17.0 QUALITY ASSURANCE

This chapter of the application describes the quality assurance (QA) program for the design, fabrication, construction, testing, and operation of the nuclear plant. In addition, this chapter addresses the reliability assurance program (RAP) in the design phase and the Maintenance Rule program.

This chapter has the following sections related to QA:

- Section 17.1, "Quality Assurance During Design,"
- Section 17.2, "Quality Assurance During Construction and Operations,"
- Section 17.3, "Quality Assurance Program Description," and
- Section 17.5, "Quality Assurance Program Description – Design Certification Early Site Permits, and New License Applicants."

This organization is consistent with the Economic Simplified Boiling-Water Reactor (ESBWR) design certification (DC), with the new Section 17.5 introduced within the COL application. Section 17.5 follows the guidance in Regulatory Guide (RG) 1.206 and the corresponding Section 17.5 in NUREG-0800. Specifically in RG 1.206 and the March 2007 revision to NUREG-0800, staff consolidated all QA program related guidance in support of new reactor licensing into Section 17.5. The combined license (COL) final safety analysis report (FSAR) maintains the general organization of the sections on QA, but in NAP-SUP 17.0-1, the applicant stated, that the detailed QA program description related to the COL is contained in Section 17.5.

In addition, since the North Anna FSAR incorporates by reference both the ESBWR DC and the North Anna ESP, there are essentially three QA programs being discussed.

- Early Site Permit (ESP) Application Development QA Manual – incorporated by reference;
- QA Program used by GE Hitachi Nuclear Energy (GEH) for the ESBWR – incorporated by reference and applicable to design, construction, and operation; and
- DOM-QA-1, Dominion Nuclear Facility QA Program Description which is based on Nuclear Energy Institute (NEI) 06-14, "Quality Assurance Program Description."

17.1 Quality Assurance During Design

17.1.1 Introduction

This section of the FSAR addresses the QA program that was applied during the design phase of the plant and the QA program that was implemented during the ESP and combined license application (COLA) development.

17.1.2 Summary of Application

Section 17.1 of the North Anna 3 COL FSAR incorporates by reference Section 17.1 of the ESBWR design control document (DCD), Revision 5. In addition, in FSAR Section 17.1, the applicant provided the following:

Supplemental Information

The applicant provided the following supplemental information.

- NAPS SUP 17.1-1

NAPS SUP 17.1-1 describes the QA program that was applied during the preparation of the ESP application. Chapter 17 of the North Anna 3 site safety analysis review (SSAR), incorporated by reference, includes the QA program that was applied during the preparation of the ESP application.

- NAPS SUP 17.1-2

NAPS SUP 17.1-2 provides a reference to Section 17.5 of the North Anna 3 COL FSAR for the description of the QA program that was applied during the preparation of site-specific design activities.

17.1.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed in the final safety evaluation report (FSER) relating to the ESBWR DCD. For additional information on the regulatory basis see Section 17.5 of this safety evaluation report (SER).

17.1.4 Technical Evaluation

The U.S. Nuclear Regulatory Commission (NRC) staff reviewed Section 17.1 of the North Anna 3 COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the information in the COL represent the complete scope of information relating to this review topic.[1] The staff review confirmed that the information contained in the application and incorporated by reference addresses the required information related to QA during design activities. The staff is reviewing Section 17.1 of the ESBWR DCD on Docket No. 52-010. The staff's technical evaluation of the information incorporated by reference from the ESBWR DCD relating to the QA program implementation during design activities will be documented in the staff SER on the design certification application for the ESBWR design.

The staff reviewed the information contained in the COL FSAR.

Supplemental Information

- NAPS SUP 17.1-1

The NRC staff reviewed the reference to the SSAR included under Section 17.1 of the North Anna 3 COL FSAR. This reference is identified as NAPS SUP 17.1-1. The staff has concluded that the SSAR, incorporated by reference, includes the QA program that was applied during the preparation of the ESP application.

[1] See Section 1.2.2, "Finality of Referenced NRC Approvals," for a discussion on the staff's review related to verification of the scope of information to be included within a COL application that references a design certification.

- NAPS SUP 17.1-2

The NRC staff reviewed the reference to Section 17.5 of the North Anna 3 COL FSAR. The staff has concluded that the referenced section contains the description of the QA program that will be applied during the preparation of site-specific design activities (see Section 17.5 of this SER).

17.1.5 Post Combined License Activities

There are no post COL activities related to this section.

17.1.6 Conclusion

The NRC staff reviewed the application and checked the referenced DCD. The staff review confirmed that the applicant addressed the required information relating to QA during activities and there is no outstanding information expected to be addressed in the COL FSAR related to this subsection.

The NRC staff is reviewing the information in DCD Section 17.1 on Docket No. 52-010. The results of the staff's technical evaluation of the information related to the QA program during design activities incorporated by reference in the North Anna 3 COL FSAR will be documented in the staff SER on the DC application for the ESBWR. The SER on the ESBWR is not yet complete and is being tracked as part of Open Item 1-1. The staff will update Section 17.1 of this SER to reflect the final disposition of the DC application.

In addition, the staff concludes that the relevant information presented in the COL FSAR is acceptable and meets the NRC regulatory requirements. This conclusion is based on the following:

- NAPS SUP 17.1-1 is acceptable because it describes the QA program that was applied during the preparation of the ESP application. Chapter 17 of the North Anna 3 SSAR, incorporated by reference, includes the QA program that was applied during the preparation of the ESP application.

- NAPS SUP 17.1-2 is acceptable because it adequately provides a reference to Section 17.5 of the North Anna 3 COL FSAR for a description of the QA program that was applied during the preparation of site-specific design activities (see Section 17.5 in this SER).

17.2 Quality Assurance During Construction and Operations

17.2.1 Introduction

This section of the FSAR addresses the QA program during construction and operations phases of the plant, including adapting the design to specific plant implementation.

17.2.2 Summary of Application

Section 17.2 of the North Anna 3 COL FSAR incorporates by reference Section 17.2 of the ESBWR DCD, Revision 5.

In addition, in FSAR 17.2, the applicant provided the following:

COL Items

- STD COL 17.2-1-A QA Program for the Construction and Operations Phases
- STD COL 17.2-2-A QA Program for Design Activities

The applicant provided additional information to address DCD COL Items 17.2-1-A and 17.2-2-A. The applicant indicated that the QA program in place during the construction and operations phases, including adapting the design to specific plant implementation, is described in Section 17.5 of the North Anna 3 COL FSAR.

17.2.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed in the FSER related to the DCD. For additional information on the regulatory basis see Section 17.5 in this SER.

17.2.4 Technical Evaluation

The NRC staff reviewed Section 17.2 of the North Anna 3 COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the information in the COL represent the complete scope of information relating to this review topic. The review confirmed that the information contained in the application and incorporated by reference addresses the required information related to QA programs during construction and operations. Section 17.2 of the ESBWR DCD is being reviewed by the staff on Docket No. 52-010. The staff's technical evaluation of the information incorporated by reference from the ESBWR DCD related to the QA program implemented during construction and operations will be documented in the staff SER on the design certification application for the ESBWR design.

The NRC staff reviewed the QA program that will be implemented during the construction and operations phases. The review includes adapting the design to specific plant implementation and is described in Section 17.5 in this SER.

17.2.5 Post Combined License Activities

There are no post COL activities related to this section.

