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SUBJECT: Forwards response to 970221 RAI re Amend 21 to DPC QA program topical rept. Revised Amend 21 to "DPC Topical Rept QA Program Duke-1-A," also encl.

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DUKE POWER

June 2, 1997

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

SUBJECT: Duke Power Company
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 Request for Additional Information

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

In a letter dated February 21, 1997, the NRC Staff requested that Duke Power provide additional information on Amendment 21 to the Duke Quality Assurance Program Topical Report, Duke-1 (hereafter referred to as Topical Report or Amendment 21). The proposed Amendment 21 had been previously submitted by Duke letter dated July 11, 1996 and supplemented by Duke letters dated November 19, 1996 and December 3, 1996. The NRC request consisted of several questions on the contents of Amendment 21.

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

As mentioned above, the February 21, 1997 NRC request for additional information contains several questions requiring a response (provided in Attachment 1) from Duke Power. The proposed resolutions contained in the Duke response to some of the NRC questions will result in the need for a revision to Amendment 21. This is necessary for question Nos. 1, 2.b, 2.c, 2.d, 2.f, 2.g, 2.h, 2.i, 3, 4, and 5. The necessary revisions to Amendment 21 have been made. For efficiency and ease of reference, a complete Amendment 21 package (with the necessary revisions included) is provided as Attachment 2 to this letter.

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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. We are hopeful that the information contained in Attachments 1 and 2 will fully answer the NRC's questions on this matter and thereby lead to the approval of Amendment 21. However, if deemed necessary, the appropriate Duke representatives are available to further discuss Amendment 21 with the NRC Staff, either at a meeting in White Flint or by conference call.

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 Power Company
Quality Assurance Program Amendment 21
NRC Request for Additional Information
Duke Power Response
- Attachment 2: Duke Power Company
Quality Assurance Program
Topical Report Duke-1
Amendment 21 (Revised)

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ATTACHMENT 1

DUKE POWER COMPANY QUALITY ASSURANCE PROGRAM - AMENDMENT 21
NRC REQUEST FOR ADDITIONAL INFORMATION
NRC Letter Dated February 21, 1997
(TAC NOS. M96624 THROUGH 96630)

DUKE POWER RESPONSE

NRC Question 1:

Item 5 - Page 17-9. ANSI/ASME N45.2.23-1978 requires that the prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to the individual's qualification. The proposed alternative qualifications are the prospective Lead Auditor shall demonstrate their ability to effectively implement the audit process and effectively lead an audit team. Upon successful demonstration of the ability to effectively lead audits, licensee management may certify the individual as a lead auditor. The NRC does not consider this to be an acceptable alternative. The NRC considers the following to be an acceptable alternative to ANSI N45.2.23-1978:

Prospective lead auditors shall demonstrate their ability to effectively implement the audit process and effectively lead an audit team. The employer shall describe this demonstration process in written procedures or instructions and shall evaluate and document the results of the demonstration, the prospective lead auditor shall have participated in at least one nuclear quality assurance audit within two years preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively implement the audit process and effectively lead audits, and having met the other provisions of ANSI 45.2.23-1978, the individual may be certified as being qualified to lead audits.

Explain and discuss how Duke's alternative will be revised to be consistent with NRC's October 24, 1996 letter to NEI entitled "Review of Nuclear Energy Institute (NEI) Proposed Improvements to Quality Assurance Programs."

Duke Response to Question 1:

Duke's submittal predates the referenced NRC letter. However,

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our purpose is to meet the intent of the Nuclear Regulatory Commission letter dated October 24, 1996 to the Nuclear Energy Institute. To that end, lead auditors would demonstrate their ability to effectively implement the audit process and effectively lead an audit team. We further expect that prospective lead auditors to have participated in at least one nuclear quality assurance audit within two years preceding the individual's effective date of qualification. Therefore, in the "Remarks" Column of Table 17-1 (Page 6 of 7), proposed Amendment 21 (see Attachment 2) has been revised to read:

"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 two years 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."

