Duke Energy®

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

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October 26, 2011

U. S. Nuclear Regulatory Commission
Washington, D. C. 20555-0001

ATTENTION: Document Control Desk

SUBJECT: Duke Energy Carolinas, LLC (Duke Energy)
Oconee Nuclear Station Units 1, 2, & 3, Docket Nos. 50-269, 50-270, 50-287
McGuire Nuclear Station Units 1 & 2, Docket Nos. 50-369, 50-370
Catawba Nuclear Station Units 1 & 2, Docket Nos. 50-413, 50-414
Oconee Nuclear Station Independent Spent Fuel Storage Installation
Docket No. 72-004
Quality Assurance Program Topical Report Amendment 39

Pursuant to 10CFR50.54(a)(3) and 10CFR50.71(e), attached is Amendment 39 to the Duke Energy Carolinas Topical Report, Duke-1-A, Quality Assurance Program (hereafter referred to as Topical Report). Amendment 39 includes organizational changes, administrative, clarification and editorial changes, and a change approved by an NRC safety evaluation of another licensee.

Attachment 1 provides a description, reason, and basis for each change since the last update, which was approved by NRC safety evaluation issued in August 2010. Duke Energy has completed an evaluation of each of these changes in accordance with provisions of 10CFR50.54(a)(3). Amendment 39 contains no reduction in commitment addressed by the Topical Report. The results of the Duke Energy evaluation are summarized in Attachment 1.

Since NRC approval is not required for these changes, Amendment 39 was implemented on September 30, 2011 and is provided for information as Attachment 2. The changes are shown by the use of indicator bars on the margin of affected pages.

Please direct your questions on this matter to L. B. Jones at (704) 382-4753 *(Luellen.Jones@duke-energy.com)*.

I certify that all statements and matters set forth herein are true and accurate to the best of my knowledge and that the information represents changes made to the Duke Energy Carolinas Quality Assurance Program Topical Report, Duke-1-A, since the previous submittal.

Sincerely,

R. Michael Glover

Attachments
1. Quality Assurance Program Topical Report Discussion of Changes
2. Quality Assurance Program Topical Report, Duke-1-A, Amendment 39

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Purpose

The purpose of this attachment is to identify the changes, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of Appendix B of 10 CFR Part 50 and the quality assurance program description commitments previously accepted by the NRC. The evaluation is consistent with the provisions contained in NRC regulation 10 CFR 50.54(a). The changes do not represent a reduction in commitment and have been implemented.

Discussion

The following changes to the Duke Energy Carolinas Topical Report have been made since the last update.

Change 1 Description: The change added the following italicized material before the final sentence of the fourth paragraph of Section 17.3.3.2.3.1:

Audits of selected aspects of operational phase activities are performed with a frequency commensurate with safety significance and in such a manner as to assure that an audit of all QA Condition 1 functions is completed within a period of two (2) years. *Except when the audit frequency is specified by regulation, the following criteria for extending audit intervals apply:*

1. *Schedules shall be based on the month in which the audit starts.*
2. *A maximum extension not to exceed 25 percent of the audit interval shall be allowed (e.g., audits on a two year frequency shall not be extended beyond 30 months, audits on an annual frequency shall not be extended beyond 15 months).*
3. *When an audit interval extension greater than one month is used, the next audit for that particular audit area shall be scheduled from the original anniversary month rather than from the month of the extended audit.*

Reason for this change: Duke Energy adopted standard criteria for maximum extension of audit intervals for internal audits. The selection of the 25% (or 6-month maximum) extension provides a standard criteria to manage audit resources and to avoid undesirable scheduling conflicts. When an extension is used, the next audit is scheduled from the original anniversary month.

Change 1 Conclusion: This change is consistent with 10 CFR 50.54(a)(3)ii, which allows the use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to Duke Energy's nuclear plants. The Safety Evaluation issued to Southern Nuclear Operating Company, Inc./Joseph M. Farley Nuclear Plant, Units 1 and 2; Edwin I. Hatch Nuclear Plant, Units 1 and 2; and Vogtle Electric Generating Plant, Units 1 and 2/Safety Evaluation Re: Proposed Change To The Quality Assurance Program (TAC Nos. MC5666, MC5667, MC5668, MC5669, MC5670, and MC5671) (ML051570349) on June 17, 2005 provides for extension of audit intervals as stated above. The following table identifies the bases from the Safety Evaluation and evaluates the applicability to Duke Energy.

Bases for NRC Approval	Applicability to Duke Energy
REGULATORY EVALUATION The NRC staff's review and evaluation of licensee programs for conducting reviews of operating phase activities are conducted in accordance with NUREG-0800, "Standard Review Plan," Section 13.4, "Operational Review." Provisions for independent review are described in Section 4.3 of ANSI N18.7, "Administrative Controls and Quality Assurance Requirements for the Operational Phase of Nuclear Plants." The Hatch and Vogtle operational QA programs follow the guidance of ANSI N18.7-1976, as endorsed by Regulatory Guide (RG) 1.33, Revision 2. The Farley QA program also follows the guidance of ANSI N18.7-1976 in implementing the independent review program, as stated in the list of regulatory commitments that are included as Enclosure 4 of SNC's submittal.	Consistent with the bases, the Duke Energy operational QA program follows the guidance of ANSI N18.7-1976, as endorsed by Regulatory Guide (RG) 1.33, Revision 2. Duke Energy adopted "Change 4" from the referenced safety evaluation. The Duke Energy program is consistent with (and did not change) the "the independent review program" described in Section 4.3 of ANSI N18.7.
TECHNICAL EVALUATION SNC proposed to make four changes, characterized as reductions in commitments, to the QA programs for the Farley, Hatch, and Vogtle nuclear power plants. • Adoption of a standard conduct of operations for the Safety Review Board, • Adoption of a standard program of QA audits, • Revision of maximum audit intervals, and • Adoption of standard criteria for maximum extending audit intervals.	Duke Energy adopted only the standard criteria for maximum extending audit intervals from SNC Change 4. The Duke Energy QA Topical already includes a standard conduct of operations for the Safety Review Board, a standard program of audits, and established audit intervals. Those are not changed.

Bases for NRC Approval	Applicability to Duke Energy
3.4 Standard Criteria for Extending Audit Intervals (Change 4) The licensee has proposed the following standard criteria for extending audit intervals. A. Audits shall be performed at the intervals designated herein for each audit area. Schedules shall be based on the month in which the audit starts.	Duke Energy includes the following: Except when the audit frequency is specified by regulation, the following criteria for extending audit intervals apply: 1. Schedules shall be based on the month in which the audit starts.
B. A maximum extension not to exceed 25 percent of the audit interval shall be allowed. That is to say that, for audits on a 24-month frequency, the maximum time between specific audits shall not exceed 30 months. Likewise, audits on an annual (12 month) frequency shall not be extended beyond 15 months.	2. A maximum extension not to exceed 25 percent of the audit interval shall be allowed (e.g., audits on a two year frequency shall not be extended beyond 30 months, audits on an annual frequency shall not be extended beyond 15 months).
C. When an audit interval extension greater than one month is used, the next audit for that particular audit area will be scheduled from the original anniversary month rather than from the month of the extended audit.	3. When an audit interval extension greater than one month is used, the next audit for that particular audit area shall be scheduled from the original anniversary month rather than from the month of the extended audit.
D. Item B shall also apply to supplier audits and evaluations except that a total combined time interval for any three consecutive inspection or audit intervals should not exceed 3.25 times the specified inspection or audit interval.	Duke Energy does not apply this extension provision to supplier audits.

Bases for NRC Approval	Applicability to Duke Energy
Evaluation Two of SNC's facilities have existing provisions for extending audit intervals by 25 percent though the wording differs slightly from the standard criteria above. The proposed criteria would standardize provisions for all facilities, clarify the current criteria that are subject to interpretation, and provide the flexibility to more effectively manage the audit schedule without reducing the effectiveness of the audit program. Similar audit extension provisions have been previously approved by the NRC staff. The audit interval extension provision conforms to the requirements of Appendix B to 10 CFR Part 50 and is consistent with the NRC staff guidance for reviewing audit programs, as delineated in Section 17.2 of NUREG-0800. The proposed change is, therefore, acceptable.	The audit interval extension provision conforms to the requirements of Appendix B to 10 CFR Part 50 and is consistent with the NRC staff guidance for reviewing audit programs, as delineated in NUREG-0800. The extension provisions are only applied to QA Program audits. The proposed change is, therefore, acceptable.

Change 2 Description: Changes to the Organization Description identified in Section 17.3.1.2 were made as follows:

1. This change consolidated the nuclear development non-QA Program related functions for overall new nuclear strategy with the Nuclear Plant Development organization pursuing a license for a new nuclear plant.
2. This change consolidated the Catawba, McGuire, and Oconee Nuclear Site organizations under a single executive for Nuclear Operations reporting to the CNO, instead of being split between the two Senior Vice Presidents in the prior organization. The executive for Nuclear Operations no longer has responsibilities for non-site organizations.
3. This change replaced the second SVP, Nuclear Operations (from the previous organization) with an executive for Nuclear Corporate reporting to the CNO. Reporting to this position are independent nuclear oversight, nuclear engineering, nuclear plant support, fleet centers of excellence, and the employee concerns program. This change consolidates the nuclear corporate functions under a single executive. This change reduces a level of management between the Chief Nuclear Officer (CNO) and the manager of independent nuclear oversight, who has unfettered access to the CNO, ensuring continued independence of that function. Consistent with 50.54(a)(3)(vi), this organizational change ensures that persons and organizations performing quality assurance functions will continue to have the

requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

4. This change elevated the executive for Major Projects, to a position reporting directly to the CNO.

Reason for this change: These organizational changes ensure our performance keeps pace with the ever-improving expectations, strengthen our governance model using industry best practices, enhance fleet solutions and utilize a strong independent oversight model.

Change 2 Conclusion: The changes are consistent with the provisions of 50.54(a)(3)(vi). This organizational change ensures that persons and organizations performing quality assurance functions will continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

Change 3 Description: The following editorial corrections are included:

1. Revised reference to 10CFR50 Appendix B to include the August 2007 Federal Register change. (Page 17-1)
2. Clarified reference to Table 17-1. (Pages 17-21 and 17-28)
3. Clarified responsibilities (on pages 17-44 and 17-45) for maintenance or transfer of records from corporate interfacing organizations consistent with the generic organization description.
4. Editorial changes for consistent use of terms and acronyms including spelling out acronyms at the first use.
5. Various changes to reflect use of generic organization titles in the document consistent with those used in the generic organization description of Section 17.3.1.2.

These changes are reflected by change bars in the margin of the affected pages.

Reason for this change: Consistency in usage.

Change 3 Conclusion: These changes are administrative improvements and clarifications, or editorial items as described in 10CFR50.54(a)(3). These items are all considered to be clarifications of existing descriptions within the Quality Assurance Program. These changes do not constitute a reduction in any commitment contained within the Quality Assurance Program. Additionally, these changes do not result in a change to our current practices.

Attachment 2

Duke Energy Carolinas Topical Report, Duke-1-A
Quality Assurance Program, Amendment 39

DUKE ENERGY CAROLINAS
TOPICAL REPORT
Quality Assurance Program

DUKE-1-A

ABSTRACT

This topical report describes the Duke Energy Carolinas Quality Assurance Program (QAP) for the operational phase of its nuclear power plants. The report is organized like and is generally used for Chapter 17, "Quality Assurance" of each of the Duke Energy Carolinas nuclear station's Updated Final Safety Analysis Reports (UFSAR).

The Duke Energy Carolinas QAP conforms to applicable regulatory requirements such as 10CFR 50, Appendix B and to approved industry standards such as ANSI N45.2-1977 and ANSI N18.7-1976 and corresponding daughter standards, or to equivalent alternatives. The Duke Energy Carolinas QAP also conforms to the regulatory position of the NRC Regulatory Guides listed in Table 17-1 of this report with the exception of the clarifications, modifications, and alternatives stated therein.

The Duke Energy Corporation QAP Policy Statement, issued by the President and Chief Executive Officer, describes the corporate policy and assigns responsibility for implementation of the QAP.

Section 17, "Quality Assurance", Introduction describes the purpose of this report, provides definitions, and shows conformance to regulations, standards, and guides.

Section 17.3, "QAP Description" describes the QAP and organization for station operation.

Section 17.3, "QAP Description" follows the format of NUREG-0800, "Standard Review Plan For The Review of Safety Analysis Reports for Nuclear Power Plants", Section 17.3, "QAP Description," except that the Duke Energy Carolinas QAP is based on ANSI N18.7-1976 in lieu of ANSI/ASME NQA-1 and NQA-2.

The topical is intended to be a comprehensive up-to-date description of Duke Energy Carolinas QAP for nuclear power plants.