17.2.6 Conclusion

The NRC staff reviewed the application and checked the referenced DCD. The staff review confirmed that the applicant addressed the required information relating to QA programs during construction and operations and there is no outstanding information expected to be addressed in the COL FSAR related to this subsection.

The NRC staff is reviewing the information in DCD Section 17.2 on Docket No. 52-010. The results of the staff's technical evaluation of the information related to QA during construction and operations incorporated by reference in the North Anna 3 COL FSAR will be documented in the staff SER on the DC application for the ESBWR. The SER on the ESBWR is not yet complete and is being tracked as Open Item 1-1. The staff will update Section 17.2 in this SER to reflect the final disposition of the DC application.

In addition, the staff concludes that the relevant information presented in the COL FSAR is acceptable and meets the NRC regulatory requirements. This conclusion is based on the following:

- The substitute paragraph indicated in COL FSAR Section 17.2 is acceptable because it adequately incorporates by reference Section 17.5 of the ESBWR DCD.

- STD COL 17.2-1-A: COL Section 17.2 is acceptable because it adequately incorporates by reference Section 17.5 of the North Anna 3 COL FSAR.

- STD COL 17.2-2-A: COL Section 17.2 is acceptable because it adequately incorporates by reference Section 17.5 of the North Anna 3 COL FSAR.

17.3 QUALITY ASSURANCE PROGRAM DESCRIPTION

17.3.1 Introduction

This section of the FSAR addresses the overall project QA program.

17.3.2 Summary of Application

Section 17.3 of the North Anna 3 COL FSAR incorporates by reference Section 17.3 of the ESBWR DCD, Revision 5.

In addition, in FSAR 17.3, the applicant provided the following:

COL Item

- STD COL 17.3-1-A Quality Assurance Program Description

The applicant provided additional information to resolve ESBWR DCD COL Item 17.3-1-A. COL information Item 17.3-1-A states:

> "The COL Applicant shall provide a Quality Assurance Program Description (QAPD) describing the overall project QA program (Section 17.3)."

The applicant indicated that the QAPD applicable to the licensee is described in Section 17.5 of the North Anna 3 COL FSAR.

17.3.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed in the FSER related to the DCD. For additional information on the regulatory basis see Section 17.5 in this SER.

17.3.4 Technical Evaluation

The NRC staff reviewed Section 17.3 of the North Anna 3 COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the information in the COL represent the complete scope of information relating to this review topic. The review confirmed that the information contained in the application and incorporated by reference addresses the

required information related to the QA program description. The staff is reviewing Section 17.3 of the ESBWR DCD on Docket No. 52-010. The staff's technical evaluation of the information incorporated by reference related to the QA program description will be documented in the staff SER on the design certification application for the ESBWR design.

The staff reviewed the information contained in the COL FSAR:

COL Item

- STD COL 17.3-1-A Quality Assurance Program Document

The applicant indicated that the QAPD applicable to the licensee is described in Section 17.5 of the North Anna 3 COL FSAR. The NRC staff reviewed the QAPD applicable to the licensee. The review is described in Section 17.5 in this SER.

17.3.5 Post Combined License Activities

There are no post COL activities related to this section.

17.3.6 Conclusion

The NRC staff reviewed the application and checked the referenced DCD. The staff review confirmed that the applicant addressed the required information relating to the QA program description and there is no outstanding information expected to be addressed in the COL FSAR related to this subsection.

The NRC staff is reviewing the information in DCD Section 17.3 on Docket No. 52-010. The results of the staff's technical evaluation of the information related to the QA program description incorporated by reference in the North Anna 3 COL FSAR will be documented in the staff SER on the DC application for the ESBWR. The SER on the ESBWR is not yet complete and is being tracked as part of Open Item 1-1. The staff will update Section 17.3 of this SER to reflect the final disposition of the DC application.

In addition, the staff concludes that the relevant information presented in the COL FSAR is acceptable and meets the NRC regulatory requirements. This conclusion is based on the following:

- STD COL 17.3-3-A: COL Section 17.3 is acceptable because it adequately incorporates by reference Section 17.5 of the North Anna 3 COL FSAR.

17.4 Reliability Assurance Program During Design Phase

17.4.1 Introduction

This section of the FSAR addresses the Commission's policy for the RAP that is presented in Item E of SECY-95-132. The RAP applies to the various structures, systems, and components (SSCs) in the plants that are identified as risk-significant (or significant contributors to plant safety). This designation is determined by using a combination of probabilistic, deterministic, or other methods of analysis, including information obtained from sources such as plant- and site-specific probabilistic risk assessment (PRA), nuclear plant operating experience, relevant component failure databases, and expert panels.

The RAP is implemented in two stages. The first stage applies to reliability assurance activities that occur before the initial fuel load. The goal of the RAP during this stage is to ensure that the reactor design meets the considerations identified earlier through the reactor design, procurement, fabrication, construction, and preoperational testing activities and programs. The second stage applies to reliability assurance activities for the operations phase of the plant life cycle. The objective during this stage is to ensure that the reliability for the SSCs within the scope of the RAP is maintained during plant operations.

17.4.2 Summary of Application

Section 17.4 of the North Anna 3 COL FSAR incorporates by reference Section 17.4 of the ESBWR DCD Revision 5.

In addition, in FSAR Section 17.4, the applicant provided the following:

COL Item

- STD COL 17.4-1-H Operation Reliability Assurance Activities

The applicant provided additional information in STD COL 17.4-1-H. The COL information item requires the applicant to address the operation reliability assurance activities. The applicant provided supplemental information in Section 17.4.1 of the COL FSAR to describe the operational reliability assurance activities.

This item also contains information related to ITAAC:

The applicant will confirm that a report containing the list of risk-significant SSCs has been generated. The reliability of each as-built risk-significant SSC is verified to be consistent with the reliability assumed in the ESBWR design PRA. This ITAAC requirement is described in Section 3.6 of Tier 1 DCD.

17.4.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is addressed within the FSER related to the DCD.

In addition, the relevant requirements of the Commission regulations for the RAP and associated acceptance criteria are given in Section 17.4 of NUREG-0800.

17.4.4 Technical Evaluation

NRC staff reviewed Section 17.4 of the North Anna 3 COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the information in the COL represent the complete scope of information relating to this review topic. The review confirmed that the information contained in the application and incorporated by reference addressed the required information related to the RAP. Section 17.4 of the ESBWR DCD is being reviewed by the staff on Docket No. 52-010. The technical evaluation of the information incorporated by reference and related to the RAP will be documented in the staff SER on the design certification application for the ESBWR design.

The staff reviewed the relevant information in the COL FSAR:

COL Item

- STD COL 17.4-1-H Operation Reliability Assurance Activities

NRC staff reviewed STD COL 17.4-1-H related to the RAP and included in Section 17.4 of the North Anna 3 COL FSAR.

In FSAR Subsection 17.4.1, the applicant states that the objectives of reliability assurance during the operations phase are integrated into the QAP, the Maintenance Rule program, and other operational programs.