NRC Question/Comment 2:

Item 12 - Pages 17-26 through 17-30. The basis/reason and discussion in this section does not provide enough information to adequately review this section.

Duke Response to Question/Comment 2:

Detailed answers to questions 2.a through 2.i are provided in the subsequent paragraphs. Additional information is contained in these responses on the basis/reason for the referenced changes to the Topical Report that were proposed in Amendment 21.

NRC Question 2.a:

Provide the basis/reason why the last sentence in the last paragraph was changed/deleted on page 17-26 (Bid evaluation includes evaluation of the technical, quality and commercial qualifications of the prospective suppliers).

Duke Response to Question 2.a:

The sentence prior to this one, in the same paragraph, ends with the words "...following evaluation of bids from qualified suppliers". The changes made to the sentence in question were

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meant to clarify and agree with previous wording; that the evaluation of bids received from suppliers include an evaluation of the supplier's technical, quality and commercial qualifications. Although the wording of this sentence was changed, it's meaning is not believed to be changed.

NRC Question 2.b:

NRC positions on the use of the ASME Accreditation Process is provided in Information Notice 86-21 and its supplements. The proposed, revised QA Program description needs to address Information Notice 86-21 (see last sentence in the first paragraph on page 17-27). For example, the extent of the surveillance, test, or inspection activities shall, in any combination, confirm/verify that the applicable portions of the supplier's QA program are being effectively implemented.

Duke Response to Question 2.b:

The last sentence of the first paragraph on page 17-27 was not intended to address ASME suppliers. In order to clarify the intent and to address the NRC comments, on Pages 17-26 and 17-27, proposed Amendment 21 (see Attachment 2) has been revised to read:

"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."

NRC Question 2.c

The last sentence of first full paragraph on page 17-27 of the proposed QA Program needs to reflect the NRC's position on third party audits. Third party audits shall be reviewed in detail to determine the scope of the audit and to ensure that items to be purchased are within the audit scope, and to ensure that any unique plant quality and technical requirements are within the

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scope of such audit. Provide the justification for not conforming to the above statement.

Duke Response to Question 2.c:

We concur with comment and have requested additional information as to the specific reference cited as "the NRC's position on third party audits." Therefore, on Page 17-27, proposed Amendment 21 (see Attachment 2) has been revised to read:

"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. Licensed operating US nuclear utilities may be placed on the Approved Suppliers list by the Supplier Verification Manager without an audit or survey."

NRC Question 2.d

Changing the audit frequency from 36 to 42 months appears to be unacceptable and no reasonable justification is provided. Why can't supplier audits be planned 3 years in advance? Also with organizations like NUPIC performing third party audits, this should not be a problem. Discuss and explain changing the audit frequency in more detail.

Duke Response to Question 2.d:

The intent of the change was to allow for some flexibility, to be used on an infrequent basis, in audit scheduling to accommodate manufacturing schedules and synchronization with other utility audits. As an alternate proposal, reduction of the extension time frame to 3 months would be acceptable. Duke believes applying this additional 3 months of flexibility to the audit scheduling process is conservative based upon industry practice. This belief was reached after the review of quality assurance programs in use at other nuclear utilities, e.g., South Carolina Electric and Gas and Virginia Power. Consequently, on Page 17-27, proposed Amendment 21 (see Attachment 2) has been revised to read:

"...audit requirement may be extended by 3 months, from 36 to 39 months,"

NRC Question 2.e:

For paragraph 4 on page 17-27 of the proposed QA Program change, provide justification and discussion why reference to specifications and Codes was deleted. No justification is provided to evaluate this change.

Duke Response to Question 2.e:

The intent of this sentence is to say that materials, parts, and components are to be procured to technical and quality requirements at least equivalent to those of the original. The new wording, "to specified technical and quality requirements," was used because of the words given in ANSI N45.2.13, Section 3.2.

