



**Florida
Power**
CORPORATION

June 14, 1985
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Dr. J. Nelson Grace
Regional Administrator, Region II
Office of Inspection and Enforcement
U.S. Nuclear Regulatory Commission
101 Marietta Street, N.W., Suite 2900
Atlanta, GA 30323

35 JUN 19 410:54

Subject: Crystal River Unit 3
Docket No. 50-302
Operating License No. DPR-72
IE Inspection Report No. 85-15

Dear Sir:

Florida Power Corporation provides the attached as our response to the subject inspection report.

Sincerely,

Walter S. Wilgus
Vice President
Nuclear Operations

DVH/kdw

Attachment

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VIOLATION 50-302/85-15-01

Stated Violations

10 CFR 50 Appendix B Criterion XVI and the accepted QA program (FSAR Section 1.7.1.16, Revision 5) collectively state that measures shall be established to assure that conditions adverse to quality are promptly corrected.

Contrary to the above, measures have not been established to clearly delineate appropriate criteria for elevating unresolved QA audit findings to higher management for resolution. Existing procedures do not provide specific conditions to guide actions in the following areas:

- a. The number of unacceptable responses to a QA audit finding and the time permitted at each step of the audit process before escalating the problem resolution to successively higher management levels in the QA organization and in the audited organization.
- b. The number of extensions to corrective action completion dates and the time permitted at each step of the audit process before the need to delay corrective action is approved by successively higher management levels in the QA organization and in the audited organization.
- c. Criteria and time permitted to resolve issues similar to those described above by which problems are presented to the Executive Vice President who is ultimately responsible for prompt and acceptable resolution of all conditions adverse to quality.

Lack of acceptance criteria of the type discussed above resulted in failure to achieve prompt corrective action on several QA audit findings.

This is a Severity Level IV violation (Supplement I).

RESPONSE:

(1) Florida Power Corporation Position

FPC takes exception to this violation. QAP-8, "Quality Program Audits", and QAP-18, "Control of Nonconformance Reports", presently contain appropriate established measures to clearly delineate the criteria for escalating unresolved QA audit findings to higher management for resolution.

Presently there are not NRC-accepted nor industry published guidelines with respect to when escalation is required. However, the FPC NRC-accepted QA program does address the question of "timeliness" in Table 1-3. The pertinent section in relation to NRC Regulatory Guide 1.1.4.4 states:

"Subsection 3.3.7 requires verification of effective corrective action on a "timely basis." Timely basis is interpreted to mean

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within the framework or period of time for completion of corrective action that is accepted by the quality organization. Each finding requires response and a corrective action completion date; these dates are subject to revision (with the approval of the quality organization) and must be escalated to higher authority when there is a disagreement between the audited and the auditing organization on what constitutes 'timely corrective action'."

Quality Programs Administrative Procedure QAP-18, "Control of Nonconformance Reports", further defines escalation criteria by stating:

"This procedure applies to nonconformances identified by the Quality Programs Department (QPD) staff and is intended to comply with applicable requirements of 10 CFR 50, Appendix B, Criteria 15 and 16. This procedure is written to identify:

- (1) Nonconformances identified by an Audit Finding Report (AFR), Quality Programs Surveillance Report (QPSR), Quality Program Review (QPR), Quality Material Problem Report (QMPR), Request for Corrective Action (RCA), or Quality Control Inspection Report (QCIR) which have not been satisfactorily resolved or which have not had timely response/closure by the responsible organizations."

Quality Programs Administrative Procedure QAP-8, "Quality Program Audits", contains both quantitative and qualitative criteria to be used for escalation of unresolved QA audit findings. Section 6.6.2.1 states:

"Responses that are determined to be inadequate must be documented on a Follow-Up Report and issued to the audited organization requesting a corrected response. If the Audit Team Leader and audited organization cannot reach agreement on the corrective actions for any finding, the Audit Team Leader will refer these items to the Supervisor, Quality Audits. If a satisfactory resolution cannot be obtained by the Supervisor, Quality Audits, within an additional thirty (30) days, he may initiate a Nonconformance Report (NCR) in accordance with QAP No. 18."