The staff finds that the applicant has addressed the following RAP information in accordance with the provisions in Standard Review Plan (SRP) Section 17.4:

- Description of the RAP that includes scope, purpose, and objectives
- Probabilistic/PRA methods and results for evaluating, identifying, and prioritizing SSCs according to their degree of risk significance
- Description of the quality controls for developing and implementing the RAP (organization, design control, procedures and instructions, records, corrective action, and audit plans)
- Implementation of the QA requirements during the design procurement, fabrication, construction, and testing of SSCs within the scope of the RAP
- Integration of the RAP activities for the operations phase into the applicant's existing operational programs (i.e., Maintenance Rule, surveillance testing, inservice testing (IST), inservice inspection (ISI), maintenance, and QA)
- The process for providing corrective action for design and operational errors that degrade non-safety-related SSCs within the scope of the RAP
- Expert panel qualification requirements.

The staff has asked the applicant to clarify the qualification requirements of the expert panel and the corrective action process through the request for additional information (RAI) process. The applicant responded that the expert panel qualification requirement would be incorporated in accordance with Nuclear Management and Resources council (now NEI) NUMARC 93-01 (Ref. 17.4.-1). NUMARC 93-01, Revision 2, page 17 states that, "[I]f a utility selects a method based on PRA to establish risk significance, it should begin the process by assembling a panel of individuals experienced with the plant PRA and with operations and maintenance." The staff finds the response acceptable. The applicant also responded that the corrective action process for design and operational errors that degrade non-safety-related SSCs within the scope of the RAP are described in FSAR Sections 17.5, "Quality Assurance Program Description," and 17.6, "Maintenance Rule Program." FSAR Section 17.6.1.2, which incorporates by reference NEI 07-02A (Ref. 17.4-2), states that corrective actions will be implemented in accordance with the site Corrective Action Program. The staff finds that the response is acceptable.

ITAAC

In Subsection 17.4.6, the applicant states that the list of risk-significant SSCs will be confirmed through ITAAC. This ITAAC requirement is described in Section 3.6 in Tier 1 DCD and the staff's evaluation of it is included in the FSER related to the DCD.

17.4.5 Post Combined License Activities

The applicant has committed to implement a process for integrating reliability assurance activities for risk-significant SSCs into operational programs (e.g., Maintenance Rule, surveillance testing, maintenance programs and QA) to meet the objectives of the RAP during plant operation. Consistent with this commitment, the following item was identified as the responsibility of the COL holder:

- STD COL 17.4-1-H Operation Reliability Assurance Activities

17.4.6 Conclusion

NRC staff reviewed Section 17.4 of the North Anna COL application and checked the referenced DCD. The review confirmed that the applicant has addressed the required information relating to the RAP and no outstanding information is expected to be addressed in the COL FSAR related to this subsection.

The staff is reviewing the information in DCD Section 17.4 on Docket No. 52-010. The results of the staff technical evaluation of the information related to the RAP incorporated by reference in the North Anna 3 COL FSAR will be documented in the SER on the DC application for the ESBWR. The SER on the ESBWR is not yet complete, and this is being tracked as part of Open Item 1-1. The staff will update Section 17.4 of this SER to reflect the final disposition of the DC application.

In addition, the staff concludes that the relevant information presented in the COL FSAR is acceptable and meets NRC regulatory requirements. This conclusion is based on the following:

- STD COL 17.4-1-H is acceptable because it is in conformance with the regulatory requirements as described in SRP Section 17.4.

17.5 Quality Assurance Program Description – Design Certification, Early Site Permits, and New License Applicants

17.5.1 Introduction

This section addresses the establishment and implementation of a QA program applicable during the design, fabrication, construction, testing, and operation of the nuclear power plant. There are two phases: the first phase applies to activities performed before the start of construction (e.g., site investigations, design and safety analyses, early procurements); and the second phase applies to QA activities performed during design implementation, construction, and operations.

17.5.2 Summary of Application

Section 17.5 of the North Anna 3 COL FSAR provides the following supplements that relate to the QA program applied to activities described in Sections 17.1 through 17.3 of the ESBWR DCD, Revision 5, and activities during the ESP application described in SSAR Chapter 17.

In FSAR Section 17.5, the applicant provided the following:

Supplemental information

- NAPS SUP 17.5-1

The applicant provided supplemental information to address the QA controls applied to DC activities and made reference to Section 17.1 of the North Anna 3 COL FSAR. This supplemental information addresses the QA program that was applied during the preparation of the ESP.

- NAPS SUP 17.5-2

The applicant provided supplemental information to address the QA controls that will be applied to activities performed before the start of construction (e.g., site investigations, design and safety analyses, and early procurements).

- NAPS SUP 17.5-3

The applicant provided supplemental information to address the QA controls that will be applied to QA activities during design implementation, construction, and operations.

17.5.3 Regulatory Basis

The relevant requirements of Commission regulations for the applicant's QA program description and associated acceptance criteria are given in Section 17.5 of NUREG-0800.

The applicable regulatory requirements are those related to QA programs that are set forth in 10 CFR 52.79(a)(25) and Appendix B to 10 CFR Part 50.

10 CFR 52.79(a)(25) requires that an application for a COL contain a description of the QA program, applied to the design and to be applied to the fabrication, construction, and testing of the SSCs of the facility. In addition, the description of the QA program must include a discussion of how the applicable requirements of Appendix B have been and will be satisfied, including a discussion of how the QA program will be implemented.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth NRC regulatory requirements related to QA programs. Appendix B establishes QA requirements for the design, fabrication, construction, and testing of the SSCs of the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

17.5.4 Technical Evaluation

The NRC staff reviewed NAPS SUP 17.5-1, NAPS SUP 17.5-2, and NAPS SUP 17.5-3 included in Section 17.5 of the North Anna 3 COL FSAR. NAPS SUP 17.5-1 and NAPS SUP 17.5-2 address the QA program applied to design activities by including a reference to the Dominion Nuclear Facility (DOM) QAPD (Ref. 17.5-201 of the North Anna 3 COL FSAR) topical report (TR) for the Dominion operating nuclear power plants. North Anna 3 will apply this TR to QA activities performed before the start of construction (e.g., site investigations, design and safety analyses, early procurements). NAPS SUP 17.5-3 addresses the QA program applied to the construction and operations phases.

The staff reviewed the relevant information in the COL FSAR:

Supplemental information

- NAPS SUP 17.5-1
- NAPS SUP 17.5-2

NAPS SUP 17.5-1 and NAPS SUP 17.5-2 address the QA program that was applied to safety-related activities performed before the start of construction (e.g., site investigations, design and safety analyses, early procurements). The applicant stated that the QA controls applied during this time period are described in the DOM QAPD TR for the Dominion operating nuclear plants supplemented by COL project procedures. The existing DOM QAPD had not been compared to the acceptance criteria in the NUREG-0800 SRP Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," (Ref. 17.5-1). This plan was in effect when the NAPS Unit 3 COL application was submitted. To meet the expectations of RG 1.206, Section C.III.1, Chapter 17, Section C.III.17.5, NRC staff therefore issued a RAI, **RAI 17.5-1.** The staff requested the applicant to provide an evaluation of the existing DOM QAPD (DOM-QA-1) against the acceptance criteria in SRP Section 17.5, which demonstrates its acceptability for controlling QA activities before the start of construction.

In the August 4, 2008, response to **RAI 17.5-1**, the applicant evaluated DOM-QA-1 with respect to SRP Section 17.5 acceptance criteria. The applicant provided a table that illustrates each acceptance criterion in SRP Section 17.5 and evaluates whether DOM-QA-1 meets a criterion or whether a criterion is not applicable. The table was included in the COL FSAR as Table 1.9-201. As a result of the evaluation, the applicant found that, with the exception of some criteria that are not applicable, the QAPD conforms to the acceptance criteria in SRP Section 17.5. The staff reviewed the table and found it to be acceptable.

