



Entergy Nuclear Generation Co.
Pilgrim Station
600 Rocky Hill Road
Plymouth, MA 02360

William J. Riggs
Director, Nuclear Assessment

10 CFR 50.54(a)(3)

August 23, 2001
ENGCLtr. 2.01.081

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

Docket No.: 50-293
License No.: DPR-35

Subject: Annual Report of Changes to the Quality Assurance Program Description for Pilgrim Nuclear Power Station

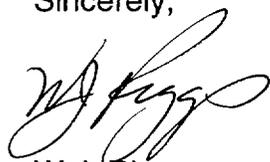
Dear Sir:

In accordance with 10 CFR 50.54(a)(3), Entergy Nuclear Generation Company submits the enclosed report of changes to the Quality Assurance Program Description as described in the Pilgrim Quality Assurance Manual (PQAM). The report covers the period from July 2000 through June 2001.

Enclosure A consists of the Annual Report, a copy of the revised PQAM section, and documentation generated during the preparation and issuance of these changes. The documentation identifies the changes made, the reasons for change, and the basis of continued compliance with 10 CFR 50 Appendix B. Results of the 10 CFR 50.54(a)(3) evaluations are also included.

Please feel free to contact Mr. Robert Sheridan, (508) 830-8291, if there are any questions regarding this subject.

Sincerely,



W.J. Riggs

DWE/

Enclosure A: Report of Quality Assurance Manual Changes (July 2000 - June 2001)

cc: (see next page)

2004

cc: Mr. Douglas Starkey, Project Manager
Office of Nuclear Reactor Regulation
Mail Stop: 0-8B-1
U.S. Nuclear Regulatory Commission
1 White Flint North
11555 Rockville Pike
Rockville, MD 20852

Mr. Hubert Miller, Administrator
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

NRC Senior Resident Inspector
Pilgrim Nuclear Power Station

**ANNUAL REPORT
OF
PILGRIM QUALITY ASSURANCE MANUAL CHANGES
[July 2000 through June 2001]**

Attachment A: PQAM Section 18 Change Documentation—PQAM Change Request No. 00-04

SUMMARY OF CHANGES

During the reporting period, one revision to the PQAM (Section 18, Audits) was issued as part of PNPS continuing efforts to revise each PQAM section to reflect the transfer of PNPS ownership and, at the same time, maximize consistency with the Entergy Nuclear South common QA Program document, which is written to an SRP 17.3 format. As part of this change, the specified frequency for the audit of Special Nuclear Material (SNM) was also revised from 12 to 24 months and an allowance for a 90-day grace period relative to the conduct of internal audits was introduced.

The detailed evaluation of the changes made are documented in Attachment A. With the exception of two specific changes identified as reductions in commitment, the balance of changes are administrative in nature in that they reflect the sale of PNPS to Entergy Nuclear Generation Company (ENGC), the revised organizational structure, and/or the realigned functional responsibilities under a format consistent with NRC SRP 17.3. All of the changes have been evaluated as being acceptable in that they have no adverse program effect relative to the Station's obligations under Criterion XVIII to 10CFR50 Appendix B. Additionally, none of the changes requires prior NRC approval under 10CFR50.54(a)(3). The two reductions in commitment represent changes previously addressed to the NRC by other licensees and approved as documented under NRC Safety Evaluation Reports for Baltimore Gas & Electric Company (dated September 25, 1996) and Rochester Gas & Electric Corporation (dated July 22, 1998).. The basis of the NRC approval for these reductions in commitment has been evaluated and found acceptable for application at PNPS.

PQAM CHANGE DESCRIPTIONS

PQAM CHANGE NO. 00-04
Section 18, "QA Assessment"
Revision 0, 12/18/00

CHANGE IDENTIFICATION

As indicated in Attachment A, Section 18 was completely rewritten to:

- ◆ Address the sale of Pilgrim Station to Entergy Nuclear Generation Company.
- ◆ Present the information in a format consistent with that of SRP 17.3.
- ◆ Change the frequency of Special Nuclear Material audits from 12 to 24 months.

- ◆ Introduce an allowance for a 90-day grace period relative to the conduct of internal audits with a 24-month frequency.

Within this attachment, PQAM Change Request 00-04 (Attachment 1) provides a verbatim copy of the previous revision in a matrix form that identifies the disposition of text as compared to the new revision. This attachment identifies two Specific Program Changes, with the balance of changes classified as General Program Changes. The General Program Changes involve the description of the PNPS QA oversight system using an SRP 17.3 format. The two Specific Program Changes involve the revised frequency of Special Nuclear Material audits from 12 to 24 months and the introduction of an allowance for a 90-day grace period in the conduct of internal audits scheduled at a 24-month frequency.

REASON FOR CHANGES

This revision to Section 18 is part of an ongoing effort to reflect the present ownership and increase Entergy corporate QA Program flexibility by presenting the PNPS QA Program description in a manner consistent with the format (SRP 17.3) and level of detail prescribed in the Entergy Nuclear South QA Manual. This revision also revised existing audit frequency commitments for consistency with applicable regulations and standards. A 90-day grace period relative to the conduct of internal audits scheduled at a 24-month frequency has also been introduced to provide the flexibility required to support the maximization of resource allocations during oversight activities.

BASIS OF CONTINUED 10CFR50 APPENDIX B COMPLIANCE

Section 18 of the Pilgrim Quality Assurance Program, as revised, continues to satisfy 10CFR50, Appendix B. The General Program Changes have been evaluated as having no adverse program effect in that the revised text effectively addresses the applicable criteria of 10CFR50, Appendix B and continues to support compliance with this regulation. The two Specific Program Changes pertain to revising the frequency for Special Nuclear Material audits from 12 to 24 months and the introduction of a 90-day grace period relative to the conduct of internal audits scheduled at a 24-month frequency. While both of these changes are considered to be reductions in program commitment, they are also determined to be within the allowances of 10CFR50, Appendix B. Further, as prescribed in 10CFR50.54(a)(3), these reductions in commitment are allowed to be made without prior NRC approval based on the evaluated application of previously issued NRC Safety Evaluation Reports for other licensees.



