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10 CFR 50.54(a)(3)
10 CFR 50.71(e)

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

BRUNSWICK STEAM ELECTRIC PLANT, UNIT NOS. 1 AND 2
DOCKET NOS. 50-325 AND 50-324 / RENEWED LICENSE NOS. DPR-71 AND DPR-62

BRUNSWICK INDEPENDENT SPENT FUEL STORAGE INSTALLATION
DOCKET NO. 72-6

CATAWBA NUCLEAR STATION, UNITS 1 AND 2
DOCKET NOS. 50-413 AND 50-414 / RENEWED LICENSE NOS. NPF-35 AND NPF-52

CATAWBA NUCLEAR STATION INDEPENDENT SPENT FUEL STORAGE INSTALLATION
DOCKET NO. 72-45

MCGUIRE NUCLEAR STATION, UNITS 1 AND 2
DOCKET NOS. 50-369 AND 50-370 / RENEWED LICENSE NOS. NPF-9 AND NPF-17

MCGUIRE NUCLEAR STATION INDEPENDENT SPENT FUEL STORAGE INSTALLATION
DOCKET NO. 72-38

OCONEE NUCLEAR STATION, UNITS 1, 2 AND 3
DOCKET NOS. 50-269, 50-270, 50-287
LICENSE NOS. DPR-38, DPR-47 AND DPR-55

OCONEE NUCLEAR STATION INDEPENDENT SPENT FUEL STORAGE INSTALLATION
DOCKET NO. 72-04

OCONEE NUCLEAR STATION INDEPENDENT SPENT FUEL STORAGE INSTALLATION
DOCKET NO. 72-40

SHEARON HARRIS NUCLEAR POWER PLANT, UNIT NO. 1
DOCKET NO. 50-400 / RENEWED LICENSE NO. NPF-63

H. B. ROBINSON STEAM ELECTRIC PLANT, UNIT NO. 2
DOCKET NO. 50-261 / RENEWED LICENSE NO. DPR-23

**H.B. ROBINSON INDEPENDENT SPENT FUEL STORAGE INSTALLATION
DOCKET NO.72-3 / LICENSE NO. SNM-2502**

**H.B. ROBINSON INDEPENDENT SPENT FUEL STORAGE INSTALLATION
DOCKET NO.72-60**

Duke Energy, Inc. Quality Assurance Program for Radioactive Packages Shipping under 10 CFR 71, Docket No. 71-266

Duke Energy, Inc. Quality Assurance Program for Radioactive Packages Shipping under 10 CFR 71, Docket No. 71-345

Subject: TRANSMITTAL of the DUKE ENERGY CORPORATION TOPICAL REPORT (DUKE QAPD-001- A), AMENDMENT 43

In accordance with 10 CFR 50.54(a)(3), Duke Energy is submitting Amendment 43 to the Quality Assurance Topical Report (QATR). This letter satisfies the 10 CFR 50.54(a)(3) requirement to provide the NRC with an update of changes to the Quality Assurance Program Description (QAPD) that did not reduce commitments in the program description and, therefore, do not require NRC approval prior to implementation.

The changes have been reviewed in accordance with 10 CFR 50.54(a)(3) and are not considered to be reductions of commitment as they involve administrative improvements and clarifications.

Attachment 1 provides a Summary Description of Changes. Attachment 2 provides a copy of Duke Energy Topical Report Quality Assurance Program Description, Amendment 43.

This document contains no regulatory commitments. Please refer any questions regarding this submittal to Mr. Art Zaremba at 980-373-2062.

Sincerely,

M. Christopher Nolan
Director Nuclear Regulatory Affairs

Attachments:

1. Summary Description of Changes
2. Copy of Duke Energy Topical Report Quality Assurance Program Description

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SUMMARY DESCRIPTION of CHANGES

Summary Description of Changes for Amendment 43 to the Quality Assurance Program Description, Operating Fleet (Duke-QAPD-001 -A-)

In accordance with 10 CFR 50.54(a)(3), Duke Energy is providing a summary of the changes to the Quality Assurance Program Description (QAPD) being submitted with this letter.

The following changes were made to the QAPD:

1. Revised Brunswick exception 10 for Regulatory Guide 1.33 in Attachment A Table A17-1 to establish a consistent fleet approach for exception to the ANSI N18.7 requirement for procedure biannual reviews. Content is added to Section 17.3.2.14 (final two paragraphs) and removed from Section D17.3.2.14 describing the administrative controls referenced in the NRC letter dated January 31, 1995 approving this exception. Conforming changes were made to Tables A17-1, C17-1, and D17-1 to state the exception consistently.
2. Revised Tables A17-1, B17-1, C17-1, and D17-1 to standardize the exception for Regulatory Guide 1.58 and ANSI N45.2.6 to allow task qualification for inspectors rather than requiring receipt inspectors to be qualified by levels.
3. Added reference to Regulatory Guide 1.164 and EPRI 3002002982 for Dedication of Commercial Grade Items to Table 17-1 (RG 1.123 and Generic Letter 89-02) and Section 17.3.2.4.1.
4. Revised the 3rd paragraph of Section 17.3.2.13 to provide clarity of requirements. This change split the paragraph to separate the first sentence from the remainder of the paragraph that was transferred to this section in Amendment 43.
5. Clarified the On-Site Review Committee review requirements in Section 17.3.3.2.1.3 by relocating a paragraph from 17.3.3.2.1.4.
6. Clarification in Section 17.3.3.3 to reduce repetition in the section.
7. Clarification in Attachment A Section A17.3 under QA Standards and Guides to remove content that needlessly duplicated Standard content. Similar clarifications are made in Attachments B, C, and D.

The identified changes meet the criteria in 10 CFR 50.54(a)(3) and do not reduce the commitments in the QAPD. Changes 1 and 2 apply exceptions previously approved for one or more of the Duke Energy sites to all six operating sites for standardization and efficiency of operations under provision of 50.54(a)(3)ii. Change 3 allows the use of a new QA standard approved by the NRC under the provision of 50.54(a)(3)i. Changes 4, 5, 6, and 7 are administrative improvements and clarifications that do not alter the implementation of the QAPD.

Copy of Duke Energy Topical Report Quality Assurance Program Description

DUKE ENERGY CORPORATION

TOPICAL REPORT

Quality Assurance Program Description

Operating Fleet

DUKE-QAPD-001 -A-

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 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 systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QA Program 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.

Figure 17-1, Duke Energy Corporation Quality Assurance Policy Statement

Summary of Changes

Changes since last NRC update at Amendment 42

DRR #	Description of Change
02125077	Revised the 3rd paragraph of Section 17.3.2.13 to provide clarity of requirements. This change split the paragraph to separate the first sentence from the remainder of the paragraph that was transferred to this section in Amendment 42. The following administrative improvements and clarifications identified during the preparation of Amendment 43 are included in this evaluation for this DRR: Addition of Regulatory Guide 1.164 and EPRI 3002002982 for Dedication of Commercial Grade Items in Table 17-1 (RG 1.123 and Generic Letter 89-02) and Section 17.3.2.4.1. Clarifications in Section 17.3.3.3 to reduce repetition in the section. Clarifications in Attachment A Section A17.3 under QA Standards and Guides to remove content that needlessly duplicates Standard content. Similar clarifications are made in Attachments B, C, and D.
02139232	Revised Brunswick exception 10 for Regulatory Guide 1.33 in Attachment A Table A17-1 to establish a consistent fleet approach for exception to the ANSI N18.7 requirement for procedure biannual reviews. Content is added to Section 17.3.2.14 (final two paragraphs) and removed from Section D17.3.2.14 describing the administrative controls referenced in the NRC letter dated January 31, 1995 approving this exception. Conforming changes were made to Tables A17-1, C17-1, and D17-1 to state the exception consistently.
02147631	Revised Section 17.3.3.2.1.3 to clarify the On-Site Review Committee review requirements. Relocated paragraph from 17.3.3.2.1.4.
02147698	Revised Tables A17-1, B17-1, C17-1, and D17-1 to standardize the exception for Regulatory Guide 1.58 and ANSI N45.2.6 to allow task qualification for inspectors rather than requiring receipt inspectors to be qualified by levels.