- NAPS SUP 17.5-3

NAPS SUP 17.5-3 addresses and resolves ESBWR DCD COL Items 17.2-1-A, 17.2-2-A, and 17.3-1-A. This supplemental information describes the QA program that will be applied to the construction and operations phases. Appendices 17AA and 17BB of the North Anna 3 COL FSAR include the QAPD and the NAPS Unit 3 QAPD, respectively, that will be applied during construction and operations.

The staff issued **RAI 17.5-2** and requested the applicant to clarify the expected scope of work for each QAPD, as it relates to design and procurement activities, by identifying when and where these design and procurement activities will take place and specifying under which QAPD the activities will be conducted.

In the August 4, 2008, response to **RAI 17.5-2**, the applicant provided the current scope of work for each QAPD as it relates to design and procurement activities. The applicant clarified that General Electric-Hitachi, Wilmington, NC) will be responsible for design activities associated with the COL review, and Bechtel (Frederick, MD) will be responsible for construction site preparation. In addition, Bechtel will oversee procurement for items and services such as design work, and GEH will oversee activities for manufacturing and fabricating the reactor pressure vessel. These activities will be conducted under the NAPS Unit 3 QAPD described in FSAR Appendix 17BB. The NAPS Unit 3 QAPD will be ready for implementation by June 2009. The staff found that the applicant had satisfactorily clarified the scope of each QAPD. Therefore, the staff found that the applicant's response to **RAI 17.5-2** is acceptable.

The NRC staff reviewed and evaluated NAPS Unit 3 QAPD supplemental information included in 17.5-3 to determine whether it met NRC regulations by adhering to the guidance in SRP Section 17.5. SRP Section 17.5 provides an outline for a QA program that is acceptable to NRC staff for DC, ESP, COL, and operating license applicants.

The QAPD for NAPS Unit 3 is the top-level document that establishes the QA measures to be applied for activities related to the design, construction, and operation of an ESBWR at the NAPS Unit 3 site. Part I Section 1.1 of the NAPS Unit 3 QAPD lists the quality activities to which the QAPD applies. Although this list is not all-inclusive, the staff noted that siting is on the list. The staff issued **RAI 17.5-3** and requested the applicant to clarify how siting activities would be subject to this QAPD since the NAPS ESP has been approved.

In the August 4, 2008, response to **RAI 17.5-3**, the applicant states that siting activities subject to this QAPD are associated with any additional design work or measurements required to support construction. Additional subsurface measurement activities would be performed consistent with Nuclear Quality Assurance (NQA)-1-1994 Basic Requirement 3 Supplement 3S-1, Basic Requirement 11 Supplement 11S-1, and subsurface investigation requirements in Subpart 2.20. The staff endorsed NQA-1-1994 as an acceptable approach to meet Appendix B to 10 CFR Part 50 requirements. Therefore, the staff finds that the applicant's response to **RAI 7.5-3** is acceptable.

The staff's review of the NAPS QAPD is provided below:

17.5.4.1 *Organization*

The QAPD for the NAPS Unit 3 follows the guidance in SRP Section 17.5, paragraph II.A related to organization. The NAPS Unit 3 QAPD includes a commitment from the applicant to comply with the quality standards for QA organizations described in NQA-1-1994, Basic Requirement 1, and Supplement 1S-1. The QAPD describes and defines the responsibility and authority for planning, establishing, and implementing an effective overall QA program. The QAPD provides a description of an organizational structure; functional responsibilities; levels of authority; and interfaces for establishing, executing, and verifying QAPD implementation. The QAPD establishes independence between the organization responsible for checking a function and the organization that performs the function. In addition, the QAPD allows NAPS Unit 3 management to size the QA organization commensurate with assigned duties and responsibilities.

The staff issued **RAI 17.5-4** and requested the applicant to provide a flowchart to delineate the organizational interfaces and interrelationships between the North Anna corporate and onsite QA organizations.

In the August 4, 2008, response and a supplemental letter dated September 11, 2008, responding to **RAI 17.5-4**, the applicant included Figures II.1-1 and II.1-2 to identify organizations for the construction and operations phases, respectively. The NRC staff is currently reviewing NEI 06-14 that the applicant used to develop the QAPD and is evaluating the extent of information that the organizational section of the QAPD needs to include. (Ref. 17.5-14) This revision to NEI 06-14 will result in changes to the organizational description contained in the QAPD. **RAI 17.5-4 is being tracked as an Open Item.**

In addition, the staff noted that the NAPS Unit 3 QAPD provides a reference to the NAPS Unit 3 COL FSAR Chapter 13 for a more detailed description of the operating organization. The staff issued **RAI 17.5-7** and requested the applicant to clarify the regulation (i.e. 50.54(a) or 50.59) that will be applied to changes in the operating organizational description included in FSAR Chapter 13.

The applicant chose to describe the detailed organizational responsibilities for operating the facility in Chapter 13 of the FSAR to minimize duplication of information between Chapters 13 and 17. This detailed description is incorporated by reference in Chapter 17. Because the organization is implementing the QA program described in Chapter 17, the applicant will manage any changes to the organization in accordance with 10 CFR 50.54(a) to ensure the appropriate review and approval process. In the August 4, 2008, response to **RAI 17.5-7**, a revised response from the applicant which included a statement in Section 13.1.1 committing that changes to the organization will be reviewed under the provisions of 10 CFR 50.54(a). This review will ensure that any reduction in commitments under the QAPD will be submitted to and approved by NRC staff before implementation. On this basis, the staff finds the response to **RAI 17.5-7** acceptable.

17.5.4.2 *Quality Assurance Program*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.B for the QA program. The QAPD establishes measures to implement a QA program to ensure that the design, construction, and operation of a nuclear power plant are in accordance with governing regulations and license requirements. The QA program comprises those planned and systematic actions that are necessary to provide confidence that SSCs will perform their intended safety function, including certain non-safety-related SSCs and activities that are significant contributors to plant safety, as described in North Anna 3 COL FSAR. The QA program requires that a list or system be maintained identifying SSCs and activities to which the QAPD applies.

10 CFR 52.79 identifies the technical information required to be included in the applicant's FSAR. NRC staff noted that the NAPS Unit 3 QAPD provides a reference to 10 CFR 50.34(b)(6)(ii). The staff issued **RAI 17.5-5** and requested the applicant to revise the cited regulation.

In the August 4, 2008, response to **RAI 17.5-5**, the applicant chose to correctly cite 10 CFR 52.79(a)(27) rather than 10 CFR 50.34(b)(6)(ii). The change was shown on the attached FSAR markup. In Revision 1 to the FSAR submitted in December 2008, NRC staff noted that the applicant did not incorporate the reference to the regulation. Instead, the applicant decided to change it to "regulations." In a conference call on February 25, 2009, the applicant mentioned that the change was based on the latest revision to the NEI 06-14 that includes the word "regulation." The staff is currently reviewing the NEI 06-14 that the applicant used to develop

the QAPD and is evaluating the reference to the regulation. **RAI 17.5-5 is being tracked as an Open Item.**

The QAPD provides measures to assess the adequacy of the QAPD at least once each year or at least once during the existence of the activity, whichever is shorter, to ensure that it is effectively implemented. The program allows the period for assessing the QAPD during the operations phase to be extended to once every 2 years. In addition, consistent with SRP Section 17.5 paragraph II.B.8, the QAPD applies a grace period of 90 days to activities that must be performed on a periodic basis. The next due date for the performance of an activity that invokes the 90-day grace period remains unchanged. The next due date for an activity performed before the scheduled due date is moved forward so that the interval prescribed for the performance of the activity is not exceeded.