Entergy

Entergy Nuclear Generation Company

RTYPE: H8.46

Pilgrim Nuclear Power Station

**PILGRIM QUALITY ASSURANCE MANUAL (PQAM)
SECTION 18**

QA ASSESSMENT

QA ASSESSMENT

18.1 PURPOSE

This section establishes an internal system of QA Program oversight through assessments performed under the following methodology:

- A. Personnel responsible for carrying out QA assessments are maintained cognizant of day-to-day activities by the ongoing involvement in the Quality Assurance Program requirements so that they can act in a management advisory function.
- B. Assessments are to be technically- and performance-oriented commensurate with the activity being reviewed.
- C. Personnel performing assessments have no direct responsibilities in the area they are assessing.
- D. Assessments are accomplished using instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.
- E. Audits and oversight program reviews required by this Section 18 are performed under the cognizance of the Nuclear Safety Review and Audit Committee (NSRAC).

18.2 GENERAL REQUIREMENTS

18.2.1 A program of planned and periodic assessments (audit, oversight program review, and surveillance monitoring) is established and implemented to confirm that activities affecting quality comply with the Pilgrim Quality Assurance Manual (PQAM) and that the PQAM has been implemented effectively. Frequencies for audits and oversight program reviews will be implemented, as required, by the applicable Code of Federal Regulations, Safety Analysis Report, and commitments by various correspondence to the NRC. Surveillance monitoring is performed, as necessary, to supplement the verification of program adequacy and effectiveness. Audits will be conducted at the frequencies listed below.

- A. Schedules assure that the following areas are audited at the indicated frequencies or more frequently as performance dictates:
 - 1. The conformance of PNPS operation to provisions contained within the Technical Specifications and applicable license conditions is audited at least once every 24 months.

2. The performance, training, and qualifications of PNPS personnel are audited at least once every 24 months.
3. The results of actions taken to correct deficiencies occurring in unit equipment, structure, systems, or method of operation that affect nuclear safety are audited at least once every 24 months.
4. The performance of activities required by the PQAM to meet the criteria of 10CFR50, Appendix B is audited at least once every 24 months.
5. A Fire Protection and Loss Prevention Program inspection and audit shall be performed using either off-site licensee personnel or an outside fire protection firm at least once every 12 months.
6. The Fire Protection Program and implementing procedures are audited at least once every 24 months.
7. A Fire Protection and Loss Prevention Program inspection and audit shall be performed using an outside fire consultant at least once every 36 months.
8. The Special Nuclear Material (SNM) Control Program and implementing procedures are audited at least once every 24 months.

B. A grace period of 90 days may be applied to the 24-month frequency for internal audits. For activities deferred in accordance with the 90-day grace period, the next performance due date will be based on their originally scheduled date.

- 18.2.2 Assessments shall provide an objective evaluation of quality-related practices, procedures, instructions, activities, and items and a review of documents and records, as applicable.
- 18.2.3 Assessments shall be performed in accordance with approved written procedures or checklists. Items from previous assessments shall be reviewed and re-assessed, as appropriate. The checklists are used as guides to the auditor.
- 18.2.4 Scheduling and resource allocation are based on the status and safety importance of the activity or process being assessed.
- 18.2.5 Scheduling is dynamic and resources are supplemented when the effectiveness of the Quality Assurance Program is in doubt.

- 18.2.6 Assessment reports are written and distributed to the appropriate levels of management for review. Follow-up action, including re-looking at deficient areas, is initiated, as deemed appropriate.
- 18.2.7 Implementation of delegated portions of the Quality Assurance Program is assessed.
- 18.2.8 Assessments are conducted using predetermined acceptance criteria.
- 18.2.9 Additional details concerning audits may be found in the Regulatory Guides (e.g., RG 1.33 and RG 1.144) and associated Standards as committed to in PQAM Section 2.



**PILGRIM NUCLEAR POWER STATION
PILGRIM QUALITY ASSURANCE MANUAL (PQAM)**

CHANGE REQUEST NO. 00-04

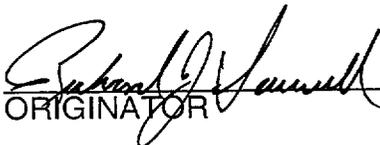
SECTION 18 REV. NO. 0 PARAGRAPH NO. All PAGE NO. All

REVISION (exact wording)

This section has been rewritten in its entirety; therefore, no mark-up of Revision 30 is provided and no revision bars are included in the new revision (Revision 0). See Attachment 1 for information relative to the existing text, the disposition of this text, and the revised wording.

PURPOSE OF REVISION

1. Complete rewrite to reformat text and provide a level of discussion consistent with the Entergy QA Manual applied to the regulated side of the Company.
2. Revise existing audit frequency commitments for consistency with applicable regulations and standards.

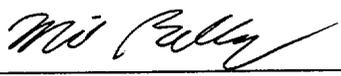


 ORIGINATOR 10/26/00
Date

12-18-00

 EFFECTIVE DATE OF PQAM SECTION

APPROVAL SIGNATURES



 VICE PRESIDENT,
 OPERATIONS PILGRIM 11/8/00
Date



 GENERAL MANAGER,
 PLANT OPERATIONS 11/4/00
Date



 DIRECTOR,
 DESIGN ENGINEERING 10/30/00
Date



 DIRECTOR,
 NUCLEAR ASSESSMENT 10/27/00
Date

QA PROGRAM CHANGE EVALUATION

PQAM Change Request No. 00-04

Section No. 18

Rev. 0

EVALUATION

Does the above change to the QA Program reduce the commitments concerning:

Yes No

- 10CFR50, Appendix B
- Program coverage documentation (policies, procedures, or inspections)
- Policy, procedure, or instruction compliance (exception to Reg Guide 1.33)
- Identification of structure systems, and components
- Identification of major participating organizations and their designated functions
- Providing control over activities affecting the quality of the identified structures, systems, and components
- Controlling conditions under which activities affecting quality are to be accomplished (e.g., equipment, environmental conditions, prerequisites)
- Attaining required quality (e.g., special controls, processes, test equipment, tools, or skills)
- Verification of quality by inspection and test
- Providing indoctrination and training of personnel performing activities affecting quality
- Regularly reviewing the status and adequacy of the QA Program
- Periodic review for status and adequacy by participating organization Managers of the part of the QA Program which they are executing
- Other (explain) -- none --

QA PROGRAM CHANGE EVALUATION (cont.)