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17 QUALITY ASSURANCE

17.1 QA DURING DESIGN AND CONSTRUCTION

NOTE: Not included, this description of the Quality Assurance Program follows Standard Review Plan Section 17.3 for format and content.

17.2 OPERATIONAL QA

NOTE: Not included, this description of the Quality Assurance Program follows Standard Review Plan Section 17.3 for format and content.

17.3 QUALITY ASSURANCE PROGRAM DESCRIPTION

INTRODUCTION

The Duke Energy Corporation Quality Assurance Program (QAP) Policy Statement in Figure 17-1 describes the corporate policy and assigns responsibility for implementation of the QAP.

Duke Energy Corporation maintains full responsibility for assuring its nuclear power plants are designed, constructed, tested and operated in conformance with good engineering practices, applicable regulatory requirements and specified design bases and in a manner to protect the public health and safety. To this end Duke Energy Corporation has established and implemented a Quality Assurance Program which conforms to the criteria established in Appendix B to Title 10 Code of Federal Regulations (10 CFR), Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" published June 27, 1970 (35 F. R. 10499), amended September 17, 1971 (36 F. R. 18301), amended January 20, 1975 (40 F. R. 3210D), and amended August 28, 2007 (72 F. R. 49505).

This document follows the format and content guidance of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants", Section 17.3, "Quality Assurance Program Description," except that the Duke Energy Corporation QAP is based on ANSI N18.7 and the ANSI N45.2 series standards in lieu of ANSI/ASME NQA-1 and NQA-2. This document is applicable to Duke Energy Corporation operating nuclear power stations as referenced by Chapter 17 of each station's UFSAR for those systems, components, items, and services that have been determined to be nuclear safety related.

This document is organized with a generic description of the organization and overview of the QAP in the main body of the document. Site specific details for the Quality Assurance Program Description along with conformance to the regulatory positions of the NRC QA Regulatory Guides are addressed in separate attachments as follows:

- Attachment A, Brunswick Specific QAPD
- Attachment B, Harris Specific QAPD
- Attachment C, Robinson Specific QAPD
- Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Each Attachment follows the section numbering in the main body of the document. The Brunswick, Harris, and Robinson attachments contain the conformance to the QA related Regulatory Guides, identified in Table 17-1, transferred from Chapter 1 of each respective UFSAR. Each attachment also contains supplemental descriptions transferred from each respective UFSAR Chapter 17, Section 17.3 when detail was included beyond the generic text

in the main body. Attachment D contains the conformance to the QA related Regulatory Guides, identified in Table 17-1, transferred from Amendment 40 of the Duke Energy Carolinas Topical Report Quality Assurance Program. Attachment D also contains supplemental descriptions from the Duke Energy Carolinas Topical Report Quality Assurance Program when detail was included beyond the generic text in the main body.

As discussed herein, the Quality Assurance Program (QAP) includes the description contained in this document and the controlled documents providing implementation of the requirements of this document, including the requirements of industry standards to the degree identified in Table 17-1, Conformance with QA Regulatory Guides and Industry Standards, and Table 17-2, Site Specific Response to Regulatory Guides and Industry Standards. The QAP provides a method of applying graded controls to certain non-safety related systems, components, items, and services (such as fire protection and radioactive waste structures, systems, and components).

Subsequent changes to the Duke Energy Corporation QAP are incorporated in this document as identified in Section 17.3.1.7. The QAP controlled implementing documents are used and updated as necessary to assure the nuclear generating units are managed such that they will be operated and maintained in a safe manner.

DEFINITIONS

The following definitions are applicable to terms used in this report. Refer to ANSI N45.2.10, "Quality Assurance Terms and Definitions" for definition of terms not included below.

Audit – The following modifications are applied to the definition in ANSI N45.2.10:

> Internal Audit - An activity to determine through investigation the adequacy of, and adherence to, established procedures, instructions, specifications, codes, and licensing requirements, and the effectiveness of implementation of the Duke Energy Corporation QAP.
>
> Supplier Audit - A documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that applicable elements of the supplier's QA program has been developed, documented and implemented in accordance with specified requirements.

Basic Component – See 10 CFR Part 21.

Commercial Grade Items - See 10 CFR Part 21.

Deficiency - Any condition considered to be adverse to quality including inadequacies of personnel, procedures, systems, methods, or items.

Engineering Change (Modification) - A planned change in plant design accomplished in accordance with the requirements and limitations of applicable codes, standards, specifications, licenses and predetermined safety restrictions.

Hold Point - That point in the manufacturing, preparation, development, installation and construction, inspection, or testing process that requires witness or review by qualified personnel.

Inspector - Any individual certified to the requirements identified in Table 17-1 for Regulatory Guide 1.58 who performs required inspections, tests or examinations.

Pre-award Survey - A documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that the supplier's QA

program has been developed, documented, and implemented in accordance with specified requirements.

Quality Assurance (QA) - The planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

QA Records - Those records which furnish documentary evidence of the quality of items and of activities affecting quality.

QA Requirements - Those inspection, test, examination, certification and documentation requirements which are imposed to provide objective evidence of the conformance of an item or activity to established design, engineering, standards, and code requirements.

Services - The performance by a supplier of activities such as calibration, design, investigation, inspection, nondestructive examination, software applications, and installation.

EXPLANATION OF "QUALITY ASSURANCE"

Quality Assurance (QA) as used in this document includes:

1) Performance of planned and systematic actions necessary to provide assurance of the safety and integrity of the facility.

   The QAP is founded on the principle that the line organization has the primary responsibility for quality and safety. Self-assessment practices are used to ensure the desired levels of quality and safety are achieved and maintained. Each individual is responsible to ensure the plant is operated in a safe, reliable, and efficient manner.

2) Quality verifications performed by those independent of the performers.

   When required, verification of conformance to established program requirements is accomplished by qualified individuals who do not have responsibility for performing or directly supervising the work. Nuclear Oversight (NOS) evaluates the performance, compliance, and effectiveness of plant programs, processes, and personnel. The activities of NOS are intended to detect deficiencies in the desired levels of performance and quality, communicating these conditions to those responsible for the activities, appropriate management and the Chief Nuclear Officer, and ensuring adequate action is taken to correct these conditions.

QA STANDARDS AND GUIDES

The Duke Energy Corporation QAP conforms to Appendix B of 10 CFR 50. This description of the QA Program is formatted per NUREG-0800 Section 17.3, "Quality Assurance Program Description;" however, the Duke Energy Corporation QAP continues to use the ANSI N45.2 series standards in lieu of ANSI/ASME NQA-1 and NQA-2.

Table 17-1 identifies the QA program Regulatory Guides and other NRC program guidance for which conformance is addressed in this description of the QA Program. Changes to conformance for the Regulatory Guides in Table 17-1 are controlled in accordance with 10 CFR 50.54(a) and are incorporated in this document as identified in Section 17.3.1.7.

Table 17-2 identifies additional Regulatory Guides that relate to QA program implementation but where the subject matter closely relates to UFSAR technical content. Conformance for those Regulatory Guides is site specific and addressed with each site's UFSAR.

Together, Tables 17-1 and 17-2 indicate where conformance is identified for the regulatory guidance documents referenced in NUREG-0800 Section 17.3.