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LIST OF AMENDMENTS

Number	Amendment Date	Number	Amendment Date
Original	March 1, 1974	38	August 17, 2010 (Reissue of Amendment 37 per NRC Safety Evaluation dated 08-17-10)
1	October 1, 1974 (Complete Revision)	39	September 30, 2011
2	February 14, 1975		
3	November 22, 1976		
4	June 29, 1978		
5	July 14, 1981		
6	February 3, 1983		
7	June 22, 1984		
8	May 20, 1985		
9	July 30, 1985		
10	October 17, 1986		
11	November 12, 1987		
12	March 30, 1989		
13	April 18, 1990		
14	August 23, 1991		
15	August 7, 1992 (Complete Rewrite)		
16	June 16, 1994		
17	June 16, 1994		
18	December 12, 1994		
19	March 30, 1995		
20	June 29, 1995		
21	July 11, 1996		
22	November 1, 1997		
23	June 30, 1998		
24	January 5, 1999		
25	May 31, 1999		
26	September 13, 2000		
27	December 14, 2000		
28	June 21, 2001		
29	December 10, 2001		
30	July 31, 2002		
31	December 16, 2002		
32	June 03 , 2004		
33	July 29, 2004		
34	May 2, 2006		
35	May 31, 2007		
36	September 18, 2008		
37	January 28, 2010		

Summary of Changes

Change Date	Description of Change
08-31-2010	Requested by the INOS Audit team in PIP G-10-125 to incorporate a grace period feature for audit frequencies into the QA Topical Report based on an NRC SER issued to Southern Nuclear. DEC adopts standard criteria for maximum extension of audit intervals. The change adds the following before the final sentence of the fourth paragraph of Section 17.3.3.2.3.1: Except when the audit frequency is specified by regulation, the following criteria for extending audit intervals apply: 1) Schedules shall be based on the month in which the audit starts. 2) A maximum extension not to exceed 25 percent of the audit interval shall be allowed (e.g., audits on a two year frequency shall not be extended beyond 30 months, audits on an annual frequency shall not be extended beyond 15 months). 3) When an audit interval extension greater than one month is used, the next audit for that particular audit area shall be scheduled from the original anniversary month rather than from the month of the extended audit. Table 17-1 is not impacted by this change.
12-15-2010	Organizational changes within Nuclear Generation. The change revises Section 17.3.1.2 using generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles and replaces Figures 17-2 and 17-3 with the use of generic organizational charts to indicate functional relationships, authorities, and responsibilities.
Amendment 39	Various editorial changes throughout for consistency.

17. QUALITY ASSURANCE

INTRODUCTION

Duke Energy Carolinas (DEC) maintains full responsibility for assuring that 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 DEC has established and implemented a Quality Assurance Program (QAP) which conforms to the criteria established in Appendix B to Title 10 Code of Federal Regulations (10CFR), 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 Topical Report is written in the format of a Safety Analysis Report (SAR) Chapter 17, "Quality Assurance", in accordance with Revision 2 of the Nuclear Regulatory Commission (NRC) Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants - LWR Edition" and subsequent NRC guidelines. The QAP described herein is applicable to DEC nuclear power stations as referenced by Chapter 17 of each station's UFSAR.

This Topical Report describes the QAP for those systems, components, items, and services which have been determined to be nuclear safety related (QA Condition 1). In addition, the QAP provides a method of applying a graded QAP to certain non-safety related systems, components, items, and services. These are classified as QA Conditions 2, 3, 4, or 5. This method involves defining a Quality Assurance (QA) "Condition" for each level of QA required. These will be designated as "QA Condition _____". The quality of systems, components, items, and services within the scope of QA Conditions 1, 2, 3, 4, and 5 is assured commensurate with the system's, component's, item's, or service's importance to safety. The following conditions have been defined.

QA Condition 1 covers those systems and their attendant components, items, and services which have been determined to be nuclear safety related. These systems are detailed in the Safety Analysis Report applicable to each nuclear station. The Topical Report applies in its entirety to systems, components, items, and services identified as QA Condition 1.

QA Condition 2 covers those systems and their attendant components, items, and structures important to the management and containment of liquid, gaseous, and solid radioactive waste.

QA Condition 3 covers those systems, components, items, and services which are important to fire protection as defined in the Hazards Analysis for each station. The Hazards Analysis is in response to Appendix A of NRC Branch Technical Position APCSB 9.5-1.

QA Condition 4 covers those seismically designed/restrained systems, components, and structures whose continued functions are not required during and after the seismic event. The general scope of these systems, components, and structures, identified as Seismic Category II (SCII) are defined in Regulatory Guide 1.29, Seismic Design Classification.

QA Condition 5 covers those systems, components, items, and services which are important to the mitigation of design basis and other selected events as defined in applicable procedures and directives. QA Condition 5 only applies to Oconee Nuclear Station.

Quality assurance program requirements for Oconee, McGuire, and Catawba dry cask storage activities are performed in accordance with applicable 10CFR72.212 reports for each site which invokes the NRC approved 10CFR50 Appendix B QAP as described in this Topical Report.

This Topical Report also provides the basis for the control and performance of safety related and quality related activities associated with new DEC nuclear plants until the NRC approves a QA Program Description specific to the new units and the associated implementing procedures are in place.

Subsequent changes to the DEC QAP shall be incorporated in this Topical Report. The Topical Report is intended to be a comprehensive up-to-date description of the DEC QAP for nuclear power plants.

Any programmatic changes to the QAP that constitute a reduction in commitment will be submitted for review and acceptance prior to implementation. Significant organizational changes will be submitted as required by 10CFR50.54 (a) (3).

DEFINITIONS

The following definitions are applicable to terms used in this report. Terms used in this report which are not defined in this section are defined in ANSI N45.2.10, "Quality Assurance Terms and Definitions."

Approver - An individual who reviews an activity for concept and conformity with codes and standards; the approver is a person other than the originator or checker.

Audit (Internal) - An activity to determine through investigation the adequacy of, and adherence to, established procedures, instructions, specifications, codes, and other applicable contractual and licensing requirements, and the effectiveness of implementation.

Basic Component – See QA Condition 1 in previous section.

Checker - An individual, other than the originator or approver, who is qualified in the area being checked and who has the responsibility to check the activity and/or all revisions for completeness, clarity, and accuracy.

Designer - The individual who performed the design.

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

Documents - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. Examples of documents are drawings, specifications, instructions and procedures significant to the design, construction, testing, maintenance and operation of QA Condition 1 equipment and systems.

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.

Engineering Change (EC) Revision - A notice to provide a process by which field variations from design drawings and specifications are evaluated and permitted.

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

Item - Any level of unit assembly, including structure, system, subsystem, subassembly, component, part, or material.

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

Problem Investigation Process - A process used during the operation phase of nuclear stations that documents an occurrence, situation, or nonconformance that resulted in other than expected equipment performance, personnel action, or failure to operate within established limits.

Quality Assurance (QA) - The planned and systematic actions necessary to provide adequate confidence that a material, component, system or facility will perform satisfactorily in service. (Note: See Section 17, "Quality Assurance," Explanation of "Quality Assurance" below for further explanation.)

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.

Quality Control (QC) - Those QA actions which provide a means to control and measure the physical characteristics of an item, process or facility to established requirements.

Quality Control Inspector (Inspector) - Any individual certified to the requirements of ANSI N45.2.6 or SNT-TC-1A who performs required inspections, tests or examinations.

Responsible Engineer - The engineer assigned responsibility for an item or service.

Revisions - Any addition, correction, deletion or change.

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

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 QAP have been developed, documented and implemented in accordance with specified requirements.

EXPLANATION OF "QUALITY ASSURANCE"

QA as used in this document includes: 1) the independent assurance activities associated with items and tasks critical to the safety and integrity of the facility and 2) quality verifications performed by the Internal and Procurement Quality audit functions and by the Nuclear Safety Review Board in Nuclear Generation. The QAP as defined above is not an alternative to good technical work. Rather, it is a system of controls to verify that quality is achieved. The QAP places the responsibility on line management of achieving and assuring quality in all areas of their operation. As defined, the Chief Nuclear Officer has been given the responsibility to develop and manage a QAP for the Corporation.

QA STANDARDS AND GUIDES

The DEC QAP conforms to Appendix B of 10CFR 50, as discussed in Section 17, "Quality Assurance." The QAP also conforms to applicable NRC Regulatory Guides and approved ANSI Standards, or applicable alternatives. Table 17-1 addresses QAP conformance to the referenced regulatory and program guidance contained in NUREG-0800.

QAP conformance with the documents identified in Table 17-1 may, however, be modified contingent upon future NRC or ANSI action. For example, if a draft document is subsequently approved and issued or if an approved document is revised, provisions of the more recent issue of such a document may be complied with in lieu of those contained in the version listed in Table 17-1, provided the more recent issue has been endorsed by the NRC. Also, formal regulatory actions of the NRC (e.g., issuance or amendment of a station's Facility Operating License) are considered to supersede the contents of Table 17-1, as applicable.

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
Regulatory Guide 1.8 Rev (1-R) – Personnel Selection and Training	Alternative	RG 1.8 Rev (1-R) incorporates ANSI N18.1. The DEC QAP conforms to ANSI N18.1-1971 or as otherwise stipulated in the Technical Specifications
Regulatory Guide 1.26 Rev (3) – Quality Group Classifications & Standards for Water, Steam, and Radioactive-Waste Containing Components of Nuclear Power Plants	Alternative	The DEC QAP conforms to this Regulatory Guide except for additional details and directions noted in each station's UFSAR.
Regulatory Guide 1.28 Rev (2) – QAP Requirements (Design and Construction)	Conforms	-------
Regulatory Guide 1.29 Rev (3) – Seismic Design Classification	Alternative	The DEC QAP conforms to this Regulatory Guide except for additional details and directions noted in each station's UFSAR.
Regulatory Guide 1.30 Rev (0) – Quality Assurance Requirements for the Installation, Inspection and Testing of Instrumentation and Electric Equipment	Conforms	RG 1.30 Rev (0) incorporates ANSI N45.2.4-1972 for both construction and operation
Regulatory Guide 1.33 Rev (2) – QAP Requirements (Operations)	Alternative	RG 1.33 Rev (2) incorporates ANSI N18.7-1976/ANS-3.2. The DEC QAP conforms to ANSI N18.7-1976 except the frequency of audits of selected aspects of operational phase activities is defined in Section 17.3.3, "Self Assessment" and the frequency for procedure review, as described in Section 17.3.2.14, "Document Control," is based on ANSI/ANS-3.2 (1994) with appropriate reviews performed when the need is identified by normal use, unusual incidents, engineering changes, or established quality programs. Review frequencies for Abnormal Procedures, Emergency Procedures, and Emergency Response Procedures shall not exceed six years. Procedures that have not been used for six years shall be reviewed prior to reuse. When purchasing commercial-grade calibration services from

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
		certain accredited calibration laboratories, the procurement documents are not required to impose a QAP consistent with ANSI N45.2-1977. Alternate requirements described in the QA Topical Report for Regulatory Guide 1.123 may be implemented in lieu of imposing a QAP consistent with ANSI N45.2-1977. A person with nondestructive testing experience is not required on the Nuclear Safety Review Board (NSRB) as required by section 4.3.1 of ANSI N18.7-1976. The technical experience requirements for NSRB members were transferred from each site's technical specifications and did not include a person with nondestructive testing experience. The transfer of NSRB requirements from each site's Technical Specification to the QA Topical Report was approved by an SER dated October 22, 1998 for amendment 23. The independent review of Technical Specification changes and license amendments shall be performed by the Plant Operations Review Committee (PORC). NSRB review and approval of Technical Specification changes and license amendment changes is not required.
Regulatory Guide 1.36 Rev. (0) – Nonmetallic Thermal Insulation for Austenitic Stainless Steel	Adopted	The conformance to this Regulatory Guide will be as addressed in each station's UFSAR.
Regulatory Guide 1.37 Rev (0) – Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants	Conforms	RG 1.37 Rev (0) incorporates ANSI N45.2.1-1973 for both construction and operation

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.38 Rev (2) – Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage and Handling of Items for Water-Cooled Nuclear Power Plants	Alternative	RG 1.38 Rev (2) incorporates ANSI N45.2.2-1972. The DEC QAP conforms to ANSI N45.2.2-1972 except container markings shall be marked on at least one side (A.3.9(1)) and shall be applied with waterproof ink or paint in characters of a legible size, and caps and plugs for pipe and fittings are required unless specified by Engineering, and off-site inspection, examination, and testing is monitored by personnel qualified to ANSI N45.2.12 in lieu of ANSI N45.2.6.
Regulatory Guide 1.39 Rev (2) – Housekeeping Requirements for Water-Cooled Nuclear Power Plants	Conforms	RG 1.39 Rev (2) incorporated ANSI N45.2.3-1973 for both construction and operation. Personnel accountability for personnel entering housekeeping zones I, II, and III without materials shall be maintained by housekeeping logs or alternate methods such as radiation work permits, confined space permits, work requests or other accepted methods capable of assuring personnel accountability.
Regulatory Guide 1.54 Rev (0) – Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants	Alternative	Catawba has adopted the Regulatory Guide. McGuire and Oconee adopt portions of the Regulatory Guide and address alternatives which meet the intent of this Guide, in each respective station's UFSAR.
Regulatory Guide 1.58 Rev (1) – Qualification of Nuclear Power Plant Inspection, Examination and Testing Personnel	Alternative	RG 1.58 Rev (1) incorporates ANSI N45.2.6-1978 for both construction and operation. DEC's nondestructive examination (NDE) personnel will meet the qualification requirements of SNT-TC-1A and ANSI/SNT-CP-189 as governed by the applicable ASME Section XI requirement or other code requirement. Operational/functional testing personnel will meet the requirements of ANSI N18.1-1971 rather than ANSI N45.2.6. Also, Level I inspectors receive a minimum of 4 months experience as Level I before being certified as Level II, in lieu of one year experience recommended by ANSI N45.2.6. Inspectors are only assigned tasks for which they have been qualified.
Regulatory Guide 1.64 Rev (2) – Quality	Adopted with	RG 1.64 Rev (2) Incorporates ANSI N45.2.11-1974. The use of

