

Attachment B  
Amended Technical Specification Page # 6-7

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6.0 ADMINISTRATIVE CONTROLS (Cont)

6.5 REVIEW AND AUDIT (Cont)

B. Nuclear Safety Review and Audit Committee (NSRAC) (Cont)

8. Audits

Audits of facility activities shall be performed in accordance with the Boston Edison Quality Assurance Manual under the cognizance of the NSRAC.

9. Authority

The NSRAC shall report to and advise the Senior Vice President - Nuclear on those areas of responsibility specified in Section 6.5.B.7 and 6.5.B.8.

10. Records

Records of NSRAC activities shall be prepared, approved and distributed as indicated below:

- a. Minutes of each NSRAC meeting shall be prepared, approved and forwarded to the Senior Vice President - Nuclear, NSRAC members, and others the Chairman may designate.

Attachment C  
Marked-up Technical Specification Page # 6-7

6.0 ADMINISTRATIVE CONTROLS (Cont)

6.5. REVIEW AND AUDIT (Cont)

B. Nuclear Safety Review and Audit Committee (NSRAC) (Cont)

8. Audits

Audits of facility activities shall be performed under the cognizance of the NSRAC. These audits shall encompass:

*in accordance with  
the Boston Edison Quality  
Assurance Manual*

- a. The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions at least once per year.
- b. The training and qualifications of the entire unit staff at least once per year.
- c. The results of all actions required by deficiencies occurring in facility equipment, structures, systems or method of operation that affect nuclear safety at least once per six months.
- d. The performance of all activities required by the Quality Assurance Program to meet the criteria of Appendix "B", 10 CFR 50, at least once per two years.
- e. The Emergency Plan and implementing procedures at least once per two years.
- f. The Station Security Plan and implementing procedures at least once per two years.
- g. Any other area of facility operation considered appropriate by the NSRAC or the Senior Vice President - Nuclear.
- h. The Fire Protection Program and implementing procedures at least once per two years.

9. Authority

The NSRAC shall report to and advise the Senior Vice President - Nuclear on those areas of responsibility specified in Section 6.5.B.7 and 6.5.B.8.

10. Records

Records of NSRAC activities shall be prepared, approved and distributed as indicated below:

- a. Minutes of each NSRAC meeting shall be prepared, approved and forwarded to the Senior Vice President - Nuclear, NSRAC members, and others the Chairman may designate.

Attachment D  
Description of Changes to the Boston Edison Quality Assurance Manual

As required by 10 CFR 50.54 (a)(3), we are submitting changes made to the Boston Edison Quality Assurance Manual (BEQAM), Volume II.

The changes involve incorporation and revision of audit program requirements formerly contained in the technical specifications. We evaluated each change to determine if any requirements contained in the previously NRC approved QA program description were deleted or made less stringent. Our evaluations concluded that some of these changes result in reductions in commitment. The identification of these changes, as well as the reasons and basis for continued compliance with 10 CFR 50 Appendix B, are provided in this attachment. Although some of the changes were considered to be reductions in commitment, overall, none of the changes made reduced the level of quality or compliance with 10 CFR 50 Appendix B. Additionally, these QA program changes were made in accordance with the guidance provided in NRC Administrative Letter 95-06, "Relocation of Technical Specification Administrative Controls Related to Quality Assurance". These changes are consistent with and satisfy the NRC position presented in the Administrative Letter.

## DESCRIPTION OF CHANGES TO THE BOSTON EDISON QUALITY ASSURANCE MANUAL (BEQAM)

### INTRODUCTION

The changes made to the BEQAM and presented in this submittal represent enhancements to the overall Quality Assurance Department (QAD) Oversight Program which consists of audits, surveillances, and reviews. The changes to each of these elements of the QAD Oversight Program is presented below.

### SECTION 18, "AUDITS"

The changes to Section 18 include revisions to the Audit Program, enhancements to Surveillance Monitoring requirements, and provides new requirements for the performance of Program Reviews.

