~ generation and transmission, including but not limited to the Duke nuclear operating fleet; ~~enterprise project management and construction;~~ new plant development and construction; and nuclear decommissioning activities. The ~~President of Duke Energy Nuclear~~ Chief Operating Officer has overall authority and responsibility for the QA Program. Reporting to the ~~President of Duke Energy Nuclear is~~Chief Operating Officer are the Chief Nuclear Officer (CNO~~) who directs several activities including~~), the ~~operation of~~executive for Nuclear Development, the ~~nuclear sites through the Senior Vice Presidents, Nuclear~~executive for Operations~~.~~ Support, the executive for Supply Chain, the executive for Environmental Health and Safety, the executive for Transmission, and the executive for Fossil Hydro Generation. The interface between Duke Energy Nuclear (see section 1.2) and non-nuclear dedicated organizations providing support to nuclear is described in Section 1.3.

Also reporting to the Chairman, President and Chief Executive Officer are Group Executives responsible for providing support to Nuclear Generation and Nuclear Development for the following: electrical ~~transmission; electrical~~ distribution; ~~laboratory services; switchyard maintenance and technical support;~~ support for the emergency response communications; and Information Technology Services~~; document control and record management activities; and administration of the Access Authorization, Fitness for Duty, and Fatigue Rule programs~~. The interface with organizations providing those activities are described in Section 1.3. As such, the attainment of quality rests with those assigned the responsibility of performing the activity. The verification of quality is assigned to qualified personnel independent of the responsibility for performance or direct supervision of the activity. The degree of independence varies commensurate with the activity's importance to safety.

1.2 Duke Energy Nuclear

Duke Energy Nuclear is responsible for: the nuclear operating fleet; new nuclear plant development and construction; ~~enterprise project management and construction;~~ and decommissioning activities. These activities are directed by the ~~President of Duke Energy Nuclear~~Chief Operating Officer.

Duke Energy Nuclear is comprised of Nuclear Generation, which is headed by the CNO having responsibility for Duke Energy Corporation operating nuclear ~~station operations~~stations; Nuclear Development, which is headed by executive for Nuclear Development whose responsibilities include activities associated with submittal, review, and approval of combined operating license for new nuclear plants~~; Site Construction responsible for~~, and the nuclear construction ~~of new nuclear plants; and Project Management and Construction responsible for project management~~ and decommissioning ~~activities~~portions of Operations Support.

1.2.1 Nuclear Generation

Nuclear Generation has direct line responsibility for all Duke Energy Corporation operating nuclear ~~station operations~~stations. Nuclear Generation is responsible for achieving quality results during engineering, preoperational testing, operation, testing, maintenance and modification of the Corporation's nuclear stations and with complying with applicable codes, standards and NRC regulations. The functions of Nuclear Generation are directed by the CNO.

The CNO formulates, recommends, and carries out plans, policies, and programs related to the nuclear generation of electric power. The CNO is informed of significant problems or occurrences relating to safety and QA through established administrative procedures, and participates directly in their resolution, when necessary.

Nuclear Generation is organized into ~~eight~~three divisions. The activities of each division are directed by an executive who reports to the CNO. ~~Three of those~~ The divisions are ~~headed by the three executives of~~ Nuclear Operations, ~~which are discussed in the~~ Nuclear ~~Site description. The remaining five divisions, which comprise the Nuclear General Office (NGO), are: Nuclear Engineering, Nuclear Major Projects,~~ Corporate, and Nuclear Oversight~~, Corporate Organizational Effectiveness, and Corporate Governance and Operations Support~~.

The CNO has the organizational flexibility to reassign responsibilities for functions, within the limits specified in the following section, between the standard divisions to provide added focus on areas determined to need increased management attention. This flexibility includes both the ability to consolidate divisions or to identify new divisions. The actual organization in-place is defined in a controlled document containing the fleet operating model.

1.2.1.1 Nuclear ~~Site Organization~~

~~There are three executives of Nuclear~~ **Operations**~~, each reporting directly~~

The executive for Nuclear Operations reports to the CNO and is located in the NGO. ~~Each Senior Vice President – Nuclear Operations~~ This executive is responsible for ~~oversight of~~ the ~~management and~~safe operation of ~~activities associated with~~ the ~~efficient, safe, and reliable operation of his designated~~ nuclear stations. Reporting to ~~each~~the CNO through this executive are the Site executives for the respective nuclear ~~station.~~stations.