PQAM Change Request No. 00-04

CONCLUSION

Section 18 of the Pilgrim Quality Assurance Program, as revised, continues to satisfy 10CFR50, Appendix B. The changes made within this section meet the criteria within 10CFR50.54(a) relative to QA program changes that can be made without prior NRC approval.

Notwithstanding two changes to specific QA Program requirements that have been identified as reductions in commitment, the balance of changes achieve a level of detail and format consistent with SRP 17.3 and have no adverse program effect. The two reductions in commitment under 10CFR50.54(a)(3) are allowed to be made without prior NRC approval based on the evaluated application of previously issued NRC Safety Evaluation Reports for other licensees.

CHANGE EVALUATION

This revision to Section 18 is part of an overall effort to rewrite the entire program document under an SRP 17.3 format. It is important to note that this revision is significantly different than that of the existing section, which is written under an SRP 17.1 format. SRP 17.1 addresses itself solely to audits, which is the only QA programmatic oversight method identified in Criterion XVIII to 10CFR50, Appendix B. SRP 17.3 addresses 10CFR50, Appendix B, Criterion XVIII with the realization that several different groups within a station's organization can perform oversight functions. Accordingly SRP 17.3 discusses the audit function as one of several acceptable oversight methods that are cumulatively categorized as "self-assessment." SRP 17.3 recognizes that licensees can take programmatic credit for these alternate auditing methods in the overall verification of QA Program adequacy and effectiveness as long as these alternate methods satisfy the stated SRP methodologies. Within this framework, a licensee can satisfy its obligations under Criterion XVIII to Appendix B by maintaining a traditional audit program executed by the QA organization or expanding the scope of this function by including other acceptable methods such as self-assessments by participating groups and/or reviews by independent committees. The proposed revision discusses alternate auditing methods by addressing QA Oversight Program Review surveillances, surveillance monitoring, and NSRAC's oversight of the audit function as part of the PNPS QA assessment function under Criterion XVIII to Appendix B. The PNPS self-assessment function has not been included.

In order to revise Section 18 consistent with the level of discussion and format of SRP 17.3, a complete rewrite of this section has been prepared. The detailed evaluations of the changes made are documented in Attachments 1 and 2. Attachment 1 provides a verbatim copy of the previous Section 18 in a matrix form that documents the disposition of text as compared to the associated wording contained in the new revision. Attachment 2 documents the evaluation of the revised Section 18 relative to the criteria of SRP 17.3. This comparison ensures all program elements and attributes within the SRP have been addressed in the revised text.

As indicated in Attachment 1, two changes affect specific QA Program requirements that are determined to be reductions in program commitment. Notwithstanding these commitment reductions that are evaluated separately hereafter, the balance of changes have been made to achieve the desired level of discussion and format consistent with SRP 17.3. The balance of changes describe Pilgrim QA assessment control measures with a minimal level of detail. While much of the text in the previous revision has been deleted, the level of detail provided in the revision effectively addresses the requirements of Criterion 18 of 10CFR50, Appendix B; PNPS commitments to Regulatory Guides 1.33 and 1.144; and ANSI Standards N18.7 and N45.2.12. Additionally, existing PNPS audit program allowances to execute Oversight Program Review surveillances in specific areas rather than audits and to supplement the audit function via surveillance monitoring have also been carried over into the new revision. These program allowances reflect previous changes to the PNPS audit program that were approved by the NRC via an SER.

Two specific changes involve reductions in QA Program commitments. The new revision changes the frequency of the Special Nuclear Material (SNM) audit from 12 to 24 months and adds a program allowance to provide a 90-day grace period that may be applied to the 24-month frequency established for internal audits. While both of these changes are considered to be within the allowances of 10CFR50, Appendix B, the changed SNM audit frequency reduces the annual frequency committed to previously. Additionally, the allowance of a 90-day grace period for internal audits deviates from present PNPS commitments to Regulatory Guide 1.33 and associated ANSI Standard N18.7.

While these changes represent reductions in commitment, they are allowed to be made without prior NRC approval using the criteria of 10CFR50.54(a)(3). Under this regulation, changes that reduce QA Program commitments can be made without prior NRC approval based on the use of a quality assurance alternative or exception approved by an NRC Safety Evaluation provided that the bases of the NRC approval are applicable to the licensee's facility.

The two reductions in commitment represent quality assurance alternatives and/or exceptions that have been previously addressed by other licensees and approved by the NRC. The evaluation of these changes, the basis of NRC approval, and acceptability of the changes for application to Pilgrim Station without prior NRC approval are as follows:

1. The PQAM requirement to perform an annual audit of SNM activities was originally introduced during Revision 30 to PQAM Section 18 based on a very

conservative approach towards 10CFR70.58. Even though 10CFR70.58(a) exempts nuclear reactors licensed pursuant to 10CFR50 from the requirements of 10CFR70.58(b) through (k), an annual SNM audit was specifically added to the list of audits identified in Section 18 that are to be performed every 12 months.

The established SNM audit frequency is overly conservative from a regulatory perspective. Accordingly, it is now desired to relax the frequency from 12 to 24 months in order to facilitate the allocation of oversight resources to other program areas.