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
Assurance Requirements for Design of Nuclear Power Plants	Clarification	the originator's immediate supervisor for design verification shall be restricted to special situations where the immediate supervisor is the only individual capable of performing the verification. Advance justification for such use shall be documented and signed by the supervisor's management. And the frequency and effectiveness of the supervisor's use as design verifier are independently verified to guard against abuse. The supervisor will not be the design verifier on work for which he is the actual performer / originator.
Regulatory Guide 1.74 Rev (0) – Quality Assurance Terms and Definitions	Conforms	RG 1.74 Rev (0) Incorporates ANSI N45.2.10-1973. Some definitions used by DEC are worded differently than those in this standard; however, the general meanings are the same.
Regulatory Guide 1.88 Rev (2) - Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records	Alternative	RG 1.88 Rev (2) Incorporates ANSI N45.2.9-1974. The DEC QAP conforms to RG 1.88 except the records storage facilities have a minimum 3-hour rating. A qualified Fire Protection Engineer will evaluate record storage areas (including satellite files) to assure records are adequately protected from damage. The fire protection engineer shall be a graduate of an engineering curriculum of accepted standing and shall have completed not less than 6 years of engineering attainment indicative of growth in engineering competency and achievement, 3 years of which shall have been in responsible charge of fire protection engineering work. The DEC program for storage of records on optical disks meets the quality controls contained in NRC Generic Letter 88-18. DEC fully meets NIRMA Technical Guide (TG) 11-1998, Authentication of Records and Media, NIRMA TG 15-1998, "Management of Electronic Records," and NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance" for managing quality assurance records in electronic media: NIRMA TG 21-1998, "Electronic Records Protection and

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
		Restoration" - The data backup provisions in sections 5.4.2 and 5.4.4 are not being fully met. Until the backup requirements are met, dual storage or microfilm will be used for all QA Records.
Regulatory Guide 1.94 Rev (1) – Quality for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants	Alternative	RG 1.94 Rev (1) Incorporates ANSI program for McGuire and Catawba conforms to ANSI N45.2.5-1974 except the length of bolts shall be flush with the outside face of the nut. Paragraph 5.5 requires inspection of structural steel welding to be performed in accordance with the provisions of Section 6 of the AWS D1.1. Visual Weld Acceptance Criteria (VWAC) for Structural Welding at Nuclear Power Plants, NCIG-01, Revision 2, prepared by the Nuclear Construction Issues Group (NCIG) and accepted by the NRC in their letter to the NCIG dated June 26, 1985 may be used as an alternative to AWSD1.1 for non ASME Code structural weld inspections. (July 31, 2000 J M Farley SER)
Regulatory Guide 1.116 Rev (0-R) – Quality Assurance Requirements for Installation, Inspections, and Testing of Mechanical Equipment and Systems	Conforms	RG 1.116 Rev (0-R) Incorporates ANSI N45.2.8-1975
Regulatory Guide 1.123 Rev (1) – Quality Assurance Requirements for control of Procurement of Items and Services for Nuclear Plants	Alternative	RG 1.123 Rev (1) Incorporates ANSI N45.2.13-1976. With respect to ANSI N45.2.13, Section 3.2, "Content of the Procurement Documents," Subsection 3.2.3, "QAP Requirement," DEC takes the following exception: When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally recognized accrediting body, the procurement documents are not required to impose a QAP consistent with ANSI N45.2-1977. Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and other accrediting bodies recognized by NVLAP via a Mutual Recognition Arrangement (MRA). In such cases, accreditation

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
		may be accepted in lieu of the purchaser imposing a QA Program consistent with ANSI N45.2-1977, provided all the following are met: 1. The accreditation is to ANSI/ISO/IEC 17025. 2. The accrediting body is either NVLAP or an accrediting body recognized by NVLAP through MRA. (NVLAP or American Association for Laboratory Accreditation (A2LA)) 3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties. 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.) 4. The purchase documents impose additional technical and administrative requirements, as necessary, to satisfy DEC QAP and technical requirements. As a minimum, the procurement documents shall require that the calibration certificate/report include identification of the laboratory equipment/standards used. 5. The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
Regulatory Guide 1.143 Rev (1) – Design Guidance For Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants	Conforms	-----
Regulatory Guide 1.144 Rev (1) - Auditing of Quality Assurance Programs for Nuclear Power Plants	Alternative	RG 1.144 Rev (1) incorporates ANSI N45.2-12, (1977). The DEC QAP conforms to ANSI N45.2.12-1977 for internal/external audits except Section 4.4.6. In lieu of making recommendations for correcting program deficiencies we will identify the deficiencies to the audited organization. For external audits, the results of the audit will be provided to the audited organization in lieu of the audit report. Also, the re-evaluation may be extended to 15 months and the triennial period as specified in the Reg. Guide may be extended by 3 months as described in Section 17.3.2.4, "Procurement Control." Additionally, the DEC QAP meets regulatory position C.3.b of this regulatory guide, as clarified by NRC Information Notice 86-21, Supplement 2. Internal Technical Audits shall require a response describing corrective action and implementation schedule as requested by the audit report but not to exceed sixty days of receipt of the audit report. The requirements of Section C.3.b(2) are accepted with the following interpretation: When purchasing commercial-grade calibrations services from calibration laboratories accredited by a nationally-recognized accrediting body, the accreditation process and accrediting body may be credited with carrying out a portion of the purchaser's duties of verifying acceptability and effective implementation of the calibration service supplier's QA program. Nationally-recognized accrediting bodies include National Voluntary Laboratory Accreditation Program (NVLAP)

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
		administered by the National Institute of Standards and Technology (NIST) and other accrediting bodies recognized by NVLAP via a Mutual Recognition Agreement (MRA). In lieu of performing an audit, accepting an audit by another licensee, or performing a commercial-grade supplier survey, a documented review of the supplier's accreditation shall be performed by the purchaser. This review shall include, at a minimum, verification of the following: 1. The accreditation is to ANSI/ISO/IEC 17025. 2. The accrediting body is either NVLAP or an accrediting body recognized by NVLAP through MRA. (NVLAP or American Association for Laboratory Accreditation (A2LA)) 3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties. 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.)
Regulatory Guide 1.146 Rev (0) – Qualification of QA Program Audit Personnel for Nuclear Power Plants	Alternative	The DEC QAP conforms to ANSI/ASME N45.2.23 – 1978 except Section 2.3.4. In lieu of prospective lead auditors participating in a minimum of five QA audits within a period of three years prior to date of certification, prospective lead auditors shall demonstrate their ability to effectively lead an audit team and shall have participated in at least one nuclear QA audit within one year preceding the individual's effective date of qualification. Upon

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
		successful demonstration of the ability to lead audits, and having met the other provisions of ANSI N45.2.23-1978, the individual may be certified as being qualified to lead audits. This process is described in approved procedures which require documentation of the evaluation and demonstration of results.
Regulatory Guide 1.152 Rev (0) – Criteria For Programmatic Digital Computer System Software In safety-Related Systems of Nuclear Power Plants	Not applicable	Regulatory Guide does not apply to plants prior to 11/85
Regulatory Guide 4.15 Rev (1) – Quality Assurance For Radiological Monitoring Program (Normal Operations) – Effluent Streams and the Environment	Adopted	Adopted at Oconee, McGuire, and Catawba via various site procedures that meet the intent of the Regulatory Guide.
Regulatory Guide 7.10 Rev (1) – Establishing QAPs For Packaging Used In The Transport of Radioactive Material	Alternative	The DEC QAP conforms to the intent of this Regulatory Guide as addressed in each station's UFSAR.
Criteria 1 of Appendix A to 10CFR 50	Conforms	------
10CFR 50, Appendix B – Quality Assurance Criteria for Nuclear Power Plants	Conforms	------
10CFR 50.55a – Licensing of Production and Utilization Facilities (ASME Boiler and Pressure Vessel Code, Section XI - Rules for Inservice Inspection of Nuclear Reactor Coolant Systems)	Conforms	10CFR 50.55a Specifies ASME Section XI Code dates. The DEC QAP conforms to 10CFR 50.55a with the specific editions and addenda of Section XI specified in the In-service Inspection (ISI) Plan for each station.
10CFR 55 – Operators Licenses	Conforms	-------
10CFR 55, Appendix A – Requalification Programs for Licensed Operators of Production and Utilization Facilities	Conforms	-------

Table 17-1 Conformance of DEC's Program to Quality Assurance Standards, Requirements and Guides		
Standard, Requirement or Guide	**Conformance Status**	**Remarks**
10CFR 50.55(e) – Conditions of Construction Permits	Conforms	-------
10CFR 21	Conforms	-------
Regulatory Positions 2 & 4 of Branch Technical Position CMEB 9.5-1	Conforms	Fire protection controls are in accordance with the intent of regulatory positions 2 & 4 of Branch Technical Position CMEB 9.5-1 as stated in the Safety Evaluation Reports for the respective nuclear stations.
Generic Letter 89-02, NCIG-07.	Conforms	-------

17.1 QA DURING DESIGN AND CONSTRUCTION

Deleted

17.2 OPERATIONAL QA

Deleted

17.3 QUALITY ASSURANCE PROGRAM (QAP) DESCRIPTION

17.3.1 MANAGEMENT

17.3.1.1 Methodology

The Group Executive, Chief Generation and Chief Nuclear Officer is the corporate executive responsible for quality assurance (QA) and is the highest level of management responsible for establishing DEC's QA policies, goals, and objectives. The QAP Policy Statement, issued by the Chairman, President and Chief Executive Officer as shown in Figure 17-1, assigns this responsibility and requires development of and compliance with procedures in all QA Condition 1 matters. All organizations performing quality affecting activities are bound by this Policy Statement. The QAP has been developed in accordance with this Policy Statement. 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 begins with initial design and continues throughout the life of the station. The DEC QAP must assure that the necessary quality requirements for QA Condition 1 structures, systems, components and materials are achieved. All special equipment, environmental conditions, skills and processes that are determined to be QA Condition 1 will be provided within the scope of the QAP.

QA Condition structures, systems, and components are specified by approved design documents and directives.

This program applies to the QA Condition 1 portions of the plant but may also be optionally applied, in whole or in part, to other selected items necessary for reliable operation. Section 17, "Quality Assurance" identifies those items currently included under the DEC QAP.

17.3.1.2 Organization

17.3.1.2.1 Corporate Organization

The Chairman, President and Chief Executive Officer has overall responsibility for Design, Construction, and Operation of generation and transmission facilities. Reporting to the Chairman, President and Chief Executive Officer is the Chief Nuclear Officer who has the overall authority and responsibility for the QAP and directs several activities including the operation of the nuclear sites through the executive of Nuclear Operations. Also reporting to the Chairman, President and Chief Executive Officer are Group Executives responsible for providing support to Nuclear Generation for the following: electrical transmission; electrical distribution; laboratory services; switchyard maintenance and technical support; support for the emergency response communications; Information Technology Services; document control and record management activities; and administration of the Access Authorization, Fitness for Duty, and Fatigue Rule programs. 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, therefore, transmitted to all levels of management.

Organization charts for the Nuclear Corporate Off-Site Organizations and the Nuclear Site Organizations are shown in Figures 17-2 and 17-3 respectively.

Organization charts for various departments/locations are contained in Chapter 13 of the respective Station Updated Final Safety Analysis Report.

17.3.1.2.2 Nuclear Generation

Nuclear Generation has direct line responsibility for all DEC 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 Chief Nuclear Officer.

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

a) Nuclear Site Organization

The executive of Nuclear Operations reports to the Chief Nuclear Officer. The Nuclear Site Vice Presidents report to the executive of Nuclear Operations. Each Site Vice President is responsible for the administration, implementation, and assessment of the QAP as it applies to station operation. In the discharge of their responsibilities, the Site Vice President directs the activities of the station organizations.

Reporting to the Site Vice President for each nuclear station is a Nuclear Station Manager who is assigned the direct responsibility for the safe operation of the facility. The qualification requirements for the Nuclear Station Manager are in accordance with the provisions of ANSI N18.1 as presented in each station's UFSAR. Each site also has an Engineering manager responsible for systems engineering and modifications; a Safety Assurance manager responsible for regulatory and environmental compliance, emergency planning, performance improvement, and security; a Site Services manager responsible for acquisition, management and maintenance services for tools, equipment and commercial facilities required for the operation of the nuclear station; and a Site Training manager.

b) Nuclear General Office

Nuclear Generation, Nuclear General Office (NGO) is organized into three divisions. The activities of each division are directed by an executive who reports to the Chief Nuclear Officer. The three divisions within the Nuclear General Office are: Nuclear Corporate, Nuclear Major Projects, and Nuclear Development.

Nuclear Corporate

The executive for Nuclear Corporate is responsible for independent nuclear oversight, nuclear engineering, plant support, centers of excellence, and the employee concerns program.

Independent Nuclear Oversight (INOS)

INOS provides support and leadership to the general office and nuclear sites with QA program audits, performance assessment, procurement quality, supplier verification, and QA, QC, NDE, and ISI. In addition, INOS provides an advisory function to senior management through the NSRB. The INOS manager has the

authority and organizational freedom to: identify quality problems, initiate, recommend or provide solutions to quality problems through designated channels, verify the implementation of solutions to quality problems, and ensure cost and schedule do not influence decision making involving quality. The INOS manager has unfettered access to the Chief Nuclear Officer to communicate QA program concerns and issues.

The INOS manager is delegated primary ownership of the department QA program description and is responsible for day-to-day administration of the program and resolution of QA issues.

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

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.

Plant Support

Plant Support provides support to the stations for rotating equipment, reactor services (fuel handling, head activities, and dry fuel storage), safety assurance (NRC interface, licensing and regulatory compliance group, fleet emergency preparedness, fleet security team, and fleet performance improvement team), scientific services (fleet radiation protection, fleet chemistry, TLD laboratory, standards lab and radiological/environmental lab), centralized training and inprocessing, and operations/work control.

Centers of Excellence

Centers of Excellence provide governance and oversight of the nuclear fleet and our fleet excellence model, promoting fleet consistency and industry best practices among the nuclear plants.