The QAPD also adheres to the guidance in SRP Section 17.5 paragraphs II.S and II.T for training. The QAPD describes measures that establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD to ensure that they achieve and maintain an appropriate level of proficiency. The technical specifications for NAPS Unit 3 delineate the minimum qualifications for plant and support staff involved in quality activities. Personnel are required to complete the training for positions identified in 10 CFR 50.120, "Training and Qualification of Nuclear Power Plant Personnel," in accordance with programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training. The QAPD also establishes minimum training requirements for managers responsible for QAPD implementation, in addition to minimum training requirements for individuals responsible for planning, implementing, and maintaining the QAPD.

The QAPD also adheres to SRP Section 17.5 paragraph II.W for independent program reviews. The QAPD provides measures for establishing an independent review program for activities occurring during the operational phase. The QAPD includes a commitment from the applicant to comply with the quality standards for independent reviews described in NQA-1-1994 (Ref. 17.5-2), Basic Requirement 2, and Supplements 2S-1 through 2S-4 with the following alternatives:

- NQA-1-1994 Supplement 2S-1, includes NQA-1-1994 Appendix 2A-1. The QAPD proposes the following alternatives to the implementation of Supplement 2S-1 and Appendix 2A-1:

  - NQA-1-1994 Supplement 2S-1 identifies the responsibility of the organization to designate those activities that require qualified inspectors and test personnel and establish written procedures for the qualifications of those personnel. As an alternative to this requirement, the QAPD proposes that a qualified engineer may plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For purposes of these functions, a qualified engineer is one who has a baccalaureate degree in engineering in a discipline related to the inspection or test activity (i.e., electrical, mechanical, or civil engineering); has at least 5 years of engineering work experience with at least 2 of those years in nuclear facilities.

    NRC staff evaluated this proposed alternative and determined that the designation of a qualified engineer to plan inspections, evaluate inspectors, or evaluate the inspector qualification programs is consistent with the training and qualification criteria in Appendix B to 10 CFR Part 50, Criterion II, "Quality Assurance Program," and NQA-1-

1994 Supplement 2S-1. Therefore, the staff concluded that this alternative is acceptable.

- NQA-1-1994 Appendix 2A-1 provides guidance for qualifying inspection and test personnel as Level I, II, or III. As an alternative to this guidance, the QAPD proposes that personnel performing independent quality verification inspections, examinations, measurements, or tests will be required to possess qualifications equal to or better than those required for performing the task being verified. In addition, the verification performed must be within the skills of these personnel and addressed by procedures. These personnel will not be responsible for planning quality verification inspections or tests (i.e., establishing hold points and acceptance criteria in procedures and determining responsibility for performing the inspection), evaluating inspection training programs, or certifying inspection personnel.

  NRC staff evaluated this proposed alternative and determined that it is consistent with initial qualification requirements for inspection and test personnel that are specified in SRP Section 17.5 paragraph II.T.5. Therefore, the staff concluded that this alternative is acceptable.

- NQA-1-1994 Supplement 2S-2 states that nondestructive examination personnel must be qualified. As an alternative to this requirement, the QAPD proposes to follow the applicable standard cited in Sections III and XI of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code. The 10 CFR 50.55a, "Codes and Standards," also requires the use of the latest edition and addenda in Sections III and XI of the ASME Code. NRC staff evaluated this proposed alternative and determined that it is consistent with the regulation in 10 CFR 50 Appendix B Criterion II, "Quality Assurance Program." Therefore, the staff concluded that this alternative is acceptable.

- NQA-1-1994 Supplement 2S-3 states that the prospective lead auditors must have participated in a minimum of five audits in the previous 3 years. As an alternative to this requirement, the QAPD proposes to follow the guidance in SRP Section 17.5 paragraph II.S.4.c, which states that prospective lead auditors shall demonstrate their ability to properly conduct the audit process as implemented by the company, to effectively lead an audit team, and to effectively organize and report results (including participation in at least one nuclear audit within the year preceding the date of qualification). NRC staff evaluated this proposed alternative and determined that it is consistent with the regulation in Appendix B to 10 CFR Part 50, Criterion II. Therefore, the staff concluded that this alternative is acceptable.

17.5.4.3 *Design Control*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.C for design control. The QAPD establishes the necessary measures to control the design, design changes, and temporary modifications of items that are subject to the provisions of the QAPD (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints). The QAPD design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces with the applicant and its suppliers. These provisions ensure that the design inputs (i.e., design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (i.e., analyses, specifications, drawings, procedures, and instructions). The QAPD provisions also call for

individuals who are knowledgeable about QA principles to review design documents and ensure that they contain the necessary QA requirements.

In the QAPD, the applicant commits to comply with the QA standards described in NQA-1-1994, Basic Requirement 3, and Supplement 3S-1 to establish the program for design control and verification; in Subpart 2.20 for the subsurface investigation requirements; and in Subpart 2.7 standards for computer software QA controls.

17.5.4.4 *Procurement Document Control*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.D for procurement document control. The QAPD establishes the necessary administrative controls and processes to ensure that procurement documents include or reference applicable regulatory, technical, and QA program requirements. As noted in SRP Section 17.5 paragraph II.D.1, applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and the regulation in 10 CFR Part 21, "Reporting of Defects and Noncompliance") must be included in procurement documents and invoked on the supplier of basic components. In the QAPD, the applicant commits to comply with the quality standards described in NQA-1-1994 Basic Requirement 4 and Supplement 4S-1, with the following alternatives and commitment:

- NQA-1-1994 Supplement 4S-1 Section 2.3 states that procurement documents must require suppliers to have a documented QA program that implements NQA-1-1994, Part I.

  - As an alternative to this requirement, the QAPD proposes that suppliers have a documented QA program that meets Appendix B to 10 CFR Part 50, as applicable to the circumstances of the procurement. NRC staff evaluated this proposed alternative and determined that it is consistent with Appendix B Criterion IV, "Procurement Document Control." Therefore, the staff concluded that this alternative is acceptable.

  - As an alternative to this requirement, the QAPD proposes that procurement documents could allow suppliers to work under the applicant's QAPD, including implementing procedures, if suppliers do not have their own QA program. NRC staff evaluated this proposed alternative and determined that the applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.G, "Control of Purchased Material, Equipment, and Services." Specifically, the QAPD provides measures to evaluate prospective suppliers so that only qualified suppliers are selected, acceptance actions are performed for procured products and services, and suppliers are periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services. Therefore, the NRC staff concluded that this alternative is acceptable.

- NQA-1-1994 Supplement 4S-1 Section 3 states that procurement documents are to be reviewed before awarding a contract. As an alternative to this requirement, the QAPD proposes to conduct the QA review of procurement documents through a review of the applicable procurement specifications, including the technical and quality procurement requirements, before awarding a contract. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive QA review. NRC staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding a contract and after any changes. Therefore, the staff concluded that this alternative is acceptable.