This change is consistent with previous changes to the Baltimore Gas and Electric (BGE) Calvert Cliffs QA Program that were submitted to the NRC as reductions in commitment and approved. In 1996, BGE submitted a QA program change (Calvert Cliffs QA Policy, Revision 53) to the NRC as a reduction in commitment. This change reduced the frequencies of several audits specifically addressed under Regulatory Guide 1.33 as requiring frequencies tighter than the 24-month frequency discussed in ANSI Standard N18.7. The NRC, as documented in correspondence dated September 26, 1996, accepted this change. As indicated therein, "Although the reduction in audit frequencies is an exception to Regulatory Guide 1.33-1978, you are maintaining an audit frequency for all safety related functions of once every two years."

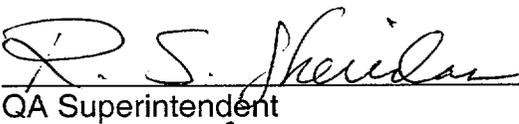
While the program activities addressed in the PQAM Section 18 revision and the BGE program changes differ, they both pertain to the relaxation of audit frequencies not uniquely mandated by 10 CFR requirements. From a regulatory perspective, the BGE changes are more significant in that they pertain to program activities specifically addressed in Regulatory Guide 1.33 as requiring audit frequencies tighter than the 24-month frequency requirement of ANSI N18.7. The NRC approved the BGE program changes even though they were exceptions to the Regulatory Guide on the basis that the BGE QA Program continues to maintain a minimum 2-year audit frequency for safety-related activities. The annual SNM audit requirement within PQAM Section 18 is of lesser significance in that it has no regulatory basis. The relaxation to a 24-month frequency does not reduce PNPS commitments to ANSI N18.7. This change is also consistent with the NRC's approval basis for the BGE program changes in that PNPS continues to maintain a minimum 2-year audit frequency for all activities performed under the PQAM. Accordingly, the NRC's approval basis for BGE program changes is determined to be acceptable for application to the PQAM Section 18 revision. Under the criteria of 10CFR50.54(a)(3), prior NRC approval is not required for this change.

2. The change pertaining to the provision of a 90-day grace period for the performance of internal audits required to be performed every 24-months can also be made without prior NRC approval under the allowances of 10CFR50.54(a)(3). This addition of a 90-day grace period is the same as a change made previously by Rochester Gas and Electric (RGE) during Revision 25 to the Ginna Nuclear Power Plant QA Program. The RGE change was submitted to the NRC and approved as a reduction in commitment that takes exception to Regulatory Guide 1.33. The NRC's approval is documented in correspondence dated July 22, 1997. As indicated in the SER, the NRC ini-

tially established nominal periodic requirements for audits in the Regulatory Guide to provide guidance regarding suitable audit intervals and not to prevent flexibility in the scheduling of these activities. The program change with the caveat that requires subsequent audits to be scheduled based on the originally scheduled date of the activity to which a 90-day grace period was applied is acceptable and meets the criteria of 10CFR50, Appendix B. The SER indicates that the NRC's approval is based on the intent of the change that simply aims to allow some limited additional flexibility in scheduling activities associated with the audit interval objective of the QA program.

The change in PQAM Section 18 is identical to the one by RGE. Accordingly, the NRC's approval basis for RGE's program change is determined to be acceptable for application to the PQAM Section 18 revision. Under the criteria of 10CFR50.54(a)(3), prior NRC approval is not required for this change.

Prepared by:  10/26/00
Cognizant QA Engineer Date

Approved by:  10/27/00
QA Superintendent Date

 10/27/00
QA Assessment Team Manager Date



**PILGRIM NUCLEAR POWER STATION
PILGRIM QUALITY ASSURANCE MANUAL (PQAM)**

ATTACHMENT 1

To

QA PROGRAM CHANGE EVALUATION

CHANGE REQUEST NO. 00-04

For

SECTION 18

Revision 0

BEQAM TEXT DISPOSITION CATEGORIES

Type A (Specific Change) = Text revised or deleted to reflect a change in QA Program requirements or commitments.

Type B (Generic Change) = Text revised to reflect the new ownership, the revised organization, or the resultant realignment of responsibilities.

Type C (Generic Change) = Text relative to system implementation that has been deleted on the basis that it is redundant to requirements in Standards committed to within the QA Program and/or text already delineated and more appropriately contained in implementing procedures.

Type D (Generic Change) = Text abbreviated to address the content in a manner consistent with the level of discussion under an SRP format and/or the level of detail provided in the Entergy QA Program applied in state regulated markets.

Type E (Generic Change) = Text deleted as not relevant under the new ownership and/or not essential to the area of discussion under the revised format.

Type F (Generic Change) = Text adopted virtually as written.

PQAM TEXT DISPOSITION CATEGORIES

"Strikethrough" Text = Entergy QA Manual text that has not been utilized.

Bold, Italic, Underlined Text = PNPS unique wording added to Entergy QA Manual text.

