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TOPICAL REPORT
QUALITY ASSURANCE PROGRAM
NUCLEAR ASSESSMENT AND ISSUES

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Q004

DUKE ENERGY CORPORATION
TOPICAL REPORT
QUALITY ASSURANCE PROGRAM

DUKE-1-A

ABSTRACT

This topical report describes the Duke Energy Corporation quality assurance program for the operational phase of its nuclear power plants. The report is organized like and is generally used for Chapter 17, "Quality Assurance" of Duke's Safety Analysis Reports.

The Duke Quality Assurance Program conforms to applicable regulatory requirements such as 10CFR 50, Appendix B and to approved industry standards such as ANSI N45.2-1971 and ANSI N18.7-1976 and corresponding daughter standards, or to equivalent alternatives. The Duke Energy Corporation Quality Assurance Program 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 Quality Assurance Program Policy Statement, issued by the Chairman and Chief Executive Officer, describes the corporate policy and assigns responsibility for implementation of the Quality Assurance Program.

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

Section 17.3, "Quality Assurance Program Description" describes the quality assurance program and organization for station operation.

Section 17.3, "Quality Assurance Program Description" follows the format of NUREG-0800, "Standard Review Plan For The Review of Safety Analysis Reports for Nuclear Power Plants", Section 17.3, "Quality Assurance Program Description," except that the Duke Energy Corporation Quality Assurance Program 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's Quality Assurance Program for nuclear power plants.

M. S. Tuckman being duly sworn states that he is Executive Vice President Nuclear Generation and Chief Nuclear Officer of Duke Energy Corporation; that he is authorized on the part of said corporation to sign and file with the Nuclear Regulatory Commission this amendment to its Topical Report, Duke-1-A; and that all statements and matters set forth herein are true and correct to the best of his knowledge.

M. S. Tuckman

M. S. Tuckman

ATTEST:

James J. Fisicaro

J. J. Fisicaro

Subscribed and sworn to me December 10, 2001
Date

Mary P. Nelms

Mary P. Nelms, Notary Public

My commission expires: JAN 22, 2006

Seal

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Original	March 1, 1974
1	October 1, 1974 (Complete Revision)
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

17. QUALITY ASSURANCE

INTRODUCTION

Duke Energy Corporation 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 Duke has established and implemented a quality assurance program which conforms to the criteria established in Appendix B to 10CFR, Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" published June 27, 1970 (35 F. R. 10499) and amended September 17, 1971 (36 F. R. 18301) and amended January 20, 1975 (40 F. R. 3210D).

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 NRC's Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants - LWR Edition" and subsequent NRC guidelines. The quality assurance program described herein is applicable to all Duke nuclear power plants as referenced by Chapter 17 of the plants' SAR's.

This Topical Report describes the Quality Assurance Program for those systems, components, items, and services which have been determined to be nuclear safety related (QA Condition 1). In addition, Duke's Quality Assurance Program provides a method of applying a graded Quality Assurance Program 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 "Condition" for each level of quality assurance 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.

Subsequent changes to Duke's Quality Assurance Program shall be incorporated in this topical report. The topical report is intended to be a comprehensive up-to-date description of Duke's Quality Assurance Program for nuclear power plants.

Any programmatic changes to the Quality Assurance Program 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.

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

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

Nuclear Station 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.

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 - 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.)

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

Quality Assurance 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 - Those quality assurance 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.

Preaward Survey - A documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that the quality assurance program has been developed, documented, and implemented in accordance with specified requirements.

Variation Notice - A notice to provide a process by which field variations from design drawings and specifications are evaluated and permitted.

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 quality assurance program have been developed, documented and implemented in accordance with specified requirements.

Explanation of "Quality Assurance"

Quality Assurance 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 Nuclear Performance Assessment and Procurement Quality sections and by the Nuclear Safety Review Board in the Nuclear Generation Department. The Quality Assurance program 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 Quality Assurance program places the responsibility on line management of achieving and assuring quality in all areas of their operation. As defined, the Executive Vice President, Nuclear Generation / Chief Nuclear Officer has been given the responsibility to develop and manage a Quality Assurance Program for the Corporation.

QUALITY ASSURANCE STANDARDS AND GUIDES

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

Quality Assurance Program 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 (Page 1 of 7) Conformance of Duke'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. Duke's program 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	Duke's Program conforms to this Regulatory Guide except for additional details and directions noted in Station FSAR's.
Regulatory Guide 1.28 Rev (2) – Quality Assurance Program Requirements (Design and Construction)	Conforms	---
Regulatory Guide 1.29 Rev (3) – Seismic Design Classification	Alternative	Duke's Program conforms to this Regulatory Guide except for additional details and directions noted in Station FSAR's.
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

Table 17-1 (Page 2 of 7) Conformance of Duke's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.33 Rev (2) – Quality Assurance Program Requirements (Operations)	Alternative	RG 1.33 Rev (2) incorporates ANSI N18.7-1976/ANS-3.2. Duke's program 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, modifications, 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.
Regulatory Guide 1.36 Rev. (0) – Nonmetallic Thermal Insulation for Austenitic Stainless Steel	Adopted	Regulatory Guide is adopted for all Austenitic Stainless Steel piping and components located outside containment. Inside containment, reflective Thermal Insulation is used.
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 (Page 2 of 7) Conformance of Duke'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. Duke's program 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.

