## PROPOSED REVISIONS TO FSAR SECTION 1.8 "QUALITY ASSURANCE PROGRAM"

To fully implement a performance-based approach for planning Quality Assurance Audits, we propose to remove the specific audit frequency requirements from FSAR Section 1.8, "Quality Assurance Program". Because there is a possibility that the actual interval between certain audit areas may be extended beyond the present requirement, the NRC may consider this change to be a reduction in commitment. Therefore, we provide the attached evaluation to demonstrate that the proposed changes will actually result in a net benefit to nuclear safety.

#### Background

On July 5, 1995, the NRC issued Amendment Nos. 162 and 166 to Facility Operating License Nos. DPR-24 and DPR-27, respectively. Those amendments relocated several audit frequency requirements from the Technical Specifications to FSAR Section 1.8.18, "Audits". As stated in your safety evaluation, the removal of those audit frequency requirements from the Technical Specifications was consistent with staff guidance and NUREG-1431. In addition, the relocation of those requirements to FSAR Section 1.8 would subject any subsequent changes to review under 10 CFR 50.54(a)(3).

## Evaluation of the Proposed Changes

This prope is change stipulates that the frequency of internal QA Audits will be determined by a "performance-based" approach with a maximum interval of two years between the audit of any safetyrelated function. Therefore, this proposed change deletes from FSAR Section 1.8.18 the list of specific audit requirements and their specific frequency requirements. The requirement to perform these specific audits will remain in the PBNP Technical Specifications, but no specific audit frequencies will be identified.

In effect, this FSAR revision may reduce the frequency of four particular audits that are presently assigned an interval less than two years. These changes could therefore be considered a reduction in commitment to the QA Program. These particular audits include:

- 1. TS Conformance (presently annual)
- 2. Licensed Operator Qualification (presently annual)
- 3. Corrective Action (presently semi-annual)
- Radiological Environmental Monitoring (presently annual)

9601220364 960118 PDR ADOCK 05000266 P PDR The proposed maximum audit intervals will be established at 2 years, except in those cases where regulation or PBNP Technical Specifications are more restrictive. The proposed 2-year maximum interval will allow some flexibility so that Quality Assurance oversight activities can be better based on performance and activities in progress, while assuring that each area will be audited at a minimum frequency.

Frequency of audits will be adjusted based on performance in the area to be audited and the safety significance of the activities being performed. Performance is assessed by the Quality Assurance Section (QAS) through audits, surveillances, and work monitoring reports (WMR). Performance is also assessed by the Nuclear Power Business Unit (NPBU) staff through performance indicators, performance trending, and performance monitoring. The results of these assessments are integrated and evaluated collectively by the Quality Assurance Section.

QAS holds periodic meetings to review performance and other pertinent information to determine whether any changes to the audit schedule are warranted. Areas that demonstrate poor or declining performance will be audited or surveilled more frequently than specified and other areas will, in some cases, be audited less frequently than currently specified due to good performance. In addition to increasing audit frequency, poor performing activities will be identified to upper management. These adjustments should have a positive impact on safety as resources are shifted to better focus on weak or declining performance areas, while still providing periodic audit coverage of other, stronger areas.

The effect of this program change on the other prescribed audits (listed below) would be conservative, and would not be a reduction in commitment. These two audits are already scheduled on a regular biannual basis, so changing to a performance-based audit system with a maximum 2-year interval would have the effect of maintaining or increasing the audit frequency, depending on the performance in these areas:

QA 10 CFR 50 Appendix B activities
Offsite Dose Calculation Manual

The purpose of the audits will not be affected, management oversight of the audit process will not be diminished, and the audits will be performed at frequencies that meet 10 CFR 50 and ANSI 18.7-1976 (as committed to in PBNP FSAR Section 1.8) requirements.

#### Summary

This change does not impact the actual operation of the plant, and will result in an improvement in plant safety by allowing greater flexibility to schedule audits and assign resources based on the level of performance in the area being audited. The audit program would focus more on areas of weak performance, and less on consistently high performance areas. Audits required to be performed at frequencies specified by regulation or Technical Specifications, however, will continue to be performed at the minimum specified frequencies. The purpose of the audits will not be affected. Management oversight of the audit process will not be diminished. The entrance to the room is closed with a Class A 250°F labeled fire door. In addition, the fire suppression system required an electrical supply, which led to the waiving of the requirement that walls could not be penetrated by electrical conduit. The electrical supply for room is brought into the room via a conduit through one of the walls and ceiling which has been installed to minimize the risk of fire passing through the wall via this penetration.

# 1.8.18 AUDITS

Procedures and practices have been established and documented to provide a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

Audits are performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. The QA program is audited periodically, by the QA Section. The QA Section also performs audits under the cognizance of the Off-Site Review Committee as required by PBNP Technical Specification 15.6. Onsite and off-site contractor audits are scheduled commensurate with the work's importance to plant safety and reliability and are timed as appropriate for the work scheduled.

Where practical, audits are conducted using performance-based techniques. As an example, periodic operational readiness assessments of safety-related plant systems may be conducted using vertical-slice audit techniques.

Audit results are documented and reviewed by management personnel having responsibility in the area audited. Audit reports are routed to management responsible for correcting any unsatisfactory items noted. Follow-up action, including reaudit of deficient areas, is taken when indicated. When follow-up audits reveal repetitive occurrences which reflect possible trends adverse to the effectiveness of the QA program, these results are reported to the appropriate management level to effect corrective action.

Sufficient audits are performed, by the QA Section, in accordance with the provisions of ANSI N45.2.12-1977 to meet the requirements of Section 4.5 of ANSI N18.7-1976. The frequency of internal audits is performance-based, and

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is determined in such a manner as to assure an audit of all safety-related functions is completed within a period of two years, unless otherwise specified in the PBNP Technical Specifications or regulations. Also, internal audits performed by the QA Section are led by individuals certified as Lead Auditors in accordance with the requirements of ANSI N45.2.23-1978. It should be noted that Section 3.2 of ANSI N18.7-1976 recognizes that quality assurance is an interdisciplinary function and that advantages may accrue from having reviews of certain plant functions performed by individuals other than quality assurance personnel. WE strongly endorses this position. The QA Section assigns gualified and technically competent guality assurance personnel to perform audits, however, when appropriate, QA personnel are supplemented with other technically qualified WE and/or contractor personnel. Audits are sometimes supplemented by surveillances of quality related activities. Surveillances are performed by gualified individuals, although not necessarily certified as lead auditors. In addition, certain review functions may be assigned to technically gualified individuals in lieu of guality assurance personnel.

The following audits identified in the PBNP Technical Specifications are performed at the indicated frequencies:

- The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions at least once per year.
- 2. The performance, training and qualification of the licensed operating staff at least once per year.
- 3. The results of actions taken to correct deficiencies occurring in facility equipment, structures, systems or method of operation that affect nuclear safety at least twice per year at approximately sixmonth intervals.
- 4. The results of audits by the quality assurance organization on the performance of activities required by the Quality Assurance Program to meet the criteria of Appendix B, 10 CFR 50 at least once per two years.

- 5. An audit of the activities encompassed by the Offsite Dose Calculation Manual and the Process Control Program and its implementing procedures at least once every 24 months utilizing either off site licensee personnel or a consulting firm.
  - 6. An audit of the radiological environmental monitoring program and the results thereof at least once every 12 months utilizing either off site licensee personnel or a qualified consulting firm.