Request for Additional Information
Regarding the Nuclear Energy Institute
Quality Assurance Program Description
Topical Report No. NEI-06-14A, Revision 5

1. Part II, Section 1, "Organization," of Nuclear Energy Institute (NEI) 06-14A should be revised to provide additional guidance to Combined License (COL) applicants on the organizational structure that needs to be described in the quality assurance program description (QAPD). The level of organizational detail should include all positions responsible for establishing, maintaining, and implementing regulatory requirements from corporate positions through plant positions responsible for implementing quality assurance (QA) program requirements. 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, NEI 06-14A should provide additional guidance for distinguishing the organizational structure for construction and for operations.

2. Part II, Section 1, "Organization" of the QAPD provides titles of certain positions and their responsibilities. Brackets are used throughout the rest of the document when referring to these responsibilities. Additional guidance needs to be provided to the users of the template for changing the responsibilities to the specific titles provided in Section 1 of the QAPD.

3. NEI 06-14A, Part II, Section 7.2 addresses a Nuclear Regulatory Commission (NRC)-approved exception to NQA-1-1994, Supplement 7S-1, for commercial-grade calibration services from NRC-recognized calibration laboratories. The staff requests that the bullet number "(3)" of this exception be revised as indicated below to restate the current regulatory position regarding acceptability and to add additional calibration laboratories, which have been recognized by the NRC.

    "(3) A documented review of the supplier's accreditation will be performed and will include a verification of the following:

    - *The calibration laboratory holds a domestic accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):*
        - *National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology,*
        - *American Association for Laboratory Accreditation (A2LA),*
        - *ACLASS Accreditation Services (ACLASS),*
        - *International Accreditation Service (IAS),*
        - *Laboratory Accreditation Bureau (L-A-B).*

    - *The accreditation encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."*

Enclosure

- *The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties."*

4. NEI 06-14A, Part II, Section 7.2, describes an exception to Nuclear Quality Assurance (NQA)-1-1994, Supplement 7S-1, Section 10, "Commercial Grade Item," which states that the applicant (user) will also use other appropriate approved regulatory means and controls to support commercial grade dedication activities. Section 7.2 cites the Regulatory Issue Summary (RIS) 2002-22 as providing an approved regulatory method for commercial grade dedication.

   Attachment 1 to the RIS, provides the NRC safety evaluation, documenting the basis for the guidelines documented in the RIS 2002-22. The regulatory basis for accepting the methods outlined by RIS 2002-22 are 1) the acceptance criteria of Standard Review Plan (SRP) Chapter 7, which pertains to licensing of digital instrumentation and control (I&C) and 2) requirements for implementing digital I&C replacements under the provisions of 10 CFR 50.59. However, RIS 2002-22 does not provide an approved regulatory method for commercial grade dedication. Based on discussions held on July 1, 2008, during an NRC public meeting with the NEI QA task force, the staff recommends changing the reference in this exception from RIS 2002-22 to Electric Power Research Institute (EPRI) topical report TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," dated October 1996, as approved in the Safety Evaluation by the Office of Nuclear Reactor Regulation, "EPRI Topical Report TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," dated July 17, 1997.

5. NEI 06-14A, Part III, Section 1.10, "Inspection," contains the following bracketed text, which was added since Revision 4: "[These inspections are performed by knowledgeable personnel who may be in the same line organization as those performing the activity in question, and are, at a minimum, as qualified as the person who performed the activity.]". This provision is included in SRP 17.5 as mandatory guidance, not optional as indicated by the brackets. Please explain the reason for presenting this provision as optional, or remove the brackets.

6. NEI 06-14A, Part II, Section 2, states that the QAPD applies to those quality-related activities that involve the functions of safety-related activities of structures, systems, and components (SSCs) as described in the COL Final Safety Analysis Report (FSAR). The staff notes that Appendix B to 10 CFR Part 50 requires, in part, that Part 52 applicants include in the FSAR a description of the quality assurance [program] applied to the design, and to be applied to the fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations. Please revise the language in this section to conform to this requirement.

   Also, the current language in this section seems to indicate that safety-related SSCs are described in the FSAR. Please identify the corresponding FSAR section. Otherwise, please clarify the purpose of this text and/or modify it accordingly.

7. NEI 06-14, Part II, Section 2.3, states that "The [ND] organization will develop annotated outlines for the COL application that will identify the sections safety classification and the regulatory requirements applicable to the section content.

   Please clarify the intent of this statement that seems to refer to the COL application development rather than the construction or operational phases of the nuclear power plant. Are the annotated outlines intended to be submitted as part of the application?

8. The staff noted that brackets should be added to the document to allow applicants/users to specify the scope of the QAPD for different types of applications. Brackets need to be added throughout the document to provide user-specific text for statements that:

   - are scope dependent;
   - are inapplicable to COL applications, having an approved early site permit (ESP); or
   - are applicable only to ESP applications.

   In addition, the staff requests that the word "licensee" in NEI 06-14A be changed to "[CA]" as indicated below in order to make it consistent with the rest of the QAPD.

Section 2 Quality Assurance Program		
1st paragraph	"This QAPD also applies to certain non-safety related structure, systems, components, and activities to a degree consistent with their importance to safety."	This statement does not apply to ESP only applications and is not consistent with Part III of the QAPD template.
2nd paragraph, 1st sentence	"… to assure that [CA] nuclear generating plants are *designed[,] constructed and operated* in accordance …"	This statement depends on the scope of the QAPD
3rd paragraph	"As described in Part III of this QAPD, specific program controls are applied to non-safety related SSCs that are significant contributors to plant safety."	This statement does not apply to ESP only applications and is not consistent with Part III of the QAPD template.
5th paragraph	"In addition, this QAPD applies to engineering activities that are used to characterize the site or analyze that characterization."	This statement does not apply to COL application with an approved ESP.
6th paragraph	The complete paragraph.	This statement does not apply to ESP only applications.
Section 2.3	The complete section.	Only applies to ESP applicants and COL applicants that do not have an approved ESP.
Section 4 Procurement Document Control		

2nd bullet	"… or the supplier may work under the licensee's approved QA program)."	Change "licensee's" to [CA] to make it consistent with Section 4.1, 3rd sub-bullet.
Section 16 Corrective Action		
2nd paragraph	"…the *licensee* may delegate specific responsibility of the corrective action program but the *licensee* maintains responsibility for the program's effectiveness."	Change "licensee" to "[CA]" to make it consistent with the rest of the QAPD.
Section 16.1	"Such reporting program applies to safety-related activities and services performed by [CA] and/or [CA] suppliers / sub-suppliers proving input to the ESP and COL application development."	It depends on the scope of the QAPD.
Section 18 Audits		
Internal Audits 5th paragraph	"… corrective actions taken following abnormal occurrences; and, observation of the performance of *construction, fabrication, operating, refueling, maintenance and modification activities* …"	It depends on the scope of the QAPD.