### IDENTIFICATION OF CHANGES

Changes to Paragraph 18.2.4 clarify and establish the BEQAM as the source for the frequency of NSRAC audits and delete the old references to the Technical Specifications for these requirements. These changes reflect the incorporation of the Nuclear Safety Review and Audit Committee (NSRAC) audit program which was previously contained in Section 6.5.B.8 of the Technical Specifications. Also, the statement reiterating compliance with the regulations, Regulatory Guides, and ANSI Standards contained in BEQAM Section 2 is redundant to actual Section 2 requirements and was deleted.

Changes to Paragraph 18.2.5 clarify BEQAM Section 18 as the source for audit program content. References to the Technical Specifications were deleted. These changes also reflect the incorporation of the NSRAC audit program which was previously contained in Section 6.5.B.8 of the Technical Specifications.

Changes to Paragraph 18.3.1 establish the specific requirements for audit program content. Audit subjects and their respective performance frequencies are now classified as either once per 24 months (QA Program, Corrective Action, Training, Technical Specifications, Refueling, Fire Protection, and Conduct of Operations) or once per 12 months (SNM, FFD, Fire Protection, and Security). These new requirements differ from the previous Technical Specification Section 6.5.B.8 requirements in the following manner:

1. The frequency of the Corrective Action Program audit changes from once per 6 months to once per 24 months.
2. The frequency of the Training and Qualification audit changes from once per 12 months to once per 24 months.

3. The frequency of the Technical Specifications audit changes from once per 12 months to once per 24 months.
4. The frequency of the Station Security Plan audit changes from once per 24 months to once per 12 months.
5. The audit of the Emergency Plan once per 24 months changes to a Program Review performed on an annual basis.

Statements in Paragraph 18.3.1 concerning references to "Technical Specifications" and "auditing all elements of the QA Program at least every two years" become obsolete with the incorporation of the specific audit requirements above and, as such, are deleted.

In addition, changes to Paragraphs 18.1, 18.2.1, 18.2.2, 18.3.2, 18.4.1, 18.4.2, 18.5.1, and 18.5.3 and the addition of Paragraphs 18.2.6 and 18.5.4 are editorial in nature and are not considered part of the reductions in commitment.

The changes made in the Surveillance Monitoring process, involving Paragraphs 18.6.1 through 18.6.7, are enhancements to the overall QA Oversight Program and, therefore, not considered part of the reductions in commitment.

New paragraphs (18.7.1 through 18.7.8) were added to provide the general requirements for the performance of "Program Reviews." Program Reviews are another method by which QAD conducts oversight of specific activities utilizing surveillance monitoring. The Program Reviews involve a series of surveillances in a specific functional area over a designated time period. The results of Program Reviews are compiled, analyzed, and reported to senior management. The performance of Program Reviews is an enhancement to the QA Oversight Program and, therefore, not considered part of the reduction in commitment.

### **REASONS FOR CHANGES**

The requirements for audit program content and frequency of performance are contained in several sources including 10CFR, Technical Specifications, Regulatory Guides, ANSI Standards, and the BECAM. This fragmentation of source requirements creates an unnecessary burden on the commitment tracking process as well as reducing the effective utilization of resources by having to manage and monitor changes to a larger document base.

At the same time, the current audit program requires audits to be performed regardless of activities in progress, adhering to typically rigid schedules. Resources are consumed to meet time and specific subject requirements. This method of oversight does not permit adjustment of schedule to focus resources more effectively on areas of declining performance or, conversely, to reduce audit frequency in those areas of superior performance.

To address both issues above, the QA Oversight Program was revised to integrate and schedule audits, reviews, and surveillances in a performance-based manner which provides management with a continuous assessment of facility operation. Specifically, the content and performance frequencies of the audit program were revamped to introduce needed flexibility in QAD oversight activities. These audit program changes will permit reallocation of resources and more frequent audits or



surveillances in those areas of perceived or demonstrated weakness. This approach should have a positive impact on safety as resources are shifted to better focus on weak or declining areas while still providing periodic audit coverage in other stronger areas. The Program Review process was created to supplement changes in the audit program by providing a method to assess certain facility activities on a more frequent and ongoing basis via surveillance monitoring, with results summarized and reported to senior management. These changes in the overall program will also enable QAD to more broadly address spontaneous or emerging issues in support of QA Program and plant needs.