Employee Concerns

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

Nuclear Major Projects

Nuclear Major Projects is responsible for contracts, engineering and management related to fleet and nuclear site major projects.

Nuclear Development

The Nuclear Development Division coordinates and provides oversight for the contracts, licensing, and construction of new nuclear generation projects.

17.3.1.2.3 Department Interfaces

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

Enterprise Operations Services

Enterprise Operations Services provides record storage and document management services for Nuclear Generation.

Generation Support

Generation Support provides support for the nuclear sites in the areas of decommissioning, workforce planning and development, document management, technology planning, and project control leadership.

Human Resources

Human Resources provides support for the nuclear sites by administering the Access Authorization, Fitness for Duty (FFD), and Fatigue Rule programs.

Information Technology

Information Technology provides a variety of services and technical support to Nuclear Generation for information technology applications and systems such as equipment databases, applications, infrastructure, and plant process information systems. IT provides development and maintenance of selected information technology services and support, including electronic document management.

Power Delivery

Power Delivery is responsible for electrical transmission, distribution and switchyard engineering, maintenance, and testing support.

Regulated Fleet Generation

Regulated Fleet Generation provides relay engineering and switchyard maintenance support services to the nuclear sites.

Supply Chain

Nuclear Supply Chain, which is a division of Supply Chain, provides procurement services, storage, inventory control, and receipt inspection/testing.

17.3.1.3 Responsibility

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.

Corporate audits are initiated and directed by the Chief Nuclear Officer. This audit is performed biennially to assess the adequacy of the QAP. This audit is discussed in greater detail in Section 17.3.3.2.4, "Corporate Audit."

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. Sufficient personnel are available and trained with necessary resources prior to performing activities that affect quality.

17.3.1.4 Authority

Anyone involved in quality activities in the DEC organization has the authority and responsibility to stop work if they discover deficiencies in quality. Personnel performing QA and quality control 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. If a member of the group performing the work disagrees, they are instructed to take the matter to their management. The disagreement may either be resolved at this level or at any level up to and including the Chairman, President and Chief Executive Officer.

17.3.1.5 Personnel Training and Qualification

A training program is established for each nuclear station and support organization to develop and maintain an organization qualified to be responsible for operation, engineering, testing, inspection, maintenance, engineering changes and other technical aspects of the nuclear station involved. The program is formulated to provide the required training based on individual employee experience and intended position. The program is in compliance with NRC licensing requirements, where applicable. The training program is such that trained and qualified operating, maintenance, work control, engineering, inspection, testing, technical support and supervisory personnel are available in necessary numbers at the times required. In all cases, the objectives of the training program shall be to assure safe and reliable operation of the station.

The training program is kept current to reflect station engineering changes and changes in procedures. A continuing effort is used after a station goes into commercial operation for training of replacement personnel and for periodic retraining, reexamining, and/or recertifying as required to assure that personnel remain proficient. Personnel receive formal orientation training in basic QA policies and practices.

Personnel receive additional formal training, as appropriate, which addresses specific topics such as NRC regulations and guides, QA procedures, auditing and applicable codes and standards. Special training of personnel in QA related matters, particularly new or revised

requirements, is conducted as necessary. Training and qualification records are maintained for each employee. Documentation of formal training includes the objectives, content of the program, attendees, and date of attendance.

17.3.1.6 Corrective Action

DEC has established a corrective action process whereby all personnel are to assure conditions adverse to quality are promptly identified, controlled, and corrected. This process is administered to correct the problem and its cause rather than establish blame or fault. This process also provides for trending of problems to detect adverse trends in quality performance, including reporting of results to appropriate levels of management. This process is discussed in Section 17.3.2.13, "Corrective Action."

17.3.1.7 Regulatory Commitments

The DEC QAP commits to applicable QA regulations, codes, and standards as identified in Table 17-1, Conformance of DEC QAP to Quality Assurance Standards, Requirements and Guides.

September 2011

DUKE ENERGY CORPORATION
QUALITY ASSURANCE PROGRAM
POLICY STATEMENT

Duke Energy Carolinas (Duke) has developed a comprehensive nuclear quality assurance program, described in the *Duke Energy Carolinas Topical Report*, to answer our needs and the regulatory requirements established by the Nuclear Regulatory Commission and other jurisdictional authorities for safe and effective design, construction, operation, and modification of nuclear stations. This program has my unqualified support and is to be followed at all times.

The authority and responsibility to administer the quality assurance program is assigned to the Chief Nuclear Officer.

The quality assurance program is documented in quality and administrative manuals prepared by the involved departments and approved by the responsible department heads. These manuals delineate the actions taken by Duke personnel during the design, construction, operation, testing, refueling, maintenance, repair, and modification of its nuclear stations.

The department heads of all the corporation's departments engaged in nuclear activities are responsible for implementing procedures required by the quality assurance program. These responsibilities are established in Service Level Agreements and Interface Agreements as defined by nuclear directives.

Duke personnel are given authority commensurate with their responsibility; all employees have 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.

All matters concerning quality that cannot be resolved through the normal interfaces among departments shall be referred to the Chief Nuclear Officer. Matters that cannot be resolved at this level shall be referred to me for final resolution.

Jim Rogers
Chairman, President, and CEO
Duke Energy

TOPICAL REPORT
QUALITY ASSURANCE PROGRAM

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

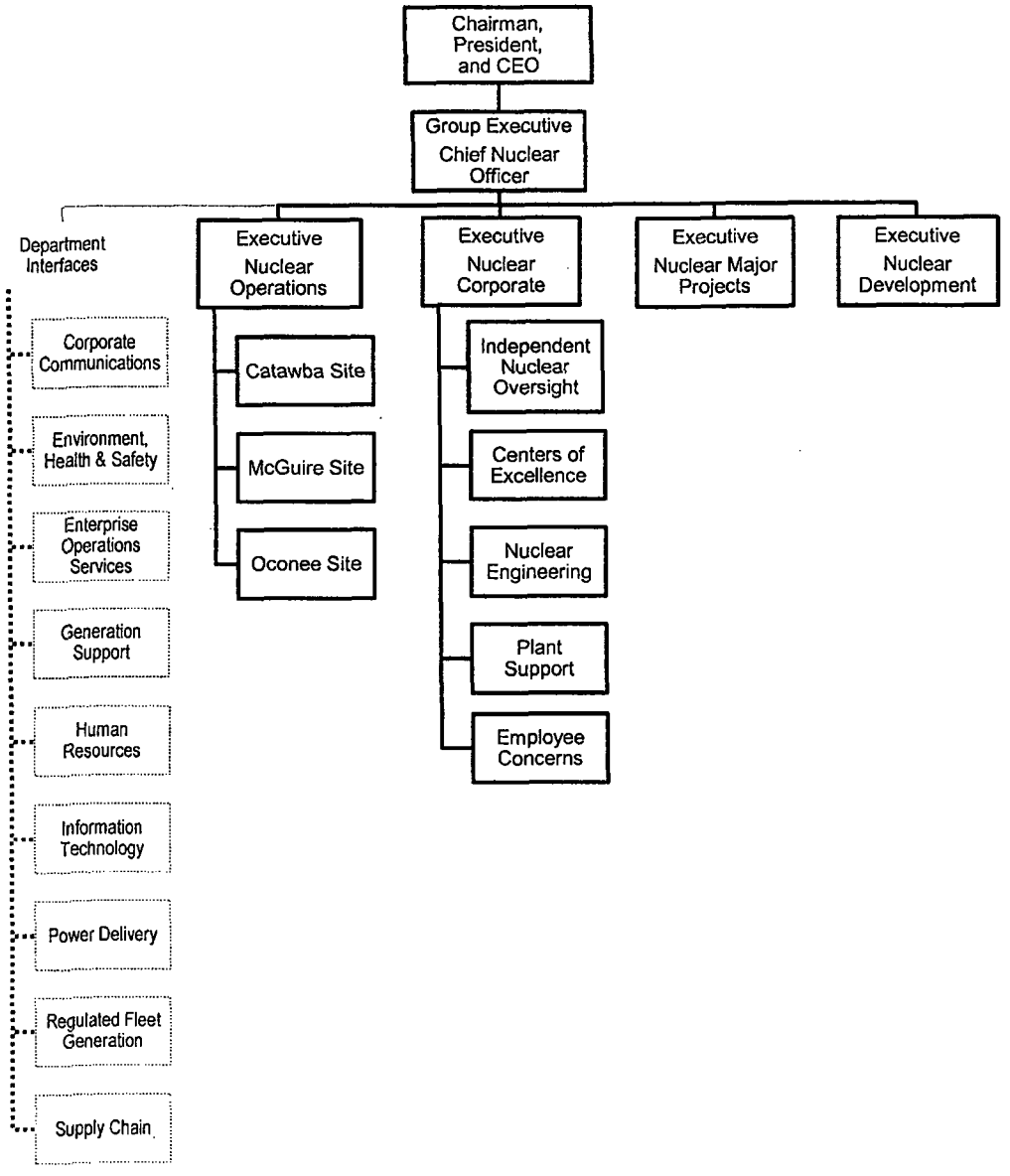

Figure 17-2. Corporate and Offsite Organization

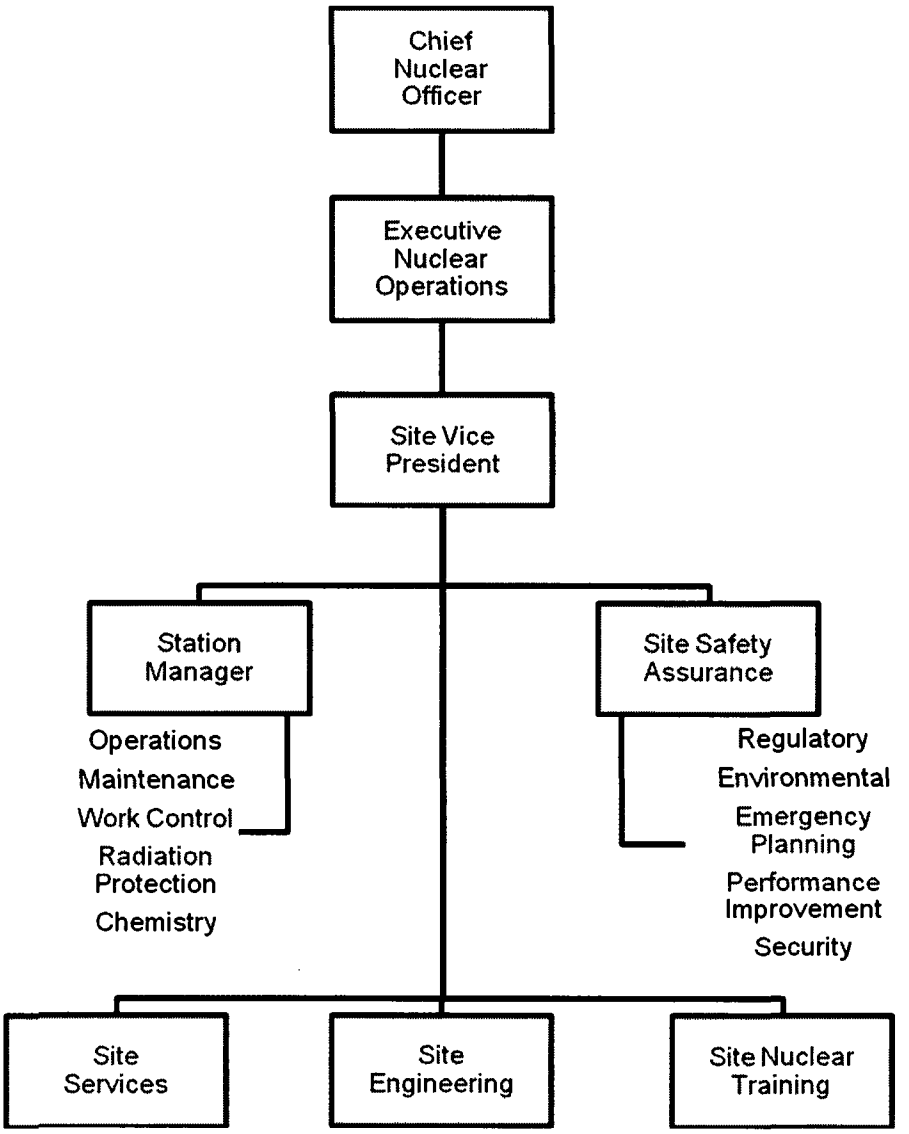

Figure 17-3. Nuclear Site Organization

17.3.2 PERFORMANCE/VERIFICATION

17.3.2.1 Methodology

The DEC QAP is described in various Corporation manuals. Procedures and work instructions necessary to implement the requirements of the QAP are developed and approved by the organization responsible for the activity. These procedures and instructions may be contained in manuals, station procedures and directives, administrative instructions and/or other documents. These documents identify the criteria to determine acceptable quality for the activity being performed. On-site implementation of procedures and work instructions is the responsibility of the Site Vice President. Verification of quality against these documents is performed by means of inspections, tests, audits, and reviews. Procedures for such inspections, audits and reviews are developed and approved by the responsible implementing manager.

The program receives on-going review and is revised as necessary to assure its continued effectiveness.

17.3.2.2 Design Control

In order to provide for the continued safe and reliable operation of a nuclear station's QA Condition 1 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.

DEC has assigned the responsibility for design activities during the operational phase of nuclear stations to Nuclear Generation.

The QAP establishes procedures and instructions for implementation and assurance of design control during the operational phases for QA Condition 1 items. These procedures and instructions assure the design is performed in accordance with approved criteria, and that deviations and nonconformances are controlled.