Table 17-1. Conformance with QA Regulatory Guides and Industry Standards

Generic Exception:

Table 17-1 addresses Duke Energy Corporation's Conformance of the Quality Assurance Program to certain NRC Regulatory Guides. In so doing, specific editions of industry standards are identified for compliance with exceptions and alternatives. Those identified standards include references to other industry standards for activities. Those referenced industry standards are considered to be guidance documents for details of how activities may be accomplished. The actual standard to be used in such cases is controlled by each station's current licensing and design bases (e.g. ANSI N18.7-1976 Section 3.4.2 identifies American National Standard for Selection and Training of Nuclear Power Plant Personnel, N18.1-1971. The actual standard used is site specific as identified in Table 17-2 for Regulatory Guide 1.8.).

Regulatory Guide 1.28, Quality Assurance Program Requirements (Design and Construction)
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.28 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.30, Quality Assurance Requirements for the Installation, Inspection and Testing of Instrumentation and Electric Equipment
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.30 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.33, Quality Assurance Program Requirements (Operation)
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.33 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Table 17-1. Conformance with QA Regulatory Guides and Industry Standards (Continued)

Regulatory Guide 1.37, Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.37 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.38, Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage and Handling of Items for Water-Cooled Nuclear Power Plants
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.38 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.39, Housekeeping Requirements for Water-Cooled Nuclear Power Plants
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.39 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.58, Qualification of Nuclear Power Plant Inspection, Examination and Testing Personnel
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.58 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Table 17-1. Conformance with QA Regulatory Guides and Industry Standards (Continued)

Regulatory Guide 1.64, Quality Assurance Requirements for the Design of Nuclear Power Plants

The Duke Energy Corporation QAP conforms to Regulatory Guide 1.64 as identified in:

- Attachment A, Brunswick Specific QAPD
- Attachment B, Harris Specific QAPD
- Attachment C, Robinson Specific QAPD
- Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.74, Quality Assurance Terms and Definitions

The Duke Energy Corporation QAP conforms to Regulatory Guide 1.74 as identified in:

- Attachment A, Brunswick Specific QAPD
- Attachment B, Harris Specific QAPD
- Attachment C, Robinson Specific QAPD
- Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.88, Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance 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.
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"

Table 17-1. Conformance with QA Regulatory Guides and Industry Standards (Continued)

Regulatory Guide 1.88, Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.88 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.94, Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.94 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.116, Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.116 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD

Regulatory Guide 1.123, Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants
Reference table content for Generic Letter (GL) 89-02 applicable to the procurement of Commercial Grade Items and services. 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 conditions for the use of this process, consistent with NRC Safety Evaluation dated April 1, 2016 to Union Electric Company, Callaway Plant (ADAMS Accession # ML16089A167), are identified in Sections 17.3.2.4 and 17.3.2.5.

Table 17-1. Conformance with QA Regulatory Guides and Industry Standards (Continued)

Regulatory Guide 1.123, Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants
Note: Well defined and documented measurement assurance techniques or uncertainty analysis may be used to verify the adequacy of the measurement process. If such techniques are not used, the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance for each characteristic being calibrated. (This is typically referred to as the four-to-one ratio.) The Duke Energy Corporation QAP conforms to Regulatory Guide 1.123 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD
Regulatory Guide 1.144, Auditing of Quality Assurance Programs for Nuclear Power Plants
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.144 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD
Regulatory Guide 1.146, Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants
The Duke Energy Corporation QAP conforms to Regulatory Guide 1.146 as identified in: • Attachment A, Brunswick Specific QAPD • Attachment B, Harris Specific QAPD • Attachment C, Robinson Specific QAPD • Attachment D, Catawba, McGuire, and Oconee Specific QAPD
Regulatory Guide 1.152 Criteria for Programmable Digital Computer System Software in Safety-Related Systems of Nuclear Power Plants
Conformance to Regulatory Guide 1.152 was not addressed during the licensing of the operating Duke Energy Corporation Nuclear plants.

Table 17-1. Conformance with QA Regulatory Guides and Industry Standards (Continued)

Regulatory Guide 7.10, Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material
Duke Energy Corporation does not conform to Regulatory Guide 7.10. This QAPD is used to satisfy applicable Quality Assurance requirements for packaging and transportation of radioactive material.
Generic Letter 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products
Duke Energy complies with the provisions of Generic Letter (GL) 89-02. GL 89-02 was issued in March 1989. This generic letter provides the staff's perspective on good practices in procurement and dedication and the NRC's conditional endorsement of an industry standard (EPRI NP-5652, Revision 0) on the methods of commercial-grade item procurement and dedication. Consistent with that guidance, Duke Energy complies with EPRI NP-5652, *"Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)".* When NRC publishes additional guidance for the dedication of Commercial Grade Items, Duke Energy may utilize that guidance in the completion documentation provided any clarifications identified by the NRC are followed. Regulatory Guide 1.164, Dedication of Commercial-Grade Items for Use in Nuclear Power Plants, Revision 0 issued June 2017 Duke Energy also complies with the provisions of Regulatory Guide 1.164, which endorses in part, with exceptions or clarifications, EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" with respect to acceptance of commercial-grade dedication of items and services to be used as basic components for nuclear power plants. Regulatory Guide 1.231, Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants, Revision 0 issued January 2017 Duke Energy complies with the provisions of Regulatory Guide 1.231 which approves for use, with clarifications, EPRI Technical Report 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications," Revision 1.
Quality assurance for Fire Protection from Positions 2 & 4 of Branch Technical Position CMEB 9.5-1 (Attachment to NUREG 0800 Section 9.5.1 Revision 3)
Quality assurance controls for non-Nuclear Safety Related components Important to Fire Protection are in accordance with the intent of Positions 2 & 4 of Branch Technical Position CMEB 9.5-1. Identification of items Important to Fire Protection is site specific consistent with each site's Fire Protection Program.

Table 17-2. Site Specific Response to Regulatory Guides and Industry Standards

Table 17-2 identifies additional Regulatory Guides addressing subjects related to implementation of the QAP but the implementation is site specific and addressed with each site's UFSAR.

Regulatory Guide 1.8, Personnel Selection and Training
Personnel selection and training is site specific addressing requirements beyond nuclear safety related applications.

Regulatory Guide 1.26, Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants
Quality group classifications and standards trace to the original design and construction of the nuclear power plant and therefore are site specific.

Regulatory Guide 1.29, Seismic Design Classification
Seismic design classification trace to the original design and construction of the nuclear power plant and therefore is site specific.

Regulatory Guide 1.36, Nonmetallic Thermal Insulation for Austenitic Stainless Steel
Nonmetallic thermal insulation for austenitic stainless steel trace to the original design and construction of the nuclear power plant and therefore is site specific.

Regulatory Guide 1.54, Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants
Requirements for protective coatings applied to water-cooled nuclear power plants trace to the original design and construction of the nuclear power plant and therefore is site specific.

Regulatory Guide 1.143, Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants
Design of radioactive waste management systems, structures, and components installed in light-water-cooled nuclear power plants trace to the original design and construction of the nuclear power plant and therefore is site specific.

Regulatory Guide 1.155, Station Blackout
Addressing Station Blackout is site specific.

Table 17-2. Site Specific Response to Regulatory Guides and Industry Standards (Continued)

Regulatory Guide 4.15, Quality Assurance for Radiological Monitoring Programs (Normal Operations) – Effluent Streams and the Environment
Requirements for radiological monitoring program (normal operations) – effluent streams and the environment is site specific.

17.3.1 MANAGEMENT

17.3.1.1 Methodology

The Chief Nuclear Officer (CNO) is the corporate executive responsible for quality assurance (QA) and is the highest level of management responsible for establishing Duke Energy Corporation's QA policies, goals, and objectives.