Another benefit of these changes provides for incorporation of the former NSRAC Technical Specification audit requirements into Section 18 of the BEQAM. This consolidation of program requirements into one source eliminates redundant licensing requirements, simplifies licensing document configuration control, and thereby reduces cost and manpower expenditures.

### **BASIS FOR SATISFYING 10CFR50 APPENDIX B**

The changes made to the BEQAM are being processed conservatively in accordance with 10CFR50.54(a) as a reduction in commitment. The revised QA Program continues to satisfy the criteria of 10CFR50 Appendix B. All of the audits previously covered by the Technical Specifications which involved 10CFR50 Appendix B and safety-related activities will continue to be performed. Audit schedules will continue to be reviewed annually and adjustments made where necessary. A maximum interval has been set to ensure all audit areas receive periodic coverage. Excluding audits required by 10CFR which will be conducted at the specified frequency, the maximum audit interval is 24 months. The 24-month frequency for most audits will allow resource focusing based on performance and activities in progress, while assuring that each area will be audited at a minimum frequency. The 24-month frequency is consistent with industry standard audit requirements.

The revision and incorporation into the BEQAM of the audit program requirements formerly contained in the "Administrative Controls" section of the Technical Specifications have been processed in accordance with the guidance contained in NRC Administrative Letter 95-06, *"Relocation of Technical Specification Administrative Controls Related to Quality Assurance."* The justifications for the changes made in the audit program frequencies, as well as the entire QA Oversight Program, detailed in this submittal are consistent with the NRC position presented in the "Reviews and Audit" section of the Administrative Letter.

As part of the reconciliation and justification for revising the audit requirements, it is also noted that audit program requirements are contained in Regulatory Guide 1.33, Rev. 2. BEQAM Section 2 requires compliance with Reg. Guide 1.33, Rev. 2, without exception. The audit requirements contained in Section 4 of the Reg. Guide are identical to the audit requirements contained in the Administrative Controls section of Technical Specifications. Therefore, the basis and justification provided for the audit program changes in this submittal are also intended to envelope the audit requirements contained in the Reg. Guide.

Additionally, the Reg. Guide endorses the QA Program requirements of ANSI N18.7 1976. BEQAM Section 2 also requires compliance with ANSI 18.7 without exception. Section 4.5 of ANSI 18.7 identifies the subject areas which must be audited on a minimum two-year frequency. The audit program changes to Section 18 of



the BEQAM incorporate the N18.7 areas with the following exception: those subject areas listed in ANSI 18.7 which have overlapping audit requirements with 10CFR (i.e., Security, Emergency Plan, and Radiation Controls) will be evaluated by the method and frequency specified by those regulations. This approach is consistent with the NRC position presented in Administrative Letter 95-06.

The basis for each specific change in the audit program requirements is provided below.

1. **The results of actions taken to correct deficiencies occurring in the facility equipment or methods of operation that affect nuclear safety.**

**FROM:** audit every 6 months  
**TO:** audit every 24 months

This requirement will be satisfied on an ongoing basis via audits and surveillances of all functional areas. Each audit will evaluate the adequacy of corrective action (C/A) taken since the previous audit. Additionally, surveillances will be performed, separate from the audit program, of selected portions of C/A controls and implementation. A dedicated audit of C/A will be conducted every two years and will focus on the programmatic controls as well as any C/A weaknesses identified in other functional area audits and surveillances.

The proposed change does not negatively impact the evaluation of the Corrective Action Program. A C/A audit will continue to be performed on a two-year basis to assess the adequacy and effectiveness of the C/A Program. C/A will also be assessed on a continual basis via review of C/A issues in each audit and through surveillance monitoring. Also, another method of evaluation of plant performance involves the Self-Assessment Program. Currently, the QAD coordinates the overall self-assessment process for the Nuclear Division and conducts oversight of the implementation of the process. The Nuclear Division Group responsible for administration of the plant Corrective Action Program conducts self-assessments on a routine basis to monitor and evaluate its processes. Its self-assessment practices will be monitored by QAD to verify implementation of the self-assessment process.