The organization structure for each site is controlled by the site's UFSAR, which may vary from the following generic description. Reporting to the site executive for each nuclear station is a Nuclear Plant Manager who is assigned the direct responsibility for the safe operation of the facility including operations, maintenance, work management, radiation protection, ~~and~~ chemistry, and environmental services. Also reporting to the site executive is ~~an Organizational~~a site Engineering manager; a site Training manager; and an Organization Effectiveness manager, ~~who is responsible~~typically having responsibility for regulatory affairs, emergency preparedness, performance improvement, ~~human performance, environmental support services, health and safety, an Engineering Manager, and a Site Training manager.~~and procedures. Each site executive also has a Security manager~~, and a Major Projects manager~~ ~~matrixed~~assigned to provide services to the site. The qualification requirements for the Nuclear Plant personnel are in accordance with the provisions of ANSI N18.1 or ANS 3.1 as identified in each site's UFSAR and Technical Specifications. Figure II.1.2 shows a typical operating nuclear site organization.

1.2.1.2 Nuclear ~~General Office~~Corporate

~~The Site Executive in charge of each site reports directly to the respective Senior Vice President Nuclear Plant Site Group for their site. The Site Executive is directly responsible for management and direction of activities associated with the efficient, safe, and reliable operation of the nuclear station. The Site Executive is assisted in management and technical support activities by the functional managers in charge of training, plant operations and support services as shown in Figure II.1-3. The Site Executive in charge is responsible for the site Fire Protection Program through the functional Supervisor in charge of Fire Protection as described in the FSAR.~~

~~Nuclear Generation, Nuclear General Office (NGO) is organized into five divisions. The activities of each division are directed by an executive who reports to the CNO. The five divisions within the Nuclear General Office are: , Nuclear Engineering, Nuclear Major Projects, Nuclear Oversight, Corporate Organizational Effectiveness, and Corporate Governance and Operations Support.~~

The senior executive(s) reports to the CNO and is responsible for Corporate Governance and support functions to the Nuclear Sites in the following areas: Nuclear Engineering; Nuclear Regulatory Affairs; Nuclear Support Services; Nuclear Protective Services; Nuclear Operations; Nuclear Corporate Organizational Effectiveness; Nuclear Training; and Emergency Preparedness.

The organizational structure for these functions may vary based on near-term activities and the strategic importance of our fleet initiatives, in our continuing efforts to set and achieve industry-leading operational and outage performance. These functions are primarily off-site located in the Nuclear General Office (NGO).

1.2.1.2.1 Nuclear Engineering

~~The executive for Nuclear Engineering reports to the CNO.~~ Nuclear Engineering provides broad engineering leadership and technical support to the nuclear sites with emphasis on generic issues and consistent practices, providing expertise in safety assessment with technical support in the areas of risk assessment, radiological engineering, and safety analysis; fuel management with leadership and technical support in the areas of fuel supply, spent fuel management, reactor core mechanical and thermal hydraulic analysis; the fleet electrical and procurement engineering with technical support in the areas of procurement engineering, nuclear process systems, and electrical systems and analysis; and programs and components support in the areas of steam generator inspections and maintenance, engineering programs, component engineering, material failure analysis and materials science, equipment reliability, and ASME Code inspections and testing. Nuclear Engineering provides support to Site engineering for contracts, engineering and management related to fleet and nuclear site modification projects.

Nuclear Engineering provides record storage and document management services, technology planning, project control and technical support for information technology applications and systems such as equipment databases, applications, infrastructure, and plant process information systems.

1.2.1.2.2 Nuclear ~~Major Projects~~Regulatory Affairs

~~The executive for~~ Nuclear ~~Major Projects reports to the CNO. Nuclear Major Projects~~regulatory affairs provides fleet support to and governance of the site regulatory affairs and licensing activities to help improve overall fleet performance.

1.2.1.2.3 Nuclear Support Services

Nuclear support services provides fleet support to the nuclear sites for laboratory, calibration, and select maintenance and refueling activities.

1.2.1.2.4 Nuclear Protective Services

Nuclear protective services provides access authorization support to the nuclear sites security organization. Nuclear protective services is responsible for ~~contracts, engineering and management related to fleet and nuclear site major projects.~~governance of the site security functions, providing assistance to help improve overall fleet performance.

1.2.1.2.5 Nuclear Operations

Nuclear operations is responsible for governance of the nuclear site operating organizations, providing assistance to promote improvements to overall fleet performance.