Table 17-1 (Page 3 of 7) Conformance of Duke's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
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
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 FSAR.
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. Duke's nondestructive examination personnel will meet the qualification requirements of SNT-TC-1A-1980. Duke's operational/functional testing personnel will meet the requirements of ANSI N18.1-1971 rather than ANSI N45.2.6. Also, Duke's 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.

Table 17-1 (Page 3 of 7) Conformance of Duke's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.64 Rev (2) – Quality Assurance Requirements for Design of Nuclear Power Plants	Adopted with Clarification	RG 1.64 Rev (2) Incorporates ANSI N45.2.11-1974. The use of 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.

Table 17-1 (Page 4 of 7) Conformance of Duke's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
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 Duke's 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 Duke Program 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 Duke program for storage of records on optical disks meets the quality controls contained in NRC Generic Letter 88-18.
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.

Table 17-1 (Page 4 of 7) Conformance of Duke's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
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	Conforms	RG 1.123 Rev (1) Incorporates ANSI N45.2.13-1976

Table 17-1 (Page 5 of 7) Conformance of Duke'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). Duke's Program 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, Duke program 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.

Table 17-1 (Page 6 of 7) Conformance of Duke's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Regulatory Guide 1.146 Rev (0) – Qualification of QA Program Audit Personnel for Nuclear Power Plants	Alternative	Duke's Program conforms to ANSI/ASME N45.2.23 – 1979 except Section 2.3.4. In lieu of prospective lead auditors participating in a minimum of five quality assurance 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 quality assurance audit within one year preceding the individual's effective date of qualification. Upon 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 Quality Assurance Programs For Packaging Used In The Transport of Radioactive Material	Alternative	Duke's Program conforms to the intent of this Regulatory Guide as addressed in each Station's FSAR

Table 17-1 (Page 6 of 7) Conformance of Duke's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
Criteria 1 of Appendix A to 10CFR 50	Conforms	------
10CFR 50, Appendix B – Quality Assurance Criteria for Nuclear Power Plants	Conforms	------

Table 17-1 (Page 7 of 7) Conformance of Duke's Program to Quality Assurance Standards, Requirements and Guides

Standard, Requirement or Guide	Conformance Status	Remarks
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 Duke program conforms to 10CFR 50.55a with the specific editions and addenda of Section XI specified in the Duke's Inservice Inspection Plan for each station.
10CFR 55 – Operators Licenses	Conforms	-------
10CFR 55, Appendix A – Requalification Programs for Licensed Operators of Production and Utilization Facilities	Conforms	-------
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 QUALITY ASSURANCE DURING DESIGN AND CONSTRUCTION

Deleted

17.2 OPERATIONAL QUALITY ASSURANCE

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17.3 QUALITY ASSURANCE PROGRAM DESCRIPTION

17.3.1 MANAGEMENT

17.3.1.1 Methodology

The Executive Vice President Nuclear Generation and Chief Nuclear Officer is the corporate executive responsible for quality assurance and is the highest level of management responsible for establishing Duke's quality assurance policies, goals, and objectives. The Duke Energy Corporation Quality Assurance Program 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 Quality Assurance Program has been developed in accordance with this Policy Statement.

The individuals who constitute Duke Energy Corporation 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 Duke Quality Assurance Program 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 Quality Assurance Program.

A controlled listing of QA Condition structures, systems, and components is approved, issued, and periodically updated. Each Nuclear Site Vice President is responsible for approval and issuance after issuance of the operating license.

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 Duke Energy Corporation Quality Assurance Program.

17.3.1.2 Organization

17.3.1.2.1 Corporate Organization

The Duke Corporate organization is shown in Figure 17-2. 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 President Duke Energy Services, who directs several activities including Duke Energy Generating Services. Reporting to the President Duke Energy Generating Services is the Executive Vice President Nuclear Generation and Chief Nuclear Officer who has the overall authority and responsibility for the quality asurance program and directs several activities including the operation of the nuclear sites through their Site Vice Presidents. Also reporting to the Chairman, President, and Chief Executive Officer is the President, Duke Power Group, who directs several activities including Group Human Resources, and Group Environmental, Health and Safety Departments.

Reporting to the Chairman, President and Chief Executive Officer is the Executive Vice President and Chief Administrative Officer, who directs several activities, including the Information Management and the Corporate Services Departments through their respective senior vice presidents.

Reporting to the Chairman, President and Chief Executive Officer is the President, Energy Transmission who directs several activities, including the Electric Transmission Department through its senior vice president.

Duke's organization reflects the concept of quality assurance as an interdisciplinary function involving various groups. 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 various departments/locations are contained in Chapter 13 of the respective Station Final Safety Analysis Report.

17.3.1.2.2 Nuclear Generation Department

The Nuclear Generation Department has direct line responsibility for all Duke Energy Corporation nuclear station operations. The Nuclear Generation Department 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 Executive Vice President, Nuclear Generation and Chief Nuclear Officer.