- The QAPD includes a commitment from the applicant that procurement documents prepared for commercial-grade items and procured as safety-related items shall contain technical and QA requirements to which the procured item can be appropriately dedicated. NRC staff evaluated this proposed commitment and determined that it is consistent with staff guidance in Generic Letter (GL) 89-02 dated March 21, 1989, (Ref. 17.5-3), "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," and GL 91-05 dated April 9, 1991, (Ref. 17.5-4), "Licensee Commercial-Grade Procurement and Dedication Programs," as delineated in SRP Section 17.5 paragraphs II.U.1.d and II.U.1.e. Therefore, the staff concluded that this commitment is acceptable.

17.5.4.5 *Instructions, Procedures, and Drawings*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.E for instructions, procedures, and drawings. The QAPD establishes the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, and drawings.

In the QAPD, the applicant commits to comply with the quality standards for instructions, procedures, and drawings described in NQA-1-1994 Basic Requirement 5 to establish procedural controls.

17.5.4.6 *Document Control*

The applicant's QAPD follows the guidance of SRP Section 17.5 paragraph II.F for document control. The QAPD establishes the necessary measures and governing procedures to control the preparation, review, approval, and issuance of as well as changes in documents that specify QA requirements or prescribe measures for controlling activities affecting quality, including organizational interfaces. The QAPD provides measures to ensure that the same organization that performed the original review and approval also review and approve revisions or changes to documents, unless other organizations are specifically designated.

A listing of all controlled documents identifying the current approved revision or date is maintained so personnel can readily determine the appropriate document for use. To ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed and updated as necessary, consistent with NRC staff guidance provided in SRP Section 17.5, paragraph II.F.8.

In the QAPD, the applicant commits to comply with the QA standards for document control described in NQA-1-1994, Basic Requirement 6, and Supplement 6S-1 to establish provisions for document control.

17.5.4.7 *Control of Purchased Material, Equipment, and Services*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.G for control of purchased materials, equipment, and services. The QAPD establishes the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The program provides measures to evaluate prospective suppliers so that only qualified suppliers are selected. In addition, the program requires that suppliers be periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides for acceptance actions such as source verification, receipt inspection, pre- and post-installation tests, and the review of documentation such as certificates of conformance to ensure that procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. Purchased items (such as components, spares, and replacement parts necessary for plant operation, refueling, maintenance, and modifications) and services are subject to QA and technical requirements at least equivalent to those specified for original equipment, or by properly reviewed and approved revisions to ensure that the items are suitable for the intended service and are of an acceptable quality that is consistent with the intended effect on safety.

In the QAPD, the applicant commits to comply with the quality standards for the control of purchased material, equipment, and services described in NQA-1-1994, Basic Requirement 7, and Supplement 7S-1 to establish procurement verification control with the following exceptions and alternatives:

- NQA-1-1994, Basic Requirement 7, and Supplement 7S-1 state that procurement sources and suppliers' performance are to be evaluated. As an exception to these requirements, the QAPD proposes that other 10 CFR Part 50 licensees (other than North Anna 3), authorized nuclear inspection agencies, the National Institute of Standards and Technology (NIST), and other State and Federal agencies that may provide items or services to North Anna 3 are not required to be evaluated or audited.

- NRC staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the National Voluntary Laboratory Accreditation Program (NVLAP) administered by NIST, and other State and Federal agencies perform work under quality programs acceptable to the NRC, and that no additional audits or evaluations are required. However, the applicant remains responsible for ensuring that procured items or services conform to the Appendix B to 10 CFR Part 50 program, applicable ASME Boiler and Pressure Vessel Code requirements, and other regulatory requirements and commitments. As discussed in the QAPD, the applicant also remains responsible for ensuring that the items or services are suitable for the intended application and for documenting the evaluation that supports this conclusion. The proposed exception provides an appropriate level of quality and safety. The staff determined that this exception is acceptable as documented in a previous safety evaluation (SE) (Ref. 17.5-5).

- SRP Section 17.5 paragraph II.L.8 establishes provisions for the procurement of commercial-grade calibration services for safety-related applications. As an exception to these provisions, the QAPD proposes that procurement source evaluations and selection measures not be required, provided that all of the following conditions are met:

  - Purchase documents impose additional technical and administrative requirements to satisfy any licensee-specific QAPD and technical requirements

  - Purchase documents require reporting as-found calibration data when calibrated items are found to be out of tolerance.

  - 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):
  - NVLAP administered by NIST
  - 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."
- The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.

NRC staff evaluated and found to be acceptable the NVLAP and A2LA accreditation programs (Ref. 17.5-6). The staff subsequently determined that the accreditation programs of ACLASS, L-A-B, and IAS are also recognized by the ILAC MRA and are therefore acceptable (Ref. 7, 8, and 9).

- NQA-1-1994 Supplement 7S-1 Section 8.1 states that documented evidence must conform to procurement documents and be available at the nuclear facility site before installation or use. As an alternative to the requirement that documented procurement evidence be available at the nuclear facility site during construction, the QAPD proposes that documented evidence may be stored in physical form or in electronic media, under the control of the applicant or its supplier(s), and at a location(s) other than the nuclear facility site as long as the documents can be accessed at the nuclear facility site during construction. After the completion of construction, sufficient documented evidence will be available to the licensee to support operations. The NRC staff determined that implementation of this alternative would allow access to and review of the necessary procurement documented evidence at the nuclear facility site, both before installation and use. Therefore, the staff concluded that this alternative is acceptable.

- As an alternative to the requirements that control commercial-grade items and services in NQA-1-1994 Supplement 7S-1 Section 10, the applicant commits in the QAPD to follow NRC guidance discussed in GLs 89-02 and 91-05. In addition, the applicant commits to establish and describe special QA verification requirements in applicable documents to assure that the commercially procured items will perform satisfactorily. In addition, the documents should determine critical characteristics, technical evaluations, receipt requirements, and QA evaluations of the items to ensure that they are suitable for their intended use. NRC staff determined that this alternative
  - is consistent with the guidance in SRP Section 17.5 paragraphs II.U.1.d and II.U.1.e,
  - will improve the likelihood of detecting counterfeit and fraudulently marked products, and

- will improve the commercial-grade dedication programs.

Therefore, the staff concluded that this alternative is acceptable.

17.5.4.8 *Identification and Control of Materials, Parts, and Components*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.H for identification and control of materials, parts, and components. The QAPD establishes the necessary measures for the identification and control of items such as materials (including consumables and items with limited shelf life), parts, components, and partially fabricated subassemblies. The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation consistent with the item's effect on safety.

In the QAPD, the applicant commits to comply with the QA standards for controlling materials, parts, and components described in NQA-1-1994, Basic Requirement 8, and Supplement 8S-1 to establish provisions for the identification and control of items.

17.5.4.9 *Control of Special Processes*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.I for the control of special processes. The QAPD establishes programs, procedures, and processes to ensure that special processes requiring interim controls to maintain quality—such as welding, heat treating, chemical cleaning, and nondestructive examinations—are implemented and controlled in accordance with applicable codes, specifications, and standards.

In the QAPD, the applicant commits to comply with the QA standards controlling special processes described in NQA-1-1994, Basic Requirement 9, and Supplement 9S-1 to establish measures for the control of special processes.

17.5.4.10 *Inspection*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.J for inspections. The QAPD establishes the necessary measures for implementing inspections to ensure that items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. The inspection program establishes requirements for planning inspections, determining applicable acceptance criteria, setting the frequency of inspections, and identifying special tools needed to perform the inspection. Properly qualified personnel independent of those who performed or directly supervised the work are required to perform the inspections.