2. **The training and qualification of the entire plant staff.**

**FROM:** audit every 12 months  
**TO:** audit every 24 months

This requirement will continue to be satisfied. Each functional area audit will incorporate verification of certain training and qualification criteria to provide continuous coverage and assessment. Additional oversight will be accomplished utilizing the surveillance program to focus on emerging issues. An audit will be conducted every two years and focus on the overall training programmatic controls. Plant problem monitoring and trending data will provide the necessary indicators of declining performance and will enable QAD to focus resources and adjust audit frequencies to address areas of noted weakness.

Reducing the frequency of this audit will not adversely impact the effectiveness of the audits performed since a dedicated audit of the Training Program will

continue to be performed and training verification criteria will be integrated into other audits and surveillances. Additionally, the self-assessment practices of the Nuclear Training Departments will be monitored by the QAD to verify proper implementation of the self-assessment process.

3. **The conformance of the facility operation to the provisions contained in the Technical Specifications and applicable license conditions.**

**FROM: audit every 12 months**  
**TO: audit every 24 months**

This requirement is satisfied by verifying that any organization responsible for implementation of procedures associated with compliance to Technical Specification surveillance requirements properly executes those responsibilities. This activity includes review of completed surveillance test procedures as well as witnessing of such tests and is evaluated on a continual basis via all QAD audits, reviews, and surveillances in those areas where Technical Specification surveillance criteria apply. Monitoring of LER issuance will provide an indicator of performance in which to target additional oversight resources.

Reducing the frequency of this audit from every 12 months to every 24 months will not adversely impact compliance with provisions of the Technical Specifications, FSAR commitments, or the effectiveness of the audits performed. Compliance with Technical Specification surveillance requirements and license conditions is evaluated on a continuing basis in various functional area audits and surveillances in addition to a dedicated audit every two years as a minimum. Additionally, those organizations of the Nuclear Division responsible for self-assessments in the area of Technical Specification surveillance performance will be monitored by the QAD to verify proper implementation of the self-assessment process.

4. **The Station Security Plan and implementing procedures.**

**FROM: audit every 24 months**  
**TO: audit every 12 months**

This requirement will continue to be satisfied via the existing audit process and to the same level of detail and scope. The audit frequency has been changed to reflect 10CFR73.55 and 10CFR50.54 requirements regarding an audit of this area every 12 months.

Increasing the audit frequency from every 24 months to every 12 months does not adversely impact compliance with FSAR commitments or the effectiveness of the audits performed. This change eliminates redundant audit program requirements between the Technical Specifications and the above 10CFR sections. Additionally, Security self-assessment practices will be monitored by the QAD to verify proper implementation of the self-assessment process.

5. The Emergency Plan and implementing procedures.

**FROM:** audit once per 24 months  
**TO:** annual review

This requirement is satisfied via performance of Program Reviews. Program Reviews involve a series of dedicated, scheduled surveillances which will evaluate the adequacy of key elements of the Emergency Plan and procedures over a 12-month period. At the conclusion of the review period, a comprehensive report will be issued to senior management providing a summary of the surveillance results as well as conclusions reached from analysis of those results. Oversight areas and frequencies will also be adjusted to respond to noted areas of weakness or improvement.

This proposed change does not adversely impact compliance with FSAR commitments or the effectiveness of the oversight performed in this area. This change reconciles overlapping requirements between the Technical Specifications and 10CFR50.54(t). Performance of annual reviews is consistent with 10CFR50.54(t) regarding evaluation of Emergency Preparedness programs and procedures. The frequency requirement has been increased while the method of oversight provides for incremental monitoring of the same key elements of the EP Program previously covered by the audit program. The Program Review process will permit more real-time assessments and provide flexibility in adjusting resources and schedules to monitor areas of declining performance. Additionally, monitoring of the EP self-assessment process will be integrated into the QAD Program Review of EP to verify proper implementation of the self-assessment process.