The Executive Vice President, Nuclear Generation and Chief Nuclear Officer formulates, recommends, and carries out plans, policies, and programs related to the nuclear generation of electric power; and reports to the President, Duke Energy Generating Services. The Executive Vice President, Nuclear Generation and Chief Nuclear Officer is informed of significant problems or occurrences relating to safety and quality assurance through established administrative procedures, and participates directly in their resolution, where necessary.

a) Nuclear Site Organization

The Nuclear Site Vice Presidents (Site Officer) report to the Executive Vice President, Nuclear Generation / Chief Nuclear Officer. The Site Officer is also responsible for the administration, implementation, and assessment of the quality assurance program as it applies to station operation. In the discharge of their responsibilities, the Site Officers direct the activities of the station organizations.

Reporting to the Site Officer for each nuclear station, is a Manager, Nuclear Station who is assigned the direct responsibility for the safe operation of the facility. The qualification requirements for the Manager, Nuclear Station are in accordance with the provisions of ANSI N18.1-1971 and are presented in each station's FSAR.

b) Nuclear Generation Department, Nuclear Generation Office

The Nuclear Generation Department, Nuclear General Office, is divided into four divisions. The activities of each division are directed by a manager who reports to the Executive Vice President, Nuclear Generation. The four divisions within the Nuclear General Office are: 1) Nuclear

Engineering, which provides support to the stations in severe accident analysis, safety analysis, nuclear design, fuels/core management, and plant engineering, (2) Nuclear Services, which provides technical support to the stations in work control, chemistry, radiation protection, steam generator maintenance, quality assurance services, inservice inspection, NDE, and special projects such as RM&C, and steam generator replacement; (3) Nuclear Supply Chain, which provides support to the station in procurement engineering, procurement, and supplier quality and (4) Nuclear Assessment and Issues, which provides technical and business support to the stations in operating experience assessment, operations assessment, business/financial support, special projects such as license renewal, regulatory/industry affairs, NSRB, and regulatory audits. The Nuclear Performance Assessment section has the authority and organizational freedom to:

1) Identify quality problems

2) Initiate, recommend or provide solutions to quality problems through designated channels.

3) Verify the implementation of solutions to quality problems.

4) Ensure cost and schedule do not unduly influence decision-making involving quality.

If significant quality problems are identified by Nuclear Performance Assessment personnel, the Manager, Nuclear Assessment and Issues Division or designee, has the responsibility and authority to notify management to direct the affected work activity to cease pending satisfactory resolution of the identified problem.

17.3.1.2.3 Duke Power Group Human Resources Department

The Duke Power Group Human Resources provides input to Duke Power Group and Energy Transmission Group in such areas as Fitness For Duty and Nuclear Access. The Duke Power Group Human Resources is directed by the Vice President, Group Human Resources who reports to the President, Duke Power Group.

17.3.1.2.4 Duke Power Group Environmental, Health and Safety Department

The Duke Power Group Environmental, Health and Safety Department provides input to the Duke Power Group in such areas as, soils testing and environmental services. The Duke Power Group Environmental, Health and Safety Department is directed by the Vice President, Group Environmental, Health and Safety who reports to the President, Duke Power Group.

17.3.1.2.6 Information Management Department

Information Management is responsible for the development and maintenance of selected information technology services and support for the Nuclear Generation Department, some of which support QA Condition activities and operation of any centralized document storage facility not directly assigned as part of a nuclear site, document management and retention services (the Nuclear Generation Department assesses the quality assurance processes for the Information Management document management function). These activities in Information Management are directed by managers and directors reporting to the Senior Vice President, Information Management.

17.3.1.2.7 Electric Transmission Department

The Electric Transmission Department provides maintenance and testing services to the nuclear stations for se ted electrical equipment. These services are directed by the Senior Vice President, Electric Trans sion who reports to the President, Duke Power Group.

17.3.1.2.8 Duke Power Information Systems

Duke Power Information Systems provides a variety of services and technical support for critical information technology applications and systems such as equipment data bases, plant process information systems, electronic document management, and operation of any document management and retention services. These activities, within Information Systems, are directed by managers and directors reporting to the Vice President, Duke Power Information Systems.

17.3.1.2.9 Department Interfaces

Quality related activities are performed by Nuclear Generation, Duke Power Group Human Resources, Duke Power Group Environmental, Health and Safety, Corporate Services and Information Management Departments. Departmental interfaces are identified in the quality assurance program manuals associated with these areas. Quality related activities performed by the Electric Transmission, Duke Power Group Environmental, Health and Safety, Information Systems, and the Information Management Departments are identified by and conducted in accordance with approved departmental interface agreements.

Organization charts for these departments are maintained in appropriate manuals for the respective departments.

17.3.1.3 Responsibility

The individuals who constitute the Duke Energy Corporate Organization 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 Quality Assurance Program.