In the QAPD, the applicant commits to comply with QA standards for inspections described in NQA-1-1994, Basic Requirement 10, Supplement 10S-1, and Subparts 2.4, 2.5, and 2.8 to establish inspection requirements with the following commitment and alternative:

- NQA-1-1994 Subpart 2.4 requires the use of the Institute of Electrical and Electronic Engineers (IEEE) Standard 336-1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities" (Ref. 17.5-10). IEEE Standard 336-1985 refers to IEEE 498-1985, "IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities" (Ref. 17.5-11). Each of these standards uses the definition of safety systems equipment from IEEE Standard 603-1980, "IEEE Standard Criteria for Safety

Systems for Nuclear Power Generating Stations" (Ref. 17.5-12). IEEE Standard 603-1980 defines "safety system" as:

> Those systems (the reactor trip system, an engineered safety feature, or both, including all their auxiliary supporting features and other auxiliary feature) which provide a safety function. A safety system is comprised of more than one safety group of which any one safety group can provide the safety function.

The QAPD must commit to the IEEE Standard 603-1980 definition of safety systems equipment to appropriately implement NQA-1-1994 Subpart 2.4. In the QAPD, the applicant commits to the definition of safety systems equipment from IEEE Standard 603-1980, but does not commit to the balance of IEEE Standard 603-1980. This definition applies only to equipment in the context of NQA-1-1994 Subpart 2.4. The NRC staff determined that the use of the definition of safety systems equipment is acceptable because it is consistent with the requirements in NQA-1-1994 Subpart 2.4.

- NQA-1-1994 Supplement 10S-1 Section 3.1 states that inspection personnel will not report to the immediate supervisor responsible for performing the work being inspected. As an alternative to this requirement, the QAPD proposes that QA inspectors will report to quality control management while performing these inspections. The NRC staff determined that the use of this alternative is consistent with SRP Section 17.5 paragraph II.J.1. Therefore, the staff concluded that this alternative is acceptable.

17.5.4.11 *Test Control*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.K for test control. The QAPD establishes the necessary measures and governing provisions to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service, that the plant can be operated safely as designed, and that the operation of the plant as a whole is satisfactory.

In the QAPD, the applicant commits to comply with the QA standards for test control described in NQA-1-1994, Basic Requirement 11, and Supplement 11S-1, to establish provisions for testing.

The applicant also commits in the QAPD to comply with the QA standards for software test control described in NQA-1-1994 Supplements 11S-2 and Subpart 2.7 to ensure that computer software used in applications affecting safety be prepared, documented, verified, tested, and used in a manner that obtains the expected outputs and maintains configuration control.

17.5.4.12 *Control of Measuring and Test Equipment*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.L for the control of measuring and test equipment (M&TE). The QAPD establishes the necessary measures to control the calibration, maintenance, and use of M&TE that provide information important to safe plant operations.

In the QAPD, the applicant commits to comply with the quality standards for M&TE described in NQA-1-1994 Basic Requirement 12 and Supplement 12S-1 to establish provisions that control M&TE with the following clarification and exception:

- The QAPD clarifies that the out-of-calibration conditions described in paragraph 3.2 of Supplement 12S-1 of NQA-1-1994 refer to cases where the M&TE are found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. NRC staff determined that the clarification for the out-of-calibration conditions is consistent with Supplement 12S-1. Therefore, the staff concluded that this clarification is acceptable.

- As an alternative to the NQA-1-1994 Subpart 2.4 Section 7.2.1 calibration labeling requirements, the QAPD proposes that when it is impossible or impractical to mark equipment with required calibration information because of equipment size or configuration, the required calibration information will be documented and traceable to the equipment. NRC staff determined that this alternative is consistent with NRC staff guidance provided in SRP 17.5 paragraph II.L.3. Therefore, the staff concluded that this alternative is acceptable.

17.5.4.13 *Handling, Storage, and Shipping*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.M for handling, storage, and shipping of procured items. The QAPD establishes the necessary measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration.

In the QAPD, the applicant commits to comply with the QA standards for handling, storage, and shipping in NQA-1-1994 Basic Requirement 13 and Supplement 13S-1 and to establish provisions for handling, storage, and shipping. In the QAPD, the applicant also commits to comply with the quality standards described in NQA-1-1994 Subparts 2.1, 2.2, and 2.15 during the construction and pre-operations phases of the plant, as applicable, with the following alternatives:

- NQA-1-1994 Subpart 2.2 Section 6.6 states that the preparation of records must include information on personnel access to QA records. The QAPD establishes the necessary measures to document personnel authorized to access storage areas and record personnel access. However, the QAPD proposes not to consider these documents as QA records. As an alternative, the applicant will retain these documents in accordance with plant administrative controls. The NRC staff determined that these records do not meet the classification of a QA record as defined in NQA-1-1994 Supplement 17S-1 Section 2.7. Therefore, the staff concluded that this alternative is acceptable.

- NQA-1-1994 Subpart 2.2 Section 7.1 refers to Subpart 2.15 for requirements related to handling items. The QAPD clarifies that the scope of Subpart 2.15 includes hoisting, rigging, and transporting items for nuclear power plants during construction. The NRC staff has determined that this clarification is acceptable because it distinguishes between the requirements for construction and operation.

17.5.4.14 *Inspection, Test, and Operating Status*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.N on the inspection, testing, and operating status of items subject to QA oversight. The QAPD establishes the necessary measures to identify the inspection, testing, and operating status of items and components subject to the provisions of the QAPD to maintain personnel and reactor safety, and to avoid the inadvertent operation of equipment.

In the QAPD, the applicant commits to comply with the QA standards in this area described in NQA-1-1994 Basic Requirement 14 to establish procurement verification controls.

17.5.4.15 *Nonconforming Materials, Parts, or Components*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.O for nonconforming materials, parts, or components. The QAPD establishes the necessary measures to control items, including services that do not conform to specified requirements, to prevent inadvertent installation or use. Instances of nonconformance are evaluated for their impact on the operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. The results of evaluations of conditions adverse to quality are analyzed to identify quality trends to be documented and reported to upper management in accordance with applicable procedures.

In addition, the QAPD provides for establishing the necessary measures to implement the requirements of Subparts A and C of 10 CFR Part 52, 10 CFR 50.55(e), and 10 CFR Part 21, where applicable.

In the QAPD, the applicant commits to comply with the QA standards for nonconforming materials, parts, or components described in NQA-1-1994, Basic Requirement 15, and Supplement 15S-1 to establish measures for nonconforming materials.

17.5.4.16 *Corrective Action*

The applicant's QAPD follows the guidance in SRP Section 17.5, paragraph II.P for corrective action programs. The QAPD establishes the necessary measures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD requires personnel to identify known conditions adverse to quality. Reports of these conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality are documented and reported to responsible management. In the case of suppliers working on safety-related activities or similar situations, the applicant may delegate specific responsibility for the corrective action program, but the applicant maintains responsibility for the program's effectiveness.

In addition, the QAPD establishes the measures necessary for implementing a reporting program in accordance with the requirements in 10 CFR Part 21.

In the QAPD, the applicant commits to comply with the QA standards for corrective action programs described in NQA-1-1994 Basic Requirement 16, to establish a corrective action program.

17.5.4.17 *Quality Assurance Records*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.Q on QA records. The QAPD establishes the necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and can be retrieved.

