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SUBJECT: Forwards response to NRC 941123 ltr re violations noted in insp repts 50-269/94-34,50-270/94-34 & 50-287/94-34. Corrective actions:evaluated PIP process as result of violation.

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**DUKE POWER**

February 24, 1995

U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555

Subject: Oconee Nuclear Site
Docket Nos. 50-269, -270, -287
Inspection Report 50-269, -270, -287/94-34
Supplemental Response to Notice of Violation

Dear Sir:

By letter dated November 23, 1994, the NRC issued a Notice of Violation as described in Inspection Report No. 50-269/94-34, 50-270/94-34, and 50-287/94-34. By letter dated December 22, 1994, Duke responded to this Notice of Violation. By letter dated January 17, 1995, the NRC requested additional information.

I am submitting a supplemental response to the violation identified in the subject Inspection Report.

Very truly yours,

J. W. Hampton /KLSwight

J. W. Hampton

cc: Mr. S. D. Ebneter, Regional Administrator
U. S. Nuclear Regulatory Commission, Region II

Mr. L. A. Wiens, Project Manager

Mr. P. E. Harmon
Senior Resident Inspector
Oconee Nuclear Site

**Attachment 1**
**Supplemental Response to Notice of Violation**
**Violation 94-34-01, Severity Level IV**

ANSI N45.2.12 - 1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants," Section 4.5.1, requires management of the audited organization or activity review and investigate any adverse audit findings to determine and schedule appropriate corrective action including action to prevent recurrence and shall respond as requested by the audit report, giving results of the review and investigation. The response shall clearly state the corrective action taken or planned to prevent recurrence.

Topical Report, Section 17.3.2.13, requires that conditions adverse to quality be corrected and action be taken to preclude repetition.

Topical Report, Section 17.3.3.2.2, "Internal Audits," requires responsible management reply in writing to the Verification Manager, Audits, describing corrective action and an implementation schedule, within thirty days after receipt of the audit report.

Quality Verification Department Procedure - 3.1, "Internal Audits," Rev.0, dated June 1, 1992, Section 5.5.2, requires the audit report cover letter request the following information for each finding:

1) Root cause for the findings;
2) Scope and the results of any investigation performed to determine the extent of each problem;
3) Corrective steps which have been taken and the results achieved;
4) Corrective actions which will be taken to avoid recurrence; and
5) Date when full compliance will be achieved.

The audit cover letter dated March 18, 1993, to the ONS Vice President, required the addressee respond to the audit findings within 30 days after receipt of the report with a written statement addressing the five elements of corrective action required by Section 5.5.2 of Quality Verification Department Procedure 3.1.

Contrary to the above requirements, during the period following the issuance of Quality Assurance Audit NG-93-04(ON) issued March 18, 1993, the licensee failed to follow the approved Quality Assurance Program requirements, in that:

1. The Oconee Nuclear Site (ONS) written response to the Verification Manager, Audits, concerning NG-93-04(ON) audit findings did not include a root cause determination for finding NG-93-04(ON)(01); the corrective steps which would be taken to avoid recurrence of findings NG-93-04(ON) (01) and (02); the corrective actions taken for NG-93-04(ON)(03); and failed to address finding number NG-93-04(ON) (5).

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2. The ONS response to the audit findings was not issued within 30 days as directed by the audit's cover letter. The audit report was issued March 18, 1993, and received by the site on March 22, 1993. The response was issued 44 days after receipt of the audit findings.

3. An alternative corrective action process, utilizing the Problem Investigation Process (PIP) program for documenting and tracking the NG-93-04(ON) audit findings, was not procedurally described in the Quality Assurance Program Topical Report and Quality Assurance implementing procedures.

4. The PIP document does not specifically require the consideration, distinction, and documentation of corrective action to prevent recurrence.

