Response to Supplemental RAIs for NEI 06-14A, Revision 6

1. With respect to RAI #1, which requested additional guidance on organizational structure, the NRC staff acknowledged the additional guidance provided. However, the organizational description and charts provided in Section 1 of NEI 06-14A still needs to include:

   a. More detail of the responsibilities and quality relationships during construction phase and operation phase is needed, including a description for the transition of responsibilities from construction to the operational phase.

   b. An organizational description that includes management levels that implement quality activities.

   c. The organizational descriptions and charts for the operations phase, including both onsite and offsite management and the independent review function.

   d. The commitment to the regulatory change process established by Title 10 of the *Code of Federal Regulations* 50.54(a) when incorporating organization information from other sections of the Final Safety Analysis Report (FSAR) by reference.

Response: NEI has added notes to provide additional guidance for the content of the organizational description. The NOTE at the beginning of the Organization was enhanced to emphasize the need for the organization description of the responsibilities and relationships during all phases of applicability for the QAPD, including those management positions responsible for implementing portions of the QA Program. A NOTE was added to the sample organization charts emphasizing that organization charts need to be included for all phases of applicability of the QAPD as well as for all on-site and off-site organizations implementing the QA Program. Emphasis was added to stress the importance for the description to address the transition of responsibilities between organizations when multiple phases are addressed for the QAPD applicability. A NOTE was added acknowledging that an applicant/licensee may provide the required organization description by incorporating by reference information from another section of the FSAR but by so doing, the regulatory change process established 10 CFR 50.54(a) would be applicable to that incorporated section.

Because the NEI template may be used by an applicant/licensee to address the QA Program for any or all of a variety of applications (e.g. Design Certification, Early Site Permit, Construction, Operations), we feel that adding additional detail to the example Organization section would only serve to confuse future users of the template. NEI added a NOTE emphasizing that the sample Organization description and Organization Charts provide a simple organization for illustration of potential applicability.

Changes to the NEI Template as a result of this RAI: Markup of QAPD Part II Section 1 is shown on the following pages. Highlighted Text identifies the newly added material. The text shown in strike-out font is deleted by this markup.

The markups provided with these responses show the revision of the QAPD Template in response to the subject RAI. The content shown may be impacted by additional NRC interactions or editorial or typographical corrections, etc. As a result, the final content that appears in the approved document may differ slightly from that presented herein.

PART II QAPD DETAILS

SECTION 1 ORGANIZATION

This section describes the *[CA]* organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes *[corporate/support/off-site]* and on-site functions for *[Nuclear Development]* including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

[CA senior management ~~Senior~~ position responsible for the Quality Assurance organization] is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned.

[NOTE: The following information will be utility specific but should follow the SRP for the content. This also includes interface responsibilities for multiple organizations performing quality-related functions. This section should be developed to include the organization that is to implement the phase the QAPD is intended to cover e.g., ESP, COLA, Construction/Pre-operation/Test, and Operations. The description should include levels of authority, interfaces, and functional responsibilities for each position. In addition, for QAPDs that cover activities during both construction and operations, it should include enough detail to distinguish the organizational structure for construction and for operations. Include organization charts that describe the QA organization that is/will be in place for all positions responsible for establishing, maintaining, and implementing QA requirements from corporate positions through plant positions.]

[NOTE: Generic titles (e.g., Nuclear Development, Quality Assurance Manager) may be used in the QAPD. ~~, however, they must be consistent throughout the entire document.~~ However, the generic titles established in the Organization Section must be used throughout the document.]

[NOTE: Provide a clear illustration of the organization's functional responsibilities, to include preparing, reviewing, approving, and verifying designs; qualifying suppliers; preparing, reviewing, approving, and issuing instructions, procedures, and procurement documents; purchasing; verifying supplier activities; identifying and controlling acceptable and nonconforming hardware and software; manufacturing; calibrating and controlling measuring and test equipment; qualifying and controlling special processes; constructing; inspecting; testing; startup; operating; performing maintenance; performing the audit function; and controlling records. Also, refer to the same organizational titles throughout the QAPD.]

[NOTE: Structure Section 1, Organization, of the QAPD such that it clearly delineates 1) how the QA program is implemented during all applicable phases such as the period of construction and testing and the operations phase. The transition process from one phase to another must be described. Position descriptions should clearly delineate these roles during each applicable phase such as the construction/preoperation phase, the operations phase, as well as the transition period between the phases. For example at the transition from construction to operations, the following text may be appropriate: No later than six months prior to fuel load of the unit, those positions which are identified for Operations will be staffed and have the

appropriate authority required to perform operations activities. It is anticipated that even after fuel load, construction activities will be ongoing. Those positions required to support these activities will retain their applicable construction/preoperation responsibilities until it is deemed that they are no longer necessary. As the construction of systems (or portions thereof) are completed, control and authority (including oversight, configuration and operations) is transferred from the contractor to the cognizant owner departments in the operations phase. During the transition, responsibilities will be clearly defined in instructions and procedures to ensure appropriate authority is maintained for each SSC.]

[NOTE: The QAPD describes the functions and responsibilities associated with the quality assurance requirements of 10 CFR 50, Appendix B, Criteria I, Organization and Criteria II, Quality Assurance. All positions associated with the establishment, implementation, and verification of quality-related activities should be shown on the organization charts and described in the QAPD. For the operations phase, the level of detail to be included should include roles, responsibilities, and lines of authority for the positions necessary to implement the requirements of Appendix B. For example, this level of detail will identify where the independent review functions report within the organization. Comparable detail should be provided for the construction/preoperation phase.]