Paragraph 3.2.2 indicates technical requirements shall be specified by reference to drawings, specifications, codes, regulations and ... so forth. To say "technical and quality requirements", we mean to include specifications and codes. Our intent is to continue to procure to requirements (specifications and codes) equivalent to those used for the original.

NRC Question 2.f:

The last sentence in paragraph 4 page 17-27 of the proposed QA Program needs to reflect Criterion VIII of Appendix B to 10 CFR Part 50 which requires in part that the effectiveness of suppliers be assessed. Proposed page 17-27 states "Supplier evaluation and re-evaluation are done in accordance with procedures to assure their documentation is valid." Section 50.34 (b) (6) (ii) requires that the QA Program describe how the requirements of Appendix B will be satisfied. The proposed QA Program would only reference procedures and does not describe how supplier evaluations/assessments are performed, therefore it appears that 50.34(b)(6)(ii) is not being met. Discuss and provide some additional detail for inclusion in the QA Program to explain how you are conforming with the regulations.

Duke Response to Question 2.f:

The last sentence of paragraph 4 page 17-27 was inadvertently included in the submittal and is not relevant to the topic of this paragraph. Supplier evaluations and re-evaluations are addressed in the second full paragraph of page 17-27 and no changes are reflected from the previously approved amendment of the Topical Report. It is proposed to delete this sentence from Amendment 21. Therefore, on Page 17-27, proposed Amendment 21 (see Attachment 2) has been revised to delete this sentence.

NRC Question 2.g:

The last sentence on page 17-27 needs to be modified to comply with 10 CFR 21.3 "Dedication" definition. Section 21.3 recognizes historical analysis only as a supplementary dedication method which should not be used as the sole method.

Duke Response to Question 2.g:

To address the NRC concern with the use of historical data analysis, the last two sentences on Page 17-27 of proposed Amendment 21 (see Attachment 2) have been revised to read:

"Historical data, when documented, will represent industry wide experience."

In the original version of Amendment 21, this last sentence was intended to clarify that when dedication is based on historical data, the data must represent industry wide experience. Clarification on the use of historical data, as well as surveys and source inspections, are described in the October 30, 1995 Nuclear Energy Institute "Regulatory Update". This document provides clarification on industry concerns with the latest PART 21 rules.

The section of the NEI document titled, "Defining a Commercial Grade Item," in the last paragraph reads:

"The NRC said it does not intend to limit, or accord supplemental status to, commercial grade survey and source inspection. Utilities may use any of the four EPRI dedication methods—alone or in combination—in dedicating commercial grade items for safety related use."

Regardless of the dedication method used, all commercial grade items go through standard receiving inspection for general PO description requirements; e.g., part number and model number, in addition to the special test and inspections identified in the commercial grade technical evaluation.

NRC Question 2.h:

The second to last paragraph in section 17.3.2.4 used to state "the certificate specifies," now states the documentation specifies." Only a certificate, signed by the vendor can certify that the purchase order requirements have been met. Please discuss and provide justification for deletion of the term

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"certificate". Also see Section 10.2 of ANSI N45.13 and its discussion on the use of certification during the receiving process.

Duke Response to Question 2.h:

This change was meant to clarify that the documentary evidence (addressed in the next sentence of the same paragraph) that must be on site, includes the certificate. The supplier documentation (including the certificate) shows that the item meets procurement requirements. The change to "supplier documentation specifies" should have said "supplier documentation shows".

However, to prevent possible confusion, it is proposed that on Page 17-28 of Amendment 21 (see Attachment 2) this be reworded to:

"The certificate and supplier documentation specifies that the item"

NRC Question 2.i:

Section 17.3.2.6c used to state "traceable to original material," now states traceable at receipt." This may be somewhat true for basic components that are procured commercially and dedicated, but may not be true for items/materials purchased from approved suppliers. Provide basis/reasons for this change. What is the meaning of "traceable to receipt?"

Duke Response to Question 2.i:

Under the Duke Power QA Program, Heat, Batch or Lot Numbers become secondary trace information once the commodity is received because a Unique Tracking Number is assigned to all safety related commodities, as described in 17.3.2.6d. In an effort to better state this, Page 17-29 of proposed Amendment 21 (see Attachment 2) has been revised to read:

"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."

