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10 CFR 50.55a

RA-23-0051

March 9, 2023

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

Duke Energy Carolinas, LLC Oconee Nuclear Station (ONS), Units 1, 2, and 3 Docket Numbers 50-269, 50-270, and 50-287 Renewed Facility Operating License Nos. DPR-38, DPR-47, and DPR-55

Subject: Response to Request for Additional Information (RAI) Regarding Proposed Alternative to Use American Society of Mechanical Engineers Code Case N-752, "Risk-Informed Categorization and Treatment for Repair/Replacement Activities in Class 2 and 3 Systems Section XI, Division 1"

By letter dated July 27, 2022 (Agencywide Document Access and Management System (ADAMS) Accession No. ML22208A031), Duke Energy Carolinas, LLC (Duke Energy), submitted a proposed alternative to the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Section XI, for Oconee Nuclear Station (ONS) Units 1, 2, and 3, and Keowee Hydro Station, Units 1 and 2. Specifically, Duke Energy requested to use the alternative requirements of ASME Code Case N-752, "Risk-Informed Categorization and Treatment for Repair/Replacement Activities in Class 2 and 3 Systems Section XI, Division 1," for determining the risk-informed categorization and for implementing alternative treatment for repair/replacement activities on moderate and high energy Class 2 and 3 items in lieu of certain ASME Code Section XI, paragraph IWA-1000, IWA-4000, and IWA-6000 requirements.

The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the proposed alternative and determined that additional information is needed to complete their review. Duke Energy received the request for additional information (RAI) from the NRC through electronic mail on February 7, 2023 (ADAMS Accession No. ML23038A183).

The enclosure provides Duke Energy's response to the RAI questions. The attachment provides the proposed update to the Duke Energy Quality Assurance Program Document for information only. Duke Energy will follow the 10 CFR 50.54(a) process for making this change and any reduction in commitment would be submitted to the NRC staff for review and approval.

No regulatory commitments are contained in this submittal.

If there are any questions or if additional information is needed, please contact Mr. Ryan Treadway, Director – Nuclear Fleet Licensing at 980-373-5873.

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I declare under penalty of perjury that the foregoing is true and correct. Executed on March 9, 2023.

Sincerely,

Mar Smider

Steven M. Snider Vice President Oconee Nuclear Station

Enclosure: Response to Request for Additional Information

Attachment: Proposed Update to Duke Energy Quality Assurance Program Document (for information only)

CC:

Ms. Laura Dudes, Administrator, Region II U.S. Nuclear Regulatory Commission Marquis One Tower 245 Peachtree Center Ave., NE, Suite 1200 Atlanta, GA 30303-1257

Mr. Shawn Williams, Senior Project Manager Office of Nuclear Reactor Regulation U.S. Nuclear Regulatory Commission 11555 Rockville Pike Rockville, Maryland 20852

Mr. Jared Nadel NRC Senior Resident Inspector Oconee Nuclear Station

# ENCLOSURE

# **RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION**

### Background

In its letter dated July 27, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22208A031), the licensee states that Code Case N-752 is based on the ANO-2 [Arkansas Nuclear One, Unit 2] relief request (ANO2-R&R-004, Revision 1), and authorized in NRC safety evaluation dated April 22, 2009 (ML090930246). The licensee further states that the ANO-2 relief request was developed to serve as an industry pilot for developing a risk-informed repair/replacement. In Section 5.2.B. of its submittal, the licensee states that:

The categorization process of Code Case N-752 is delineated in Appendix I of the Code Case. This categorization process is technically identical to the process approved by the NRC under Relief Request ANO2-R&R-004, Revision 1 (Reference 8.8), which, in turn, is based on founding principles in [Electric Power Research Institute] EPRI Report TR-112657, Revision B-A, "Revised Risk-Informed Inservice Inspection Evaluation Procedure," and the categorization process of Code Case N-660, but with improvements and lessons learned from trial applications.

### <u>RAI No. 1</u>

Section 3.5.1. of the EPRI report contains the definition of piping segment consisting of four criteria. The EPRI report is referenced in CC N-752 without a clear reference to whether the definition of piping segment is used.

- a. Explain how the piping segments are defined in the licensee's proposed alternative, that is in accordance with CC N-752.
- b. If the definition is different from that which is described in EPRI TR 1122657, provide an evaluation and justification for any deviations in the definition of piping segments for Code Case N-752 from N-660, or from ANO-2 R&R-004.