The QAP Policy Statement, shown in Figure 17-1, requires compliance with the QAP implementing documents in nuclear safety related matters. Organizations performing quality affecting activities are bound by this Policy Statement. The QAP has been developed in accordance with this Policy Statement. The QAP applies to individuals and organizations responsible for operating and supporting the nuclear plants in the performance of activities affecting quality (e.g., operation, maintenance, modification, and refueling). The implementing documents define responsibilities and authorities, prescribe measures for the control and accomplishment of activities for the operation of nuclear safety related structures, systems, and components and requires appropriate verification of conformance to established requirements to an extent consistent with their importance to safety. The individuals who constitute Nuclear Generation have full personal and corporate responsibility to assure that nuclear power plants are designed, constructed, tested and operated in a manner to protect the public health and safety. The comprehensive program to assure this began with initial design and continues throughout the life of the station. The Duke Energy Corporation QAP assures that the necessary quality requirements for nuclear safety related structures, systems, components and materials are achieved. All special equipment, environmental conditions, skills and processes that are determined to be nuclear safety related will be provided within the scope of the QAP.

Nuclear safety related structures, systems, and components (SSCs) are specified by approved design documents. Each nuclear plant has a controlled system for identifying items and activities to which the QAP applies. Controls and responsibilities for maintaining the system are prescribed in procedures.

The QAP applies to the nuclear safety related portions of the plant. The program is applied, in whole or in part, to other selected items based on the item's or activity's importance to safety. This application includes but is not limited to control and accomplishment of activities for radioactive waste, fire protection, seismically designed/restrained SSCs whose continued functions are not required during and after a seismic event, and License Renewal non-safety-related SSCs that are subject to an aging management review. Procedures provide a graded application of this QAP to non-safety related systems, components, items, and services by prescribing measures for the control and accomplishment of activities for their operation. For example, aging effects of non-safety related SSCs that were determined to be within the scope of License Renewal Aging Management Program as identified in Chapter 18 of the applicable site UFSAR, are included in the QAP for the administrative controls, corrective actions and confirmation processes described in Sections 17.3.1.6 and 17.3.2.13, Corrective Action, and 17.3.2.14, Document Control.

The QAP is founded on the principle that the line organization has the primary responsibility for quality and safety. Self-assessment practices are used to ensure the desired levels of quality and safety are achieved and maintained. This consists of each individual being involved with plant performance to ensure the plant is operated in a safe, reliable, and efficient manner. The Nuclear Oversight (NOS) Department evaluates the compliance, and effectiveness of plant programs, processes, personnel, and the line organization's self-assessment.

17.3.1.2 Organization

This section provides a generic functional description of the organization. The actual organization in-place is defined in a controlled implementing document containing the fleet operating model.

Plant specific details for the organization responsible for the safe plant operation are described in Chapter 13 of the UFSAR for each plant and in implementing documents. The term "line organization" refers to the production organization reporting to the CNO and the interfacing department staff supporting the Nuclear Generation as identified in Section 17.3.1.2.3, Department Interfaces. "Line organization" does not include the independent verification functions of the Nuclear Oversight organization.

17.3.1.2.1 Corporate Organization

The Chairman, President and Chief Executive Officer has overall responsibility for Design, Construction, Operation, and Decommissioning of generation facilities. Reporting to the Chairman, President and Chief Executive Officer is the Executive Vice President and Chief Operating Officer, who is responsible for generation and transmission including nuclear operations, nuclear development and nuclear decommissioning. Reporting to the Executive Vice President and Chief Operating Officer are the Senior Vice President and Chief Nuclear Officer (CNO), who has the overall authority and responsibility for Nuclear Generation, and the executive for Operations Support, whose responsibilities include Nuclear Decommissioning. Nuclear Decommissioning is controlled under a separate description of the quality assurance program as identified in the Defueled Safety Analysis Report for that facility.

As described in Section 17.3.1.2.3, Nuclear Generation receives support services from other organizations, reporting to the Chief Operating Officer, having responsibilities for supply chain, environmental, health and safety and non-nuclear generation activities including: fossil and hydro generation; coal combustion product strategic management; and fuels and system optimization. Services also are provided to Nuclear Generation by Group Executives, reporting to the President and Chief Executive Officer, responsible for the following: electrical distribution; support for the emergency response communications; and Information Technology Services. The interfaces with organizations providing those activities are described in Section 17.3.1.2.3. 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.

The policies described in this document are implemented through departmental program manuals and procedures, and are, thereby, available to all levels of management.

17.3.1.2.2 Nuclear Generation

Nuclear Generation has direct line responsibility for Duke Energy Corporation nuclear station operations. 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, where 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 Corporate, Nuclear Oversight, and Nuclear Operations.

The CNO has the organizational flexibility to reassign responsibilities, 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.

a) NUCLEAR CORPORATE

The senior executive(s) reports to the CNO and is responsible for Corporate Governance and providing 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).

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 and engineering related to fleet and nuclear site major project modifications.

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.

Nuclear engineering is also responsible for Nuclear Development, which includes the licensing actions needed in support of new nuclear site development under 10 CFR Part 52. Responsibilities also include engineering oversight of contractors, site layout, staffing and program development, and operational readiness. Nuclear Development activities are controlled under a separate description of the quality assurance program as identified in the UFSAR for those facilities.

NUCLEAR MAJOR PROJECTS

Nuclear major projects provides project management for select projects critical to the success of the Nuclear Generation Department. This responsibility includes scope development,

estimating, planning and scheduling, project controls, timely and accurate financial reporting, contract management, and execution of assigned projects.

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.

NUCLEAR SUPPORT SERVICES

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

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.

NUCLEAR OPERATIONS

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

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.

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.

EMERGENCY PREPAREDNESS

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

b) NUCLEAR OVERSIGHT

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. NOS provides oversight of the NGO, Departmental Interfaces, and the nuclear sites with QA program audits, vendor quality, and quality control. In addition, NOS coordinates the off-site review board, which provides an advisory function to senior management. NOS also provides oversight of Nuclear Development and Nuclear Decommissioning through QA program audits. 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. This includes full access to Nuclear Development and Nuclear Decommissioning and all levels of management up to and including the Chief Executive Officer.

The NOS executive has primary ownership of the department QA program description (this document) and is responsible for interpretation and resolution of QA issues.

If significant quality problems are identified, NOS personnel have the authority to stop work as discussed in Section 17.3.1.4 pending satisfactory resolution of the identified problem.

Also reporting to the executive for NOS is Employee Concerns, which investigates concerns identified through the Employee Concerns Program 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.

c) 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 this executive are the executives for the operation of the 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.

17.3.1.2.3 Department Interfaces

Quality related activities performed by departments other than 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 QAP to the services they provide.

CORPORATE COMMUNICATIONS

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

ENVIRONMENTAL HEALTH AND SAFETY

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

NUCLEAR FINANCE

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

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, and infrastructure including the electronic document management system and telecommunication systems.

CUSTOMER OPERATIONS

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

NUCLEAR SUPPLY CHAIN

Nuclear Supply Chain provides procurement services including receipt inspection/testing, storage, and inventory control of materials, parts, and components.

17.3.1.3 Responsibility

The primary responsibility for quality performance, including the identification and effective correction of problems potentially affecting the safe and reliable operation of the Company's nuclear facilities, resides with the line organization. The individuals who constitute Nuclear Generation have full personal and corporate responsibility to assure nuclear power plants are designed, constructed, maintained, tested and operated in a manner to protect the public health and safety; and to assure the effectiveness of the QAP.

Appropriate procedures are developed, approved by the responsible implementing manager, issued for use, and used at the location where the prescribed activity is performed, where appropriate. Managers assure that their personnel are adequately trained for their jobs and they have the experience and education required to carry out their assigned responsibilities. These managers ensure that adequate resources and procedures are available for correctly implementing the work activities. Sufficient personnel, including necessary resources, are available and trained prior to performing activities that affect quality.