These base requirements come from 10 CFR 50, Appendix B which requires that "action taken shall be documented and reported to appropriate levels of management." Since the Audit Supervisor is fully aware of open items, and as long as progress towards resolution is being made, then "appropriate levels of management" are aware of and are tracking the issues. The qualitative acceptance criteria (i.e., "If a satisfactory resolution cannot be obtained. . .") and the quantitative acceptance criteria (i.e., ". . . within an additional thirty days. . .") established in QAP-8 meet the requirements of 10 CFR 50 Appendix B Criterion XVI.

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It should also be noted that Violation 50-302/85-15-02 documents the failure to follow the approved escalation criteria for unresolved QA audit findings. As discussed in the next section of this response, we have agreed with this violation in that FPC has violated the criteria of QAP-8, Section 6.6.2.1.

Based upon the above response, Florida Power Corporation is in compliance with 10 CFR 50, Appendix B, Criterion XVI and requests that your office retract this item of noncompliance.

VIOLATION 50-302/85-15-02

Stated Violation:

10 CFR 50 Appendix B Criterion V and the accepted QA program (FSAR Section 1.7.1.5, Revision 5) state that activities affecting quality shall be prescribed by procedures and accomplished in accordance with these procedures. Procedure QAP 8, Quality Program Audits, Revision 9, Section 6.6.2.1, states that if the audit team leader and the audited organization cannot reach agreement on corrective action for any finding, the audit team leader will refer these items to the Supervisor, Quality Audits. If a satisfactory resolution cannot be obtained by the Supervisor, Quality Audits, within an additional 30 days, he initiates a nonconformance report (NCR).

Contrary to the above, the Supervisor, Quality Audits, has not initiated an NCR for Audit QP 249 finding 11. The initial response to this item dated March 28, 1984, stated that the Manager, Site Services, did not agree with the QA audit finding. Additional correspondence dated November 30, 1984, from the Site Director reiterated this position and the disagreement between the QA staff and the line organization had not been resolved at the time of this inspection.

This is a Severity Level IV violation (Supplement I).

RESPONSE:

(1) Florida Power Corporation Position

Florida Power Corporation agrees with this violation; however, we request that you reevaluate the assigned severity level.

While we admit that we did not properly follow the quantitative acceptance criteria contained in Quality Programs Administrative Procedure QAP-8, it is felt that this represents an isolated event and is not a recurring problem. On this basis we believe that the Severity Level V is applicable.

(2) Apparent Cause of Violation

The failure to escalate Audit QP-249 finding 11 to a Nonconformance Report (NCR) was due to a failure of Quality Programs Department management to follow established procedures. This failure centered on the use of the NCR process as a means for escalating only those issues having significant deficiencies. This in turn has led to a reluctance to escalate nonconformance reports for items having minor significance for fear of reducing the effectiveness of the NCR process.

(3) Corrective Actions

Quality Programs Department has conducted an evaluation of all open AFR's since the time of the NRC inspection. We have determined that QP-249 finding 11 is an isolated case. We have concluded that the remaining open audit findings have acceptable schedules and plans for corrective action.

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The Emergency Planning Section has revised their procedures and is now assembling their QA records in accordance with the requirements of the Quality Assurance Program. Subsequently corrective action for audit QP-249 finding 11 was verified as complete and the finding was closed. This corrective action was completed on April 26, 1985.

(4) Action Taken To Prevent Recurrence

Quality Programs Department personnel, including management, have been reinstructed on the proper and intended use of the NCR process. In the future, any nonconforming conditions, regardless of significance, will be escalated via the NCR process if adequate resolution cannot be obtained.

(5) Date of Full Compliance

Florida Power Corporation is presently in full compliance with the requirements relative to the NCR process.

VIOLATION 50-302/85-15-03

Stated Violation:

10 CFR 50 Appendix B Criterion XVIII and the accepted QA program (FSAR Section 1.7.1.2, Revision 5) collectively require a comprehensive system of planned and periodic audits. The frequency requirements for various audits are stated in Technical Specification (TS) 6.5.2.9 and in different sections of the accepted QA Program. Current procedures apply a variation to the stated audit and review frequency by allowing up to a 25% deviation in the stated frequency.