Identification of findings and reporting of annual Program Review results will be communicated in the same manner and to the same level of management as in the audit process.

Attachment E  
Amended Boston Edison Quality Assurance Manual Pages

## ATTACHMENT E

**AUDITS****18.1 PURPOSE**

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.

**18.2 GENERAL REQUIREMENTS**

- 18.2.1 QAD performs audits of all activities to which this Quality Assurance Program applies. Activities to which the QA Program do not apply are audited to the extent necessary to assure proper and safe operation of PNPS.
- 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.
- 18.2.3 Audits 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. Technical Specialists shall be utilized, as deemed necessary.
- 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.
- 18.2.5 Audits required by this Section are performed under the cognizance of the Nuclear Safety Review and Audit Committee (NSRAC).
- 18.2.6 Audit results, including findings, shall be documented and distributed to appropriate levels of management.

**18.3 AUDIT PROGRAM ELEMENTS**

- 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:



**A. Once per 24 Months**

- 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.

**B. Once per 12 Months**

- 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.

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.

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.

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.



- 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.
- 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.
- 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.

#### **18.4 AUDIT REPORTS**

- 18.4.1 All QA audits are followed by an Audit Report, signed by the audit team leader, within 30 working days of completion of the audit.
- 18.4.2 The Audit Report includes, as a minimum:
- 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:
    - Management of the audited organization(s),
    - QA Department Management,
    - NSRAC Coordinator.

#### **18.5 AUDIT FINDINGS**

- 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).
- 18.5.2 Audit findings are discussed, as they are identified, with management of the audited organization(s).

- 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.
- 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.

## **18.6 SURVEILLANCE MONITORING PROGRAM**

- 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.
- 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.
- 18.6.3 Surveillances shall be performed in accordance with written procedures which provide instructions on surveillance planning, performance, and reporting as a minimum.
- 18.6.4 Surveillances shall be performed by personnel qualified in accordance with approved procedures.
- 18.6.5 Surveillance monitoring shall be both planned and unplanned in order to evaluate personnel and equipment performance under changing plant conditions.
- 18.6.6 Results of surveillance monitoring activities shall be documented. Reports shall include, as a minimum:
- Identification of subject area;
  - Surveillance scope;
  - Summary of results, including descriptions of findings.
- Reports shall be distributed to the appropriate levels of management of the affected area.
- 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.

## **18.7 PROGRAM REVIEWS**

- 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.

- 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:

**Every 12 Months**

- 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.

- 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.

- 18.7.4 Program review periods shall be established for each review subject, including beginning and end dates.

- 18.7.5 Program review surveillances shall be both planned and unplanned. Surveillance content shall include, as a minimum:

- Identification of program review subject;
- Identification of Oversight Plan elements verified;
- Summary of results, including description of findings and corrective action documents issued.

- 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.

- 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.

18.7.8 Program Review Reports shall be issued within 30 working days of the end of the review period.

Attachment F  
Marked-up Boston Edison Quality Assurance Manual Pages

## ATTACHMENT F

**AUDITS****18.1 PURPOSE**

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. ~~Audits of suppliers' quality assurance programs are addressed in Section 7.~~ *This section also provides the general requirements for other QAD oversight functions, including surveillance monitoring and performance of program reviews.*

**18.2 GENERAL REQUIREMENTS**

- 18.2.1 QAD performs audits of all activities to which this Quality Assurance Program applies. Activities to which the QA Program do not apply are audited to the extent necessary to assure proper ~~classification~~ *and safe operation of PNPS.*
- 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.*
- 18.2.3 Audits 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. Technical Specialists shall be utilized, as deemed necessary.
- 18.2.4 *Audit subject and frequency is based on the requirements of Paragraph 17.3.1 regulations, regulatory guides, and ANSI standards identified in Section 2, as well as the PNPS Technical Specifications. Additional or more frequent audits may be performed when significant changes or problems arise, and upon management request by NSRAC or the Senior VP, Nuclear.*
- 18.2.5 Audits required by ~~this Section 6.0 of the PNPS Technical Specifications Section~~ are performed under the cognizance of the Nuclear Safety Review and Audit Committee (NSRAC).
- 18.2.6 *Audit results, including findings, shall be documented and distributed to appropriate levels of management.*