Independent inspections are conducted to verify specific critical quality attributes. Individuals performing these inspections have access to necessary information to ensure that activities and equipment meet established acceptance criteria.

NOS is responsible for monitoring and auditing activities that are performed by the line organization for, or in support of, Duke Energy Corporation's Nuclear Plants and Nuclear Generation. These activities include those performed at the individual plant sites, corporate offices, and other Nuclear Generation locations. NOS performs audits to verify that applicable elements of the quality assurance and other regulatory required programs have been developed, documented and effectively implemented in accordance with specified requirements. NOS monitors supplier performance to assure implementation of the applicable quality assurance program requirements. A periodic briefing of NOS activities, along with any potential findings and recommendations, is presented to the CNO.

The CNO is responsible for ensuring that the results and effectiveness of the nuclear oversight program are regularly evaluated as discussed in Section 17.3.3.3.6, Independent Audit of QA Functions.

17.3.1.4 Authority

Personnel involved in quality activities have the authority and responsibility to stop work if they discover deficiencies in quality.

Personnel performing the QA functions have the authority and responsibility to stop unsatisfactory work and to assure the item/activity is controlled to prevent further processing, delivery, installation, or use until authorized by appropriate management.

Procedures outline the methodology for resolution of disputes involving quality and nuclear safety issues arising from a difference of opinion between identifying personnel and other groups.

17.3.1.5 Personnel Training and Qualification

Both on-site and off-site personnel who perform activities affecting quality (implement requirements of the QAP) are indoctrinated and trained such that they are knowledgeable and capable of performing their assigned tasks.

Training programs and reviews ensure that proficiency of personnel performing activities affecting quality is achieved and maintained by training, examining, and/or certifying, as appropriate.

Training programs are modified to reflect station engineering changes and changes in procedures.

Personnel training and qualification records are to be maintained in accordance with procedures.

Personnel within the Operating organization performing duties of a licensed operator are indoctrinated, trained, and qualified as required by 10 CFR Part 55 Operators' Licenses.

17.3.1.6 Corrective Action

It is the policy of Duke Energy Corporation to seek improvement in each nuclear plant's performance as well as in the performance of supporting Departments. Duke Energy Corporation has established a corrective action process whereby all personnel are expected to assure conditions adverse to quality are promptly identified, controlled, and corrected. Individuals are encouraged to voluntarily report events, near misses, and potential problems. In the case of significant conditions adverse to quality, the process assures that the cause of the condition is determined and action be taken to preclude repetition. This process also provides for trending of problems to detect adverse trends in quality performance, including reporting of results to appropriate levels of management.

Management will emphasize to all levels in the organization the importance of identifying and effectively correcting situations that can adversely affect human and equipment performance. An important aspect of this program is the assignment of qualified personnel to accurately evaluate equipment/human performance problems, implement appropriate corrective actions, and verify corrective action adequacy.

Management is responsible for fostering a positive environment that encourages the self-identification of adverse conditions and trends. This includes assuring the process is administered to correct the problem rather than to establish blame or fault.

License Renewal non-safety-related SSCs that are subject to an aging management review are included in the scope of the corrective action program.

Section 17.3.2.13, Corrective Action provides additional detail.

17.3.1.7 Regulatory Commitments

The operation of nuclear plants is accomplished in accordance with the U.S. Nuclear Regulatory Commission (NRC) regulations specified in Title 10 of the U.S. Code of Federal Regulations.

The operation of the Company's nuclear power plants is in accordance with the terms and conditions of the facility operating license issued by the NRC.

The QAP provides for compliance with QA regulatory guides and the related codes and standards as identified in Table 17-1, Conformance with QA Regulatory Guides and Industry Standards.

The requirements of this section (17.3) may provide additional details for implementation of exceptions to these Regulatory Guides and codes and standards.

Changes to the description of the QAP contained in this document are controlled in accordance with 10 CFR 50.54(a).

Table 17-2, Site Specific Response to Regulatory Guides and Industry Standards, identifies additional Regulatory Guides that relate to implementation of the QAP but the implementation is site specific and controlled with each site's UFSAR in accordance with 10 CFR 50.59.

17.3.2 PERFORMANCE/VERIFICATION

17.3.2.1 Methodology

Personnel performing work activities are responsible for achieving the acceptable level of quality.

Personnel performing verification activities are responsible for verifying the achievement of acceptable quality.

Work is accomplished and verified using instructions, procedures, or appropriate means that are of a detail commensurate with the activity's complexity and importance to safety. The implementing manager is responsible to ensure instructions and procedures provide adequate detail for achieving an acceptable level of quality.

Criteria that define acceptable quality are specified in procedures and/or other documents, and verification, when required is performed against these criteria.

17.3.2.2 Design Control

In order to provide for the continued safe and reliable operation of a nuclear station's nuclear safety related structures, systems and components, design control measures commensurate with those applied to the original design are implemented during the operational phase to assure that the quality of such structures, systems and components is not compromised by engineering changes.

Nuclear Engineering is responsible for design activities during the operational phase of nuclear stations to Nuclear Generation. Nuclear Engineering will assure that the organization performing design has access to pertinent background information, including an adequate understanding of the requirements and intent of the original design, and that the organization has demonstrated competence in applicable design areas.

Procedures and instructions for design control during the operational phases for nuclear safety related items provide controls to assure the design is performed in accordance with approved criteria, and that deviations and nonconformances are controlled.

Procedures identify the responsibilities of the various individuals/organizations involved in nuclear safety related engineering changes. The assignment of responsibility for the evaluation and design of a particular engineering change to a specific individual/organization is documented. Procedures addressing the control, including the review, approval, release, and distribution of engineering changes, address the communication of information between internal and external individuals/organizations and, where appropriate, require documentation of such communications.

The procedures include measures to assure that the design selected to accomplish a necessary or desirable change does not create "new" problems in off-normal modes of operation or in adjacent inter-tied systems. For each proposed nuclear safety related engineering change, the individual/organization assigned responsibility for evaluation and design of the engineering change considers the following in the design of the engineering change:

a. Necessary design analyses, e.g., physics, stress, thermal, hydraulic, accident, etc.
b. Compatibility of materials.
c. Accessibility for operation, testing, maintenance, inservice inspection, etc.

d. Necessary installation and periodic inspections and tests, and acceptance criteria therefore.
e. The suitability of application of materials, parts, components, and processes that are essential to the function of the structure(s), system(s) and/or component(s) to be modified.
f. Materials, parts, and equipment which are commercial grade items or which have been previously approved for a different application are evaluated for suitability prior to selection.

Engineering changes are then executed in accordance with approved checklists, instructions, procedures, drawings, etc., appropriate to the nature of the work to be performed. These checklists, instructions, procedures, drawings, etc., include criteria for determining the acceptability of the engineering change.

Any errors or deficiencies found in the design process or the nuclear safety related design itself are documented and corrected using the corrective action program.

Prior to a structure, system, or component that has been modified by engineering change being declared operable and returned to service, the procedures governing the operation are reviewed and revised as necessary. If the engineering change significantly alters the function, operating procedure, or operating equipment, then additional training is administered as necessary.

Adequate identification and retrievable documentation of station engineering changes is retained for the life of the station.

Engineering changes are reviewed to determine whether or not the modification is a change in the facility as described in the UFSAR, involves a change to the Technical Specifications, or requires a license amendment in accordance with 10 CFR 50.59(c)(2). Engineering changes which are determined to require a license amendment are reviewed by the On-Site Review Committee and must be authorized by the NRC prior to implementation.