Corporate audits are initiated and directed by the Executive Vice President, Nuclear Generation / Chief Nuclear Officer. This audit is performed biennially to assess the adequacy of the Quality Program. This audit is discussed in greater detail in Section 17.3.3.2.5, "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 Duke organization has the authority and responsibility to stop work if they discover deficiencies in quality. Personnel performing quality assurance 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 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, modification 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 Nuclear Regulatory Commission licensing requirements, where applicable. The training program is such that trained and qualified operating, maintenance, 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 modifications 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 quality assurance policies and practices.

Personnel receive additional formal training, as appropriate, which addresses specific topics such as NRC regulations and guides, quality assurance procedures, auditing and applicable codes and standards. Special training of personnel in quality assurance 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

Duke 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

Duke management is committed to applicable quality assurance regulations, codes, and standards as identified in Section 17, "Quality Assurance, Quality Assurance Standards and Guides" of this report.

Duke Energy.

Richard B. Priory
Chairman, Presidents and
Chief Executive Officer

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June 18, 2001

DUKE ENERGY CORPORATION
QUALITY ASSURANCE PROGRAM
POLICY STATEMENT

Duke Energy Corporation has developed a comprehensive quality assurance program, described in the 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 Executive Vice President Nuclear Generation and 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 Energy Corporation 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.

Duke Energy Corporation personnel are given authority commensurate with their responsibility, including the authority to stop work that does not conform to established requirements. This stop work authority must be exercised in accordance with approved procedures.