### Duke Energy Response to RAI No. 1.a

Duke Energy is requesting to use ASME Code Case N-752 with no exceptions or deviations.

ASME Code Case N-752 provides a definition of piping segment in -9000 Glossary (shown below), which Duke Energy will utilize to define a pipe segment for categorization.

piping segment: a portion of piping, components, or a combination thereof, and their supports, in which a failure (i.e. loss of its pressure-retaining function) at any location results in the same consequence (e.g. loss of a system, loss of a pump train, indirect effects)

### Duke Energy Response to RAI No. 1.b

The ASME Code Case N-752 definition of a piping segment is the same as the ASME Code Case N-660 and ANO2-R&R-004 definition of a piping segment. Note: The ANO2-R&R-004 definition of piping segment is determined from Reference 1 (February 2008 document) where the glossary of the ANO2-R&R-004 method was provided in a submittal November 15, 2006 (Reference 4). Additionally, N-660 was conditionally approved by the NRC in RG 1.147 Revision 15 for class 2, 3 and non-class pressure retaining components and their associated supports.

The ASME Code Case N-752 definition of a piping segment is very similar to that contained in EPRI TR-112657 Rev B-A with the exception that failure likelihood is not include in the ASME Code Case N-752 definition of a piping segment. That is because ASME Code Case N-752 conservatively assume a failure probability of 1.0 and does not "reduce the risk" associated with the piping segment if it has a lower failure potential as is done in the EPRI-112657 Rev B-A RI-ISI methodology.

To provide some additional background EPRI TR-112657, Rev B-A is also codified in ASME Code Case N-578 and Appendix R, Supplement 2. And a streamlined version of the RI-ISI methodology is contained in NRC endorsed ASME Code Case N-716.

While slightly different in wording, each of these approaches as to "piping segments" have the same purpose. That is, to group pressure retaining items (e.g., welds, valve bodies, pipe runs, etc.) by common consequence.

## <u>RAI No. 2</u>

Code Case N-752 specifies corrective actions for those structures, systems and components (SSCs) which have been categorized low safety significance (LSS). Describe how corrective actions will be programmatically addressed, including deviations from these program requirements.

## Duke Energy Response to RAI No. 2

Duke Energy is requesting to use ASME Code Case N-752 with no exceptions or deviations.

As described in section -1420 of ASME Code Case N-752, Duke Energy shall define the requirements to confirm reasonable confidence that each LSS item remains capable of performing its safety-related function(s) under design basis conditions, including the considerations (a through j) noted in the code case and the Oconee request.

LSS item requirements will be determined and documented per Duke Energy procedures. Deviations from these requirements are considered undesired conditions and will be reported through the Duke Energy corrective action process. The Duke Energy corrective action process takes appropriate actions to monitor, investigate, and/or correct undesired conditions with the level of emphasis and effort commensurate with the risk and significance of the issue.

Section E item 12 from the Oconee request also provides additional details and notes:

Corrective action of adverse conditions associated with LSS items will be identified and addressed in accordance with Duke Energy's existing corrective action program.

### <u>RAI No. 3</u>

In Section 5.2.F of the proposed alternative, the licensee states that "...categorization and treatment requirements of Code Case N-752 applicable to repair/replacement activities are consistent with NRC requirements specified in 10 CFR 50.69."

Discuss all deviations in categorization of SSCs from the 10 CFR 50.69 risk-informed categorization program and the licensee's proposed alternative, that is in accordance with Code Case N-752. Discuss why any deviations are acceptable in accordance with 10 CFR 50.55a(z).

### Duke Energy Response to RAI No. 3

Duke Energy is requesting to use ASME Code Case N-752 with no exceptions or deviations. Oconee is not approved to use 10 CFR 50.69.

As specified in Oconee's request Section 5.2.F, the categorization methodology of ASME Code Case N-752 is consistent with that used in 10 CFR 50.69. Many licensees, including other Duke Energy stations, have adopted 10 CFR 50.69 citing the ANO2-R&R-004 methodology (References 1 and 2) for the categorization of passive components and the passive function of active components. A comparison of the ANO2-R&R-004 methodology to ASME Code Case N-752 is provided in Reference 3, Enclosure Attachment 1 and is incorporated by reference. This comparison demonstrates that the categorization methodology of ASME Code Case N-752 is technically identical to that used in relief request ANO2-R&R-004 and many 10 CFR 50.69 applications.