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p style="text-align: center;">AUDITS</p> <p>18.1 PURPOSE</p> <p>This section establishes requirements for an internal auditing program to verify the implementation of and to assess the effectiveness of the Boston Edison Quality Assurance Program. This section also provides the general requirements for other QAD oversight functions, including surveillance monitoring and performance of program reviews.</p> <p>18.2 GENERAL REQUIREMENTS</p> <p>18.2.1 QAD performs audits of all activities to which this Quality Assurance Program applies.</p> <p style="text-align: center;">↓</p> <p>Activities to which the QA Program do not apply are audited to the extent necessary to assure proper and safe operation of PNPS.</p>	<p>Type D Ref. 18.1</p> <p>New Text → No Program Impact</p> <p>Type D Ref. 18.2.1</p> <p>Type E</p> <p>Type D Ref. 18.2.1</p> <p>Type E</p>	<p style="text-align: center;">QA ASSESSMENT</p> <p>18.1 PURPOSE</p> <p><u>This section establishes an internal system of QA Program oversight through assessments performed under the following methodology:</u></p> <p>A. Personnel responsible for carrying out audits- <u>QA assessments</u> are maintained cognizant of day-to-day activities by the ongoing involvement in the Quality Assurance Program requirements so that they can act in a management advisory function.</p> <p>B. Organizations performing audits <u>Assessments</u> are to be technically- and performance-oriented commensurate with the activity being reviewed.</p> <p>C. Personnel performing audits <u>assessments</u> have no direct responsibilities in the area they are assessing.</p> <p>D. Audits <u>Assessments</u> are accomplished using instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.</p> <p><u>E. Audits and oversight program reviews required by this Section 18 are performed under the cognizance of the Nuclear Safety Review and Audit Committee (NSRAC).</u></p> <p>18.2 GENERAL REQUIREMENTS</p> <p>18.2.1 A program of planned and periodic audits- <u>assessments (audit, oversight program review, and surveillance monitoring)</u> is established and implemented to confirm that activities affecting quality comply with the <u>Pilgrim Quality Assurance Manual (PQAM)</u> and that the <u>PQAM</u> has been implemented effectively. Frequencies for audits <u>and oversight program reviews</u></p>

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p>18.2.2 Formal QAD audits may be supplemented by surveillance monitoring to provide adequate assurance of program compliance and effectiveness. Surveillance monitoring shall be performed in accordance with Section 18.6.</p>	<p>Type D Ref. 18.2.1</p>	<p>will be implemented, as required, by the applicable Code of Federal Regulations, Safety Analysis Report, and commitments by various correspondence to the NRC. <u>Surveillance monitoring is performed, as necessary, to supplement the verification of program adequacy and effectiveness.</u> Audits will be conducted at the frequencies listed below.</p>
<p>18.2.3 Audits and program review surveillances are performed by qualified personnel, using checklists to evaluate conformance to specified requirements, as well as to assess program effectiveness. Auditors shall not have direct responsibility in the areas being audited or surveyed. Technical Specialists shall be utilized in audits or program review surveillances under the direction of an auditor, as deemed necessary.</p>	<p>Type D Ref. 18.1.a-d</p> <p>New Text → Not Incorporated</p>	<p>a. Audit frequencies will be determined in accordance with a performance based audit scheduling program. The scheduling program, through an expert panel, uses assessment indicators to identify and schedule audits based on performance results and importance of the activity relative to safety. Potential audit subject areas are periodically assessed against appropriate performance criteria. From these reviews a determination is made in regard to the depth, scope, and scheduling of specific audits. Functional areas important to safety are assessed annually (+25%) to identify strengths and weaknesses (if applicable) to determine the level and focus of independent oversight activities for the upcoming year. The basis for the assessment shall include the results of audits and surveillance, NRC inspections, LERs, self-assessments, and applicable conditions reports (e.g., non-conformance and corrective action reports). Personnel changes, change/increase in functional area, responsibilities, industry operating experience, and INPO evaluations will also be considered. Each area will be assigned a rating with a comparison to previous years. This assessment will be documented, reviewed, and approved by quality assurance management. This document is considered a quality assurance record and will be available for NRC review. Audit subject areas of Section C.2.a.2 shall continue to be audited on the frequencies designated unless expert panel judgment, based on performance results, determines such an audit to be unnecessary. In such cases the expert panel basis shall be documented.</p>
<p>18.2.4 Audit subject and frequency is based on the requirements of Paragraph 18.3.1. Additional or more frequent audits may be performed when significant changes or problems arise, and upon request by NSRAC or the Senior VP, Nuclear.</p>	<p>Type D Ref. 18.2.1</p>	<p>a. Audit frequencies will be determined in accordance with a performance based audit scheduling program. The scheduling program, through an expert panel, uses assessment indicators to identify and schedule audits based on performance results and importance of the activity relative to safety. Potential audit subject areas are periodically assessed against appropriate performance criteria. From these reviews a determination is made in regard to the depth, scope, and scheduling of specific audits. Functional areas important to safety are assessed annually (+25%) to identify strengths and weaknesses (if applicable) to determine the level and focus of independent oversight activities for the upcoming year. The basis for the assessment shall include the results of audits and surveillance, NRC inspections, LERs, self-assessments, and applicable conditions reports (e.g., non-conformance and corrective action reports). Personnel changes, change/increase in functional area, responsibilities, industry operating experience, and INPO evaluations will also be considered. Each area will be assigned a rating with a comparison to previous years. This assessment will be documented, reviewed, and approved by quality assurance management. This document is considered a quality assurance record and will be available for NRC review. Audit subject areas of Section C.2.a.2 shall continue to be audited on the frequencies designated unless expert panel judgment, based on performance results, determines such an audit to be unnecessary. In such cases the expert panel basis shall be documented.</p>
<p>18.2.5 Audits and program review surveillances required by this Section are performed under the cognizance of the Nuclear Safety Review and Audit Committee (NSRAC).</p>	<p>Type F Ref. 18.1.e</p>	<p>a. Audit frequencies will be determined in accordance with a performance based audit scheduling program. The scheduling program, through an expert panel, uses assessment indicators to identify and schedule audits based on performance results and importance of the activity relative to safety. Potential audit subject areas are periodically assessed against appropriate performance criteria. From these reviews a determination is made in regard to the depth, scope, and scheduling of specific audits. Functional areas important to safety are assessed annually (+25%) to identify strengths and weaknesses (if applicable) to determine the level and focus of independent oversight activities for the upcoming year. The basis for the assessment shall include the results of audits and surveillance, NRC inspections, LERs, self-assessments, and applicable conditions reports (e.g., non-conformance and corrective action reports). Personnel changes, change/increase in functional area, responsibilities, industry operating experience, and INPO evaluations will also be considered. Each area will be assigned a rating with a comparison to previous years. This assessment will be documented, reviewed, and approved by quality assurance management. This document is considered a quality assurance record and will be available for NRC review. Audit subject areas of Section C.2.a.2 shall continue to be audited on the frequencies designated unless expert panel judgment, based on performance results, determines such an audit to be unnecessary. In such cases the expert panel basis shall be documented.</p>
<p>18.2.6 Audit results, including findings, shall be documented and distributed to appropriate levels of management.</p>	<p>Type D Ref. 18.2.6</p>	<p>a. Audit frequencies will be determined in accordance with a performance based audit scheduling program. The scheduling program, through an expert panel, uses assessment indicators to identify and schedule audits based on performance results and importance of the activity relative to safety. Potential audit subject areas are periodically assessed against appropriate performance criteria. From these reviews a determination is made in regard to the depth, scope, and scheduling of specific audits. Functional areas important to safety are assessed annually (+25%) to identify strengths and weaknesses (if applicable) to determine the level and focus of independent oversight activities for the upcoming year. The basis for the assessment shall include the results of audits and surveillance, NRC inspections, LERs, self-assessments, and applicable conditions reports (e.g., non-conformance and corrective action reports). Personnel changes, change/increase in functional area, responsibilities, industry operating experience, and INPO evaluations will also be considered. Each area will be assigned a rating with a comparison to previous years. This assessment will be documented, reviewed, and approved by quality assurance management. This document is considered a quality assurance record and will be available for NRC review. Audit subject areas of Section C.2.a.2 shall continue to be audited on the frequencies designated unless expert panel judgment, based on performance results, determines such an audit to be unnecessary. In such cases the expert panel basis shall be documented.</p>
<p>18.3 <u>AUDIT PROGRAM ELEMENTS</u></p> <p>18.3.1 An audit schedule is prepared annually. The schedule reflects the applicable regulatory, license, and QA Program requirements. The audit program shall encompass, as a minimum, the following:</p>	<p>Types C & D; Ref. 18.2.1, 18.2.9, and QA18.04</p>	<p>a. Audit frequencies will be determined in accordance with a performance based audit scheduling program. The scheduling program, through an expert panel, uses assessment indicators to identify and schedule audits based on performance results and importance of the activity relative to safety. Potential audit subject areas are periodically assessed against appropriate performance criteria. From these reviews a determination is made in regard to the depth, scope, and scheduling of specific audits. Functional areas important to safety are assessed annually (+25%) to identify strengths and weaknesses (if applicable) to determine the level and focus of independent oversight activities for the upcoming year. The basis for the assessment shall include the results of audits and surveillance, NRC inspections, LERs, self-assessments, and applicable conditions reports (e.g., non-conformance and corrective action reports). Personnel changes, change/increase in functional area, responsibilities, industry operating experience, and INPO evaluations will also be considered. Each area will be assigned a rating with a comparison to previous years. This assessment will be documented, reviewed, and approved by quality assurance management. This document is considered a quality assurance record and will be available for NRC review. Audit subject areas of Section C.2.a.2 shall continue to be audited on the frequencies designated unless expert panel judgment, based on performance results, determines such an audit to be unnecessary. In such cases the expert panel basis shall be documented.</p>