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

R. B. Priory

TOPICAL REPORT
QUALITY ASSURANCE PROGRAM

Figure 17-1 Duke Energy Corporation Quality Assurance Policy Statement

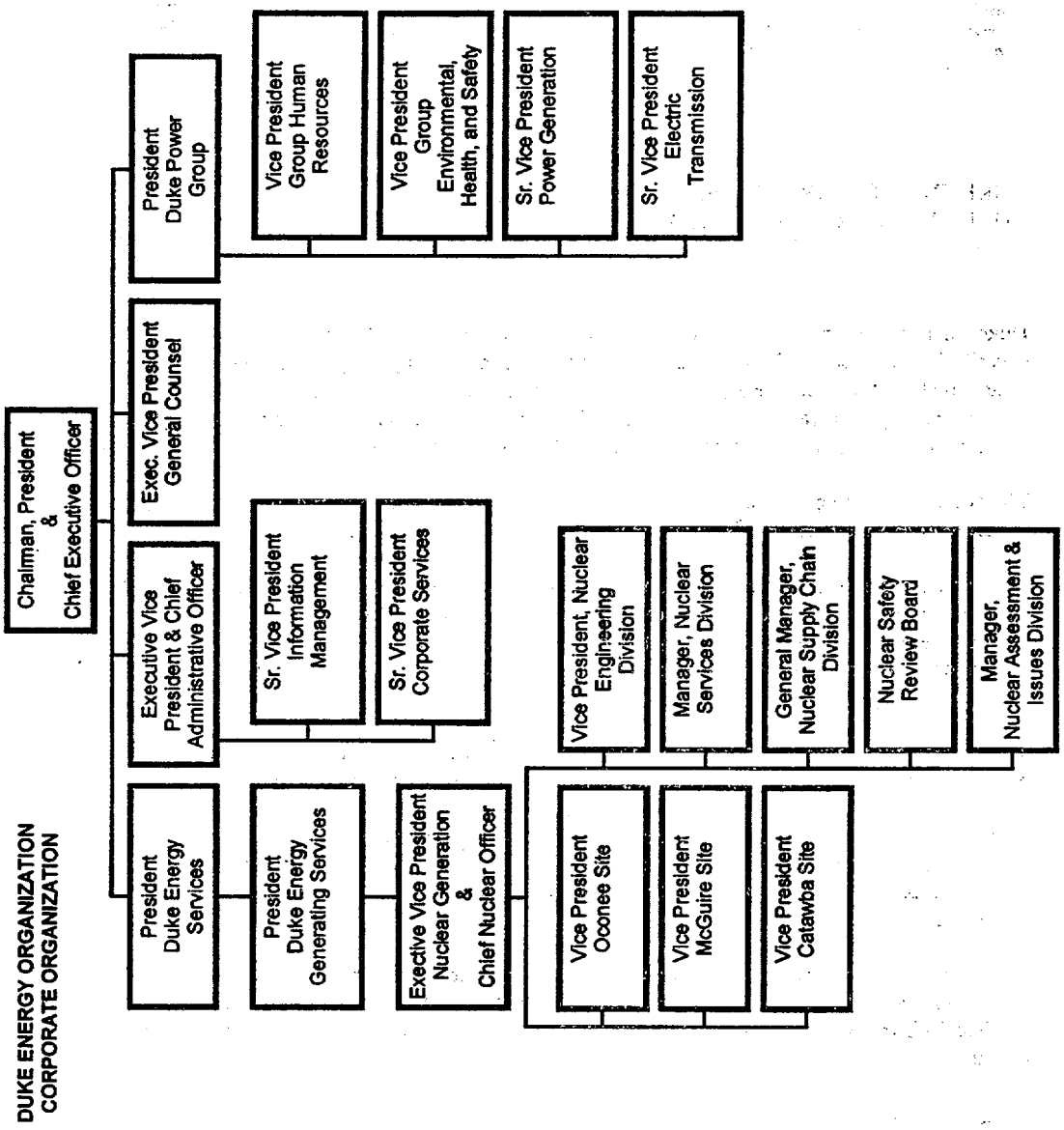

Figure 17-2 Duke Energy Corporation Corporate Organization

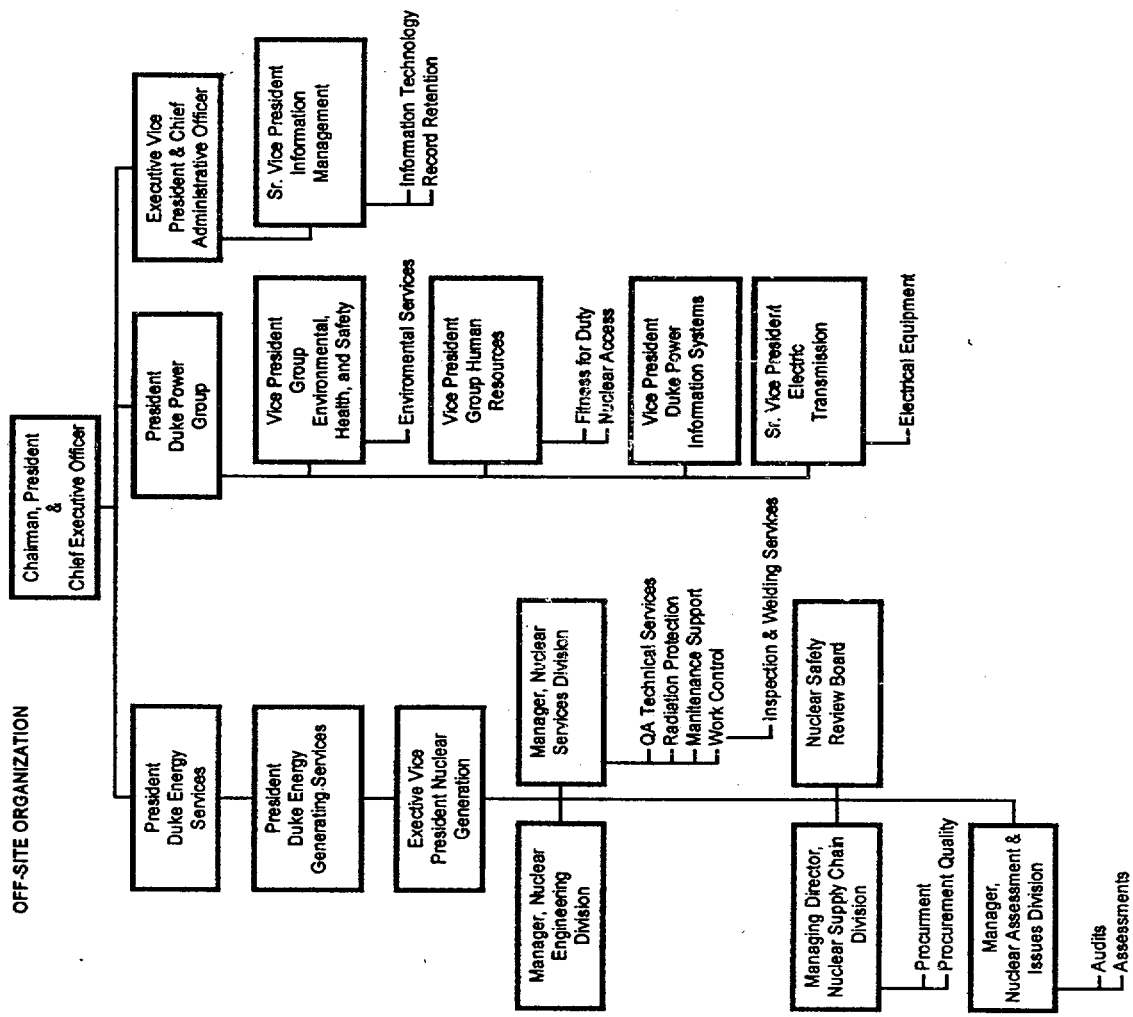

Figure 17-3 Off-Site Organization

Figure 17-4 Nuclear Site Organization

17.3.2 PERFORMANCE/VERIFICATION

17.3.2.1 Methodology

The Duke Energy Corporation operational quality assurance program is described in various Corporation manuals. Procedures and work instructions necessary to implement the requirements of the operational quality assurance program 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 Officer. 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 modifications.

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

The operational quality assurance program 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 quality assurance 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 modifications are formally identified. The assignment of responsibility for the evaluation and design of a particular modification to a specific individual/organization is documented. Also, the written instructions addressing the control of modifications address the communication of information between

involved individuals/organizations and, where appropriate, require documentation of such communications.

For each proposed modification, the individual/organization assigned responsibility for evaluation and design of the modification considers the following in the design of the modification:

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 modification shall be by the Station Manager or the Manager of Engineering; or for the Station Manager by the Operations Superintendent, the Maintenance Superintendent, the Work Control Superintendent, or the On-Duty Emergency Coordinator as previously designated by the Station Manager. Modifications 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 modification.