Each QA Condition 1 design document, such as a calculation, specification, or drawing, is prepared by a knowledgeable individual who specifies and includes the appropriate codes, standards, SAR commitments, and other design input within the design documents. The preparer notes any deviations or changes from such standards within the design documentation package. Each design document is then checked by another individual qualified in the same discipline and is reviewed for concept and conformity with applicable codes, standards, and other design inputs (as specified within the design documentation package). The document is approved by the individual having overall responsibility for the design function. A review of each specification is made to assure incorporation of necessary QA information. The entire review process is documented.

Prior to the release of any QA Condition 1 design document, it is reviewed to assure coordination of disciplines. If the document clearly involves no coordination with the other disciplines, this review may be waived by the sponsor, with documented concurrence by the other disciplines.

In order to assure proper interface control, the responsibilities of the various individuals/organizations involved in engineering changes are formally identified. The assignment of responsibility for the evaluation and design of a particular engineering change to a specific individual/organization is documented. Also, the written instructions addressing the

control of engineering changes address the communication of information between involved individuals/organizations and, where appropriate, require documentation of such communications.

For each proposed 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.

Final approval prior to implementation of each station engineering change shall be by the Nuclear Station Manager or the Manager of Engineering; or for the Nuclear Station Manager by the Operations Superintendent, the Maintenance Superintendent, the Work Control Superintendent, or the On-Duty Emergency Coordinator as previously designated by the Nuclear Station Manager. 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.

Errors and deficiencies noted in the design of an engineering change are corrected by means of an EC Revision. The control measures applied to each such EC Revision are equivalent to the control measures applied to the engineering change originally. Each EC Revision and the review and approval thereof, is documented.

Prior to an engineering change being declared operable and returned to service, all procedures governing the operation of the engineering change 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.

Computer programs are controlled in accordance with appropriate department procedures, whereby programs are certified to demonstrate their applicability and validity.

17.3.2.3 Design Verification

During the check and review of design documents, particular emphasis is placed on assuring conformance with applicable codes, quality standards, SAR design commitments, and other design input. The individuals assigned to perform the check and review of a QA Condition 1 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 Chief Nuclear Officer by individuals in Nuclear General Office or to the Site Vice President by individuals in Site Engineering for resolution. The checker verifies calculations by checking or by alternate computations. Analytical models, theories, examples, tables, codes, computer programs, etc., used as bases for design must be referenced in the design document and their

application verified during check and review. Model tests, when required, to prove the adequacy of concept or design are reviewed and approved by the responsible engineer. The tests used for design verification must meet all the requirements of the designing activity. Computer programs are controlled in accordance with the applicable QA Manual whereby programs are certified to demonstrate their applicability and validity.

Design verification may consist of reviews, alternate calculations, and/or qualification testing. Design reviews are intended to verify the correctness of design inputs, logic, calculations, and analyses. Calculations by alternate methods provide assurance that, for instance, computer codes are performing as expected, and that no systematic error in calculation procedures exists. Qualification testing, when suitable, is guided by DEC's adoption of various regulatory guides which deal with qualification testing. Qualification testing will simulate the most adverse design conditions that are expected to be encountered. Design verification is performed by qualified individuals in accordance with approved procedures which identify the responsibilities, features and pertinent considerations to be verified such as verification method, design parameters, acceptance criteria, and documentation requirements. Design verification is required to be completed before relying on the item to perform its function and 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 individual/organization assigned responsibility for evaluation and design of a engineering change performs an evaluation of the proposed engineering change. This evaluation provides the bases for whether or not the engineering change requires a license amendment. This evaluation is reviewed by an individual/group other than the individual/group performing the evaluation, but who may be from the same organization as the individual/group which performed the evaluation. This evaluation and the review thereof are documented.

Following completion of design and evaluation of an engineering change, the responsible individual/organization summarizes the engineering change design and identifies the design documents and information required for engineering change implementation. This addresses such items as:

a) A description of the engineering change.

b) References utilized in the evaluation and design of the engineering change, and necessary for the implementation of the engineering change.

c) Special installation instructions.

d) Operational, test, maintenance and inspection requirements.

e) Materials, parts and components required in order to implement the engineering change.

f) Drawings revised and/or requiring revision.

g) UFSAR revision(s) and/or Technical Specifications amendment(s) necessary.

h) Whether or not the engineering change requires a license amendment.

The reviews of the proposed engineering change, including applicable implementing procedures associated therewith, certify that QA requirements have been met and determine inspection requirements prior to implementation of the engineering change. Engineering changes which

are determined to require a license amendment are reviewed by the PORC and must be authorized by the NRC prior to implementation.

17.3.2.4 Procurement Control

The DEC QAP requires the control of QA Condition 1 items or services purchased from a supplier, subsupplier, or consultant through appropriate processes and specific procurement documents. Pertinent provisions of 10CFR50, Appendix B are applied to these organizations. If a supplier is providing commercial-grade calibration services and is accredited by a nationally-recognized accrediting body as described in Table 17-1 for Regulatory Guides 1.123 and 1.144, a documented review of the supplier's accreditation by the purchaser may be used in lieu of inspections or tests following delivery or in-process surveillances during performance of the service. This review shall include, at a minimum, all of the following:

1. The accreditation is to ANSI/ISO/IEC 17025.
2. The accrediting body is either National Voluntary Laboratory Accreditation Program (NVLAP) or an accrediting body recognized by NVLAP through an MRA. (NVLAP or American Association for Laboratory Accreditation (A2LA))
3. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

   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 QAP supplements appropriately the ASME Code QA requirements with the regulatory guides listed in Table 17-1, with the clarifications or alternatives stated therein.

Procurement of QA items is to the quality program requirements in effect at the time of purchase.

Nuclear Generation is responsible for the technical qualification of suppliers and control of the initial procurement of all QA Condition 1 items and services. Procurement requirements/specifications are prepared, checked, and approved by appropriate personnel and forwarded to the Nuclear Supply Chain division, who prepares an inquiry and forwards it to approved suppliers. INOS-Procurement Quality is responsible for qualification of supplier QA programs.

QA Condition 1 material, equipment and services procured as basic components may only be procured from qualified suppliers. Supplier qualification is accomplished by an INOS-Procurement Quality evaluation of the supplier QA program. An audit or pre-award survey is performed by INOS-Procurement Quality 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 10CFR50, Appendix B, the ASME Code when required, and any other codes and standards determined to be appropriate for the prospective scope of supply. The audit or survey includes a review of the supplier QA program manuals. The audit team prepares a formal audit report which states whether or not the supplier is qualified to supply the specific items or services. The audit report is reviewed and approved or disapproved by the INOS-Procurement Quality Manager. Approved suppliers of basic components will then be included on the Qualified Supplier List. Technical qualifications are determined by engineering personnel. Commercial qualification is determined

by the Nuclear Supply Chain division following evaluation of bids from qualified suppliers. Bid evaluation includes evaluation of the technical, quality and commercial qualifications of the prospective suppliers.

When QA Condition 1 basic components and services are procured from a supplier whose quality performance has not been verified by audit, additional assurance of product quality shall be obtained by supplier surveillance, inspection or test.

The Manager, INOS-Procurement Quality may place a supplier on the Qualified Suppliers List following review, approval and acceptance of an audit performed by another licensed nuclear utility or joint utility audit team. Review of such third party audits shall ensure that items to be procured are within the audit scope and any unique plant quality and technical requirements are adequately addressed by such audits.

INOS-Procurement Quality will perform a documented on-going evaluation of each supplier in order to maintain the supplier on the Qualified Suppliers List. Where applicable, this evaluation will take into account (1) review of supplier-furnished documents such as certificates of conformance, nonconformance notices, and corrective actions, (2) results of previous source verifications, audits, and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources (e.g., customer, ASME, or NRC audits). The results of the evaluations will be reviewed and appropriate corrective action will be taken. Adverse findings resulting from these evaluations will be periodically reviewed in order to determine if, as a whole, they result in a significant condition adverse to quality and to provide input to support supplier audit activities conducted by the licensee or a third party auditing entity. Additionally, suppliers will be re-evaluated by means of an audit at least triennially, if initial approval was by audit or survey. The triennial audit requirement may be extended by 3 months, from 36 to 39 months, with written approval of the Manager, INOS-Procurement Quality. Extensions would be on an infrequent basis for reasons such as: accommodating manufacturing schedules, synchronizing with other utility audits, or allowing time for implementation of supplier QA program changes.

Materials, parts and components shall be procured to specified technical and quality requirements at least equivalent to those applicable to the original equipment or those specified by a properly reviewed and approved revision. As required by the applicable purchase documents, suppliers furnish documentation which identifies the material and equipment purchased and the specific procurement requirements met by the items. Also, as required by the applicable purchase documents, suppliers will provide documentation which identifies any procurement requirements which have not been complied with, together with a description of any deviations and repair records.

When QA Condition 1 products/services are not supplied as a basic component and meet the definition of commercial grade, 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 QA Condition 1 applications require evaluation, dedication and approval by Nuclear Generation personnel. Supplier selection for commercial grade items is the responsibility of the responsible engineering personnel. These items are subject to the same verification and checking process for suitability of application as other QA Condition 1 items.

Critical characteristics for the dedication of Commercial Grade Items are determined by Procurement Engineering or Nuclear Supply Chain technical sponsors and approved by the responsible engineering personnel based on the manufacturer's published specifications and the intended safety function for the items. Critical characteristics used for acceptance and dedication of commercial grade items are selected to provide reasonable assurance that the items will meet their catalog or manufacturer specifications and will perform the necessary

safety functions in the intended applications. Verification of critical characteristic acceptability will be by manufacturer/supplier survey, source verification, receipt tests or inspections, or post installation testing. Historical data, when documented, will represent industry wide experience.

If verification of a critical characteristic is to be by supplier survey, INOS-Procurement Quality is responsible for verifying the acceptability of the supplier control of the identified critical characteristic.

Procurement of materials, parts, components and services associated with QA Condition 1 structures, systems, and components is controlled during the operational life of the station so as to assure the suitability for their intended service and that the safety and reliability of the station are not compromised.

Procurement information for materials, parts, components, and services associated with QA Condition 1 structures, systems and components is identifiably designated as such. The procurement requirements applicable to each item are determined by a cognizant individual. This determination is reviewed by another cognizant individual who may be from the same organization as the individual/group making the determination. Procurement information must include or reference other documents such that sufficient information is fully identified to specify the items being procured. Subsequent to preparation, procurement information is approved by the Procurement Engineering or Nuclear Supply Chain manager or designee who is qualified by experience and training for the function.

Procurement information for QA Condition 1 materials, parts and components is reviewed to assure that QA, technical and regulatory requirements including supplier documentation requirements are adequately incorporated into the purchase document(s). Significant changes to the content of such purchasing information are reviewed and approved in a manner consistent with the original.

Where necessary, procurement documents require that QA Condition 1 materials, parts, and components be acquired from suppliers determined to be acceptable by INOS-Procurement Quality – see Section 17.3.3.2.3.2, "Independent Nuclear Oversight-Procurement Quality." Determination of acceptability requires that a supplier provide DEC the right of access to the supplier's facilities and records for inspection and audit.

Except for some commercial grade items each shipment of items procured from a supplier must be accompanied by a certificate of conformance (or equivalent) which identifies the applicable procurement documents and item(s). The certificate and supplier documentation specifies that the item meets the procurement requirements and includes repair records and a description of any deviations. This documentary evidence must be on site (any location under the QA Program) and all procurement, inspection, and testing requirements satisfied before the item is placed in service or used.

Nuclear Generation personnel will review and approve this documentary evidence of item conformance with procurement requirements.

17.3.2.5 Procurement Verification

The approved procurement documents along with all quality and technical requirements are provided to the supplier by Nuclear Supply Chain. Procurement information is provided to the INOS-Procurement Quality section and the receiving location.

As required by procurement criteria, in order to assure that material and equipment are fabricated in accordance with applicable requirements, supplier review, audit and surveillance are performed by the INOS-Procurement Quality section. The review, audit and surveillance

may include witnessing of tests, observation of fabrication checkpoints, and documentation review. Evaluation of overall supplier performance is performed at intervals and to a depth consistent with the item's or service's importance to safety, complexity, and the quantity and frequency of procurement.

Procedures are established which implement the surveillance program for suppliers. This assures that items and services procured for use in nuclear QA Condition 1 applications are in compliance with applicable procurement requirements/specifications.

These procedures provide for surveillance of those characteristics or processes to be witnessed, inspected or verified. Surveillance activities assure that the supplier complies with all quality requirements outlined in the procurement document(s). The surveillance report becomes a part of the INOS-Procurement Quality section files. The surveillance representative has the authority and responsibility to stop work when the required quality standards are not met.

Upon receipt, QA Condition 1 materials, parts and components are placed in a controlled, designated area and are subjected to a receipt inspection. This inspection is intended to determine whether or not each item received conforms with applicable procurement requirements. Such inspections and the subsequent determination of conformance or nonconformance are documented by means of reports, which are retained on file and as appropriate, by tags attached to the items. Until a determination of conformance is made, a QA Condition 1 material, part or component cannot be placed in service.

17.3.2.6 Identification and Control of Items

Control of materials, parts, and components at nuclear sites is the ultimate responsibility of the Chief Nuclear Officer with responsibilities delegated to Nuclear Supply Chain.

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

a) Materials, parts, components, assemblies, and subassemblies shall be identified either on the item or records traceable to the item to show that only correct items are received, issued and installed.

b) Some components, such as pressure vessels are identifiable by nameplates as required by applicable codes, or DEC specifications. Materials, parts, and components are traceable from such identification to a specific purchase order to manufacturer's records and to QA records and documentation.

c) When required by procurement documents, materials are identified by heat, batch or lot numbers which are traceable to the original material at receipt. Upon receipt, a unique tracking number is assigned to provide traceability. When several parts are assembled, a list of parts and corresponding numbers is included in the documentation.

d) When required by specifications or codes and standards, identification of material or equipment with the corresponding mill test reports, certifications and other required documentation is maintained throughout the life of the material or equipment by a unique tracking number.

e) Sufficient precautions will be taken to preclude identifying materials in a manner that will affect the function or quality of the item being identified.