NRC Question 3:

Item 16 - Page 17-37. In what manuals are the governing procedures for the Nuclear Assessment and Issues Division? What is the Assessment Organization? Discuss and explain.

Duke Response to Question 3:

The assessment functions, for the purposes of this report, are describe in section 17.3.3 Self Assessment. The Nuclear Assessment and Issues division is discussed in Section 17.3.1.2.2 sub paragraph (b), item (3). The paragraph that was removed had previously referenced a manual that has now been incorporated into the Nuclear Policy Manual (already discussed in Section 17.3.2.14). The Regulatory Audits work place procedures are contained in the Nuclear Assessment Functional Area Manual in accordance with Section 17.3.2.1, Methodology.

Assessment activities are performed by both General Office and site organizational units, as described in the following two paragraphs.

In the General Office, the Operational Assessment Section provides independent assessment and audit services to the Nuclear Generation Department. This Section consists of the Regulatory Audits Group, the Performance Assessment Group, and the NSRB Staff Support Group. Additionally, there is an Operational Assessment Section that is responsible for the formation and implementation of the Significant Event Investigation Teams (SEIT) and the coordination of the Self Initiated Technical Audits (SITA). The General Office assessment organization reports to the Manager, Nuclear Assessment & Issues Division as shown in Topical Report Figure 17-3, Off-Site Organization. Figure 17-3 of proposed Amendment 21 (see Attachment 2) has been revised to show the location of the assessment function in the General Office organization.

At the nuclear sites, the site Safety Review Groups are responsible for, and have established programs for carrying out, effective self-assessment of site activities. The objective of self-assessment is to verify that established programs, functions, and controls are achieving expected results with maximum quality and to initiate improvements where warranted. The site Safety Review Group reports to the Manager, Safety Assurance as shown in Topical Report Figure 17-4, Nuclear Site Organization.

NRC Question 4

Item 17 - Page 17-37. Approval of the procedures for the Nuclear Safety Review Board (Nuclear System Directive) by the Senior Vice President, Nuclear Generation, has been deleted. Discuss and explain the justification for this removal.

Duke Response to Question 4:

The procedure for governing the Nuclear Safety Review Board has been converted into a procedure contained in the Duke Nuclear Policy Manual (NPM), which is currently described in Section 17.3.2.14 of the Topical Report. Procedures in the NPM are approved by the Site Vice President level of management. As a result of this NRC question, and further review of the purpose of the NSRB, it has been decided that the Senior Vice President, Nuclear Generation, is the appropriate level of management to approve the procedure governing the NSRB. As such, on Pages 17-36 and 17-37, proposed Amendment 21 has been revised to require approval of the NSRB procedure by the Senior Vice President, Nuclear Generation.

NRC Question 5:

Item 18 - Page 17-38. How does one know that the maintenance and testing of electrical equipment procedures is contained in the Nuclear Policy Manual or the ESS functional manuals? Where in the QA Program is this stated? What are the ESS functional manuals? Discuss and explain.

Duke Response to Question 5:

This question apparently resulted from proposed deletion of the Power Delivery Department Manual from the Topical Report. This deletion was proposed because the responsibility for providing the referenced electrical equipment maintenance and testing functions at the nuclear sites has moved from the Power Delivery Department to the Electric System Support Department. This change was regarded as organizational/administrative in nature, with no resulting impact on quality level. However, the implications this change has on Document Control are discussed in more detail in the subsequent paragraphs.

The Electric System Support (ESS) Department Quality Assurance Program Manual in conjunction with applicable Nuclear System Directives govern the electrical equipment maintenance and testing functions that the ESS Diversified Services- Electrical Maintenance Section perform. The ESS Department Quality Assurance

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Program Manual is approved by the Vice President, ESS or designee. In addition, actual work is performed under the direction of station technical procedures which are written, approved and controlled by the individual nuclear stations. The quality programs applicable to procedures are also currently discussed in detail in Section 17.3.2.14 of the QA Topical Report.