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p><u>Once per 24 Months</u></p> <ul style="list-style-type: none"> • The performance of activities required by the QA Program to meet the criteria of 10CFR50 Appendix B. • The results of corrective actions taken to correct deficiencies in the facility equipment, structures, systems, or methods of operation that affect nuclear safety. • The training and qualification of the entire unit staff. • The conformance of facility operation to the provisions contained within the Technical Specifications (Tech Specs) and applicable license conditions. • The Fire Protection Program and implementing procedures. • Refueling activities and procedures. • Conduct of operations and implementing procedures. • Any other area of facility operation considered appropriate by the NSRAC or the Senior Vice President, Nuclear. 	<p>Type F Ref. 18.2.1.A.4</p> <p>Type F Ref. 18.2.1.A.3</p> <p>Type F Ref. 18.2.1.A.2</p> <p>Type F Ref. 18.2.1.A.1</p> <p>Type F Ref. 18.2.1.A.6</p> <p>Type D Ref. 18.2.1.A.4</p> <p>Type D Ref. 18.2.1.A.4</p> <p>Type E</p>	<p>A. Schedules assure that the following areas are audited at the indicated frequencies or more frequently as performance dictates:</p> <ol style="list-style-type: none"> 1. The conformance of PNPS operation to provisions contained within the Technical Specifications and applicable license conditions is audited at least once every 24 months. 2. The performance, training, and qualifications of PNPS personnel are audited at least once every 24 months. 3. The results of actions taken to correct deficiencies occurring in unit equipment, structure, systems, or method of operation that affect nuclear safety are audited at least once every 24 months. 4. The performance of activities required by the PQAM to meet the criteria of 10CFR50, Appendix B is audited at least once every 24 months. 5. A Fire Protection and Loss Prevention Program inspection and audit shall be performed using either off-site licensee personnel or an outside fire protection firm at least once every 12 months. 6. The Fire Protection Program and implementing procedures are audited at least once every 24 months. 7. A Fire Protection and Loss Prevention Program inspection and audit shall be performed using an outside fire consultant at least once every 36 months.