[NOTE: Sufficient detail must be included to fully describe how the organization will perform, manage, and/or oversee activities affecting the quality and performance of safety-related SSCs, including: testing, preoperational activities such as ITAAC, receiving, storing, repairing, decommissioning, refueling, and shipping.]

[NOTE: The applicant/licensee may provide the required organization description by incorporating by reference information from another section of the FSAR but by so doing, the regulatory change process established 10 CFR 50.54(a) would be applicable to that incorporated section. If incorporation by reference is used, care must be taken to use the appropriate titles from that section in the QAPD in replacing bracketed text.]

[NOTE: Below is an example of ~~the level of detail which illustrates~~ a new plant organization, its independence, and its linking within an existing utility. The sample organization presented here is for illustration only. This is not representative of the level of detail sufficient to address all phases of potential applicability.]

[The [CA] [Nuclear Development (ND)] organization is responsible for new nuclear plant licensing, engineering, procurement, construction, startup and operations development activities. ~~There are several organizations within [CA] which~~ Several organizations within [CA] implement and support the QAPD. These organizations include, but are not limited to [Nuclear Development], Technical Services, Corporate Services and Quality Assurance.

Design, engineering and environmental services are provided to the [CA] [Nuclear Development] organization by ~~[~~two~~]~~ primary contractors in accordance with their QAPDs. These two contractors are [A/E Firm] and [NSSS vendor].

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the [Nuclear Development] QA Program. The [CA] organization and the [Nuclear Development] organization are shown in Figures II.1-1 and II.1-2 respectively.

Figure II.1-1

[CA] Organization

[NOTE: This is a sample organization chart and should be replaced by actual organization.]
[NOTE: Organization charts should be included for all phases of applicability of the QAPD. Organization Charts should show on-site and off-site organizations implementing the QA Program.]

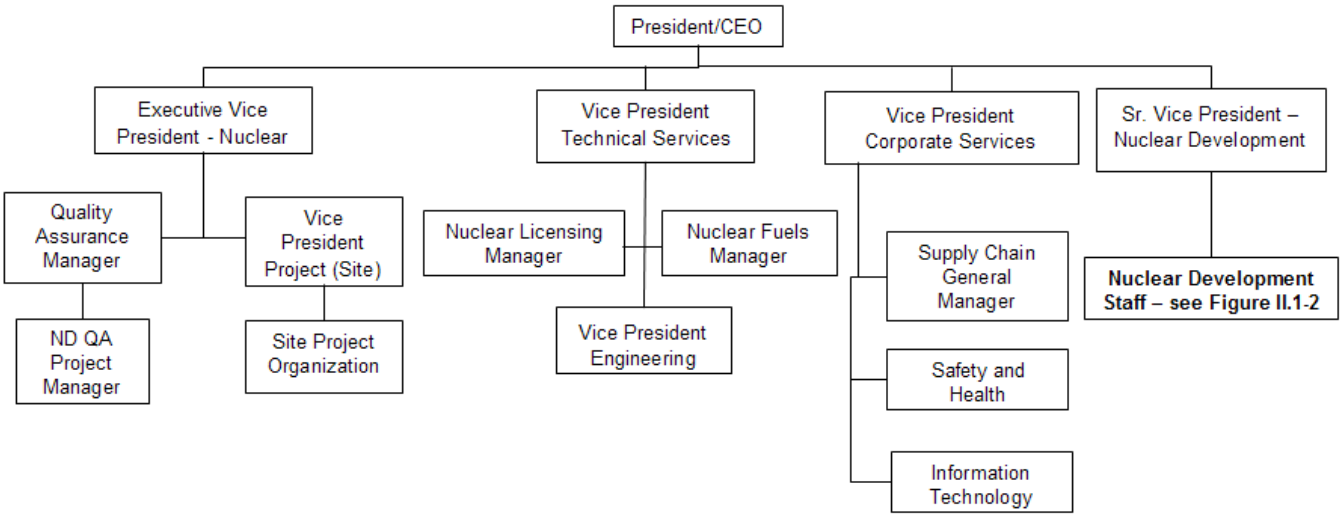
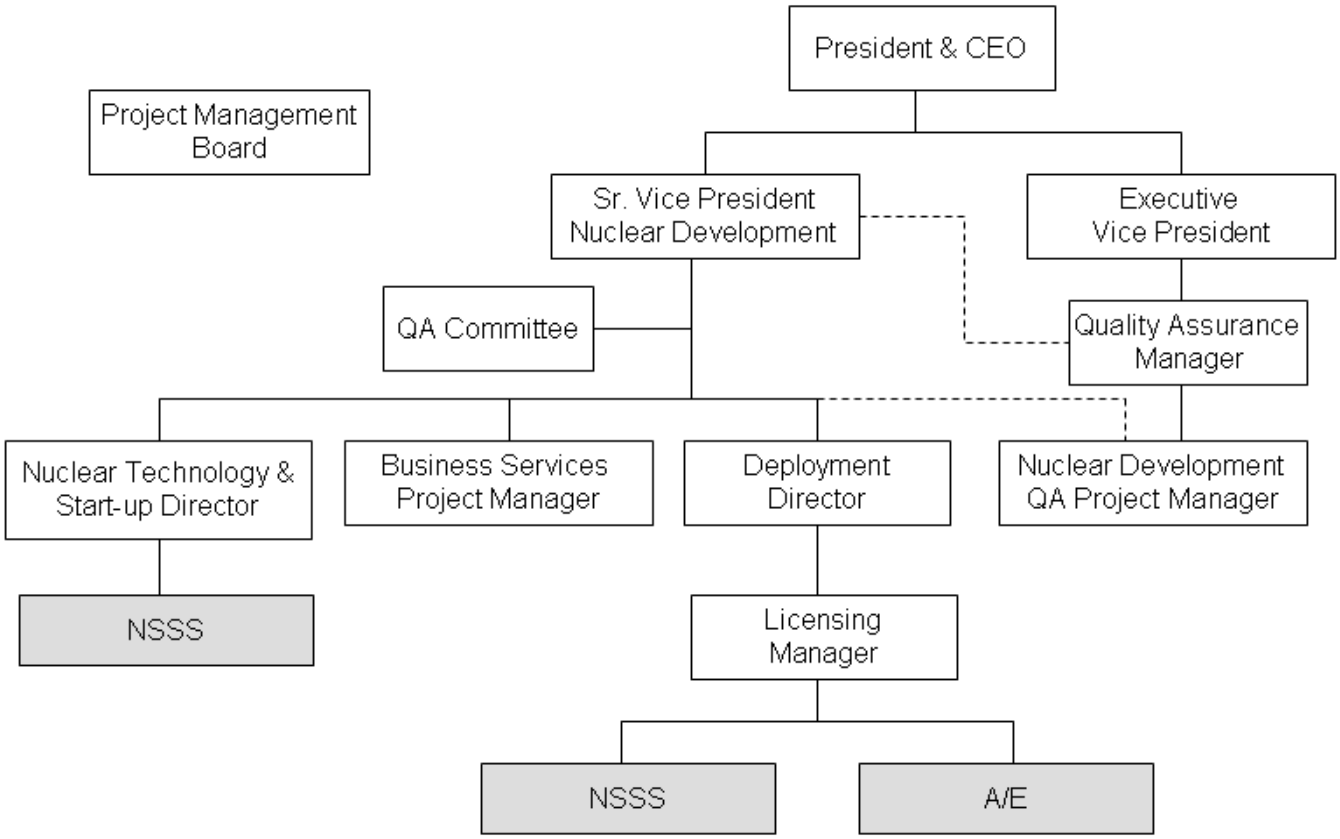