**18.3 AUDIT PROGRAM ELEMENTS**

- 18.3.1 An audit schedule is prepared annually. The schedule reflects ~~those audits required by Section 18.2.5, as a minimum. The audit schedule is reviewed periodically to assure that all elements of this Quality Assurance Program are audited at least every two years.~~



*the applicable regulatory, license, and QA Program requirements. The audit program shall encompass, as a minimum, the following:*

**A. Once per 24 Months**

- *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.*

**B. Once per 12 Months**

- *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.*

- 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, ~~audit schedule~~, and procedures or checklists.
- 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.
- 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.

- 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.
- 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.
- 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.

#### 18.4 AUDIT REPORTS

- 18.4.1 All QA audits are followed by an Audit Report, signed by the audit team leader, within 30 *working* days of completion of the audit.
- 18.4.2 The Audit Report includes, as a minimum:
  - 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 ~~are~~ *shall be addressed to the Senior Vice President, Nuclear, with copies* distributed, as a minimum, to:
    - Management of the audited organization(s),
    - QA Department Management,
    - NSRAC Coordinator.

#### 18.5 AUDIT FINDINGS

- 18.5.1 Findings identified during QA audits ~~and surveillances~~ are documented on the appropriate corrective action document (refer to Section 15 or 16 of this manual).

- 18.5.2 Audit findings are discussed, as they are identified, with management of the audited organization(s).
- 18.5.3 Organizations responsible for identified audit/~~surveillance~~ findings are required to respond to ~~QAD~~ within specified time limits. Responses are required to address the actions specified by the finding.
- 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.*

## 18.6 PERFORMANCE FOR SURVEILLANCE MONITORING PROGRAM

- 18.6.1 ~~QAD performs surveillance monitoring of the activities related to the Station Organization and its supporting organizations to assess compliance with established Quality Assurance Program requirements, written policies, procedures, instructions, directives, codes, standards, specifications, and control documents. Surveillances can be performed by direct observation or records review. Surveillances shall be planned and unplanned, selectively and randomly, and with sufficient detail to effectively monitor and report the conditions at the Pilgrim Nuclear Power Station and at the supporting facilities. 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.~~
- 18.6.2 ~~Discrepancies noted during surveillance monitoring shall be recorded on a Deficiency Report tracked and dispositioned using approved procedures. 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.~~
- 18.6.3 *Surveillances shall be performed in accordance with written procedures which provide instructions on surveillance planning, performance, and reporting as a minimum.*
- 18.6.4 *Surveillances shall be performed by personnel qualified in accordance with approved procedures.*
- 18.6.5 *Surveillance monitoring shall be both planned and unplanned in order to evaluate personnel and equipment performance under changing plant conditions.*
- 18.6.6 *Results of surveillance monitoring activities shall be documented. Reports shall include, as a minimum:*
- *Identification of subject area;*

- Surveillance scope;
- Summary of results, including descriptions of findings.

*Reports shall be distributed to the appropriate levels of management of the affected area.*

- 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.*

## **18.7 PROGRAM REVIEWS**

- 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.*

- 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:*

### **Every 12 Months**

- *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.*

- 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.*

- 18.7.4 *Program review periods shall be established for each review subject, including beginning and end dates.*

- 18.7.5 *Program review surveillances shall be both planned and unplanned. Surveillance content shall include, as a minimum:*

- *Identification of program review subject;*
- *Identification of Oversight Plan elements verified;*
- *Summary of results, including description of findings and corrective action documents issued.*

- 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.*
- 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.*
- 18.7.8 *Program Review Reports shall be issued within 30 working days of the end of the review period.*