17.3.2.3 Design Verification

Procedures require that the adequacy of nuclear safety related designs and design changes be verified by the performance of design reviews, alternate calculations, or qualification testing. The control measures specified in the plan for control of design verification activities are as follows:

a. Personnel responsible for design verification do not include the original designer or the designer's immediate supervisor unless the immediate supervisor is the only one capable of verifying the design, in which case additional requirements apply as identified below.
b. Procedures identify the positions or organizations responsible for design verification and define their authority and responsibility. Procedures also provide guidelines as to the method of design verification to be used. Unless otherwise specified, design verification is performed by the method of independent design reviews and includes verification that UFSAR commitments have been addressed.
c. Qualification tests to verify the adequacy of the design are performed using the most adverse specified design conditions.
d. Design changes are reviewed to assure that design parameters are defined and that inspection and test criteria are identified.
e. Design verification is completed prior to relying upon the component, system or structure to perform its function or before its installation becomes irreversible.

The use of the originator's immediate supervisor for verification is:

1) restricted and justified to special situations where the immediate supervisor is the only individual capable of performing the verification
2) the need is individually documented and approved in advance by the supervisor's management and
3) the frequency and effectiveness of the supervisor's use as design verifier are independently verified to guard against abuse.

The individuals assigned to perform the design verification of a nuclear safety related document have full authority to withhold approval of the document until every question concerning the work has been resolved. If required, the matter can be carried up to the CNO for resolution.

17.3.2.4 Procurement Control

Duke Energy Corporation maintains a program for supplier evaluation, results of supplier evaluation, surveillance of suppliers, supplier furnished records, certificates of conformance, effectiveness of supplier quality control, and the purchase of spare or replacement parts. The Duke Energy Corporation QAP requires the control of nuclear safety related items or services purchased from a supplier, subsupplier, or consultant through appropriate processes and specific procurement documents.

Procedures identify the responsibilities and requirements for the control of procurement documents and ensure that purchased material and services are of acceptable quality. Procurement of QA items is to the quality program requirements in effect at the time of purchase.

Nuclear safety related material, equipment and services procured as basic components may only be procured from qualified suppliers. Supplier qualification is accomplished by NOS evaluation of the supplier QA program. An audit or pre-award survey is performed by NOS when required. The audit or pre-award survey is carried out in accordance with a comprehensive audit checklist to determine the ability of the supplier QA program and manual(s) to meet applicable criteria of 10 CFR 50, Appendix B; 10 CFR 21; the ASME Code, when required, and any other codes and standards determined to be appropriate for the prospective scope of supply.

The above requirements apply to procurement of services and items as basic components, including obtaining a Commercial Grade Item dedicated as basic component from an approved third party dedicator. The remainder of this section addresses alternate requirements for purchase of Commercial Grade Items or services.

17.3.2.4.1 Commercial Grade Dedication

When nuclear safety related items/services are not supplied as a basic component and meet the definition of Commercial Grade Item, the item may be procured without the performance of a supplier qualification audit or the existence of a documented supplier QA program. These Commercial Grade Items used in nuclear safety related applications require evaluation, dedication and approval by Nuclear Generation personnel. Commercial Grade Dedication is performed using NRC endorsed industry standards EPRI NP-5652, EPRI Technical Report 102260, EPRI 3002002982, and EPRI Technical Report 1025243 consistent with the NRC exceptions or clarifications identified in GL 89-02, RG 1.123, RG 1.164, and RG 1.231 providing the endorsements. Supplier selection for Commercial Grade Items is the responsibility of the responsible engineering personnel or designated supply chain personnel as identified in

procedures. These items are subject to the same verification and checking process for suitability of application as other nuclear safety related items.

17.3.2.4.2 Commercial Grade Dedication of Laboratory and Testing Services

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 as part of commercial grade dedication provided all of the following are met:

1. A documented review of the supplier's accreditation is performed and includes a verification of the following:
    a. 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."
    b. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
    c. 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.
2. The purchase documents require that:
    a. The service must be provided in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation.
    b. 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)
    c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration. (for calibration services only)
    d. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
    e. Additional technical and quality requirements, as necessary, are specified for verification at receipt 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.
3. It is validated, at receipt inspection as part of the commercial grade dedication process, that the laboratory's documentation certifies that:
    a. 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
    b. The purchase order's requirements are met.

17.3.2.5 Procurement Verification

Duke Energy Corporation procurement documents are prepared, reviewed, approved, and controlled in accordance with procedures to assure that requirements are correctly stated, inspectable, verifiable, and controllable, and there are adequate acceptance/rejection criteria. Procurement documents are reviewed by personnel knowledgeable in applicable technical and quality requirements, and documentary evidence of that review and approval is retained and available for verification.

As required by procurement criteria, in order to assure that material and equipment are fabricated in accordance with applicable requirements, supplier reviews are performed by Vendor Quality. Those reviews may include witnessing of tests, observation of fabrication checkpoints, and documentation review.

Receipt inspections are performed by qualified inspectors in accordance with procedures to assure that:

1. Materials, equipment, or components are properly identified and correspond with associated documentation.
2. Inspection records or certificates of conformance attesting to the acceptance of materials, equipment, and components are completed and are available prior to installation or use.
3. Materials, equipment, and components are inspected and judged acceptable in accordance with predetermined inspection instructions prior to installation or use.
4. Items not meeting applicable requirements are identified and controlled until proper disposition is made.

The process ensures that required documentation of compliance is received and available on site and procurement, inspection, and testing requirements are satisfied before the item is placed in service.

As identified in Section 17.3.2.4.2, specific to the commercial grade dedication of Calibration Testing and Laboratory Services, receipt inspection verifies that:

- The laboratory's documentation certifies that:
    - contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 program,
    - has been performed within their scope of accreditation, and
    - the purchase order's requirements are met.
- Additional technical and quality requirements are met.

17.3.2.6 Identification and Control of Items

Procedures require spare or replacement parts to be subject to QAP controls, codes and standards, and technical requirements which ensure they are suitable for their intended service. Items accepted or released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work. Bulk items will not require individual accept tags; however, status of unacceptable bulk items will be so indicated.

Identification requirements for materials, parts and components important to nuclear safety are stated in specifications, drawings and purchase documents.

Control of material, parts and components is governed by approved procedures.

Following QA receipt inspection, materials, parts and components which are determined to be acceptable are assigned an identifying designation such as a unique tracking number in order to provide traceability of each item. This traceability is maintained for nuclear safety related items. In the event that the identification of an item becomes lost or illegible, the item is considered nonconforming and not utilized until proper resolution of the nonconformance.

Consumables utilized in nuclear safety related structures, systems and components are subject to appropriate controls as described in procedures.

17.3.2.7 Handling, Storage, and Shipping

Procedures utilized by suitably trained individuals define requirements for the control of the handling, storage, and shipping of safety-related items. These procedures require measures to be taken to ensure special handling, storage, cleaning, packaging, shipping, and preservation requirements are established to control these activities in accordance with design and specification requirements to preclude damage, loss or deterioration by environmental conditions such as temperature or humidity. Nuclear safety related materials, parts and components are handled, stored, issued and shipped in such a manner that the serviceability and QA traceability of an item is not impaired.

Nonconforming items are identified, segregated, or otherwise controlled in such a manner as to preclude their inadvertent substitution for and use as conforming materials parts and components.

17.3.2.8 Test Control

The QAP addresses both preoperational and periodic (surveillance) testing. The program requires that such testing associated with nuclear safety related structures, systems and components demonstrate that the items will perform satisfactorily in service. Testing activities are accomplished in accordance with approved, written procedures. Testing schedules are provided and maintained in order to assure that all necessary testing is performed and properly evaluated on a timely basis. Test controls include requirements on the review and approval of test procedures, and on the review and approval of changes to such procedures, as discussed in Section 17.3.2.14, Document Control.

Modifications, repairs, and replacements are accomplished in accordance with the original design and testing requirements or acceptable alternatives.