Figure II.1-2

[Nuclear Development] Organization

[NOTE: This is a sample organization chart and should be replaced by actual organization.]
[NOTE: Organization charts should be included for all phases of applicability of the QAPD. Organization Charts should show on-site and off-site organizations implementing the QA Program.]



2. In response to RAI #2, which addresses the use of generic titles, NEI 06-14, Revision 6 was revised to add a statement explaining that generic titles can be used throughout the QAPD if they are used consistently. However, Revision 6 of NEI 06-14 needs to clearly state that generic titles should be consistent with those used in the Organization section.

Response: The NOTE added in Revision 6 was amended to clearly state that the generic titles used in the balance of the document must be consistent with those established in the Organization Section.

Changes to the NEI Template as a result of this RAI: Markup of QAPD Part II Section 1 presented with the response to RAI #1 includes this identified change. Highlighted Text identifies the newly added material. The text shown in strike-out font is deleted by this markup.

3. In response to RAI #4, which suggests a more appropriate reference be used to illustrate commercial grade dedication, NEI 06-14, Revision 6 replaced the reference to Regulatory Issue Summary 2002-22 with a reference to Electric Power Research Institute (EPRI) Topical Report (TR) 106439. However, the use of EPRI TR-106439 is limited to digital instrumentation and control (I&C). The staff requests that the reference be removed from the template and placed in implementing procedures specific to digital I&C.

Response: NEI has removed the reference from the template.

Changes to the NEI Template as a result of this RAI: Markup of QAPD Part II Section 7.2 on the following page includes this identified change. There is no added material with this markup. The text shown in strike-out font is deleted by this markup.

Mark-up of QAPD Part II, Section 7.2

- In lieu of the requirements of Section 10, Commercial Grade Items, controls for commercial grade items and services are established in *[CA]* documents using 10 CFR 21 and the guidance of EPRI NP-5652 as discussed in Generic Letter 89-02 and Generic Letter 91-05.

    - For commercial grade items, special quality verification requirements are established and described in *[CA]* documents to provide the necessary assurance an item will perform satisfactorily in service. The *[CA]* documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

    - *[CA]* will also use other appropriate approved regulatory means and controls to support *[CA]* commercial grade dedication activities. ~~One example of this is Electric Power Research Institute (EPRI) Topical Report TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," dated July 17, 1997.~~ *[CA]* will assume 10 CFR 21 reporting responsibility for all items that *[CA]* dedicates as safety-related.

4. In response to RAI #5, which addresses the use of generic brackets to inspection controls applied to non-safety-related structures, systems, and components, NEI 06-14, Revision 6 removed the bracket and changed the qualification requirements. Instead of requiring the inspection personnel to be "at a minimum as qualified as the person who performed the activity," the revised requirement states that "inspections are performed by knowledgeable personnel." Please provide justification on the change to the qualification requirements.

Response: This change was made to be consistent with the acceptance criteria of SRP 17.5, which states "Inspections are performed where necessary to verify conformance of an item or activity to specified requirements or verify that activities are satisfactorily accomplished. Inspections need not be performed by personnel who are independent of the line organization. However personnel that perform inspections must be knowledgeable." Consistent with the wording of the related acceptance criteria the intention of the change was to remove the potential interpretation that the person performing the inspection currently holds the active qualification to perform the activity being inspected. The individual performing the inspection must be knowledgeable of the work being inspected. Knowledgeable personnel are personnel that are from the same discipline and have experience related to the work being inspected. Section 1.10 was revised to provide further clarification of the expectation.