Errors and deficiencies noted in the design of a modification are corrected by means of a variation notice or a revision to the modification. The control measures applied to each such modification revision or variation notice are equivalent to the control measures applied to the modification originally. Each modification revision or variation notice and the review and approval thereof, is documented.

Prior to a modification being declared operable and returned to service, all procedures governing the operation of the modification are reviewed and revised as necessary. If the modification significantly alters the function, operating procedure, or operating equipment, then additional training is administered as necessary.

Adequate identification and retrievable documentation of station modifications 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 Executive Vice President, Nuclear Generation Department by individuals in Nuclear General Office or to the Site Officer 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 Quality Assurance 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 exist. Qualification testing, when suitable, is guided by Duke'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 modification performs a safety evaluation of the proposed modification. This evaluation provides the bases for the determination that the modification does or does not involve an unreviewed safety question. This evaluation is reviewed by an individual/group other than the individual/group performing the safety evaluation, but who may be from the same organization as the individual/group which performed the safety evaluation. This evaluation and the review thereof are documented.

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

a) A description of the modification.

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

c) Special installation instructions.

d) Operational, test, maintenance and inspection requirements.

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

f) Drawings revised and/or requiring revision.

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

h) Whether or not the modification involves an unreviewed safety question.

The reviews of the proposed modification, including applicable implementing procedures associated therewith, certifies that quality assurance requirements have been met and determines inspection requirements prior to implementation of the modification. Modifications which are determined to involve an unreviewed safety question are reviewed by the Nuclear Safety Review Board and must be authorized by the Nuclear Regulatory Commission prior to implementation.

17.3.2.4 Procurement Control

Duke's Quality Assurance Program 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.

The Quality Assurance Program supplements appropriately the ASME 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. The Nuclear General Office, Nuclear Supply Chain Procurement Quality section is responsible for qualification of supplier's quality assurance programs.

QA Condition 1 material, equipment and services procured as basic components may only be procured from qualified suppliers. Supplier qualification is accomplished by a Procurement Quality section evaluation of the supplier's quality assurance program. An audit or pre-award survey is performed by the Procurement Quality section 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's quality assurance 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's 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 Procurement Quality section Manager. Approved suppliers of basic components will then be included on the Approved Supplier's 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 Procurement Quality section manager may place a supplier on the Approved 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.

The Procurement Quality section will perform a documented on-going evaluation of each supplier in order to maintain the supplier on the Approved 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 Procurement Quality section manager . 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 Quality Assurance Program. These commercial grade items used in QA Condition 1 applications require evaluation, dedication and approval by Nuclear Generation Department 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 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, manufacturing surveillance, 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, Procurement Quality section is responsible for verifying the acceptability of the supplier control of the identified critical characteristic.

Procurement of materials, parts, components and services associated with a station's 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.

Each 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 to assure sufficient information is fully identified to specify the items being procured. Subsequent to preparation, procurement information is approved by the 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 quality assurance, 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 the Nuclear General Office, Procurement Quality section – see Section 17.3.3.2.6, "Suppliers." Determination of acceptability requires that a supplier provide Duke 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 Department 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 the Nuclear Generation Department. Procurement information is provided to the 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 Nuclear General Office, 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 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 Nuclear General Office, 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 issued and installed.

17.3.2.6 Identification and Control of Items

Control of materials, parts, and components at nuclear sites is the ultimate responsibility of the Executive Vice President, Nuclear Generation Department 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 Duke specifications. Materials, parts, and components are traceable from such identification to a specific purchase order to manufacturer's records and to quality assurance 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, 2, 3, and 4 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 quality assurance program requires that QA Condition 1 materials, parts and components be handled, stored, issued and shipped in such a manner that the serviceability and quality assurance 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 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 operational quality assurance program 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 Nuclear General Office, Nuclear Performance Assessment section verifies implementation of the calibration program through periodic audits.

The basis for this exception on the installed Technical Specification required equipment is the PMPT, Preventive Maintenance Periodic Testing program. This is a computerized scheduling program that automatically schedules PMPT using SWR's, Standing Work Requests. 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 operational quality assurance program 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 Department personnel are controlled by the Nuclear Generation Department

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 Non Destructive Examination (NDE).

The operational quality assurance program contains or references procedures for the control of special processes such as welding, heat treating, non-destructive examination, 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 a station's 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. Non-destructive examination 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. 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. The program addresses:

a) Inservice inspections required by Section XI of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code.

b) Inspections to verify compliance with cleanliness criteria.

c) Inspections to verify compliance with certain instrument and maintenance procedures.

d) Inspections to verify conformance of materials, parts, and components received at a nuclear station with applicable specifications and requirements.

e) Inspections to verify the integrity of QA Condition 1 structures, systems and components during and/or after maintenance and modification.

The personnel performing these inspections are examined and certified in their particular category. Current qualification and certification files are maintained for each inspector. Nondestructive examination 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 quality assurance 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 Department personnel responsible for these processes. These procedures comply with the requirements of applicable codes and standards.

Modifications, repairs and replacements are inspected in accordance with 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. 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.