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p>B. <u>Once per 12 Months</u></p> <ul style="list-style-type: none"> • The Special Nuclear Material Control Program and implementing procedures. • The Station Security Plan and implementing procedures. • The Fitness for Duty Program and implementing procedures. • The Fire Protection equipment and program implementation, utilizing either qualified off-site licensee personnel or an outside fire protection firm. An outside independent fire protection consultant shall be used at least every third year. • Any other area of facility operation considered appropriate by NSRAC or the Senior Vice President, Nuclear. 	<p>BEQAM text not incorporated due to BEQAM allowances to review these areas annually via Oversight Program Reviews. This allowance was approved by an NRC SER for the previous revision to Section 18.</p> <p>Type A Ref. 18.2.1.A.8 Reduction in QA Program Commitment BGE SER Applied</p> <p>Type D Ref. 18.2.1</p> <p>Type D Ref. 18.2.1</p> <p>Type F Ref. 18.2.1.A.5 and 18.2.1.A.7</p> <p>Type E</p> <p>New Text → Type A Reduction in Commitment RGE SER Applied</p>	<p>The Offsite Dose Calculations Manual and Process Control Program and implementing procedures is audited at least once every 24 months.</p> <p>The radiological environmental monitoring program and the results thereof is audited at least once every 24 months.</p> <p>18.2.1.A (cont.)</p> <p>8. The Special Nuclear Material (SNM) Control Program and implementing procedures are audited at least once every 24 months.</p> <p>B. A grace period of 90 days may be applied to the 24-month frequency for internal audits. For activities deferred in accordance with the 90-day grace period, the next performance due date will be based on their originally scheduled date.</p>

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p>18.3.2 Prior to each audit, a written audit plan is issued which identifies the audit scope and schedule, reference documents, organizations to be audited, and procedures or checklists.</p>	<p>Types C & D Ref. 18.2.3 and QA18.01</p>	<p>18.2.2 Assessments shall provide an objective evaluation of quality-related practices, procedures, instructions, activities, and items and a review of documents and records, as applicable.</p>
<p>18.3.3 Management of the audited organization(s) is notified in writing prior to each audit. The audit notification includes the audit scope, the audit schedule, and identifies the audit team.</p>	<p>Types C & D Ref. 18.2.9 and QA18.01</p>	<p>18.2.3 Assessments shall be performed in accordance with approved written procedures or checklists. Items from previous assessments shall be reviewed and re-assessed, as appropriate. The checklists are used as guides to the auditor.</p>
<p>18.3.4 Prior to the start of each audit, a pre-audit conference is conducted with the audited organization(s) to confirm the audit scope, introduce the audit team, and establish channels of communication.</p>	<p>Types C & D Ref. 18.2.9 and QA18.01</p>	<p>18.2.4 Scheduling and resource allocation are based on the status and safety importance of the activity or process being assessed.</p>
<p>18.3.5 Audits are conducted utilizing checklists as a guide. Additional attributes may be added as conditions dictate. The audit process includes review of objective evidence, and utilizes performance-based auditing techniques such as personal interviews and the witnessing of activities, if possible, to assess overall program effectiveness.</p>	<p>Types C & D Ref. 18.2.3, 18.2.9, and QA18.01</p>	<p>18.2.5 Scheduling is dynamic and resources are supplemented when the effectiveness of the Quality Assurance Program is in doubt.</p> <p>18.2.6 Assessment reports are written and distributed to the appropriate levels of management for review. Follow-up action, including re-looking at deficient areas, is initiated, as deemed appropriate.</p>
<p>18.3.6 Where applicable, the audit includes a review of findings from previous audits in the area to assess the status of ongoing corrective actions and the effectiveness of completed corrective and preventive actions.</p>	<p>Type D Ref. 18.2.3 and QA18.01</p>	<p>18.2.7 Implementation of delegated portions of the Quality Assurance Program is assessed.</p>
<p>18.3.7 At the conclusion of the audit, a formal post-audit conference is held with management of the audited organization(s) to discuss the audit results and present the audit findings.</p>	<p>Type C Ref. 18.2.9 and QA18.01</p>	<p>18.2.8 Assessments are conducted using predetermined acceptance criteria.</p>
<p>18.4 <u>AUDIT REPORTS</u></p>		
<p>18.4.1 All QA audits are followed by an Audit Report, signed by the audit team leader, within 30 days of completion of the audit.</p>	<p>Type C Ref. 18.2.9 and QA18.01</p>	<p>18.2.9 Additional details concerning audits may be found in the Regulatory Guides (e.g., RG 1.33 and RG 1.144) and associated Standards as committed to in <u>PQAM Section 2</u>.</p>

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p>18.4.2 The Audit Report includes, as a minimum:</p> <ul style="list-style-type: none"> • Audit scope. • Identity of the audit team, as well as key personnel contacted during the audit. • Summary of the audit results, including an evaluation statement regarding the overall effectiveness of the area and organization(s) audited. • A description of deficiencies, as well as recommendations for improvement identified during the audit. • Audit Reports shall be addressed to the Senior Vice President, Nuclear, with copies distributed, as a minimum, to: <ul style="list-style-type: none"> • Management of the audited organization(s), • QA Department Management, • NSRAC Coordinator. 	<p>Type C Ref. 18.2.9 and QA18.01</p>	
<p>18.5 <u>AUDIT FINDINGS</u></p>		
<p>18.5.1 Findings identified during QA audits are documented on the appropriate corrective action document (refer to Section 15 or 16 of this manual).</p>	<p>Type C Ref. 18.2.9, and QA 16.03 and QA18.01</p>	
<p>18.5.2 Audit findings are discussed, as they are identified, with management of the audited organization(s).</p>	<p>Type C Ref. 18.2.9 and QA16.03 and QA18.01</p>	
<p>18.5.3 Organizations responsible for identified audit findings are required to respond within specified time limits. Responses are required to address the actions specified by the finding.</p>	<p>Type C Ref. 18.2.9 and QA16.03 and QA18.01</p>	
<p>18.5.4 QAD performs follow-up activities for significant audit findings, to include verification of the effectiveness of stated corrective actions. Such follow-up activities shall be documented.</p>	<p>Types C & D Ref. 18.2.3, 18.2.9, and QA16.03 and QA18.01</p>	