Changes to the NEI Template as a result of this RAI: Markup of QAPD Part III Section 1.10 on the following page includes this identified change. Highlighted Text identifies the newly added material. The text shown in strike-out font is deleted by this markup.

Mark-up of QAPD Part II, Section 1.10

1.10 Inspection

[CA] uses documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. ~~These inspections are performed by knowledgeable personnel who may be in the same line organization as those performing the activity being inspected.~~ These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

5. The NRC staff noted that the following regulatory guides (RGs) are referenced in FSAR Chapter 1 of applications submitted by combined license (COL) applicants, as commitments with exceptions, pointing to the QAPD for clarification. NEI 06-14 should be revised to address how QAPDs submitted by early site permit and COL applicants will either commit to these RGs or take exceptions from them.

    - RG 1.8, Revision 3, May 2000, "Qualification and Training of Personnel for Nuclear Power Plants"

    - RG 1.28, Revision 3, August 1985, "Quality Assurance Program Requirements (Design and Construction)"

    - RG 1.33, Revision 2, February 1978, "Quality Assurance Program Requirements (Operations)"

Response: NEI has revised NEI 06-14A to provide applicants with guidance for addressing conformance for the three Regulatory Guides (RGs) identified in this question. The guidance, which is consistent with RG 1.206, section C.I.1.9, provides information to support addressing the conformance in Chapter 1 of the Final Safety Analysis Report (FSAR). Additionally, the current text in the template is revised to provide similar information for the RGs already addressed in Part III, Section 2 and Part IV. To accomplish this, Part III, Section 2 and Part IV have been revised to provide explanatory text for how NEI 06-14A complies with or represents an NRC-approved alternative approach to these RGs. A note has been added reminding applicants using the template that they should state such in the FSAR and reference the Safety Evaluation Report approving the template as justification. For completeness, NEI also added that the template was reviewed to NUREG 0800 Standard Review Plan Section 17.5 March 2007 and provided a warning to an applicant that, if there is a later version, the applicant would need to address conformance to the later revision in the FSAR.

After reviewing the regulatory positions, NEI decided to provide additional clarification in QAPD Part II, Section 2.8 for qualification of inspection and test personnel and Part II, Section 17 for record retention. The change in Section 2.8 includes the addition of an option during operations taking exception to the use of NQA-1-1994 Non-mandatory Appendix 2A-1. This option is consistent with SRP Section 17.5 Section II.V items 5 and 6.

The response to RAI #6 relates to regulatory position 2.14 of RG 1.8. That response is reflected in the discussion of RG 1.8 added in the QAPD by this RAI.

We feel that these changes will help the applicant satisfy the guidance in RG 1.206, C.I.1.9.

Changes to the NEI Template as a result of this RAI: Markup of QAPD Part II Sections 2.8 and 17.1, Part III Section 2, and Part IV on the following pages includes the identified changes. The highlighted text identifies added material with this markup. The text shown in strike-out font is deleted by this markup.

Mark-up of QAPD, Part II, Section 2.8

2.8 NQA-1-1994 Commitment / Exceptions

In establishing qualification and training programs, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3 and 2S-4, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 2S-1 *[NOTE: The applicant may either adopt non-mandatory Appendix 2A-1 as if it were part of the supplement by following option 1 below or take exception to 2A-1 following option 2.]*

  - *[NOTE Option 1]* [Supplement 2S-1 will include use of the guidance provided in Appendix 2A-1 the same as if it were part of the Supplement.] *[NOTE: When applying Option 1, either or both of the following two alternatives may be applied to the implementation of this Supplement and Appendix:]*

    - *[In lieu of being certified as Level I, II, or III in accordance with NQA-1-1994, personnel that perform independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.]*

    - *[A qualified engineer may be used to plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purpose of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, civil) and has a minimum of five years engineering work experience with at least two years of this experience related to nuclear facilities.]*

  - *[NOTE: Option 2 is based on SER ML050700416 and may only be applied during the Operations Phase. The post-TMI regulations at 10 CFR 50.34(f)(3)(iii) apply during construction phase.]*

    - [In lieu of Nonmandatory Appendix 2A-1, *[CA]* does not establish levels of qualification/ certification for inspection personnel. Instead, *[CA]* establishes initial qualification requirements and determines individual qualification through evaluation of education, training and experience, and through demonstration of capability in performing the type of inspections expected on the job.]

    - *[NOTE: When selecting option 2, the following alternative may be*

applied to the implementation of Supplement 2S-1.] [Inspections, examinations or tests may be performed by individuals in the same organization as that which performed the work, provided that (a) the qualifications of the inspector for an activity are equal to or better than the minimum qualifications for persons performing the activity, (b) the work is within the skills of personnel and/or is addressed by procedures, and (c) if work involves breaching a pressure-retaining item, the quality of the work can be demonstrated through a functional test. When a, b and c are not met, inspections, examinations or tests are carried out by individuals certified in accordance with Supplement 2S-1. Individuals performing visual inspections required by the ASME Boiler and Pressure Vessel Code are qualified and certified according to Code requirements.]