One specific difference between implementation of ANO2-R&R-004 methodology for 10 CFR 50.69 and ASME Code Case N-752 is the code case allows implementation on a system basis or on individual items as noted in the Code Case Section -1100 "Scope" (included in response to RAI 4.a below).

As noted in Reference 2, the ASME Code Case N-752 categorization methodology will satisfactorily classify the affected Class 2 and 3 components as HSS or LSS.

Licensees that have implemented 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," may specify alternative treatment for Risk-Informed Safety Class (RISC)-3 and RISC-4 SSCs to the ISI, and repair and replacement (with the exception of fracture toughness), requirements for ASME Class 2 and Class 3 SSCs in 10 CFR 50.55a(g). Duke Energy has not yet implemented 10 CFR 50.69 at Oconee. However, Code Case N-752 also permits exemptions from ASME Code, Section XI, Subsection IWA requirements for repair/replacement activities. The specified exemptions in Code Case N-752 are consistent with scope of the requirements for RISC-3 and RISC-4 SSCs listed in 10 CFR 50.69(b)(1) that licensees can voluntarily exempt after implementation of 10 CFR 50.69.

Code Case N-752 requires the licensee to define alternative treatment requirements that confirm with reasonable confidence that each LSS item remains capable of performing its safety-related functions under design-basis conditions. Code Case N-752, paragraph –1420, "LSS Items," describes the characteristics that must be addressed by the licensee's alternate treatment for these activities on LSS components, including the specific elements delineated in the code case and in the relief request section E.

Duke Energy's adherence to the above elements covered in Code Case N-752 for repair/replacement activities provides reasonable confidence that each LSS item will remain capable of performing its safety-related function.

The list of treatment requirements in Code Case N-752, paragraph -1420, however, is not totally consistent with 10 CFR 50.69(d)(2), "RISC-3 SSCs." The regulation at 10 CFR 50.69(d)(2) states, in part, that "inspection and testing, and corrective action shall be provided for RISC-3 SSCs." In Oconee's Relief Request, Duke Energy stated that the ISI, inservice testing (IST), snubber IST, and other inspection programs of LSS components were not affected by this Request (Section E item 11). In addition, Section E, Item No. 12 of the application defines

corrective actions for LSS items. Therefore, the Duke Energy alternative treatment requirements are consistent with the requirements in 10 CFR 50.69(d)(2)(ii), "Corrective action."

Duke Energy intends to review and assess the existing PRAs to verify that they support the evaluations required by Code Case N-752, and will also maintain a feedback and adjustment process as defined in 10 CFR 50.69(e), which will require updates to the PRA and categorization and treatment process based on review of changes to the plant, operational practices, and applicable plant and industry operational experiences. In the request, Duke Energy states that these reviews and process adjustments will be done in a timely manner and at a period not to exceed every two refueling outages (Section D).

### <u>RAI No. 4</u>

NRC Safety Evaluation for Relief Request ANO2-R&R-004 states, in part, that:

"Entergy...has requested to categorize passive SSCs (e.g., piping) and implement alternative special treatment activities limited to the repair/replacement activities for Class 2 and 3 pressure retaining items or their associated supports..."

- a) Describe how the licensee's application of Code Case N-752 in the proposed alternative aligns or deviates from the intent of the statement above.
- b) If the licensee's use of Code Case N-752 allows categorization of components with active functions, describe how those components are evaluated for categorization and provide justification that active components are not categorized solely based on their pressure retaining function.

### Duke Energy Response to RAI No. 4.a

Duke Energy is requesting to use ASME Code Case N-752 with no exceptions or deviations.

The Oconee request aligns with the statement above from the NRC Safety Evaluation for Relief Request ANO2-R&R-004 (Reference 2). Duke Energy is requesting to categorize passive SSCs (e.g., piping) and implement alternative special treatment activities limited to the repair/replacement activities for Class 2 and 3 pressure retaining items or their associated supports with exceptions noted in ASME Code Case N-752 Section -1100 "Scope." The exceptions noted in the Code Case are also reflect in the Oconee request.

Specifically, ASME Code Case N-752 Section -1100 "Scope" states:

"This Case provides a process for determining the risk-informed categorization and treatment for repair/replacement activities on Class 2 and 3 items, except

(a) that portion of the Class 2 feedwater system [>NPS 4 (>DN 100)] of pressurized water reactors (PWRs) from the steam generator, including the steam generator, to the outer containment isolation valve

(b) piping within the break exclusion region [>NPS 4 (>DN 100)] for high energy piping systems as defined by the Owner.