17.3.2.9 Measuring and Test Equipment Control

The organizations performing nuclear safety related work activities have the responsibility to assure the required accuracy of tools, gauges, instruments, radiation measuring equipment, non-destructive testing equipment and other measuring and test devices affecting the proper functioning of nuclear safety related structures, systems and components and that a program of control and calibration for such devices is provided.

Procedures define requirements for the control of measuring and test equipment (M&TE) used. These procedures include requirements to establish procedures for the calibration technique and frequency, maintenance, and control of measuring and test equipment. The requirements include the following:

a. M&TE is assigned permanent, identifying designations. M&TE is identified and traceable to the calibration test data.
b. M&TE is calibrated at prescribed intervals against certified equipment having known, valid relationships to nationally recognized standards or where national standards do not exist, provisions are established to document the basis for the calibration. The calibration interval is based on the applicable manufacturer's recommendations. If experience shows that the manufacturer's recommendations are not appropriate, the calibration interval is changed as necessary. One or more of the following may be used to adjust intervals: 1. Technical Specifications; 2. Required accuracy; 3. Intended use; 4. Frequency of usage; 5. Stability characteristics; 6. Other conditions affecting

measurement. In lieu of specified intervals, infrequently used M&TE may be calibrated immediately before and after use.

c. Status of calibration for M&TE is provided through the use of tags, stickers, labels, routing cards, computer programs, or other suitable means. The status indicators indicate the date recalibration is due or the frequency of recalibration.
d. M&TE failing to meet calibration specifications is identified through the use of tags, stickers, labels, routing cards, computer programs, or other suitable means, showing the date of rejection, the reason for rejection and the identification of the individual rejecting the device. "Accepted" and "Rejected" calibration identification is sufficiently different to preclude confusion between them.
e. Items and processes determined to be acceptable based on measurements made with M&TE that subsequently cannot be demonstrated to meet calibration specifications are re-evaluated to determine the validity of previous inspections and test results and the results of the evaluation documented.
f. M&TE is stored under conditions which are in accordance with, or more conservative than, the applicable manufacturer's recommendations.
g. M&TE is issued under the control of responsible personnel so as to preclude unauthorized use.
h. M&TE is shipped in a manner that is in accordance with, or more conservative than, the applicable manufacturer's recommendations.
i. Records are maintained for each item of M&TE identifying the device designation, the calibration frequency and specifications. Records are maintained reflecting current calibration status, the date of calibration, the date the next calibration is due, and the identification of the individual who was responsible for performing the calibration.
j. As a rule, the calibration program achieves a minimum ratio of 4-to-1 calibration standard accuracy to measuring and test equipment accuracy is used. However, well defined and documented measurement assurance techniques or uncertainty analysis may be used to verify the adequacy of the measurement process. See site specific requirements for other exceptions to the 4:1 rule.

M&TE is selected to assure accurate measurement (i.e., to overcome inherent inaccuracies associated with environment, human error, equipment, etc.).

17.3.2.10 Inspection, Test, and Operating Status

Procedures define requirements for the identification and control of the inspection, test, and operating status of safety-related structures, systems, and components, to assure that equipment operating status is clearly evident, and to prevent inadvertent operation of nuclear safety related structures, systems and components which, if operated, could cause damage to other equipment/systems or to personnel

These measures include the use of checklists, computer programs, logs, stickers, tags, labels, record cards, and test records to indicate the acceptable operating status of installed equipment. Where appropriate, an independent verification of the correct implementation of such identification measures is performed.

When tags, labels or stamps are utilized for the identification of equipment status, the issuance and removal thereof is documented in order to assure proper control of such identification measures. Also, procedures require that the operability of an item removed from operation for maintenance or testing be verified prior to returning the item to normal service.

Selected plant procedures and subsequent revisions receive separate technical review to ensure required inspections, tests, and other critical operations are included.

17.3.2.11 Special Process Control

Procedures define requirements for the control of special processes, such as welding, heat treating, nondestructive examination (NDE), coatings, and chemical cleaning when the performance of such processes affects the proper functioning of nuclear safety related structures, systems, and components.

Procedures require that special processes be performed by qualified personnel using proper equipment and in accordance with written qualified procedures. These personnel and procedures are to be qualified in accordance with applicable codes, standards, and specifications as described in procedures.

Qualification records of special process procedures and personnel performing special processes are maintained and available for verification.

17.3.2.12 Inspection

Procedures define requirements for an inspection program to verify conformance to performance and quality requirements specified for nuclear safety related structures, systems, and components.

Inspections are performed by personnel who are not directly responsible for performing or supervising the activity being inspected. Inspection personnel are qualified in accordance with applicable codes and standards, and their qualifications and certifications are maintained current.

Inspections are performed in accordance with procedures or other documents, which provide for the following:

1. Identification of individuals or groups responsible for performing the inspections
2. Identification of characteristics and activities to be inspected
3. Acceptance criteria
4. Inspection techniques
5. Recording the results of the inspection, review of the results, and identification of the inspector
6. Indirect control by monitoring of processing methods, equipment, and personnel when direct inspection is not possible

Mandatory inspection hold points are included in the documents addressing the activities being performed, as necessary and work does not proceed until satisfactory completion of the required inspection.

When acceptance criteria are not met, the condition will be documented in accordance with the corrective action program procedures and work does not proceed until satisfactory disposition of any item not meeting the acceptance criteria and satisfactory completion of any required re-inspection.

Modification, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

17.3.2.13 Corrective Action

Station personnel are responsible for the implementation of the QAP as it pertains to the performance of their activities. Specific to this responsibility is the requirement for informing the

responsible supervisory personnel and/or for taking appropriate corrective action whenever any deficiency in the implementation of the requirements of the program is determined.

Procedures define requirements for a corrective action program that charges personnel working at or supporting the nuclear plants with the responsibility to identify adverse conditions (including conditions adverse to quality). Conditions adverse to quality are identified through inspections, assessments, tests, checks, and review of documents. Procedures require that conditions adverse to quality be corrected. In the case of significant conditions adverse to quality, the procedures assure that the cause of the condition is determined and action be taken to preclude repetition.

Significant conditions adverse to quality are reported to appropriate management for review and evaluation.

Violations of Technical Specifications, safety limit violations, and other reportable events are investigated to correct the condition and to support the reporting requirements of 10 CFR 50.73(b). Reports of such investigations are reviewed by a knowledgeable individual other than the individual who prepared the report.

Periodic reviews and evaluations of adverse conditions are performed to identify and correct adverse trends.

17.3.2.14 Document Control

Procedures define requirements for the development, review, approval, issue, use, revision, and control of documents. These procedures define the scope of which documents are to be controlled. These activities include measures to control the issuance of documents such as, instructions, procedures, and drawings, and changes thereto, which prescribe activities affecting quality.

A document control system has been established to identify the current revision number of instructions, procedures, specifications, and drawings. This system includes provisions to ensure that superseded documents are controlled to prevent inadvertent use.

Controlled documents are to be distributed to and used by the person performing the activity in accordance with procedures. These controlled documents are distributed electronically. Hardcopy distribution, if required, is by distribution indices.

Procedures require the identification of those individuals or organizations responsible for reviewing, approving, and issuing documents and revisions thereto. The required reviews include reviews verifying that changes to the procedures, tests or experiments do not involve a change in the Technical Specifications or otherwise require prior NRC approval.