Mark-up of QAPD Part II, Section 17.1

17.1 Record Retention

Measures are ~~required to be~~ established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for *[design, engineering, procurement, manufacturing, construction, inspection and test, installation, pre-operation, startup, operations, maintenance, modification, decommissioning, and audits]* ~~Such records~~ and their retention times are defined in appropriate procedures. The records and retention times are *[based on Regulatory Position C.2 and Table 1, of Regulatory Guide 1.28, Revision 3 for design, construction, and initial start-up. Retention times for operations phase records are based on construction records that are similar in nature.] [NOTE: The applicant/licensee must address the records retention schedule for their plant by either referencing Table 1 of Regulatory Guide 1.28, Rev. 3, or including their specific table in the QAPD]* In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

Mark-up of QAPD Part III, Section 2

SECTION 2 Nonsafety-Related SSCs Credited for Regulatory Events

[NOTE: The applicant should provide an evaluation of conformance with the guidance in NRC regulatory guides in effect 6 months before the submittal date of the application. That evaluation should also include an identification and description of deviations from the guidance in the regulatory guides as well as suitable justifications for any alternative approaches proposed by the applicant. Section 2 provides alternative approaches for satisfying the following NRC guidance:

- *Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."*

- *Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Nonsafety Systems and Equipment," in Regulatory Guide 1.155 Revision 0 August 1988, "Station Blackout."*

The specific program controls identified in Part III, Section1 for nonsafety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, are commensurate with the NRC Guidance identified above.]

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related;

- *[CA]* implements quality requirements for the fire protection system in accordance with *[Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants" as identified in FSAR Chapter 1.] [NOTE: The applicant/licensee must address the conformance to Regulatory Guide 1.189. Part III Section 1 may not adequately address regulatory position 1.7 of that document. In reviewing the Regulatory Positions the applicant should reference FSAR Section 9.5.]*

- *[CA]* implements the quality requirements for ATWS equipment in accordance with Part III, Section1.~~Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."~~

- ~~[~~*[CA]* implements quality requirements for SBO equipment in accordance with Part III, Section1.~~*Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Nonsafety Systems and Equipment," in Regulatory Guide 1.155, "Station Blackout."*~~

[*NOTE: In addressing applicability of ~~this~~ these Regulatory Guides care must be exercised to ensure conformance identified for design is consistent with the technology specific design as documented in the applicable DCD.****]***~~]~~

Mark-up of QAPD Part IV

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards which have been selected to supplement and support the *[CA]* QAPD. *[CA]* ~~commits to compliance~~ complies with these standards to the extent described or referenced ~~herein~~. Commitment to a particular RG~~Regulatory Guide~~ or ~~other QA~~ standard does not constitute a commitment to the RG~~Regulatory Guides~~ or ~~QA~~ standards that may be referenced therein.

[NOTE: NEI 06-14A was prepared and reviewed to NUREG 0800 Standard Review Plan Section 17.5 March 2007; if there is a later version, an applicant would need to address conformance to the later revision in the FSAR.]

[NOTE: The applicant should provide an evaluation of conformance with the guidance in NRC regulatory guides in effect six months before the submittal date of the application. That evaluation should also include an identification and description of deviations from the guidance in the regulatory guides as well as suitable justifications for any alternative approaches proposed by the applicant. The section on Regulatory Guides below identifies where the template conforms with or provides alternative approaches for satisfying the identified NRC guidance.]

Regulatory Guides:

[See FSAR Chapter 1 for the [CA] evaluation of conformance with the guidance in NRC Regulatory Guides in effect six months prior to the submittal date of the application.]

[NOTE: The notes provide an applicant information to support addressing Regulatory Guide conformance in Chapter 1 of the FSAR consistent with RG 1.206, section C.I.1.9. The formatting of this section assumes the applicant will address conformance with RGs in a single location in Chapter 1 of the FSAR. If an applicant elects to provide the identification of conformance in this section for the identified RGs, conformance, exceptions, or alternatives for all regulatory positions of each RG should be included.]

[*NOTE: The information below identifies where this template conforms with or provides alternatives to the RGs and the indicated regulatory positions. Regulatory Positions determined to not be directly applicable to the QAPD include a pointer to the potentially applicable Chapter of the FSAR. The applicant is responsible to review this information and confirm its accuracy at the time of submittal of an application. In addressing conformance with the Regulatory Guides, the applicant must also consider the status of conformance for design and construction consistent with the referenced DCD. The revisions used below were in effect when this document was prepared. Use the appropriate revisions based on the time of application.****]***

Regulatory Guide 1.8, *[Rev. 3, May 2000]*, Qualification and Training of Personnel for Nuclear Power Plants

Regulatory Guide 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This regulatory guide endorses ANSI/ANS-3.1-1993, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants," with certain additions and exceptions that are listed in the Regulatory Position of this guide. Some of the exceptions are endorsements of certain sections of two other standards, ANSI N18.7-1976 (ANS-3.2), "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," and ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants." Rather than to commit to those Standards in the QAPD, appropriate requirements have been directly incorporated into the text. These requirements are consistent with the identified acceptance criteria in SRP Section 17.5.]

[NOTE: Regulatory Positions C.1.1 through C.1.4 address definitions in ANSI/ANS-3.1-1993. Conformance with ANSI/ANS-3.1-1993 and those Regulatory Positions should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Position C.2.1 (2.1.1, 2.1.2, and 2.1.3) address alternatives and substitutions for education and experience for quality assurance personnel. Those alternatives and substitutions are reflected in Part II, Section 2.6 of the QAPD template.]

[NOTE: Regulatory Position C.2.2 through C.2.10 are not directly applicable to quality assurance personnel. Those Regulatory Positions should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Position C.2.11 addresses ANSI/ANS-3.1-1993 Section 4.5.5, Quality Control. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.8. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.T.]

[NOTE: Regulatory Position C.2.12 addresses ANSI/ANS-3.1-1993 Section 4.5.6, Quality Assurance. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.8. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.S.]

[NOTE: Regulatory Position C.2.13 is not directly applicable to quality assurance personnel. Those Regulatory Positions should be addressed by FSAR Chapter 13.]