Control of material, parts and components is governed by approved procedures. Specific control requirements include:

a) Nonconforming or rejected materials, parts, or components are identified to assure that they will not be inadvertently used.

b) The verification of correct identification of material, parts, and components is required prior to release for assembling, shipping and installation.

c) Upon receipt, procedures require that materials, parts or components undergo a receipt inspection to assure they are properly identified and that the supporting documentation is available as required by the procurement requirements/specifications. Items having limited shelf or service life are identified and controlled.

d) Each organization which performs an operation that results in a change in the material, part or component is required to make corresponding revisions and/or additions to the documentation record as applicable.

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 QA Condition 1 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. When a designated item is subdivided, each subdivision is identified in accordance with the above requirements. Where physical identification of an item is impractical or insufficient, physical separation, administrative controls or other appropriate means are utilized.

17.3.2.7 Handling, Storage, and Shipping

The QAP requires that QA Condition 1 materials, parts and components be handled, stored, issued and shipped in such a manner that the serviceability and QA traceability of an item is not impaired. Handling, storage and shipping of an item is in accordance with any special requirements identified in documents pertaining to the item. Such requirements may include special handling tools and equipment, special protective coverings and/or special protective environments. Items are to be marked or labeled to preserve the item's integrity and indicate the need for any special controls. Procedures identify predetermined requirements for handling, preservation, storage, cleaning, packaging, issuing and shipping and are utilized by suitably trained individuals.

Conforming QA Condition 1 materials, parts and components are stored in controlled, segregated areas designated for the storage of such items. Inspections and examinations are performed on a periodic basis to assure that recommended shelf life of chemicals, reagents, and other consumable materials is not exceeded. Hazardous items are stored in suitable environments with controls to prevent contamination of QA Condition 1 structures, systems, or components.

Nonconforming items are identified, segregated, or otherwise controlled (e.g. by a conditional release) 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 QA Condition 1 structures, systems and components

demonstrate that they 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." Also, specific criteria are established with regard to procedure content. Examples of items which must be considered in the preparation and review of procedures include:

a) References to material necessary in the preparation and performance of the procedure, including applicable design documents.

b) Tests which are required to be completed prior to, or concurrently with, the specified testing.

c) Special test equipment required to perform the specified testing.

d) Limits and precautions associated with the testing.

e) Station, unit and/or system status or conditions necessary to perform the specified testing.

f) Criteria for evaluating the acceptability of the results of the specified testing, compatible with any applicable design specifications.

Test procedures contain the following information or require this information be documented:

a) Requirements and acceptance limits contained in applicable design and vendor documents.

b) Instructions for performing the test.

c) Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation including their accuracy requirements, completeness of the item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.

d) Mandatory inspection hold points.

e) Acceptance and rejection criteria.

f) Methods of documenting or recording test data and results.

g) Provisions to assure test prerequisites have been met.

Requirements are also established for verification of test completion and for determining acceptability of tests results. Test results are reviewed and accepted by the testing organization and the organization responsible for the item being tested. In the event that test results do not meet test acceptance criteria, a review of the test, test procedure and/or test results is conducted to determine the cause, required corrective action, and retest as necessary.

In addition to the above periodic testing, after maintenance to, or modification of, QA Condition 1 structures, systems and components, other post maintenance testing, post modification testing, or functional verifications are performed and documented as required to verify satisfactory performance of the affected items. Post maintenance/modification functional verifications are not subject to the requirements of periodic testing described above because they are acceptable good industrial practices that are simple and straightforward. Included in

these tests are such items as diesel generators, reactor control rod systems, and leak testing of appropriate pressure isolation valves.

17.3.2.9 Measuring and Test Equipment Control

The organizations performing QA Condition 1 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 QA Condition 1 structures, systems and components and that a program of control and calibration for such devices is provided. This program includes the following:

a) Devices are assigned permanent, identifying designations.

b) Devices are calibrated at prescribed intervals, and/or prior to use, against certified equipment having known, valid relationships to nationally recognized standards. The calibration interval for a device is based on the applicable manufacturer's recommendations. If experience dictates that the manufacturer's recommendations are not appropriate, the calibration interval is changed as necessary.

c) Devices that have been acceptably calibrated are affixed, where practical, with a tag, or tags, showing the date of calibration, the date the next calibration is due, an indication that the device is within calibration specifications and the identification of the individual who was responsible for performing the calibration. When attaching tags is not practical, the device is traceable by unique identification to the applicable calibration records.

d) Devices which fail to meet calibration specifications are affixed with a tag, or tags, showing the date of rejection, the reason for rejection and the identification of the individual rejecting the device. "Accepted" and "Rejected" calibration tags are sufficiently different to preclude confusion between them.

e) Items and processes determined to be acceptable based on measurements made with devices subsequently found to be out of calibration are re-evaluated.

f) Devices stored under conditions which are in accordance with, or more conservative than, the applicable manufacturer's recommendations.

g) Devices are issued under the control of responsible personnel so as to preclude unauthorized use.

h) Devices are shipped in a manner that is in accordance with, or more conservative than, the applicable manufacturer's recommendations.

i) Records are maintained on each device which identify such items as the device designation and the calibration frequency and specifications. Records are maintained to reflect current calibration status.

j) As a rule, the calibration program achieves a minimum ratio of 4-to-1 calibration standard accuracy to measuring and test equipment accuracy unless limited by the state of the art; however, when an accuracy ratio of less than 4-to-1 is utilized, an evaluation of the specific case is made and documented.

Installed instrumentation is subject to the requirements of the Technical Specification and is not subject to the tagging requirements discussed in (c) and (d) above. The INOS-Audit section verifies implementation of the calibration program through periodic audits.

The basis for this exception on the installed Technical Specification required equipment is the Preventive Maintenance Periodic Testing (PMPT) program. This is a computerized scheduling program that automatically schedules PMPT using model work orders. When devices have been acceptably calibrated, the clock starts for the next calibration due date. The indication that the device is within calibration specifications and identification of the individual who was responsible for performing the calibration is documented within the calibration procedure for the device. If the device fails to meet calibration specifications, it will be repaired, replaced and/or engineering involvement will be requested to further evaluate. The PMPT program along with the calibration procedures address all the requirements in Topical Report Sections 17.3.2.9 c and d listed above. Therefore, there is no need to place tags on the devices to identify the calibration status.

17.3.2.10 Inspection, Test, and Operating Status

In order to assure that equipment status is clearly evident, and to prevent inadvertent operation, the QAP requires QA Condition 1 structures, systems and components which are in an other than operable status to be identified as such. This identification may be means of tags, labels, stamps or other suitable methods. 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.

Inspections and tests required by the written approved procedures which address work activities are infrequently, temporarily deferred. When such a deferral does occur, a discrepancy is considered to exist and documentation of the acceptable completion of the affected work activity is not performed until the discrepancy is resolved.

Proposed tests and experiments which affect station nuclear safety and are not addressed in the Updated Final Safety Analysis Report or Technical Specifications shall be prepared and approved in a manner identical to that used for station procedures as described in Section 17.3.2.14, "Document Control." These proposed tests and experiments shall be reviewed by a knowledgeable individual/organization other than the individual/organization which prepared the proposed tests and experiments.

Measures taken to identify equipment inspection and test status by Nuclear Generation personnel are controlled by Nuclear Generation.

17.3.2.11 Special Process Control

The Nuclear Station Manager is responsible for directing the organization and performance of the station's program for the control of special processes, and for assuring the necessary qualified personnel are available.

Nuclear Generation is responsible for furnishing qualified personnel, performance of and documentation of NDE.

The QAP contains or references procedures for the control of special processes such as welding, heat treating, NDE, coatings, crimping, and cleaning. The program requires that approved, written procedures, qualified in accordance with applicable codes and standards, be utilized when the performance of such processes affects the proper functioning of QA Condition 1 structures, systems, and components. These procedures shall provide for

documented evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

Personnel performing such activities must be qualified in accordance with applicable codes and standards. Adequate documentation of personnel qualifications is required prior to performance of the applicable special process. NDE personnel are certified to required codes and standards.

17.3.2.12 Inspection

In order to assure safe and reliable operation, a program of inspections for QA Condition 1 structures, systems, and components is established at each nuclear station. Inspection procedures for those activities affecting QA Condition 1 structures, systems and components are established by Nuclear Generation personnel.

Independent inspections, examinations, measurements, observations, or tests of materials, products or activities are conducted, where necessary, to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel is provided. Both inspection and process monitoring are provided when control is inadequate without both.

Inspection procedures, instructions, and checklists contain the following information or require this information on inspection reports:

a) Characteristics to be inspected

b) Method of inspection

c) Measuring and test equipment information

d) Responsibility for the inspection

e) Acceptance or rejection criteria

f) Identification of required procedures, drawings, specifications, etc.

g) Signature or initials of inspector

h) Record of results of the inspection

The personnel performing these inspections are examined and certified in their particular category. Current qualification and certification files are maintained for each inspector. NDE inspectors are certified in accordance with ANSI/American Society for Non-destructive Testing (SNT-TC-1A, ANSI/SNT-CP-189) recommended practice. Written procedures require the test and certification of inspectors in other categories such as Mechanical, Electrical, and Structural as described in the appropriate QA manual. For cases where inspectors will perform limited functions within a category, they are tested and certified to those limitations. These inspectors are only allowed to perform inspections specifically defined in this limited certification.

For inspections of concrete containments, personnel fulfilling the role of Responsible Engineer, shall be a Registered Professional Engineer experienced in evaluating the in-service condition of structural concrete and knowledgeable of the design and construction codes and other criteria used in the design and construction of the concrete containment structure. The Responsible Engineer may also perform inspections as discussed in this section.

Certification procedures and certifications are approved by Nuclear Generation personnel responsible for these processes. These procedures comply with the requirements of applicable codes and standards.

The inspection criteria for performing inspections are established from codes, specifications, and standards applicable to the activity. Examples of activities subject to inspection include:

a) Activities specified by the ASME Code Section XI

b) Special processes

c) Modifications

d) Maintenance

e) Material Receipt

Inspection requirements for maintenance or engineering changes are equivalent to the original design and inspection requirements, or acceptable alternatives. Mandatory inspection hold points are included in the documents addressing the activities being performed, as necessary, and work does not proceed beyond such hold points until satisfactory completion of the required inspection, disposition of any item not meeting the acceptance criteria, and any required reinspection.

After inspection data is collected and reviewed by the inspector, the reports are technically reviewed by personnel designated to perform that QA function.

Inspection activities involving the supplier QAP are evaluated and approved by INOS-Procurement Quality.

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 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. Performance and verification personnel are to:

a) Identify conditions that are adverse to quality.

b) Suggest, recommend, or provide solutions to the problems as appropriate.

c) Verify resolution of the issue.

Additionally, performance and verification personnel are to ensure that reworked, repaired, and replacement items are to be inspected and tested in accordance with the original inspection and test requirements or specified alternatives.

For significant incidents occurring during operation where a safety limit is exceeded, or which could otherwise be related to the nuclear safety of the station, the Site Vice President shall be notified and reports are generated. These reports:

a) Contain a summary description of the circumstances and information relating to the subject incident.

b) Contain an evaluation of the effects of the incident.

c) Describe corrective action taken or recommended as a result of the incident.

d) Describe, analyze and evaluate any significant QA Condition 1 implications of the incident.

Such reports shall be reviewed by the Nuclear Station Manager (or for the Nuclear Station Manager by: 1) the Operations Superintendent, 2) the Maintenance Superintendent, 3) or the Work Control Superintendent, as previously designated by the Nuclear Station Manager) and approved by the Manager, Safety Assurance. Such reports shall be provided to the Site Vice President, the PORC, the NSRB, and the NRC as required by applicable regulations. Outstanding corrective action commitments made with regard to such incidents are identified and periodically reviewed to assure that the identified corrective actions are properly completed and documented. An identified corrective action commitment is closed out upon written notification by a cognizant, responsible individual or other written documentation, of the satisfactory completion thereof. Closure of corrective action commitments which specifically involve other Department(s) require written notification by the other Department(s) of the satisfactory completion thereof.

All violations of Technical Specifications, safety limit violations, and all other reportable events shall be investigated and a report prepared which evaluates the occurrence and which provides recommendations to prevent recurrence. Such reports and other special reviews and investigations shall be reviewed by a knowledgeable individual/organization other than the individual/organization which prepared the report. Reports of safety limit violations shall be reviewed by the Nuclear Station Manager and the Operations Superintendent. A knowledgeable individual/organization shall review every unplanned onsite release of radioactive material to the environs and prepare reports covering evaluation, recommendations, and disposition of the corrective action to prevent recurrence. All special reviews and investigations, and the preparation of reports thereon, shall be performed by a knowledgeable individual/organization.

Electronic processes are used to track, trend, and to facilitate in the resolution of site problems. Additionally, these electronic processes are used to measure and classify nuclear performance. Identified problems are considered for generic implications. Monthly reports are processed electronically and are also provided directly to senior management and the NSRB.

Discrepancies revealed during the performance of station operation, maintenance, inspection and testing activities must be resolved prior to verification of the completion of the activity being performed. In the event of a significant malfunction of QA Condition 1 structures, systems, and components, the cause of the failure is evaluated and appropriate corrective action taken. Items of the same type are evaluated to determine whether or not they can be expected to continue to function in an appropriate manner. This evaluation is documented in accordance with applicable procedures.

