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SUBJECT: Responds to NRC 941123 ltr re violation noted in Insp Repts
 50-269/94-34, 50-270/94-34 & 50-287/94-34. Corrective actions:
 violation reviewed w/Regulatory Audit Group personnel &
 training completed & documented re revised audit procedures.

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DUKE POWER

December 22, 1994

U.S. Nuclear Regulatory Commission
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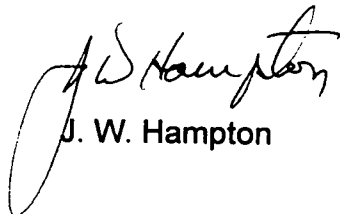
Subject: Oconee Nuclear Site
Docket Nos. 50-269, -270, -287
Inspection Report 50-269, -270, -287/94-34
Reply to Notice of Violation

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.

Pursuant to the provisions of 10 CFR 2.201, I am submitting a written response to the violation identified in the subject Inspection Report.

Very truly yours,


J. W. Hampton

Attachment

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

Mr. L. A. Wiens, Project Manager
Office of Nuclear Reactor Regulation

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

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Attachment 1
Reply 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.

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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).
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.

RESPONSE:

- 1) **The reason for the violation, or if contested, the basis for disputing the violation:**

Duke Power Company acknowledges this violation.

For Item # 1 the following explanation is provided:

The NRC cites that for Audit Finding NG-93-04(ON)(01) that no root cause determination was included. Duke admits that no formal root cause process

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Reply to Notice of Violation
Violation 94-34-01, Severity Level IV

1) continued

was conducted to identify the root cause for this item. In the subject Problem Investigation Process form (PIP), a brief discussion of the cause of the problem is required and was conducted. Although this issue is highly subjective in nature as to how much detail should be pursued regarding this particular root cause analysis, Duke admits that more detail should have been provided in this case. The cause for this item is that clear expectations were not established through the Audit Team's implementing procedures regarding use of the PIP process.

The NRC states that Corrective Steps to avoid recurrence of findings NG-93-04(ON)(01) and (02) were not included in the PIP for this item. Since a root cause was not clearly identified for item NG-93-04(ON)(01), Duke admits that specific, detailed, corrective steps to avoid recurrence of this issue were not clearly documented in the PIP. Corrective actions to avoid recurrence of findings were taken in that a "Count Room Working Group" was established to resolve this issue. Therefore, Duke concludes that this is a documentation issue and does not appear to be a process issue with the PIP system. Regarding finding NG-93-04(ON)(02), Duke specified that the RP technician at fault "was counselled concerning (the matter)". Although subjective in nature, the NRC identified that this did not appear to be adequate to prevent recurrence of this problem. Duke agrees that this item could have been addressed on a more generic basis in that the item could have been addressed as a training deficiency vice simply being limited to lack of training/knowledge of the individual involved.

The NRC states that Corrective Actions taken for finding NG-93-04(ON)(03) were not discussed. Duke specifies one corrective action for this finding and discusses the results and actions surrounding the completion of the item in the PIP.

The NRC states that Oconee Nuclear Site Audited personnel failed to address finding NG-93-04(ON)(05). Duke admits that this issue was not completely addressed in the PIP in that corrective actions were proposed but never documented in the "Corrective Actions" section of the PIP. This is a documentation problem since the proposed corrective actions were completed (and were identified in the PIP). It appears that the root cause of this problem was that the problem was addressed and solved before it was formally identified in the PIP Corrective actions section. Therefore, this appears to warrant training on the required PIP process necessary for proper documentation of these type of audits.

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Violation 94-34-01, Severity Level IV

1) continued

For Item # 2 the following explanation is provided:

The NRC identified that the audit findings were not answered within 30 days by the applicable ONS personnel as directed by the audit's cover letter. Duke power admits that this audit was answered approximately 8 days late by ONS personnel. The Audit team was aware of the Oconee Safety Assurance Group's decision to handle the identified Audit items within the PIP system as a means of addressing the audit concerns and providing the necessary information for an acceptable response. The Lead Auditor for this audit provided verbal approval to the Oconee site audit contact for a minor extension in order to complete the PIP resolutions although this was not documented within the audit file in a timely manner. (This item has subsequently been included in the audit file.) The cause of the late response to the audit was a misinterpretation of the QA Topical Report by the Lead Auditor. Although the QA Topical Report requires a "report" to be submitted within thirty days which "describe(s) corrective actions and an implementation schedule", it does not require a descriptions of completed corrective actions such as were (in part) documented in the PIPs addressing the findings. The Lead Auditor allowed extension of completion of the PIPs since he recognized that the requirements of report content per the QA Topical report had already been exceeded (i.e., the corrective actions were not only specified, but completed). This warrants clarification in the QA implementing procedures.

For Item # 3 the following explanation is provided:

The NRC states in part that the PIP process is not procedurally described in the QA Topical Report or the QA implementing procedures. Duke acknowledges that this was the case at the time of the NRC audit. Since the NRC audit, Duke has included the PIP process into the applicable QA implementing procedures. However, it has always been Duke's position that the QA Topical Report is a general document used to describe Duke's QA process, while "second tier" documents (such as Nuclear System Directives) and "third tier" documents (procedures) would be used to describe the specifics of procedures for the QA program. The QA Topical Report has always provided the flexibility of delegation by management of specific tasks. Duke therefore takes the position that it would be inappropriate to include this level of detail in the QA Topical Report.

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1) continued

For Item # 4 the following explanation is provided:

Duke admits that the PIP was not efficiently used to document the results of the findings of the QA Audit Team. However, this is considered to be a PIP documentation problem rather than a process issue with the PIP system. The PIP system provides a universal tracking process, promotes increased timeliness, and contains efficiencies over our previous methods of resolving audit findings. All of the concerns identified by the NRC Auditors could have been addressed within the PIP system had clear expectations been provided to the finding responders via the QA Implementing procedures. The cause of this item is that the guidance within the QA implementing procedures was not as clear as it could have been.

In summary, Duke's ongoing effort to include all facets of corrective actions into the PIP system continues to be effective. However, Duke must resolve each corrective action process as it is included into the PIP database. In the case of this corrective action process, the NRC audited a program in its infancy stage, and therefore some problems would be expected until the process is completely addressed in all applicable procedures. Therefore, the primary root cause of all the problems above appears to be due to lack of specific procedural guidance to the QA Auditors and finding responders via the QA Implementing procedures.

2) The corrective steps that have been taken and the results achieved:

Duke has revised our implementing procedures (Nuclear Assessment Functional Area Manual, (Operational Assessment) 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 (a "second tier" QA document) 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).

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3) The corrective steps that will be taken to avoid further violations:

This violation has been reviewed with all Regulatory Audit Group personnel to ensure that they establish consistent expectations with the audited groups.

Training has been completed and documented regarding the revised audit procedures and utilization of the PIP process for resolution of audit findings.

4) The date when full compliance will be achieved:

Duke Power Company is in full compliance with the above corrective actions.