In addition to procedures and engineering documents (e.g. specifications and drawings), the following are considered to be controlled documents:

- The station Facility Operating License and Technical Specifications
- Updated Final Safety Analysis Reports
- Process Control Program
- Offsite Dose Calculation Manual
- Radiological Effluent Controls of the UFSAR, and radwaste treatment systems

Procedures established for operational phase activities include:

1. Operating Procedures
2. Alarm Responses

3. Radiation Protection Procedures
4. Maintenance Procedures
5. Instrument Procedures
6. Chemistry Procedures
7. Process Control Program Implementing Procedures
8. Periodic Test Procedures
9. Abnormal Procedures
10. Emergency Procedures
11. Emergency Response Procedures
12. License Renewal Aging Management Program

In lieu of the two year procedure review prescribed by ANSI N18.7-1976 Section 5.2.15, Duke Energy Corporation has programmatic controls in place to continually identify procedure revisions which may be needed to ensure that procedures are appropriate for the circumstance and are maintained current. These controls include the following:

- The procedure revision process includes a mechanism for procedure users to request changes to the procedures.
- The modification process requires that procedures be reviewed to determine the effects of a planned plant modification.
- Procedures are reviewed for adequacy based upon lessons learned from the operating experience program, training programs, emergency plan reviews, drills and exercises, and normal use.
- The work control process includes pre job review process and a procedure adherence policy requiring that, if procedures cannot be implemented as written, the job be stopped and the procedure be revised or the situation resolved prior to work continuing.

The line organization performs a biennial self-assessment of the procedure process to assure their procedures are maintained current. This assessment includes a requirement to evaluate potential adverse trends in the procedure change process to ensure that changes required to maintain procedures current and technically accurate are being implemented in a timely manner.

17.3.2.15 Records

Each nuclear station is required to maintain adequate identifiable and retrievable QA records. The QAP requires that sufficient records be maintained to provide documentary evidence of the quality of items and the accomplishment of activities affecting quality.

Procedures define requirements for the identification, collection, and storage of quality assurance records.

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

Media used for retention of records include (but are not limited to): microfilm, compact disk recordable (CD-R), and magnetic media including videotape, computer tape, optical disks, and hard disk storage. Electronic records retention is an integral component of the Record Retention Program, approved by the management position responsible for Nuclear Generation Department records. The format used must be capable of producing legible, accurate, and complete documents supporting the required retention period. Electronic approval and

authorization procedures are established to assure that only those persons authorized grant the required approvals.

For creation and maintenance of on-line electronic records, Duke Energy Corporation follows the Nuclear Information and Records Management Association (NIRMA) Technical Guides as identified in Table 17-1, Conformance with QA Regulatory Guides and Industry Standards.

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.

Records are identifiable and retrievable through the use of indexes and filing systems, which are required by the program.

Procedures are required to be developed to indicate responsibilities and retention periods.

The actual retention times for the various QA records are in accordance with corporate retention policies. The development of these retention policies includes consideration of applicable requirements, including those of the Code of Federal Regulations, a station's Technical Specifications, established national codes and standards, and regulatory guidance as listed in Table 17 1, Conformance with QA Regulatory Guides and Industry Standards.

The following is a list of typical QA Records retained for the operational phase:

1. Records and drawing changes reflecting facility design modifications made to systems and equipment described in the Final Safety Analysis Report. These include: drawings, design specifications, calculations, design analyses, and vendor documents for nuclear safety related structures, systems and components.
2. Records of new and irradiated fuel inventory, fuel transfers and assembly burn-up histories.
3. Radiation monitoring records, including records of radiation and contamination surveys.
4. Personnel radiation exposure records.
5. Records of radioactive releases and waste disposal, records of gaseous and liquid radioactive material released to the environs.
6. Records of component cyclic or transient limits established for the reactor coolant system, reactor vessel, and secondary coolant system.
7. Records of the qualifications, experience and training of appropriate station personnel
8. Records of quality control inspections.
9. Records of reviews performed for changes made to procedures or safety related SSCs or reviews of tests and experiments pursuant to 10 CFR 50.59.
10. Changes to station procedures; including review and approval documentation.
11. Records of meetings of the off-site review committee.
12. Records of Independent Review. These records include on-site review committee meeting minutes.
13. Records of reactor tests and experiments.
14. Records of inservice inspections performed pursuant to Technical Specifications and 10 CFR 50.55a(g).

15. Records of the service lives of all safety-related snubbers (required by Technical Specification) including the data at which the seal service life commences and associated installation and maintenance records.
16. Records of analyses required by the Radiological Environmental Monitoring Program that would permit evaluation of the accuracy of the analysis at a later date.
17. Records of secondary water sampling and water quality.
18. Records of reviews performed for changes made to the Off-Site Dose Calculation Manual, the Process Control Program, and Radwaste Treatment Systems.
19. Isotopic and physical inventory records of special nuclear materials.
20. Nuclear safety related preoperational testing records.
21. Records such as vendor documentation packages and inspection reports, piping isometric drawings, welding records, etc. compiled during the design and construction of a nuclear station.
22. Approved purchasing documents for items requiring QA certification.
23. Purchase specifications.
24. Records of special processes affecting nuclear safety related structures, systems and components.
25. Records of off-site environmental surveys.
26. Records of environmental qualification.
27. By-product material inventory records.
28. Radioactive liquid effluent, gaseous effluent, and gaseous process monitoring instrumentation alarm/trip setpoints.
29. Records of reviews performed for changes made to Radiological Effluent Controls.
30. Records of reviews performed on the Fire Protection Program and implementing procedures.
31. Audit reports and required written responses.
32. Records and logs of facility operation covering time interval at each power level, including: switchboard record, reactor operator logbook, and shift supervisor logbook.
33. Records and logs of principal maintenance activities, inspections, repair and replacement of principal items of equipment related to nuclear safety.
34. Reports of all reportable and other significant events.
35. Records of surveillance activities, inspections, and calibrations required by Technical Specifications.
36. Records of radioactive shipments.
37. Records of sealed source and fission detector leak tests and results.
38. Records of annual physical inventory of all sealed source material of record.
39. Calibration standard records and Measuring and Test Equipment (M&TE) calibration records.

Dry cask storage records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures, systems, and components important to safety must be maintained for the life of the storage mode.

17.3.3 SELF-ASSESSMENT

17.3.3.1 Methodology

Each site executive and the CNO are responsible for ensuring that an environment exists for a strong assessment program at each nuclear site and within Nuclear Generation, respectively.

The overall objective at Duke Energy Corporation is to encourage ownership, involvement, and dedication by each individual supporting Nuclear Generation. This involves continually looking for ways to improve the overall performance and safety at each plant. This approach of identifying and correcting conditions early, requires active support by management and employees.

The Duke Energy Corporation self-assessment process includes the line organization self-assessment activities, independent review activities, and an independent assessment process implemented by NOS that encompasses internal and supplier audits. NOS may perform in-plant reviews and other independent assessments requested by the CNO.

The managers of line organizations are responsible for ensuring that self-assessment activities and processes are implemented within their functions to promote continuous improvements. A process of self-assessment is an attitude by personnel that the Duke Energy Corporation Nuclear Generation is improving on a continual basis. This process, along with an effective corrective action program, ensures that conditions are identified early, corrected promptly and effectively before becoming significant quality or safety problems.

The independent review activities are discussed in Section 17.3.3.2.

As directed by the CNO, an off-site review board periodically performs independent reviews of matters involving the safe operation of its fleet of nuclear power plants. The review addresses matters that plant and corporate management determine warrant special attention, such as plant programs, performance trends, employee concerns, or other matters related to safe plant operations. 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) from the organizations responsible for those activities. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence. Results are documented and reported to responsible management.

The independent assessment process is to confirm to management that activities affecting quality comply with the QAP and that the QAP has been implemented effectively. The assessment activities are performed in accordance with instructions and procedures by organizations independent of the areas being assessed. This process is discussed in detail in Section 17.3.3.3.

17.3.3.2 Independent Review

The independent review function is provided through a combination of the On-Site Review Committee, Nuclear Oversight, and the line organization executing quality assurance program required reviews as follows:

- Reviews of the independent review subjects are performed by the On-Site Review Committee as described in Section 17.3.3.2.1, On-Site Review Committee.