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

Inspection activities involving the supplier quality assurance program are evaluated and approved by the Nuclear General Office, Procurement Quality section.

17.3.2.13 Corrective Action

Station personnel are responsible for the implementation of the quality assurance program 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 aregenerated. 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 Station Manager (or for the Station Manager by: 1) the Operations Superintendent, 2) the Maintenance Superintendent, 3) or the Work Control Superintendent, as previously designated by the Station Manager) and approved by the Manager, Safety Assurance. Such reports shall be provided to the Site Vice President, the Plant Operations Review Committee, the Nuclear Safety Review Board, and the Nuclear Regulatory Commission 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 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 in such a manner as to prevent installation and/or use. The determination of an item's nonconformance is documented and is retained on file by the Nuclear Generation Department and, as appropriate, by tags attached to the item. Nuclear Generation Department personnel are notified of any nonconformances identified in accordance with approved procedures.

The Nuclear Generation Department 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 issued or installed. 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 the Nuclear General Office, Procurement Quality section.

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

17.3.2.14 Document Control

The Topical Report describes Duke's Quality Assurance Program for the operational phase of Duke's Nuclear Stations. This document is certified to meet NRC Quality Assurance Regulations by the Executive Vice President Nuclear Generation / Chief Nuclear Officer. The Nuclear Policy Manual establishes the policies and instructions governing activities associated with Duke'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 Executive Vice President, Nuclear Generation / 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, Nuclear Assessment and Issues Division or designee.

The station Facility Operating License and Technical Specifications are considered Nuclear Regulatory Commission controlled documents and are distributed within Duke Energy Corporationby 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 Station Manager, or for the 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 Corporation.

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

The Nuclear Generation Department 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 Assessment Organization, the Plant Operations Review Committee and the Nuclear Safety Review Board. This manual is approved by the Site Vice Presidents or designee, except for the Nuclear Safety Review Board procedure, which is approved by the Executive Vice President, Nuclear Generation / Chief Nuclear Officer.

The Nuclear Procurement Engineering Program Manual (NPEP) 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 Executive Vice President, Nuclear Generation or designee.

The policies and procedures governing the fire protection functions of the Duke Power Group Environmental, Health and Safety Department are contained in the Safe Work Practices Manual and the Safety and Industrial Hygiene Compliance Manual. Both of these manuals are approved by the President, Duke Power Group.

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, checklists, etc. 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) Plant Operations Review Committee 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 modifications, 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 Manger.

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 Nuclear Safety Review Board, 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 Executive Vice President Nuclear Generation Department / 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, Environmental Radiological 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 head of the appropriate site organization, the head of the appropriate station organization, or the head of the appropriate site engineering organization; such as the appropriate division manager, superintendent/manager, or one of their designated direct reports. 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, Environmental Radiological 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 quality assurance records. 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 that location in a manner similar to that of the stations. Records required to be retained include:

a) QA Condition 1 preoperational testing records.

b) Records of modifications 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 quality assurance 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's 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 Nuclear General Office, Nuclear Performance Assessment 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 inservice 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, Process Control Program, 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 maintained by the station that 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 Nuclear Safety Review Board are maintained. These records include:

a) Nuclear Safety Review Board meeting minutes.

b) Audit reports for audits conducted under the cognizance of the Nuclear Safety Review Board.

Records of activities within the purview of the Safety Review Groups are maintained. These records include:

a) Records of in-plant reviews performed on station activities.

b) Records of special reviews and investigations.

c) Copies of special reports.

Records of activities within the purview of the Plant Operations Committees are maintained. These records document the meetings of the Plant Operations Review Committees. These records include:

a) Identification of the chairperson for each meeting.

b) A listing of the Plant Operations Review Committee 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 Plant Operations Review Committee 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.

Records of activities within the purview of the Information Management Department are maintained by the Information Management Department in a manner similar to that described above for station quality assurance records. These records include:

a) Software requirements.

b) Software test plans.

c) Software test results.

d) Program/Module specifications and source codes.

Records of activities within the purview of the Group Environmental, Health and Safety Department are maintained by the Group Environmental, Health and Safety Department in a manner similar to that described above for station quality assurance records. These records include:

a) Laboratory quality control records

b) Environmental records

The retention times for the various quality assurance 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 quality assurance program and that the quality assurance program has been implemented effectively. These functions are directed by the Manager, Nuclear Assessment & Issues Division and the Managers of Safety Assurance. 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 Executive Vice President, Nuclear Generation, 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 quality assurance practices.

The Director, members and alternate members of the NSRB are appointed in writing by the Executive Vice President, Nuclear Generation 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 Director, which constitutes a quorum. Alternate Director/Members may replace Regular Members as necessary. Members of the NSRB may be from the Nuclear Generation Department, 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 Director 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) Proposed changes to procedures, equipment or systems which when evaluated under the provisions of 10CFR50.59 require a license amendment pursuant to 10CFR50.90;

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

d) 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;

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

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

g) Review reports that describe reportable events;

h) 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

i) Review reports that describe Quality Assurance Program 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 director of the NSRB.

The NSRB shall report to and advise the Executive Vice President, Nuclear Generation on those areas of responsibility specified in Items (a) through (i) above.