QA Condition 1 materials, parts and components which are determined to be nonconforming are identified, segregated or otherwise controlled (e.g. by a conditional release) in such a manner as to preclude their inadvertent substitution for and use as conforming materials, parts and components. The determination of an item's nonconformance is documented and is retained on file by Nuclear Generation and, as appropriate, by tags attached to the item. Nuclear Generation personnel are notified of any nonconformances identified in accordance with approved procedures.

Nuclear Generation maintains a listing of the status of all nonconformance documents. These reports, when complete, identify the nonconforming material, part or component; applicable inspection requirements; and the resolution, and approval thereof, of the nonconformance. Provisions are established for identifying those personnel with the responsibility and authority for approving the resolution of nonconformances. Until a determination of conformance is

made, a QA Condition 1 material, part or component cannot be placed in service. Tags which are placed on items to identify nonconformances are removed upon resolution.

Information relating to nonconforming materials, parts and components is analyzed by Safety Assurance to determine if any discernible trends which might affect quality exist. When recurring nonconformances indicate possible supplier deficiencies, such information is considered in evaluation of supplier acceptability by INOS-Procurement Quality.

Significant trends will be/are reported to appropriate levels of management.

17.3.2.14 Document Control

The Nuclear Policy Manual establishes the policies and instructions governing activities associated with DEC's nuclear stations and identifies the various departments performing these activities. These activities include measures to control the issuance of documents such as, instructions, procedures, and drawings, and changes thereto, which prescribe all activities affecting quality. This manual is approved by the Chief Nuclear Officer, or the Site Vice Presidents, or designee. These manuals are considered controlled documents and copies are distributed by distribution indices from the Manager, Licensing and Regulatory Compliance or designee.

The station Facility Operating License and Technical Specifications are considered NRC controlled documents and are distributed within DEC by appropriately authorized personnel under the cognizance of the site Regulatory Compliance Manager. Proposed changes to the station Facility Operating License or Technical Specifications shall be prepared in accordance with appropriate administrative controls by a knowledgeable individual/organization. Each proposed change shall be reviewed by a knowledgeable individual/organization other than the individual/organization that prepared the proposed change. Proposed changes to the station Facility Operating License and Technical Specifications shall be approved by the Nuclear Station Manager, or for the Nuclear Station Manager by a designated manager or corporate officer. Submittal cover letters for proposed changes to the station Facility Operating License and Technical Specifications shall be signed by an officer of Duke Energy Carolinas.

The Safety Analysis Reports are considered controlled documents and are distributed by cover letter from the Site Vice President or his designee.

The Nuclear Policy Manual and the manuals listed below specify the requirements for the development, review, approval, issue, control, and use of manuals and procedures to implement the requirements contained within the Topical Report.

The Nuclear Policy Manual also provides the governing procedures for the INOS organization, the PORC and the NSRB. This manual is approved by the Site Vice Presidents or designee, except for the NSRB procedure, which is approved by the Chief Nuclear Officer.

The Nuclear Supply Chain Process Manual contains the policies and procedures that control nuclear procurement and supplier qualification. This manual imposes requirements on all departments involved with procurement. This manual is approved by the Chief Nuclear Officer or designee.

With regard to specific operational activities associated with QA Condition 1 structures, systems and components, it is required that such activities be accomplished in accordance with procedures, instructions, drawings, and checklists, appropriate to the nature of the activities being performed. As necessary, such documents identify equipment necessary to perform an activity, specify conditions which must exist prior to and during performance of an activity, and include quantitative and/or qualitative acceptance criteria, compatible with any applicable design

specifications, for determining that the activity addressed is satisfactorily accomplished. Also, the procedure will require independent verification by qualified personnel of the performance of specific procedural steps. Examples of documents established concerning quality related operational activities are:

a) Preoperational Test Procedures

b) Periodic Test Procedures

c) Operating Procedures

d) Emergency Procedures

e) Maintenance Procedures

f) Instrument Procedures

g) Radiation Protection Procedures

h) Alarm Responses

i) Chemistry Procedures

j) Process Control Program Implementing Procedures

k) PORC Implementing Procedures

l) Abnormal Procedures

m) Emergency Response Procedures

Procedures are reviewed for adequacy based upon: lessons learned from normal use, audits, unusual incidents (such as an accident, unexpected transient, significant operator error, or equipment malfunction), station engineering changes, the operating experience program, root cause analysis, or the corrective action program. The frequency of review for Abnormal Procedures, Emergency Procedures, and Emergency Response Procedures shall not exceed six years. Procedures that have not been used for six years shall be reviewed before reuse to determine if changes are necessary or desirable. Reviews of procedures can be accomplished in several ways, including (but not necessarily limited to) documented step-by-step use of the procedure (such as occurs when the procedure has a step-by-step checkoff associated with it), or detailed scrutiny of the procedure as part of a documented training program, drill, simulator exercise, or other such activity. A revision of a procedure can constitute a procedure review.

A knowledgeable individual/organization shall review changes to the Process Control Program, Offsite Dose Calculation Manual, radiological effluent controls of the UFSAR, and radwaste treatment systems. A knowledgeable individual/organization shall review the Fire Protection Program and implementing procedures. Changes to the Offsite Dose Calculation Manual shall be reviewed for acceptability by either the Radiation Protection Manager or the Station Manager.

In addition to the above, files of drawings and supplier documents applicable to the station's structures, systems and components are maintained at each nuclear station and are utilized, as appropriate, in the performance of quality related activities.

Station procedures which address activities associated with QA Condition 1 structures, systems and components are subjected to a well-defined and established preparation, review, and approval process. This process includes the requirement that procedures be prepared by a knowledgeable individual/organization. This process also includes the requirement that each procedure be reviewed for adequacy by an individual/organization other than the individual/organization which prepared the procedure. As appropriate, such procedures are

also reviewed by personnel from the Nuclear General Office, by other departments within the Corporation, by the NSRB, or by vendor personnel. Individuals responsible for procedure reviews and reviews of changes to the radiological effluent controls of the UFSAR performed in accordance with this Section shall have been previously designated by the Chief Nuclear Officer or direct reports, or Site Vice President or direct reports to perform such reviews and have as a minimum a high school diploma or equivalent and four years of technical experience. Review of environmental radiological analysis procedures shall be performed by the manager of the environmental laboratory, or designee. Each such review shall include a determination of whether or not additional, cross-disciplinary, review is necessary. If deemed necessary, such review shall be performed by the appropriate designated review personnel. Reviews performed in accordance with this Section shall be documented. Approvals shall be by the Site Vice President or his/her direct reports or one of their designees. Each procedure and changes thereto, shall be reviewed and approved prior to implementation. Temporary changes to procedures may be made provided: a) the intent of the original procedure is not altered; and b) the change is approved by two members of the plant management staff, at least one of whom holds a Senior Reactor Operator License on the affected unit; and c) the change is approved by an appropriate division manager, superintendent/manager, or one of their designated direct reports within 14 days of implementation. For procedures which implement offsite environmental, technical, and laboratory activities, the above approval may be performed by the manager of the environmental laboratory, or designee. Maintenance, instrumentation, and modification procedures are reviewed by cognizant station personnel to determine the need for inspections. Procedures developed and implemented for inspection identify the certifications, inspection methods, acceptance criteria, and provide means for documenting inspection results.

In the case of station activities of a non-recurring nature, e.g., preoperational tests, only an original copy of an approved procedure is available for use. Such copies are controlled and are replaced whenever the procedure is superseded by a new issue. For activities which are of a recurring nature, e.g., surveillance testing, current original copies of approved procedures are maintained in a controlled manner. Copies of these original copies are then utilized in the performance of work activities. When such "working copies" involve the documentation of compliance with acceptance criteria contained in the procedure, the "working copy" of the procedure utilized is compared with the applicable original copy to assure validity. Station procedures administratively control and provide means to document this comparison. Such completed procedures are retained - See Section 17.3.2.15, "Records." When recurring work activities do not involve documentation of compliance with acceptance criteria within the procedure, e.g., certain operating activities, issuance of the applicable "working copies" is controlled to assure that only current copies are available for use.

Drawings and supplier documents, as-built drawings and changes thereto, are normally received from Engineering for distribution and use. Distribution indices are established and utilized for such documents within each station in order to assure their proper distribution and use. A master file of drawings is maintained and a master index, updated regularly, is used to identify drawings, revisions, number of copies, and distribution. Design and procurement documents are maintained, controlled, and are updated, as necessary, by Engineering. As documents are received from Engineering all superseded copies shall be destroyed or clearly marked superseded.

A master copy of all controlled documents is maintained in the document control area of each station. Copies of controlled documents are distributed by station document control personnel utilizing a distribution index to assure proper distribution and use. Station line organizations may maintain the index of records for technical procedures under their organizational responsibility. These station line organizations may directly issue control copies without

issuance directly from Document Control personnel. Document Control personnel will review the index of records periodically for station line organizations that maintain an index and issue control documents in this manner. Controlled documents may also be provided to station personnel by use of an electronic medium. Reviews are performed regularly and documented to assure proper functioning of the control system.

17.3.2.15 Records

Each nuclear station is required to maintain adequate identifiable and retrievable QA records. Records may be stored in electronic media provided that the process for managing the stored data is documented in procedures that comply with applicable regulations. Media used for retention of records include (but are not limited to): microform, compact disk recordable (CD-R), and magnetic media including videotape, computer tape, optical disks, and hard disk storage. Electronic records retention must be 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 during the required retention period. Electronic approval and authorization procedures are established to assure that only those persons authorized grant the required approvals.

Such records are managed in a controlled and systematic manner by means of a station Master File Index. Access to, and use of, this file is controlled. Some records noted below may be generated by the Nuclear General Office and are retained at one of the nuclear stations. Records required to be retained include:

a) QA Condition 1 preoperational testing records.

b) Records of engineering changes to station QA Condition 1 structures, systems and components described in the Updated Final Safety Analysis Report.

c) Radiation monitoring records, including records of radiation and contamination surveys.

d) Personnel radiation exposure records.

e) Records of radioactive releases, shipments, and waste disposal.

f) Isotopic and physical inventory records of special nuclear materials.

g) Records of the qualifications, experience and training of appropriate station personnel.

h) Current calibrations for measuring and test devices.

i) Copies of approved purchasing documents for items requiring QA certification.

j) Maintenance histories on QA Condition 1 instrumentation and electrical, mechanical, and civil structures, systems, and components.

k) Records of special processes affecting QA Condition 1 structures, systems and components.

l) Copies of purchase specifications.

m) Operating records and logbooks covering time interval at each power level, including: switchboard record, reactor operator logbook, and shift supervisor logbook.

n) Periodic testing records.

o) Records of inspections.

p) Copies of approved and of completed station procedures, and changes thereto; including review and approval documentation.

q) Copies of audit reports received from the INOS-Audit section, and responses thereto.

r) Copies of drawings, design specifications, calculations, design analyses, and vendor documents.

s) Copies of reports of all reportable and other significant events.

t) Records of in-service inspections.

u) Records of quality control inspections.

v) 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.

w) Records of the qualifications of quality control and other appropriate personnel.

x) Records of off-site environmental surveys.

y) Records of special reactor tests or experiments.

z) Records of environmental qualification.

aa) Records of the service life of all snubbers, including the date at which seal service life commences and associated installation and maintenance records.

ab) Records of the reviews performed for changes made to the Process Control Program, Offsite Dose Calculation Manual, and Radwaste Treatment Systems.

ac) By-product material inventory records.

ad) Radioactive liquid effluent, gaseous effluent, and gaseous process monitoring instrumentation alarm/trip setpoints.

ae) Records of sealed source and fission detector leak tests and results.

af) Records of annual physical inventory of all sealed source material of record.

ag) Records of new and irradiated fuel inventory, fuel transfers, and assembly burnup histories.

ah) Records of review performed for changes made to procedures; or modifications to station structures, systems, and components; or reviews of tests and experiments pursuant to 10CFR50.59.

ai) Records of secondary water sampling and water quality.

aj) Records of analyses required by the Radiological Environmental Monitoring Program that would permit evaluation of the accuracy of the analysis at a later date. This should include procedures effective at specified times and QA records showing that these procedures were followed.

ak) Records of component cyclic or transient limits established for the reactor coolant system, reactor vessel, and secondary coolant system.

al) Records of reviews performed for changes made to Radiological Effluent Controls.

am) Records of reviews performed on the Fire Protection Program and implementing procedures.

an) Calibration standard records and Measuring and Test Equipment (M & TE) calibration records.

Test, inspection, and NDE records for QA Condition 1 structures, systems, and components are maintained by the station and contain the following:

a) A description of the activity performed.

b) The date and results of the activity.

c) Information relating to discrepancies identified with regard to the activity.

d) An identification of the data recorder(s) or inspector(s) involved in the activity.

e) Evidence of the completion, and verification thereof, of the activity.

f) An identification of the acceptability of the results of the activity.

Records of activities within the purview of the NSRB are maintained. These records include:

a) NSRB meeting minutes.

b) Audit reports for audits conducted under the cognizance of the NSRB.

Records of activities within the purview of INOS-Performance are maintained. These records include:

a) Records of assessments performed on station activities.

b) Records of special reviews and investigations.

c) Copies of special reports.

Records of activities within the purview of the PORC are maintained. These records document the meetings of the PORC for each site. These records include:

a) Identification of the chairperson for each meeting.

b) A listing of the PORC members present at each meeting.

c) A listing of others present at each meeting.

d) A summary of the items/issue(s) discussed during each meeting.

e) The decisions/approvals reached by the PORC during each meeting.

Records of activities within the purview of the Nuclear General Office are maintained. These records include:

a) Supplier audit reports and surveillances.

b) Audit reports of Duke Energy Corporation activities.

c) Audit and Supplier personnel qualification records.

d) NDE inspection personnel certification records.

e) Laboratory QA records.