An addition (see below) will be made to Amendment 21 (Section 17.3.2.14) in order to clearly state which documents control the electrical equipment maintenance and testing function.

The ESS functional area manuals are currently described in Section 17.3.2.14 of the QA Topical Report. These manuals contain the procedures governing the functions performed by this department, such as NDE, calibration, and soils testing. In order to clarify the relationship to the ESS Quality Assurance Manual, as well as state that these functions also include the maintenance and testing of electrical equipment, Page 17-37 of proposed Amendment 21 (see Attachment 2) has been revised to include:

"The ESS Department Quality Assurance Program Manual in conjunction with ESS functional area manuals, applicable nuclear system directives, and applicable station procedures contain the policies and procedures governing the functions that this department performs in support of the nuclear sites. These functions include such activities as NDE, calibration, soils testing, and electrical equipment maintenance and testing. The ESS Department Quality Assurance Program Manual and the ESS functional area manuals are approved by the Vice President, ESS or designee."

NRC Question 6

Item 24 - Page 17-37. Where is it stated that Department Heads and the Senior Vice President, Nuclear Generation, will receive the results of the audit? Who does "senior management" include? Are the audit results reported to all of the senior management? Who is coordinating these assessments? Discuss and explain.

Duke Response to Question 6:

Topical Report paragraph 17.3.3.2.3 states within thirty 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 and other management as appropriate. Also, Section 6 of each site's Technical Specifications states that the

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Senior Vice President, Nuclear Generation shall be forwarded a copy of the audit report.

Senior management includes the Site Vice President and the Senior Vice President, Nuclear Generation. Audit results are reported to these management positions within 30 days of the post-audit conference.

The Manager, Regulatory Audits, as described in Topical Report Section 17.3.3.2.3, is the management position responsible for initiating the regulatory audit program. Additionally, the scope of the audits performed under the cognizance of the Nuclear Safety Review Board (NSRB) are reviewed by the NSRB staff to ensure any NSRB concerns are included in the audit checklist.

NRC Question 7:

Item 26 - Page 17-45. Why were there originally commitments to perform Integrated Safety Assessments? How has the original reason changed? How does the monthly trend tracking report maintain independence for the station operation management? Discuss and explain.

Duke Response to Question 7:

The original commitment to perform the Integrated Safety Assessment (ISA) was included in Amendment 14 of the Topical Report, Section 17.1.18.5. The ISA Program was initiated in early 1990 to systematically and independently assess plant performance from a nuclear safety and operational performance perspective and provide a focus report on the results to senior management. This process, although effective in the past, has been antiquated by more real-time and modern information systems now used by Duke Power to assess plant performance. These processes include: 1) A nuclear events report processed by the Nuclear Engineering Division on a monthly basis which measures nuclear performance; 2) NSRB meetings are held on a more frequent basis which contributes to Duke's ability to more accurately assess nuclear performance at the three sites; 3) Duke has updated its investigative and corrective action process to electronically track and trend site problems as described in Section 17.3.2.13 of the Topical Report; and 4) data obtained from internal audits is now being provided to management through periodic trend summaries as described in Section 17.3.3.2.3 of the Topical Report.

The reason for performing the ISA has not changed, in that the processes described herein (excluding the corrective action process) are independent of the site organization and provide

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senior management with the same plant performance information. The corrective action process, i.e., the monthly trend tracking report is performed by the Safety Assurance Group at each site as described in section 17.3.3.2.4 of the Topical Report. This group is responsible for monitoring day-to-day and overall plant performance of each nuclear site. The Safety Assurance Group is independent of station operation management and reports to each Site Vice President. Duke Power believes the new information processes described above are effective in systematically evaluating plant performance from a nuclear safety and operational performance perspective.

Attachment 2

Quality Assurance Program
Topical Report Duke-1
Amendment 21 (Revised)