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

17.3.3.2.2 Plant Operations Review Committee

The 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.

17.3.3.2.3 Internal Audits

Duke's Quality Assurance Program requires a comprehensive system of planned and periodic internal audits for all phases of station operations and supporting activities.

All organizational units conducting quality assurance 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 Quality Assurance Program are performed. Internal audits are initiated under

the direction of the Manager, Nuclear Performance Assessment. The Manager, Nuclear Assessment and Issues Division 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, Nuclear Performance Assessment. Additionally, the scope of audits performed under the cognizance of the Nuclear Safety Review Board (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 Operational Quality Assurance Program 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 Executive Vice President, Nuclear Generation;

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. 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 Executive Vice President and other management as appropriate.

Within thirty days after receipt of the audit report, responsible management replies in writing to the Manager, Nuclear Performance Assessment, 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 QA program, 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.

17.3.3.2.4 Safety Assurance

Safety Assurance, through the Safety Review Group, Regulatory Compliance, Environmental Compliance, Health and Safety, and Emergency Planning, monitors the day to day and overall performance of each nuclear station.

The Safety Review Group (SRG) functions to provide the review and assessment of plant design and operating experience for potential opportunities to improve plant safety; evaluation of plant operations and maintenance activities; and, to advise management on the overall quality and safety of plant operations. The SRG makes recommendations for procedure revisions, equipment modifications, or other means of improving plant safety to appropriate station/corporate management. The SRG shall report to and advise the Manager of Safety Assurance. Investigations and reviews performed by the SRG are documented in reports that are submitted to management, the NRC, and other agencies as appropriate.

The SRG shall be composed of at least five dedicated individuals. Each individual shall have either:

a) A bachelor's degree in engineering or related science and at least 2 years professional level experience in his/her field, at least 1 year of which experience shall be in the nuclear field; or

b) At least 15 years of professional level experience in his/her field, at least 10 years of which experience shall be in the nuclear field, at least 3 years of which nuclear experience shall be supervisory/managerial experience in Engineering, and shall hold or have held a Senior Reactor Operator License; or

c) At least 5 years of nuclear experience and hold or have held a Senior Reactor Operator License; or

d) At least 8 years of professional level experience in his/her field, at least 5 years of which experience shall be in the nuclear field.

A minimum of two of these individuals shall have the qualifications specified in Item a provided that at least one individual has the qualifications of Item b. Otherwise, a minimum of three of these individuals shall have the qualifications specified in Item a.

The SRG shall be responsible for:

a) Review of selected plant operating characteristics and other appropriate sources of plant design and operating experience information for awareness and incorporation into the performance of other duties.

b) Review of the effectiveness of corrective actions taken as a result of the evaluation of selected plant operating characteristics and other appropriate sources of plant design and operating experience information.

c) Review of selected programs, procedures, and plant activities, including maintenance, modification, operational problems, and operational analysis.

d) Surveillance of selected plant operations and maintenance activities to provide independent verification (not a sign-off function) that they are performed correctly and that human errors are reduced to as low as practicable.

e) Investigation of selected unusual events and other occurrences as assigned by Station Management or the Manager of Safety Assurance.

f) Preparation of summary reports of activities performed by the SRG. These reports are provided to the Manager of Safety Assurance each calendar month.

The Regulatory Compliance Group is responsible for the preparation, issue, and maintenance of all site licensing documents; providing site personnel with interpretations on the licensing documents, the preparation and submittal of violation responses, and coordination of NRC inspection activities on site.

The Environmental Compliance Group is responsible for the overall coordination of the site Environmental Management Programs to assure compliance with applicable Federal, State, and Local requirements.

The Emergency Planning Group is responsible for the overall coordination of the Site Emergency Plan to assure compliance with applicable FEMA and NRC requirements.

17.3.3.2.5 Corporate Audit

Corporate audits are initiated and directed by the Executive Vice President, Nuclear Generation. This audit is performed within a period of two years on the Duke Quality Assurance Program.

The Executive Vice President, Nuclear Generation 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 Executive Vice President, Nuclear Generation and the audit team. Each audit includes a review of internal audits performed by the Nuclear General Office, Nuclear Performance section. The audit is performed with preapproved 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 President, Duke Power Group and the Executive Vice President, Nuclear Generation.

The Executive Vice President, Nuclear Generation 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.

17.3.3.2.6 Suppliers

Suppliers quality assurance programs are evaluated and monitored by the Nuclear General Office, Nuclear Supply Chain, Procurement Quality section to assure that quality assurance requirements are met. Supplier Quality Assurance Programs require a system of periodic and planned supplier and subsupplier audits conducted by persons not directly involved in the activity being audited.

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

The Nuclear General Office, Nuclear Supply Chain, Procurement Quality section maintains surveillance and performs audits on suppliers' quality assurance programs including the activities of their suppliers and subsuppliers, to assure that operations are in compliance with specified quality assurance 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 suppliers quality assurance organization, which takes appropriate steps to resolve the deficiencies.

A reaudit is performed, if appropriate, to verify the implementation of the corrective action.