1.2.1.2.6 Nuclear Corporate Organizational Effectiveness

Nuclear corporate organizational effectiveness is responsible for governance of the nuclear site performance improvement organizations, providing assistance to promote improvements to overall fleet performance through the corrective action and self-assessment programs. This group also supports implementation of the corrective action and self-assessment programs by the Nuclear Corporate Organization.

1.2.1.2.7 Nuclear Training

Nuclear training is responsible for governance of the nuclear site training organizations, providing assistance to promote improvements to overall fleet performance. This group also supports implementation of the training programs by the Nuclear Corporate Organization.

1.2.1.2.8 Emergency Preparedness

Emergency preparedness is responsible for governance of the nuclear site emergency response organizations, providing assistance to promote improvements to overall fleet performance.

1.2.1.3 Nuclear Oversight (NOS)

The executive for Nuclear Oversight (NOS) reports to the CNO~~. The executive for Nuclear Oversight (~~ and is located in the NGO. NOS~~)~~ consists of both site assigned and NGO located personnel. The executive for NOS is responsible for ~~and reports to the CNO on~~ all matters related to the independent monitoring and ~~assessing of activities performed by the line organizations for, or in support of Nuclear Generation activities. The executive for NOS is responsible for and reports to the President, Duke Energy Nuclear on all matters related to the independent monitoring and assessing~~auditing of activities performed by or in support of the development, deployment, and construction of new nuclear generating plants, decommissioning activities, and project management and construction activities not controlled by the CNO. In executing this responsibility, the executive for NOS reports to the Chief Operating Officer. The NOS executive has the authority and organizational freedom to: identify quality problems, initiate, recommend or provide solutions to quality problems through designated channels, verify the implementation of solutions to quality problems, and ensure cost and schedule do not influence decision making involving quality.

NOS provides oversight of the general office including Nuclear Development activities and all nuclear sites with QA program audits, performance assessments, ~~procurement~~vendor quality, supplier verification, and quality control activities. ~~In addition, NOS provides an advisory function to senior management through the Nuclear Safety Review Board (NSRB).~~ The NOS executive has the authority and organizational freedom to: identify quality problems, initiate, recommend or provide solutions to quality problems through designated channels, verify the implementation of solutions to quality problems, and ensure cost and schedule do not influence decision making involving quality.

The executive for NOS ~~shall have~~has unfettered access to corporate executive management to resolve any quality or nuclear safety related concerns that cannot be resolved satisfactorily at a lower management level.

The NOS executive is delegated primary ownership of the department QA program description (this document) and is responsible for day-to-day administration of the program and resolution of QA issues. If significant quality problems are identified, NOS personnel have the authority to stop work as discussed in Section 1.5 pending satisfactory resolution of the identified problem.

Also reporting to the executive for Nuclear Oversight is Employee Concerns, which investigates concerns identified through the Employee Concerns Programs to determine their validity and initiate corrective actions as appropriate. Employee Concerns also promotes the Safety Conscious Work Environment (SCWE) Program and is sensitive to SCWE concerns during investigations performed.

1.2.2 Nuclear Development

Nuclear 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, and operational readiness. The executive in charge of Nuclear Development reports directly to the ~~President of Duke Energy Nuclear~~Chief Operating Officer and is assisted by a support staff. Initially, Nuclear Development is responsible for construction planning and preparation. The responsibility for construction transitions to the executive for Site Construction at the start of construction activities when filled. Nuclear Development responsibilities include the establishment and execution of a contract or contracts for the engineering, procurement, construction, and startup activities of new nuclear plants. Organizational control and responsibility for newly constructed nuclear generating units transfers to the Chief Nuclear Officer following the completion of unit specific construction activities and prior to loading of fuel. Figure II.1.3 shows the Nuclear Development/Construction Organization. As a new nuclear plant approaches startup, the site organization transitions from the development / construction focused organization in Figure II.1.3 to the Operating Plant Site Organization shown in Figure II.1.2.

1.2.3 Site Construction

The executive for Site Construction reports ~~directly~~ to the ~~President Duke Energy Nuclear~~Chief Operating Officer through the executive for Operation Support. This reporting relationship allows the Chief Nuclear Officer and Nuclear Generation to remain focused on improving the performance of the operating fleet and minimize the distractions associated with the construction of new nuclear generating plants. This position will be filled in support of the start of construction activities for a new nuclear plant. This position is responsible for the control and oversight of all construction activities associated with a new nuclear unit. Reporting to this position will be the manager for construction; manager for site engineering; and the site plant manager as shown on QAPD Figure II.1-3. This position will transfer responsibility for the constructed unit to the site executive reporting to the CNO at the completion of construction activities and prior to the loading of fuel in that unit. This position will retain responsibilities for other units under construction at a multi-unit site until construction activities for each unit are completed. This position is supported during these construction activities by other Duke Energy Nuclear organizations as needed.