[NOTE: Regulatory Positions C.2.14 and C.2.15 address ANSI/ANS-3.1-1993 Sections 4.7.1 and 4.7.2 relative to Independent Review qualifications. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.7. As documented in SER ML070510300, the QAPD template follows SRP Section 17.5, paragraph II.W for providing guidance to the applicant to establish an independent review program for activities occurring during the operational phase.]

Regulatory Guide 1.26, ***[****Revision 4, March 2007]* - Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26 defines classification of systems and components.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]* ~~*[CA]* commits to the~~

~~applicable regulatory position guidance provided in this regulatory guide for *[ND] [with the exception of Criteria C.1, C.1.a, C.1.b, and C.3. Refer to the Westinghouse AP1000 Design Control Document, Appendix 1A for a detailed discussion of these exceptions[NOTE: Other technologies may have exceptions that will need to be addressed.]]*.~~

[NOTE: This Regulatory Guide provides guidance on establishing quality group classifications for components of the nuclear plant and the appropriate industry standards to apply that ensure proper quality requirements. Regulatory Positions C.1 through C.3 provide guidance in establishing quality group classifications of components that correspond to ASME Section III, Class 2 and 3, and those that are not part of the reactor coolant system but may contain radioactive material. Table 1 of the RG identifies the industry standards that would be applied to establishing appropriate quality requirements. The classification of components would be addressed through the FSAR (and associated DCD) Section 3.2. The application of specific standards would be addressed in the FSAR/DCD sections that describe the identified components.]

Regulatory Guide 1.28, *[Rev. 3, August 1985]*, Quality Assurance Program Requirements (Design and Construction)

Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This regulatory guide endorses the basic and supplementary requirements in ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants" and the ANSI/ ASME NQA-1a-1983 Addenda along with the regulatory positions discussed below for the establishment and execution of quality assurance programs during the design and construction phases of nuclear power plants. The QAPD provides adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance.]

[NOTE: Regulatory Position C.1 addresses the qualification of inspection and test personnel. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.8. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.T. Note that SRP Section 17.5 paragraph II.T.5 and 6 represent alternatives to this regulatory position that were approved in SER ML050700416.]

[NOTE: Regulatory Position C.2 addresses quality assurance records. Guidance is included in the QAPD, Part II, Section 17.1 for the applicant to address this regulatory position.]

[NOTE: Regulatory Position C.3 addresses scheduling of audits. In establishing the independent audit program, the QAPD template commits the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1. It follows SRP Section 17.5, paragraph II.R, for establishing the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established. The scheduling of Internal Audits is addressed in QAPD

Part II Section 18.2 and is consistent with position C.3.1 for the phase prior to placing the facility into operation. External Audits are addressed in QAPD Part II Section 7.1. The requirements are consistent with SRP paragraph II.R.11 and II.R.12. These requirements address regulatory position C.3.2.]

Regulatory Guide 1.29, *[Revision 4, March 2007],* - Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]* ~~*[CA]* commits to the applicable regulatory position guidance provided in this regulatory guide for *[ND] [with the exception of Criteria C.1.d, C.1.g, and C.1.n. Refer to the Westinghouse AP1000 Design Control Document, Appendix 1A, for a detailed discussion of these exceptions[NOTE: Other technologies may have exceptions that will need to be addressed.]]*~~.

[NOTE: This Regulatory Guide describes an acceptable method for identifying and classifying the features of nuclear power plants that must be designed to withstand the effects of the Safe Shutdown Earthquake(SSE). Regulatory Positions C.1 through C.3 provide guidance in establishing the SSCs, or portions thereof, classified as needing to meet seismic design requirements. The seismic design classification of SSCs would be addressed through the FSAR (and associated DCD) Section 3.2.]

[NOTE: Regulatory Position C.4 addresses the application of the QA requirements of Appendix B to 10 CFR Part 50 to all activities affecting the safety-related functions of those portions of the SSCs that are covered by Regulatory Positions 2 and 3. Those in Regulatory Position 1 are considered safety-related. The QAPD described in Section 17.5 of the FSAR addresses the QA program requirements applied to safety-related activities.]

[NOTE: Regulatory Position C.5 addresses the application of design requirements for portions of the fire protection SSCs as discussed in Regulatory Guide 1.189. The design and quality assurance requirements for fire protection SSCs is addressed in Section 9.5.1 of the FSAR (and associated DCD).]

Regulatory Guide 1.33, *[Rev. 2, February 1978]*, Quality Assurance Program Requirements (Operations)

Regulatory Guide 1.33 describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]*

[NOTE: This Regulatory Guide endorses ANSI N18.7-1976/ANS-3.2 for complying with the quality assurance program requirements for the operation phase of nuclear power plants, subject to five regulatory positions. SER ML070510300 for NEI 06-14A concluded that the QAPD provides adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance identified in SRP

Section 17.5. This represents an approved alternative for Regulatory Positions C.2, C.3, C.4, and C.5.]

[NOTE: Regulatory Position C.1 addresses "Typical Procedures for Pressurized Water Reactors and Boiling Water Reactors." QAPD Part II, Sections 5 and 6 address requirements on review and approval of safety-related procedures consistent with requirements addressed in SRP 17.5 section II.F and ANSI N18.7-1976. However, FSAR Chapter 13, Conduct of Operations, which addresses plant procedures, should be used in addressing this regulatory position.]

