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SUBJECT: Forwards response to questions in 970821 telcon re proposed amend 21 to Duke QAP Topical Rept,Duke-1.

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M. S. Tuckman
Executive Vice President
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August 26, 1997

U. S. Nuclear Regulatory Commission
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Washington, DC 20555-0001

SUBJECT: Duke Energy Corporation
Oconee Nuclear Station - Docket Nos. 50-269, 270, 287
McGuire Nuclear Station - Docket Nos. 50-369, 370
Catawba Nuclear Station - Docket Nos. 50-413, 414

Quality Assurance Program
Topical Report Duke-1, Amendment 21
Response to NRC Questions

TAC Nos. M96624, M96625, M96626, M96627, M96628, M96629, and M96630

Proposed Amendment 21 to the Duke Quality Assurance Program Topical Report, Duke-1 (hereafter referred to as Topical Report or Amendment 21) was submitted to the NRC by Duke letter dated July 11, 1996 and supplemented by Duke letters dated November 19, 1996, December 3, 1996, June 2, 1997, and August 13, 1997. On August 21, 1997, a telephone conference call was held between NRC Staff members and Duke representatives. During this conference call, the NRC Staff asked that Duke respond to two additional questions. These questions, along with the Duke answers, are contained in Attachment 1 to this letter.

Attachment 1 to this letter restates the NRC questions and provides the associated Duke response for each.

The proposed resolutions contained in the Duke responses to the NRC questions will result in the need for a revision to four pages of Amendment 21. The necessary revisions to Amendment 21 have been made on pages 17-9, 17-10, 17-26, and 17-27. These pages (with the necessary revisions included) are provided as Attachment 2 to this letter. Following NRC approval of Amendment 21, the appropriate number of copies of the complete final version of Amendment 21 will be

provided to the NRC by means of the normal Duke distribution process.

Duke requests that the NRC review the information contained in the attachments in a manner such that the approval of Amendment 21 can be finalized on a timely basis. Duke knows of no other outstanding issues related to Amendment 21.

Please direct any further questions or comments on this matter to J. S. Warren at (704) 382-4986.

Very truly yours,

M. S. Tuckman.

MST/JSW

Attachments:

Attachment 1: Duke Energy Corporation
Quality Assurance Program Amendment 21
NRC Questions and Duke Responses

Attachment 2: Duke Energy Corporation
Quality Assurance Program
Topical Report Duke-1
Amendment 21
Revised Pages 17-9, 17-10, 17-26, and 17-27

xc w/att: L. A. Reyes
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ATTACHMENT 1

DUKE ENERGY CORPORATION ASSURANCE PROGRAM - AMENDMENT 21
NRC QUESTIONS AND DUKE RESPONSES
Discussed During NRC/Duke Conference Call on August 21, 1997
(TAC NOS. M96624 THROUGH 96630)

NRC Question 1:

Need clarification on two paragraphs in section 17.2.3.4. We would like to hear from Duke's procurement personnel about the process described below. Is Duke proposing an additional alternative to Regulatory Guide 1.144 Rev(1) in addition to the stated alternative in Table 17-1? Is Duke following IN 86-21 Supplement 2?

"The Supplier Verification Manager may place a supplier on the Approved Suppliers list without the performance of an audit or pre-award survey when the prospective supplier holds an appropriate ASME Certificate of Authorization or Quality Systems Certificate issued by the ASME. Surveillance, test or inspection activities shall be performed to verify that applicable portions of the supplier's QA program are being effectively implemented.

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."

Duke Response to Question 1:

As discussed in the August 21 conference call, the first paragraph above will be deleted from the Topical Report. See revised Pages 17-26 and 17-27 contained in Attachment 2.

No additional alternatives are being proposed. Duke's commitment for compliance with regulatory position C.3.b of Regulatory Guide 1.144 Rev(1), as clarified by NRC Information Notice 86-21, Supplement 2, is being stated in Table 17-1 (Page 5 of 7). See revised Page 17-9 contained in Attachment 2.

NRC Question 2:

Table 17-1 Regulatory Guide 1.146. The description for lead auditor qualifications states, "... shall have participated in at least one nuclear quality assurance audit within two years preceding the individual's date of qualification." The two years may need to be changed to one year according to NRC's October 24, 1996 letter to NEI entitled "Review of Nuclear Energy Institute (NEI) Proposed Improvements to Quality Assurance Programs." The NRC's February 21, 1997 request for additional information letter incorrectly stated two years instead of one year.

Duke Response to Question 2:

This has been changed to one year in Table 17-1 (Page 6 of 7). See revised Page 17-10 contained in Attachment 2.

Attachment 2
(Duke Letter Dated August 26, 1997)

Quality Assurance Program
Topical Report Duke-1
Amendment 21

Revised Pages 17-9, 17-10, 17-26, and 17-27

Table 17-1 (Page 5 of 7). Conformance of Duke Power 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 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. Self Initiated Technical Audits (Section 17.3.3.2.6, "Self-Initiated 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 Power 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 Program conforms to ANSI/ASME N25.2.23 - 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 N45.2.23-1977, 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 Program conforms to the intent of this Regulatory Guide as addressed in each Station's FSAR
Criteria 1 of Appendix A to 10CFR 50	Conforms	------
10CFR 50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants	Conforms	------

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 Senior 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 Power'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.

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 or Electric System Support 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 PSM Department, who prepares an inquiry and forwards it to approved suppliers. The Nuclear General Office, Supplier Verification 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 Supplier Verification Section evaluation of the supplier's quality assurance program. An audit or pre-award survey is performed by the Supplier Verification 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 Supplier Verification 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 PSM Department 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 Supplier Verification 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 Supplier Verification Section shall complete a satisfactory re-evaluation of a supplier every 12 months in order to maintain the supplier on the Approved Suppliers List. Annual re-evaluations may be extended by 3 months, from 12 to 15 months, with written approval of the Supplier Verification Manager. Additionally, suppliers shall 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 Supplier Verification 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 engineering 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, Supplier Verification 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, and components 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 Procurement Engineering 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, Supplier Verification Section - see Section 17.3.3.2.7. 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 documention 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 or Electric System Support 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 and/or PSM Department. Procurement information is provided to the Supplier Verification Section and the receiving location.