This Case may be applied on a system basis, including all pressure-retaining items and their associated supports, or on individual items categorized as low-safety significant (LSS) within the selected systems."

The Oconee request section 1.0 states:

"This request applies to ASME Class 2 and 3 items or components except the following:

- 1. Piping within the break exclusion region [> Nominal Pipe Size (NPS) 4 (DN 100)] for high energy piping systems<sup>1</sup> as defined by the Owner.
- 2. That portion of the Class 2 feedwater system [> NPS 4 (DN 100)] of pressurized water reactors (PWRs) from the steam generator (SG), including the SG, to the outer containment isolation valve.

This request does not apply to Class CC and MC items."

### Duke Energy Response to RAI No. 4.b

Many pressure retaining components only have a pressure boundary (passive) function (e.g., a run of piping, an elbow). However, there are a number of pressure retaining components that have a passive function as well as an active function (e.g., valve opens / closes). The ASME Code Case N-752 categorization process as well as the alternate treatment process of ASME Code Case N-752 only applies to the pressure boundary function of these components. That is, the active function of these components will be "uncategorized" by the ASME Code Case N-752 application and there will be no changes to treatment applied to the active function of these components due to the ASME Code Case N-752 application.

### <u>RAI No. 5</u>

The ANO2-R&R-004 LAR (ML071150108) states the following:

"This process shall be applied on a system basis, including pressure-retaining items and their associated supports within the selected system."

"Entergy will define the boundaries included in the scope of the RISC evaluation process consistent with the previously approved [risk-informed inservice inspection] (RI-ISI) application."

- a) Describe how the licensee's application of Code Case N-752 in the proposed alternative aligns or deviates from the intent of the statements above.
- b) If the licensee's use of Code Case N-752 deviates from the scope as defined above, provide justification for how the evaluation process sufficiently captures impacts from unanalyzed components within a system.

### Duke Energy Response to RAI No. 5.a

Duke Energy is requesting to use ASME Code Case N-752 with no exceptions or deviations.

As discussed in the Oconee relief request (and Entergy precedent), Paragraph -1200 of Code Case N-752 states: "This Case may be applied on a system basis, including all pressure retaining items and their associated supports, or on individual items categorized LSS within the selected systems." The risk-informed methodology contained in Code Case N-752 requires that the component's pressure boundary function be assumed to fail with a probability of 1.0, and all impacts caused by the loss of the pressure boundary function be identified. This would include

identifying impacts of the pressure boundary failure on the component under evaluation, identifying impacts of the pressure boundary failure of the component on the system in which the component resides, as well as identifying impacts of the pressure boundary failure of the component on any other plant SSC. This includes direct effects (e.g. loss of the flow path) of the component failure and indirect effects of the component failure (e.g. flooding, spray, pipe whip, loss of inventory). This comprehensive assessment of total plant impact caused by a postulated individual component failure is then used to determine the final consequence ranking. As such, the final consequence rank of the individual component is subject to the risk-informed methodology.

The boundaries of the evaluation are determined by the owner and documented as part of the categorization.

## Duke Energy Response to RAI No. 5.b

Code Case N-752 is limited to Class 2 and 3 items. All unanalyzed Class 2 and 3 components will continue to meet their applicable nuclear special treatment requirements (e.g., Repair & Replacement per ASME Section XI requirements, QA per Appendix B, etc.).

## <u>RAI No. 6</u>

Section 5.2.E.14 states, in part, that "As permitted by Code Case N-752, Duke Energy intends to implement the QA Program exemption applicable to IWA-1400(n) and IWA-4000 when performing repair/replacement activities on LSS items. That said, this code case exemption only applies if compliance with 10 CFR 50, Appendix B, or NQA-1 is not required by the NRC at the Owner's facility. To address this issue, Duke Energy will update the Fleet Quality Assurance Program Description (QAPD) for safety-related Class 2 and 3 SSCs identified as LSS in accordance with ASME Code Case N-752 to not be required to meet the requirements of the QAPD."

In accordance with 10 CFR 50.54(a), when the use of a quality assurance exception is approved by an NRC safety evaluation, licensees may make changes to a previously accepted quality assurance program description without prior NRC approval provided the bases of the approval are applicable to the licensee's facility. Any deviations from the original approved wording in the safety evaluation approving the QAPD change may result in a reduction in commitment that must be submitted to the NRC for review and approval under 10 CFR 50.54(a)(4).