[NOTE: Regulatory Position C.2 identifies additional standards referenced by ANSI N18.7-1976/ANS-3.2 and provides a cross reference for a regulatory Guide that addressed each of those standards. The QAPD identifies commitments to ASME NQA-1-1994 instead of the listed ANSI N45.2 series standards listed. Regulatory Guides 1.28, 1.37, 1.38, 1.39, 1.30, 1.94, 1.58, 1.116, 1.88, 1.74, 1.64, and 1.123 are listed for positions on the ANSI N45.2 series standards. RG 1.8, 1.17, and 1.54 are included as addressing other ANSI Standards. RG 1.8, 1.28, and 1.37 have been revised to reference newer standards and are discussed specifically in this section. RG 1.17, 1.58, 1.64, 1.74, 1.88, and 1.123 have been withdrawn. For RG 1.30, 1.38, 1.94 and 1.116 the QAPD provides an acceptable alternative using ASME NQA-1-1994 Subparts 2.2, 2.4, 2.5, and 2.8 as identified in Part II Sections 10.3 and 13.2 and SRP 17.5 Section II.U.2. For RG 1.39 the QAPD provides an acceptable alternative in Part II, Section 13.1, which is consistent with SRP Section 17.5, paragraph II.M. for operations; controls during design and construction should be addressed in the DCD. For applicability of RG 1.54, FSAR Chapter 6 should be consulted.]

[NOTE: Regulatory Position C.3 identifies a position related to Independent Review. The QAPD provides an alternative for this position by addressing Independent Review requirements specifically in Part II, Section 2.7 consistent with SRP 17.5 Section II.W rather than referencing ANSI N18.7. Item 2.7 c. specifically relates to the concern of this regulatory position.]

[NOTE: Regulatory Position C.4 relates to provisions of the audit program. In establishing the independent audit program, the QAPD provides an alternative for this position by committing the applicant to comply with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1. It follows SRP Section 17.5, paragraph II.R, for establishing the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established.]

[NOTE: Regulatory Position C.5 identifies concerns of the NRC with the usage of the verbs "should" and "shall" in ANSI N18.7-1976. QAPD provides an alternative to this position by providing adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance identified in SRP Section 17.5.]

***/*Regulatory Guide 1.37**, *[Revision 1, March 2007],* – Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants

Regulatory Guide 1.37 provides guidance on specifying water quality and precautions related to the use of alkaline cleaning solutions and chelating agents.

[CA] identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in *[state location, e.g. FSAR Chapter 1.]* *[CA]* ~~commits to the~~

~~applicable regulatory position guidance provided in this regulatory guide for *[ND]*~~ *[NOTE: Does not apply to ESP-only or Operations-only QAP]]*

[NOTE: This Regulatory Guide finds that the provisions and recommendations included in ASME NQA-1-1994, Part II, Subpart 2.1 are generally acceptable for onsite cleaning of materials and components, cleanness control, and preoperational cleaning and layup of water-cooled nuclear power plant fluid systems with three regulatory positions. QAPD Part II, Section13.2 addresses the commitment to NQA-1-1994, Part II, Subpart 2.1.]

[NOTE: Regulatory Position C.1 identifies that the applicability and acceptability of any of the codes, standards, and specifications referenced in the text are or will be addressed through other regulations or NRC guidance. FSAR Chapter 1 addresses the codes, standards, and other documents that are used in the COL and any exceptions or alternatives to those documents.]

[NOTE: Regulatory Position C.2 identifies the NRC position that the water quality for final flushes of fluid systems and associated components should be at least equivalent to the quality of the operating system water. The applicant will need to identify if there is a reason to deviate from this regulatory position.]

[NOTE: Regulatory Position C.3 recommends following Sections 8.2.2 and 8.2.3 of ASME NQA-1-1994, Part II, Subpart 2.1 precautions related to the use of alkaline cleaning solutions and chelating agents, respectively, by the use of the guidance in nonmandatory Appendix 2.1 to ASME NQA-1-1994, Part III, Subpart 3.2. In addition, this position recommends that a suitable chloride stress-cracking inhibitor be added to the fresh water used to flush systems containing austenitic stainless steels. QAPD Part II, Section13.2 addresses the commitment to NQA-1-1994, Part II, Subpart 3.2. The applicant will need to identify if there is a reason to deviate from this regulatory position.]

6. NEI 06-14A, Revision 6, Section 2, Subsection 2.7, "Independent Review," Option I, needs to address the qualification for the independent review staff. The qualification requirements for these personnel should meet or exceed those described in Section 4.7 of ANSI/ANS-3.1-1978 and the regulatory position of Regulatory Guide 1.8, Rev. 3.

Response: NEI has revised Part II, Section 2.7, "Independent Review," Option 1 to clearly state the qualification requirements for the independent review staff consistent with the qualification criteria described in Section 4 of ANSI/ANS-3.1-1993 as endorsed by Regulatory Guide 1.8 Revision 3, including regulatory positions 2.14 and 2.15.

Changes to the NEI Template as a result of this RAI: Markup of QAPD Part II Section 2.7 on the following page includes this identified change. The highlighted text identifies added material with this markup. The information shown in strike-out font is deleted by this markup.

[2.7 Independent Review

[*Note: Section 2.7 only applies to Operations-phase QAPs.****]***

Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading. The independent review function performs the following:

a. Reviews proposed changes to the facility as described in the safety analysis report (SAR). The [*Independent Review Body (IRB)/Independent Review Committee (IRC)]* also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.

b. Reviews proposed tests and experiments not described in the SAR. Changes to proposed tests and experiments not described in the SAR that do require a technical specification change must be reviewed by the *[IRB/IRC]* prior to NRC submittal and implementation.

c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.

d. Reviews violations, deviations, and events that are required to be reported to the NRC. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

e. Reviews any matter related to nuclear safety that is requested by the *[Site Vice President, Site Director, Plant Manager,] [NOTE: the generic titles used here must match those established in Part II, Section 1 Organization]* or any *[IRB/IRC]* member.

f. Reviews corrective actions for significant conditions adverse to quality.

g. Reviews the adequacy of the audit program every 24 months.