Records for major station projects will be maintained at that station as appropriate. These records include:

a) Copies of procurement documents.

b) Copies of vendor documents.

Records of activities within the purview of the department interfacing organizations are maintained by these departments in a manner similar to that described above for station QA records or transferred to the station, as appropriate. These records include:

a) Laboratory QA records.

b) Environmental records.

c) Software requirements.

d) Software test plans.

e) Software test results.

f) Program/Module specifications and source codes.

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 until the NRC terminates the license or Certificate of Compliance.

The retention times for the various QA records are in accordance with corporate retention policies. The development of these retention policies includes 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. To the maximum extent practicable, records are stored such that they are protected from possible destruction by causes such as fire, flooding, theft, insects and rodents and from possible deterioration due to a combination of extreme variations in temperature and humidity conditions.

Record storage areas shall be evaluated by a qualified Fire Protection Engineer to assure the records are adequately protected from damage. The evaluation shall include the following considerations as a minimum:

a) Structural collapse.

b) Unprotected steel (suspended floor slab or roof).

c) Fire frequency of similar occupancies.

d) Quantities of combustible materials.

e) Ceiling height/Room configuration which would contribute to heat dissipation.

f) Fire detection.

g) Fixed fire suppression systems.

h) On-site fire fighting organizations including available equipment.

This evaluation shall be documented for each record storage area (includes satellite file locations).

17.3.3 SELF ASSESSMENT

17.3.3.1 Methodology

The Self-Assessment process encompasses internal and corporate audits, independent review committee activities, in-plant reviews, and other independent assessments. This 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. Organizations performing self-assessment activities are technically and performance oriented, with the primary focus on the quality of the end product and a secondary focus on procedures and processes.

17.3.3.2 Assessment

17.3.3.2.1 Nuclear Safety Review Board

The Chief Nuclear Officer appoints a Nuclear Safety Review Board (NSRB) to serve as a nuclear safety review and audit backup to the normal operating organization.

The NSRB shall function to ensure independent review and audit of designated activities in the areas of: nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, instrumentation and control, radiological safety, mechanical and electrical engineering, and administrative control and QA practices.

The Chair, members, and alternate members of the NSRB are appointed in writing by the Chief Nuclear Officer and shall have an academic degree in an engineering or physical science field; and in addition, shall have a minimum of 5 years technical experience, of which a minimum of 3 years shall be in one or more of the above areas. In special cases, candidates for appointment without an academic degree in engineering or physical science may be qualified with a minimum of ten years experience in one of the above areas. The NSRB shall be composed of at least five members including the Chair, which constitutes a quorum. Alternate Chair/Members may replace Regular Members as necessary. Members of the NSRB may be from the Nuclear Generation, from other departments within the Corporation, or from external to the Corporation. A maximum of one member of the NSRB may be from the nuclear site staff for which a review is being conducted. Consultants shall be utilized as determined by the NSRB Chair to provide expert advice to the NSRB. Staff assistance may be provided to the NSRB in order to promote the proper, timely, and expeditious performance of its functions.

The NSRB shall meet at least twice per calendar year. The NSRB shall ensure independent reviews of and provide oversight for the following items:

a) The evaluations for: (1) changes to procedures, equipment, or systems, and (2) tests or experiments completed under the provision of 10CFR50.59 to verify that such actions did not require a license amendment pursuant to 10CFR50.90;

b) Onsite safety review function (PORC).

c) Review reports that describe violations of Codes, regulations, orders, Technical Specifications, license requirements, or of internal procedures or instructions having nuclear safety significance;

d) Review reports that describe significant operating abnormalities or deviations from normal and expected performance of unit equipment that affect nuclear safety;

e) Review reports that describe reportable events;

f) Review reports that describe all recognized indications of an unanticipated deficiency in some aspect of design or operation of structures, systems or components that could affect nuclear safety; and

g) Review reports that describe QAP audits relating to station operations and actions taken in response to these audits.

Reviews may be conducted by an organizational unit, subgroup, or member of the NSRB. In either case the review body will collectively have requisite knowledge, experience, and competence to perform reviews in the above areas. Organizations/individuals/groups conducting these reviews will functionally report to the Chair of the NSRB.

The NSRB shall report to and advise the Chief Nuclear Officer on those areas of responsibility specified in Items (a) through (g) above.

Minutes of each NSRB meeting where a quorum is required to be present, shall be prepared, approved, and forwarded to the Chief Nuclear Officer and to the Site Vice Presidents within 30 days following each meeting.

17.3.3.2.2 Plant Operations Review Committee

Each Site Vice President appoints a Plant Operations Review Committee (PORC) to review selected nuclear safety related issues. The PORC is composed of specified senior members of the site management team most responsible for the safe and reliable operation of the station. The PORC also reviews the effectiveness of corrective actions taken for specified reportable events. The PORC shall review and recommend approval of items requiring NRC approval prior to station approval for implementation. The reviews shall include:

a) Proposed changes to procedures, equipment or systems which when evaluated under the provisions of 10CFR50.59 require a license amendment pursuant to 10CFR50.90;

b) Proposed tests or experiments which involve a license amendment pursuant to 10CFR50.90 as defined in 10CFR50.59; and

c) Proposed changes to the stations' Facility Operating Licenses, including Technical Specifications prior to implementation except in those cases where the change is identified to a previously proposed change.

In discharging its independent review responsibilities, PORC shall keep safety considerations paramount when opposed to cost or schedule considerations. Should a voting member have direct responsibility for the preparation or technical review of the item requiring PORC independent review, where a conflict of such considerations is likely, that member shall be replaced (to fill the quorum) by another voting member.

In discharging its independent review responsibilities the PORC shall provide meeting minutes that include a detailed description of items reviewed, key discussion points with questions/responses, and recommendation, including the basis for the determination made.

17.3.3.2.3 Independent Nuclear Oversight

The Manager, INOS provides guidance and support to section managers INOS-Audit, INOS-Procurement Quality, and INOS-Performance, who have responsibilities described in the following sections. Also reporting to the INOS Manager is a manager with responsibilities for INOS-Inspection, which are described in Section 17.3.2.12.

17.3.3.2.3.1 INOS-Audit

The DEC QAP requires a comprehensive system of planned and periodic internal audits for all phases of station operations and supporting activities.

All organizational units conducting QA activities are evaluated with a system of audits. These audits are performed to determine the effective implementation of all applicable criteria of 10CFR 50, Appendix B. Periodic audits of activities or records of processes (e.g., welding, maintenance, development of design, record management, or system testing), to verify

compliance and effectiveness of the implementation of the QAP are performed. Internal audits are initiated under the direction of the Manager, INOS-Audit. The Manager, INOS may initiate special audits or expand upon the scope of an existing audit. The scope of each audit is determined by the responsible Lead Auditor, under the direction of the Manager, INOS-Audit. Additionally, the scope of audits performed under the cognizance of the NSRB is reviewed by the NSRB staff. The lead auditor directs the audit team in developing checklists, instructions, plans and in the performance of the audit. The audit shall be conducted in accordance with checklists; the scope may be expanded upon by the audit team during the audit, if needed. One or more persons comprise an audit team, one of whom shall be qualified lead auditor.

Audits of site activities shall be performed under the cognizance of the NSRB. These audits shall encompass:

a) The conformance of each nuclear unit's operation to provisions contained within the Technical Specifications and applicable Facility Operating License conditions;

b) The performance, training, and qualifications of the entire station staff;

c) The results of actions taken to correct deficiencies occurring in unit equipment, structures, systems, or method of operation that affect nuclear safety;

d) The performance of activities required by the QAP to meet the criteria of 10CFR50, Appendix B;

e) The Emergency Plan and implementing procedures;

f) The Security Plan and implementing procedures;

g) The Facility Fire Protection programmatic controls including the implementing procedures;

h) The fire protection equipment and program implementation utilizing either a qualified offsite license fire protection engineer or an outside independent fire protection consultant. An outside independent fire protection consultant shall be used at least every third year;

i) The Radiological Environmental Monitoring Program and the results thereof;

j) The Offsite Dose Calculation Manual and implementing procedures;

k) The Process Control Program and implementing procedures for Solidification of radioactive wastes;

l) The performance of effluent and environmental monitoring activities;

m) Any other area of site operation considered appropriate by the NSRB or the Chief Nuclear Officer;

n) The acceptability of a representative sample of station procedures, including the effectiveness of the procedure review and revision program.

Audits of selected aspects of operational phase activities are performed with a frequency commensurate with safety significance and in such a manner as to assure that an audit of all QA Condition 1 functions is completed within a period of two (2) years. Except when the audit frequency is specified by regulation, the following criteria for extending audit intervals apply:

1) Schedules shall be based on the month in which the audit starts.

2) A maximum extension not to exceed 25 percent of the audit interval shall be allowed (e.g., audits on a two year frequency shall not be extended beyond 30 months, audits on an annual frequency shall not be extended beyond 15 months).

3) When an audit interval extension greater than one month is used, the next audit for that particular audit area shall be scheduled from the original anniversary month rather than from the month of the extended audit.

The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities.

The audit team concludes with a post-audit conference between the audit team and responsible management. The conference includes a brief discussion of audit results, including any deficiencies and recommendations. The audit results are documented in a report.

Within thirty (30) days of the post-audit conference, a report is issued to the responsible management with copies sent to the Vice President of the audited Site or department, the Chief Nuclear Officer and other management as appropriate.

Within thirty days after receipt of the audit report, responsible management replies in writing to the Manager, INOS-Audit, describing corrective action and an implementation schedule. The established electronic corrective action process may be used to convey this information. When necessary, after receipt of the management reply, a re-evaluation is made to verify implementation of corrective action. This re-evaluation is documented. The audit is closed with a letter to audit management. All pertinent correspondence, checklists, and reports related to the audit are filed.

Audit data are analyzed and the resulting reports on the effectiveness of the QAP, including any quality problems, are reported to management for review and assessment through periodic performance trend summaries. This data is also used to modify the audit schedule as necessary to assess potential weaknesses.

17.3.3.2.3.2 INOS-Procurement Quality

Supplier QA programs are evaluated and monitored by the INOS-Procurement, to assure that QA requirements are met. Supplier QA programs require a system of periodic and planned supplier and sub-supplier audits conducted by persons not directly involved in the activity being audited.

DEC assures that supplier QA programs provide for surveillance, evaluation and approval of sub-supplier supplying items and services. This assurance is accomplished by reviewing supplier audits of sub-supplier as part of the pre-bid audit, by making supplier control of sub-supplier work a criterion for supplier approval or disapproval, and by making supplier surveillance of sub-supplier a requirement of the purchase requisition.

The INOS-Procurement Quality section maintains surveillance and performs audits on suppliers' QA programs including the activities of their suppliers and sub-suppliers, to assure that operations are in compliance with specified QA requirements. In the case of an audit of a supplier, any deficiencies noted by the auditor are clearly outlined in writing and given to the supplier's QA organization, which takes appropriate steps to resolve the deficiencies.

A re-audit is performed, if appropriate, to verify the implementation of the corrective action.

17.3.3.2.3.3 INOS-Performance

The INOS-Performance group conducts assessments, observations or surveillances of specific activities, and processes on the basis of their impact and importance relative to safety.

Assessments can be focused on areas most in need of improvement. An annual assessment of PORC effectiveness shall be conducted at each site by INOS-Performance and the results shall be reported to appropriate management and the NSRB.

A documented plan or agenda identifies an assessment scope, requirements, assessment personnel, activities to be evaluated, organizations to be notified, applicable documents, and schedule.

An annual schedule for assessment activities at each nuclear site shall be established by INOS-Performance personnel and approved by the Manager, INOS-Performance. This schedule should be reviewed every six months to adjust for emerging trends and major changes in processes, procedures or personnel.
Experienced and qualified personnel perform assessments and are familiar with written procedures, standards, and processes applicable to the area being evaluated.
INOS-Performance personnel shall have sufficient authority to make the assessment process meaningful and effective and shall not have direct responsibilities in the areas to be assessed. They shall have access to plant activities and records necessary to fulfill their function.
An assessment team leader shall organize and direct assessments and ensure the team collectively has the required experience or training for the activities to be evaluated.

The assessment report shall be performed in accordance with approved procedures. The report shall include a description of the assessment scope, a summary of the results, and a description of each concern identified.

Assessment results are communicated to the appropriate site managerial level of the organization having responsibility for the area or activity assessed and are documented in the corrective action program. Concerns requiring prompt corrective action are reported immediately to the management of the audited organization and entered into the electronic corrective action program.

Assessment results are documented and periodic reports are provided to senior leadership at each site. Associated documentation is on file at the appropriate location. Personnel qualifications records for assessment personnel are established, maintained and reviewed.

17.3.3.2.4 Corporate Audit

Corporate audits are initiated and directed by the Chief Nuclear Officer. This audit is performed within a period of two years on the DEC QAP.

The Chief Nuclear Officer selects the audit team and appoints a team leader. The audit team consists of at least three qualified individuals, none of which is from the area audited.

The scope of the audit is determined by the Chief Nuclear Officer and the audit team. Each audit includes a review of internal audits performed by the INOS-Audit. The audit is performed with pre-approved checklists, instructions, or plans.

The audit team conducts a post-audit conference with the responsible management of the area audited to discuss the audit results, including deficiencies. The audit team prepares checklists and the audit report. The report is sent to the Chief Nuclear Officer.

The Chief Nuclear Officer and/or responsible management of the area being audited determines the need for corrective action and re-evaluation. Necessary corrective action and re-evaluation are performed as required.

All pertinent correspondence, checklists, and reports related to the audit are filed.