1.2.4 ~~Project Management and Construction~~Nuclear Decommissioning

~~Project Management and Construction is responsible for contracts, engineering oversight, and management related to existing plant upgrades, modifications, and new plant construction, as requested. Project Management and Construction will also be responsible for~~The executive for Nuclear Decommissioning reports to the Chief Operating Officer through the executive for Operation Support. This reporting relationship allows the Chief Nuclear Officer and Nuclear Generation to remain focused on improving the performance of the operating fleet and minimizes the distractions associated with defining and executing the decommissioning strategy for Crystal River Unit 3 to meet required regulations and ~~commitments~~obligations.

1.3 Department Interfaces

~~Departmental interfaces are identified in appropriate procedures.~~ Quality related activities performed by departments other than Duke Energy Nuclear ~~Generation~~ are identified by and conducted in accordance with controls identified in approved departmental interface agreements. The following are generic descriptions of those other corporate departments and the services they provide. These generic organizations are referred to, as appropriate, within this document; however, approved departmental interface agreements establish and define the applicability of the ~~QAPD~~Quality Assurance Program to the services they provide~~:~~.

1.3.1 Corporate Communications

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

1.3.2 Environmental Services

Environmental, Health and Safety ~~will provide~~provides environmental and laboratory support services.

1.3.3 Nuclear Finance

Nuclear Finance provides support for the nuclear sites in the areas of ~~decommissioning, workforce~~financial planning ~~and development~~.

1.3.4 Customer Operations

Customer Operations provides electrical transmission, distribution, and switchyard engineering, as well as providing electrical maintenance and testing support.

1.3.5 ~~Human Resources~~

~~Human Resources provides support for the nuclear sites Access Authorization, FFD, and Fatigue Rule programs.~~

~~1.3.6~~ Information Technology

Information Technology provides a variety of services and technical support to Nuclear Generation for information technology applications and systems such as equipment databases, applications, infrastructure, and plant process information systems. They are also responsible for the development and maintenance of selected information technology services and support, including electronic document management, some of which support QA related activities.

1.3.~~7~~6 Supply Chain

Nuclear Supply Chain provides procurement services~~,~~ to Duke energy Nuclear. Nuclear Supply Chain also provides storage, inventory control, and receipt inspection/testing for Nuclear Generation.

1.4 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.

1.5 Authority to Stop Work

Quality assurance and inspection personnel have the authority, and the responsibility, to stop work in progress which is not being done in accordance with the Quality Assurance Program requirements, approved procedures or where safety, nuclear safety or System, Structure and Component (SSC) integrity may be jeopardized. This extends to off-site work performed by suppliers furnishing safety-related materials and services to Duke Energy Corporation.

7.2 NQA-1-1994 Commitment~~/~~/Exceptions

In establishing procurement verification controls, Duke Energy Corporation commits to compliance with NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 7S-1

  - Duke Energy Corporation considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to Duke Energy Corporation plants are not required to be evaluated or audited.

  - ~~When purchasing~~ For the procurement of commercial grade calibration and/or testing services ~~from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:~~

    ~~(1) The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the~~ , Duke Energy Corporation ~~QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.~~

    ~~(2) The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.~~

    ~~(3) A documented review of the supplier's accreditation will be performed and will include a verification of each of the following:~~

  - ~~The calibration laboratory holds a domestic (United States) accreditation by any one of the following accrediting bodies, which are recognized by the~~ uses NEI 14-05A, Revision 0, "Guidelines For The Use Of Accreditation In Lieu Of Commercial Grade Surveys For Procurement Of Laboratory Calibration And Test Services." The use of this process was approved for licensees in NRC Safety Evaluation (ADAMS Accession Number ML16089A167) dated April 1, 2016 to Union Electric Company, Callaway Plant. As identified in NEI 14-05A, commercial grade calibration or testing services may be procured from commercial laboratories based on the laboratory's accreditation to ISO/IEC-17025 by an Accreditation Body (AB) which is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA~~):~~) without performing commercial grade surveys provided all of the following are met:

- ~~National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology;~~
- ~~American Association for Laboratory Accreditation (A2LA);~~
- ~~ACLASS Accreditation Services (ACLASS);~~
- ~~International Accreditation Services (IAS);~~
- ~~Laboratory Accreditation Bureau (L-A-B);~~