[Note: Option I or Option II may be used. The generic terms Independent Review Body (IRB) and Independent Review Committee (IRC) may be substituted with the specific company terms.]

[Option I - Independent Review Body

A group may function as an independent review body (IRB). In discharging its review responsibilities, the IRB keeps safety considerations paramount when opposed to cost or schedule considerations. One or more organizational units may collectively perform this function.

1. IRB reviews are supplemented as follows:

a. A qualified person, independent of the preparer, reviews proposed changes in the procedures as described in the SAR prior to implementation of the change to determine if a technical specification change or NRC approval is required.

b. Audits of selected changes in the procedures described in the SAR are performed to verify that procedure reviews and revision controls are effectively implemented.

c. Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.

2. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed. This review is intended to support management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.

a. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities. The IRB supervisor or chairman has a minimum six (6) years combined managerial and technical support experience. The members of the IRB should have a minimum of five years of experience in their own area of responsibility as applicable to the activities being reviewed (i.e., a minimum of five years of experience in one of the twelve areas listed below:
(1) Nuclear power plant operations
(2) Nuclear engineering
(3) Chemistry and radiochemistry
(4) Metallurgy
(5) Nondestructive testing
(6) Instrumentation and control
(7) Radiological safety
(8) Mechanical engineering
(9) Electrical engineering
(10) Administrative control and quality assurance practices
(11) Training
(12) Emergency plans and related procedures and equipment.)

b. If sufficient expertise is not available from within the owner organization, the review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.

c. Results of the review are documented and reported to responsible management.

d. Management periodically consider issues they determine warrant special attention, such as deficient plant programs, declining performance trends, employee concerns, or other issues related to safe plant operations and determine what issues warrant the review.

e. Management determines the scheduling and scope of review and the composition of the team performing the review.]

[Option II - Independent Review Committee

1. An independent review committee is assigned independent review responsibilities.
2. The independent review committee reports to *[CA is to identify a management level above the ~~[~~plant manager as described in the organization in Part II Section 1]*.

3. The independent review committee is composed of no less than 5 persons and no more than a minority of members are from the on-site operating organization.

   For example, at least 3 of the 5 members must be from off-site if there are 5 members on the committee. A minimum of the chairman or alternative chairman and 2 members must be present for all meetings.

4. During the period of initial operation, meetings are conducted no less frequently than once per calendar quarter. Afterwards meetings are conduced no less than twice a year.

5. Results of the meeting are documented and recorded.

6. Consultants and contractors are used for the review of complex problems beyond the expertise of the off site/on site independent review committee.

7. Persons on the independent review committee are qualified as follows:

   a. Supervisor or Chairman of the Independent Review Committee
      - Education: baccalaureate in engineering or related science
      - Minimum experience: 6 years combined managerial and technical support

   b. Independent Review Committee members

   Education: Baccalaureate in engineering or related science for those Independent review personnel who are required to review problems in
      - nuclear power plant operations,
      - nuclear engineering,
      - chemistry and radiochemistry,
      - metallurgy,
      - nondestructive testing,
      - instrumentation and control,
      - radiological safety,
      - mechanical engineering, and electrical engineering.

   High school diploma for those independent review personnel who are required to review problems in administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment.

   Minimum experience: 5 years experience in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, nondestructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment).]]

NEI revised QAPD Part II, Sections 15 and 16 as shown on the following page. The changes are made to clarify the relationship between the 10 CFR 50, Appendix B requirements for Nonconforming Materials, Parts, or Components and for Corrective Action with the reporting program requirements. Evaluating and reporting as required by 10 CFR Part 21, 10 CFR 50.55, and 10 CFR Part 52 are regulatory requirements the licensee must satisfy. It is necessary for procedures satisfying nonconforming materials, parts, or components and corrective action requirements to interface with the reporting program. However, the reporting program itself is not a program that satisfies criteria of 10 CFR 50, Appendix B. Therefore, Sections 15 and 16 have been revised to clearly indicate that the reporting programs are not a required part of the Quality Assurance Program.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

[CA] has established the necessary measures and governing procedures to control items, including services, that do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with *[CA]* procedures, regulatory requirements, and industry standards.

15.1 Interface with the Reporting Program

[CA] has appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the ~~necessary measures and governing procedures that implement a~~ non-QA Reporting Program ~~that conforms~~ to satisfy the requirements of *[10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during ~~[~~ESP/COL design and construction and 10 CFR 21 during operations]*.

15.2 NQA-1-1994 Commitment

In establishing measures for nonconforming materials, parts, or components, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 15, and Supplement 15S-1.

SECTION 16 CORRECTIVE ACTION

[CA] has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. *[CA]* procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. *[CA]* procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, *[CA]* documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, the *[CA]* may delegate specific responsibilities for corrective actions ~~of the Corrective Action program~~ but the *[CA]* maintains responsibility for the ~~program's~~ effectiveness of corrective action measures.

16.1 Interface with the Reporting Program

[CA] has appropriate interfaces between the QAP for corrective actions and the ~~necessary measures and governing procedures that implement a~~ non-QA Reporting Program ~~that conforms~~ to satisfy the requirements of *[10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during ESP/COL design and construction, and 10 CFR 21 during operations]*.

16.2 NQA-1-1994 Commitment

In establishing provisions for corrective action, *[CA]* commits to compliance with NQA-1-1994, Basic Requirement 16.