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p><u>18.6 SURVEILLANCE MONITORING PROGRAM</u></p> <p>18.6.1 QAD performs surveillances of selected NuOrg activities to assess compliance with and performance to regulatory, license, and QA Program requirements. Surveillance monitoring may also be performed on non-safety-related activities or equipment, at the discretion of QAD management.</p> <p>18.6.2 Surveillances are intended to be narrowly-focused, short-duration evaluations which may involve direct observation of ongoing activities or reviews of completed records. Surveillances shall be of sufficient detail as to assess the performance and/or effectiveness of the subject area or activity adequately.</p> <p>18.6.3 Surveillances shall be performed in accordance with written procedures which provide instructions on surveillance planning, performance, and reporting as a minimum.</p> <p>18.6.4 Surveillances shall be performed by personnel qualified in accordance with approved procedures.</p> <p>18.6.5 Surveillance monitoring shall be both planned and unplanned in order to evaluate personnel and equipment performance under changing plant conditions.</p> <p>18.6.6 Results of surveillance monitoring activities shall be documented. Reports shall include, as a minimum:</p> <ul style="list-style-type: none"> • Identification of subject area; • Surveillance scope; • Summary of results, including descriptions of findings. <p>Reports shall be distributed to the appropriate levels of management of the affected area.</p> <p>18.6.7 Surveillance findings shall be recorded and processed in accordance with the appropriate corrective action document specified in Sections 15 or 16 of this manual.</p>	<p>Types C & E Ref. QA18.04</p> <p>Types C & E Ref. QA16.03 and QA18.04</p>	

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p>18.7 PROGRAM REVIEWS</p> <p>18.7.1 QAD performs reviews of selected facility programs in order to verify compliance with applicable regulatory, license, and Station requirements. Reviews consist of a series of surveillances which are designed to evaluate key elements of a specific program, incrementally, over a designated period of time. At the conclusion of the review period, the results of the individual surveillances are compiled and collectively evaluated for presentation in report format to upper management.</p> <p>18.7.2 The Program Review Subject List and schedule is prepared annually. The content of the list, as well as the key elements of each subject, is reviewed periodically to assure that sufficient coverage of the review subject will be achieved. As a minimum, the program review subject list shall encompass:</p> <p><u>Every 12 Months</u></p> <ul style="list-style-type: none"> • The program and implementing procedures for the processing, packaging, and shipping of radioactive wastes. • The Radiological Environmental Monitoring Program (REMP). • The Radiation Protection Program and implementing procedures. • The Emergency Plan and implementing procedures. <p>18.7.3 Program Review Oversight Plans shall be developed for each review subject. These plans shall identify the key elements and attributes that must be verified during the review period in order to ensure sufficient coverage of a subject area. The content of the plans shall be derived from the applicable regulatory, license, and QA Program requirements. Also, content of the plans may be altered to reduce or increase the emphasis in those elements where exceptional or declining performance has been observed.</p>	<p>Type D Ref. 18.2.1, 18.2.9, and QA18.04</p> <p>Type D Ref. 18.2.1.2 and QA18.04</p> <p>Type C Ref. QA18.04</p> <p>Type C Ref. QA18.04</p>	

BEQAM Section 18	BEQAM Text Disposition	PQAM Section 18
<p>18.7.4 Program review periods shall be established for each review subject, including beginning and end dates.</p>	<p>Type C Ref. QA18.04</p>	
<p>18.7.5 Program review surveillances shall be both planned and unplanned. Surveillance content shall include, as a minimum:</p> <ul style="list-style-type: none"> • Identification of program review subject; • Identification of Oversight Plan elements verified; • Summary of results, including description of findings and corrective action documents issued. 	<p>Type C Ref. QA18.04</p>	
<p>18.7.6 A Program Review Report shall be generated by QAD at the conclusion of each subject review period. The report shall provide a summary of the subject surveillance results of the preceding period and a collective analysis of the overall results. The analysis of the overall results should focus on areas of declining performance and adverse trends, as well as noted subject strengths and improvements.</p>	<p>Type C Ref. QA18.04</p>	
<p>18.7.7 Findings identified during the analysis of results shall be processed in accordance with Sections 15 or 16 of this manual, as appropriate.</p>	<p>Type C Ref. QA16.03 and QA18.04</p>	
<p>18.7.8 Program Review Reports shall be issued within 30 days of the end of the review period.</p>	<p>Type C Ref. QA18.04</p>	



**PILGRIM NUCLEAR POWER STATION
PILGRIM QUALITY ASSURANCE MANUAL (PQAM)**

ATTACHMENT 2

To

QA PROGRAM CHANGE EVALUATION

CHANGE REQUEST NO. 00-04

For

SECTION 18

Revision 0

**STANDARD REVIEW PLAN 17.3
EVALUATION CHECKLIST**

QA ASSESSMENT

PQAM Section 18

SRP Para.	Attribute	PQAM Section 18 Coverage
C.1.a	Personnel executing the self-assessment function are cognizant of day-to-day activities so that they can act in a management advisory function.	SAT
C.1.b	Organizations performing self-assessments are technically- and performance-oriented, with primary focus on end product quality and secondary focus on procedures and processes.	SAT
C.1.c	Personnel performing self-assessment do not have direct responsibility in the area assessed.	SAT
C.1.d	Self-assessments are accomplished using procedures or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.	SAT
C.2.a	A program of planned periodic assessments is established and implemented to confirm that activities affecting quality comply with the QA program and that the program has been implemented effectively.	SAT
C.2.b	Assessments provide a comprehensive independent evaluation of activities and procedures.	SAT
C.2.c	Planning activities identify the characteristics and activities to be assessed and the acceptance criteria.	SAT
C.2.d	Scheduling and resource application are based on the status and safety importance of the activity assessed.	SAT
C.2.e	Scheduling is dynamic and resources supplemented when QA program effectiveness is in doubt.	SAT
C.2.f	Assessment results are documented and reviewed by the assessor's management and by management responsible for the area assessed. Follow-up action, including re-looking at deficient areas, is initiated as necessary.	SAT
C.2.g	For activities under the QA program that are delegated, the implementation of these activities is assessed.	SAT
C.2.h	Assessments are conducted using predetermined acceptance criteria.	SAT

SAT = Satisfactory