Contrary to the above, the applied frequency variation is inappropriate for audits and reviews required by TS Section 6.5.2.9 and the accepted QA Program. The two-year status and adequacy review required by the accepted QA Program, Section 1.7.1.2, is scheduled for completion in April 1985 which is 30 months since the last review.

This is a Severity Level V violation (Supplement I).

RESPONSE:

Florida Power Corporation Position

FPC requests that imposition of this violation be withheld. In discussions with your staff we understand that the issue of audit frequency deviations is under debate within the NRC. FPC requests that our evaluation of this proposed violation of audit frequency deviations and audit intervals be delayed until an NRC decision is reached.

VIOLATION 50-302/85-15-04

Stated Violation:

10 CFR 50 Appendix B Criterion XVII and the accepted QA Program (FSAR Section 1.7.1.17, Revision 5) state that sufficient records shall be maintained to furnish evidence of activities affecting quality. The accepted QA program commits to Regulatory Guide 1.88, Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records, which endorses ANSI N45.2.9, Requirements for Collection, Storage and Maintenance of Quality Assurance Records for Nuclear Power Plants. Regulatory Guide 1.88 also allows record storage in accordance with NFPA-232 1975, Standard for the Protection of Records.

Contrary to the above, record storage facilities in the Quality Programs Department do not meet ANSI N45.2.9 requirements and have not been evaluated to meet NFPA-232 1975 requirements.

This is a Severity Level V violation (Supplement I).

RESPONSE:

(1) Florida Power Corporation Position

FPC takes exception to this violation. The current process of collecting, storing and transmitting audit records meets all requirements of 10 CFR 50, Appendix B, Criterion XVII and ANSI N45.2.9-1974 as clarified in the NRC approved QA Program for FPC.

ANSI N45.2.9-1974 contains the following definition of Quality Assurance Records.

"Quality Assurance Records - Those records which furnish documentary evidence of the quality of items and of activities affecting quality. For the purpose of this standard a document is considered a Quality Assurance Record when the document has been completed."

Furthermore, the scope of ANSI N45.2.9-1974 states:

"It (this standard) is not intended to cover the preparation of the records, nor to include working documents not yet designated as Quality Assurance Records."

The audit records in the General Office Complex of Florida Power Corporation are working records in which there are open audit findings. These documents are periodically updated to reflect actions taken to resolve the audit findings. Audit records are divided into two functional "packages". These packages consist of:

1. Audit Notice and Plan
Audit Report
and
2. Audit Responses
Follow-up Correspondence
Closure Notices

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Until all the documents within each "package" are assembled, the "packages" are considered working documents and subsequently not within the scope of ANSI N45.2.9-1974.

This practice also meets the intent of ANSI N45.2.9 with respect to the ability to assure that, in the event of loss or destruction, the documents in question can be accurately reconstructed without undue delay. The Audit Notice and Plan and Audit Report receive a fairly wide distribution: 15 - 20 copies are distributed. This "package" typically remains in temporary storage for an average of 60 days (from the date the Notice/Plan is sent to the day the "package" is transmitted to Document Control).

There are other considerations for continuing to follow our current practices. Our AFRs are usually issued in a "group" to the audited organization. Their responses to several AFRs are typically contained in a single transmittal letter. In order to transmit each AFR to the file when closed, QPD would have to duplicate this single response letter and put a copy with each AFR transmitted. In addition, AFRs are typically interrelated to some degree. The responses often reference other AFRs and determination of adequate corrective action can often only be determined by looking at the response(s) for related AFRs. Thus we feel that keeping the responses, follow-up records, and closure records as a "package" is the best way to assure a complete review of the issues identified in our audit.

If any of the above audit related records should be lost or destroyed, they could be reconstructed from other copies which are held by several other addressees. Our specific plans to transmit the records as a group is delineated in specific terms in Exhibit 1 of Quality Program Administrative Procedure QAP-9, "Transmittal of Quality Records". Compliance with these specific transmittal conditions is covered in Quality Programs Administrative Procedure QAP-8, "Quality Program Audits", which states that records are collected and ultimately transmitted to the Plant Quality Document File in accordance with QAP-9.

Based upon the above response, Florida Power Corporation is in compliance with 10 CFR 50, Appendix B, Criterion XVII and requests that your office retract this item of noncompliance.