**SUPPLEMENTAL RESPONSE**:

1) ***Describe activities that contributed to the inadequate procedural guidance for correcting QA Audit findings with the PIP corrective action process and expand on the corrective actions taken to prevent recurrence.***

Duke acknowledges that the PIP process was not procedurally described in the QA implementing procedures at the time of the NRC audit. The Regulatory Audit Group evaluated the PIP process and felt that this process could be used to effectively answer audit findings. The PIP process was considered to adequately address "significant" conditions adverse to quality by means of an MSE. Less significant items would be handled as an LSE which would ensure that the problems were corrected, furthermore, any repetitive LSE's would be upgraded to an MSE. The Regulatory Audit Group believed that they had the latitude to utilize the PIP process since it was felt that it accomplished the same end result via an electronic corrective action method as was previously achieved through the audit program. **Further evaluation of the PIP process as a result of this violation has confirmed that this was not the case and that Duke Power Company was not in full compliance with the DPC Topical Report as currently written.** Section 17.3.1.6 of the DPC Topical Report does not distinguish between the handling of "significant" and "less significant" conditions which are adverse to quality, as 10CFR50 Appendix B, Criterion XVI does. The Topical Report section implies that any condition adverse to quality will be evaluated for action to prevent recurrence. In reality, a detailed analysis of action to prevent recurrence primarily occurs

1) *continued*

with an MSE which is used to evaluate significant conditions adverse to quality. This meets the intent of 10CFR50, Appendix B, Criterion XVI and ANSI N18.7; both of which require evaluation to prevent recurrence for significant conditions adverse to quality. Appropriate efforts have been initiated to clarify the DPC Topical Report so that it agrees with 10CFR50 and ANSI N18.7. The applicable QA implementing procedure, Nuclear Assessment Functional Area Manual (NAFAM) Section 5.1, Regulatory Audits, has been revised to reflect our utilization of the PIP process. The cause for the violation is that clear expectations were not established through the Audit Team's implementing procedures regarding use of the PIP process and that an adequate evaluation of the PIP process was not made by the Regulatory Audit Group prior to converting to the PIP process.

2) ***Identify appropriate procedures that have or will be modified to provide proper guidance to QA and duty personnel responsible for determining and evaluating corrective actions and responding to QA Audit findings.***

Duke has revised our implementing procedures (Nuclear Assessment Functional Area Manual, Section 5.1, Regulatory Audits) to address utilizing electronic methods to reply to audits and to fully incorporate the established PIP process system as an acceptable means of satisfying the objective. Revisions have been made to the Nuclear Policy Manual NSD 208 which clearly state the Corrective Action is defined as "Action taken to prevent recurrence of an identified adverse condition or trend in accordance with established procedures or processes (e.g., PIP). NSD 208 addresses how conditions adverse to quality will be responded to and who is responsible for disposition. Site duty personnel are responsible for determining corrective actions and responding to QA Audit findings; evaluating audit actions is described in NAFAM 5.1. Amendment 19 to the DPC Topical Report will clarify, in Section 17.3.1.6, that action to prevent recurrence will be considered for "significant" conditions adverse to quality which are addressed by an MSE. This clarification will align the DPC Topical Report with 10CFR50, Appendix B, Criterion XVI and ANSI N18.7.

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3) ***Identify staff positions responsible for determining and evaluating corrective actions and responding to QA Audit findings through the PIP process. Briefly describe the nature of the training provided to those individuals.***

Supervisors or their designees are responsible for determining and evaluating corrective actions and responding to QA Audit Findings through the PIP process. Classroom training on PIP process has been provided. Site communication has been provided on management expectations and Problem Reporting, as described in the Work Standards Handbook for Oconee Nuclear Site, April 1994, has been issued to site personnel and covered in team meetings.

4) ***Identify the controls which will ensure that corrective actions to prevent recurrence are considered, identified, and documented for QA Audit Findings or any other significant adverse conditions processed with the PIP program.***

Nuclear Policy Manual NSD 208 describes the normal PIP process and classification of significant problems. NSD 208 states, in part, that in any given activity, there is a level of excellence that must be met. Whenever there is a change to this level, a problem exists that should be investigated. It should be understood that all items identified by the Regulatory Audit Group are not of equal significance and therefore should be measured against the criteria dictated by NSD 208. NSD 208 has the mechanism in place to ensure significant and repetitive type problems are evaluated and appropriate actions are taken to preclude recurrence. Personnel have been trained to make the determination of which findings are significant or repetitive.

5) ***The date when full compliance will be achieved:***

Corrective actions are complete with the exception of our quarterly Topical Report update. Amendment 19, pending approval, will be implemented March 30, 1995.