- ~~Other NRC approved~~A documented review of the supplier's accreditation is performed and includes a verification of the following:
  - ~~-~~The calibration or test laboratory holds accreditation by an accrediting body~~.~~
    - recognized by the ILAC MRA. The accreditation encompasses ~~ANS/~~ISO/IEC-17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories~~.~~."
    - For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the ~~necessary~~needed measurement parameters, ranges, and uncertainties.
    - For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
- The purchase documents require that:
  - The service must be provided in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation.
  - As found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance. (for calibration services only)
  - The equipment/standards used to perform the calibration must be identified in the certificate of calibration. (for calibration services only)
  - The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of

accreditation.

- Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

- It is validated, at receipt inspection, that the laboratory's documentation certifies that

  - The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 program, and has been performed within their scope of accreditation, and

  - The purchase order's requirements are met.

For Section 8.1, Duke Energy Corporation considers documents that may be stored in approved electronic media under Duke Energy Corporation or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to Duke Energy Corporation to support operations. The Duke Energy Corporation records management system will provide for timely retrieval of necessary records.

- In lieu of the requirements of Section 10, Commercial Grade Items, controls for commercial grade items and services are established in Duke Energy Corporation documents using 10 CFR 21 and the guidance of EPRI NP-5652 as discussed in Generic Letter 89-02 and Generic Letter 91-05.

  - For commercial grade items, special quality verification requirements are established and described in Duke Energy Corporation documents to provide the necessary assurance an item will perform satisfactorily in service. The Duke Energy Corporation documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

  - Duke Energy Corporation will also use other appropriate approved regulatory means and controls to support Duke Energy Corporation commercial grade dedication activities Duke Energy Corporation will assume 10 CFR 21 reporting responsibility for all items that Duke Energy

SECTION 17 QUALITY ASSURANCE RECORDS

Duke Energy Corporation has the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for Duke Energy Corporation and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

17.1 Record Retention

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, startup, operations, maintenance, modification, decommissioning, and audits and their retention times are defined in appropriate procedures. The records and retention times are based on Regulatory Position C.2 and Table 1, of Regulatory Guide 1.28, Revision 3 for design, construction, and initial startup. Retention times for operations phase records are based on construction records that are similar in nature. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2 Electronic Records

~~When using optical disks for electronic records storage and retrieval systems, Duke Energy Corporation complies with NRC guidance Generic Letter 88-18, "Plant Record Storage on Optical Disks." Duke Energy Corporation will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG 11-1998, TG15-1998, TG16-1998, and TG21-1998.~~

The Duke Energy program for storage of records on microfilm, dual storage or in electronic format meets the preservation requirement for the retention of QA Records.

As identified in NRC Safety Evaluation dated May 26, 2015 to Duke Energy Carolinas (ADAMS Accession No. ML15138A347), for management of electronic records, the appropriate controls on quality are summarized as follows:

a) The Electronic Records Management (eRM) system does not allow deletion or modification of records. (NOTE: Authorized deletion of records per the Record Retention Rules is controlled.)

b) The eRM system provides redundancy (i.e., system backup, dual storage, etc.).

c) The legibility of each record is verified prior to acceptance into the eRM system.

d) The media used by the eRM system is maintained to ensure the records are acceptably copied onto a new media before the manufacturer's certified useful life of the media is exceeded. This includes verification of the records so copied.

e) Periodic random inspections of records are performed to verify that there has been no degradation of record quality.

f) If the eRM system in use is to be replaced by new system, the records stored on the old system are acceptably converted into the new system before the old system is taken out of service. This includes verification of the records so copied.

To implement those controls, Duke Energy Corporation uses the following Nuclear Information and Records Management Association (NIRMA) standards:

- NIRMA TG 11-2011 "Authentication of Records and Media"
- NIRMA TG 15-2011, "Management of Electronic Records,"
- NIRMA TG 16-2011, "Software Quality Assurance Documentation and Records"
- NIRMA TG 21-2011, "Required Records Protection, Disaster Recovery and Business Continuation"

There is no requirement to convert records stored on media including hardcopy, microfilm, compact disk recordable (CD-R), and magnetic media including videotape, computer tape, and optical disks to on-line electronic records. Those records may be maintained in their current form as long as retrieval technology and media life support the continued use of the media. If records stored on one media are to be converted to a new media, the records stored on the old system's media are acceptably converted into the new system before the old system is taken out of service. This includes verification of the records so copied are complete and accurate in the new system.