Provide the proposed update to Duke Energy's QAPD to ensure consistency with the NRC's previously approved QAPD change for Entergy in conjunction with their request for Arkansas Nuclear One to adopt ASME Code Case N-752.

### Duke Energy Response to RAI No. 6

The attachment to this enclosure provides the proposed update to the Duke Energy QAPD for information only. The Duke Energy 10 CFR 50.54(a) process for making this update will be followed and any reduction in commitment associated with the proposed update will be submitted to the NRC staff for review and approval.

### Request for Confirmation of Information (RCI) No. 1

In Section 5.2.E.12 of the proposed alternative, the licensee states that "Conditions that would prevent a LSS item from performing its safety-related function(s) under design basis conditions will be corrected in a timely manner."

Confirm that for those SSC under 10 CFR 50.36, "Technical Specifications," they will be addressed within the timeline of the limiting conditions of operability or the necessary action statements will be performed.

### Duke Energy Response to RCI No. 1

For the proposed alternative to adopt ASME Code Case N-752, Duke Energy hereby confirms that the ONS Technical Specifications required by 10 CFR 50.36 will continue to be complied with in every aspect. Specifically, in accordance with limiting condition for operation (LCO) 3.0.1, LCOs will be met during the Modes or other specified conditions in the Applicability. This includes LCOs containing SSCs that have been categorized as LSS. If a LCO is not met during the Modes or other specified conditions of the associated Conditions will be met in accordance with LCO 3.0.2. The Required Actions would be taken within the associated Completion Times. Required Actions must be completed prior to the expiration of the specified Completion Time.

### References:

- Entergy Letter to NRC dated April 17, 2007, "Request for Alternative ANO2-R&R-004, Revision 1, Request to Use Risk-Informed Safety Classification and Treatment for Repair/Replacement Activities in Class 2 and 3 Moderate Energy Systems," (ML071150108) as supplemented by letters dated August 6, 2007 (ML072220160), February 20, 2008 (ML080520186), and January 12, 2009 (ML090120620).
- Safety Evaluation Report (SER) by the Office of Nuclear Reactor Regulation "Approval of Request for Alternative ANO2-R&R-004, Revision 1, Request to Use Risk-Informed Safety Classification and Treatment for Repair/Replacement Activities in Class 2 and 3 Moderate and High Energy Systems," dated April 22, 2009 (ML090930246).
- Entergy letter to NRC, "Relief Request Number EN-20-RR-001 Proposed Alternative to Use ASME Code Case N-752, Risk-Informed Categorization and Treatment for Repair/Replacement Activities in Class 2 and 3 Systems, Section XI, Division 1," dated May 27, 2020 (ML20148M343).
- Entergy letter to NRC dated November 15, 2006, "Request for Alternative ANO2-R&R-004 Request to Use ASME Code Case N-752, Risk-Informed Safety Classification and Treatment for Repair / Replacement Activities in Class 2 and 3 Moderate Energy Systems" (ML063250351).

### ATTACHMENT

## PROPOSED UPDATE TO DUKE ENERGY QUALITY ASSURANCE PROGRAM DOCUMENT (FOR INFORMATION ONLY)

[2 PAGES FOLLOW THIS COVER PAGE]

# **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 – with the exception that SSCs categorized as Safety-Related, Low Safety Significant (RISC-3) in accordance with 10CFR50.69 and the site license are no longer subject to the requirements of this document. These 50.69 LSS SSCs are no longer subject to the requirements of 10 CFR 50 Appendix B, 10 CFR Part 21 and other regulations as noted in the rule.

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

### Add new text here.

Guides, s Topical tions from s included

For those sites who have received NRC authorization to use the alternative repair/ replacement categorization and treatment requirements of Code Case N-752 in lieu of the corresponding sections of ASME Section XI, as referenced in 10 CFR 50.55a, Codes and Standards, treatment of safety-related SSCs identified as low safety significant (LSS) Class 2 and 3 SSCs in accordance with ASME Code Case N-752 is not required to meet the requirements of this document. Instead, treatment of these LSS SSCs is performed in accordance with existing QAP procedures and processes which include supplemental controls to ensure the capability and reliability of the SSCs design basis function.

ontained in ents of this Table 17-1, te Specific of applying

fire protection and radioactive waste structures, systems, and components) – with the exception that SSCs categorized as Low Safety Significant in accordance with 10CFR50.69 and the site license are no longer subject to the requirements of this document as allowed by the rule.

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:

<u>Internal Audit</u> - 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.

<u>Supplier Audit</u> - 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.

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

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

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

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