Concerning the use of electronic records storage and retrieval systems, the QAPD complies with the NRC guidance in GL 88-18, "Proposed Final NRC," GL 88-18, Supplement 1, "Guidance on Managing Quality Assurance Records in Electronic Media," dated September 13, 1999; Regulatory Issue Summary 2000-18, "Guidance on Managing Quality Assurance

Records in Electronic Media," dated October 23, 2000, and associated Nuclear Information and Records Management Association (NIRMA) Technical Guides (TG) 11-1998, TG 15-1998, TG 16-1998, and TG 21-1998.

In the QAPD, the applicant commits to comply with the quality standards for QA records described in NQA-1-1994, Basic Requirement 17, and Supplement 17S-1 establishing provisions for records, with the following alternative:

- NQA-1-1994 Supplement 17S-1 Section 4.2(b) states that records must be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. As an alternative to this requirement, the QAPD proposes that hard-copy records be stored in steel cabinets or on shelving in containers, except that methods other than binders, folders, or envelopes may be used to organize records for storage. The NRC staff determined that this alternative is acceptable as documented in a previous SE (Ref. 17.5-13).

17.5.4.18 *Quality Assurance Audits*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.R on QA audits. The QAPD establishes the necessary measures to implement audits for verifying that activities covered by the QAPD are performed in conformance with documented requirements. The audit program is reviewed for effectiveness as part of the overall audit process.

The QAPD provides for the COL applicant or holder to conduct periodic internal and external audits. Internal audits are conducted to determine that the program and procedures being audited comply with the QAPD. Internal audits are performed with a frequency commensurate with the safety significance of the program or activity and in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area within a period of 2 years after determining that the program is well established. External audits determine the adequacy of a supplier's or contractor's QA program.

The applicant ensures that audits are documented and audit results are reviewed. In accordance with the QAPD, the COL applicant or holder will respond to all audit findings and initiate appropriate corrective actions. In addition, where corrective actions are indicated, the applicant will document the follow-up of applicable areas through inspections, review, repeat audits, or other appropriate means to verify the implementation of assigned corrective actions.

In the QAPD, the applicant commits to comply with the standards for QA audits described in NQA-1-1994, Basic Requirement 18, and Supplement 18S-1 to establish an independent audit program.

17.5.4.19 *Non-Safety-Related SSC Quality Assurance Control*

17.5.4.19.1 Non-Safety-Related SSCs – Significant Contributors to Plant Safety

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.V.1 for controls related to non-safety-related SSCs. The QAPD establishes program controls applied to non-safety-related SSCs that are significant contributors to plant safety and to which Appendix B does not apply. The QAPD applies specific controls to these items in a selected manner,

targeting the characteristics or critical attributes that render the SSCs significant contributors to plant safety that are consistent with applicable sections in the QAPD.

17.5.4.19.2 Non-Safety-Related SSCs Credited for Regulatory Events

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.V.2 to establish the QA requirements for non-safety-related SSCs credited for regulatory events. In the QAPD, the applicant commits to comply with the following regulatory guidance:

- The applicant shall implement quality provisions for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants," issued April 2001.

- The applicant shall implement QA provisions for anticipated transient without scram (ATWS) equipment in accordance with GL 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," issued January 1985.

- The applicant shall implement quality provisions for station blackout (SBO) equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in RG 1.155, "Station Blackout," issued August 1988.

17.5.4.20 *Regulatory Commitments*

The applicant's QAPD follows the guidance in SRP Section 17.5 paragraph II.U for describing its regulatory commitments. The QAPD establishes QA program commitments. In the QAPD, the applicant commits to comply with the following NRC RGs and other QA standards to supplement and support the QAPD:

- RG 1.26, Revision 3, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," issued February 1976. In the QAPD, the applicant commits to comply with the regulatory positions of this guidance, with the exception of Criteria C.1, C.1.a, C.1.b, and C.3 (these four criteria are only applicable to the AP1000 Design).

- RG 1.29 Revision 3, "Seismic Design Classification," issued September 1978. In the QAPD, the applicant commits to comply with the regulatory positions of this guidance with the exception of Criteria C.1.d, C.1.g, and C.1.n (these three criteria are only applicable to the AP1000 Design).

- ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described in Sections 17.5.4.1 through 17.5.4.18 of this SER.

- NIRMA technical guides as described in Section 17.5.4.17 of this SER.

The staff issued **RAI 17.5-6 and** requested the applicant to clarify its intent regarding its commitment to the guidance of RG 1.37 in the QAPD, noting that although Section 13.2 of the applicant's QAPD references the commitment to RG 1.37, Revision 1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled

Nuclear Power Plants," issued March 2007, but Part IV, "Regulatory Commitments," of the QAPD does not identify RG 1.37 as a commitment.

In an August 4, 2008, response to **RAI 17.5-6**, the applicant stated that the omission of the commitment to RG 1.37 in Part IV of the QAPD was inadvertent. The applicant has revised the FSAR to include the commitment to the guidance of RG 1.37. The staff finds the response to this **RAI 17.5-6** acceptable.

17.5.5 Post Combined License Activities

There are no post COL activities related to this section.

17.5.6 Conclusion

The staff confirmed that the application addressed the required information relating to the QA Program.

The NRC staff used the requirements of Appendix B to 10 CFR Part 50 and the guidance in SRP Section 17.5 as the underlying premises for evaluating the acceptability of North Anna 3 COL FSAR supplemental information Items 17.5-1, 17.5-2, and 17.5-3 in Section 17.5 of the COL FSAR. Furthermore, the staff evaluated the QAPD guidance that will be applied to activities during design implementation, construction, and operations and arrived at the following conclusions:

- The QAPD provides adequate guidance for the applicant to apply a QAPD to activities and items that are important to safety.

- The QAPD provides adequate guidance for the applicant to establish controls that, when properly implemented, comply with Appendix B to 10 CFR Parts 21, 50, 52, and 10 CFR CFR 50.55(e). The controls also comply with the acceptance criteria in SRP Section 17.5 and with the commitments to applicable regulatory guidance.

However, as a result of Open Items 17.5-4 and 17.5-5, the staff is unable to finalize its conclusions related to the QA Program.

17.6 Maintenance Rule Program

17.6.1 Introduction

This section addresses the program for Maintenance Rule implementation based on the requirements of 10 CFR 50.65 and the guidance in NUMARC 93-01, "Industry Guidance for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," as endorsed by RG 1.160. For 50.65(a) (4), the guidance contained in the February 22, 2000, revision to Section 11 of NUMARC 93-01, as endorsed by RG 1.182, is effective for NUMAC 93-01 Revision 2.

17.6.2 Summary of Application

Section 17.6 of the North Anna 3 COL FSAR incorporates by reference NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52."

In addition, in FSAR Section 17.6, the applicant provided the following:

COL Items

- STD COL 17.4-1-H Operation Reliability Assurance Activities

The applicant provided an additional section in the COL FSAR, Revision 1, addressing compliance with the "Maintenance Rule," which states that the NEI 07-02A guidance for the Maintenance Rule program is incorporated by reference into Section 17.6 of the North Anna 3 COL FSAR.

Supplemental Information

- STD SUP 17.6-1

The applicant stated that the text of the template provided in NEI 07-02A is generically numbered as "17.X." When the template is incorporated by reference into this section, the numbering will change from "17.X" to "17.6."

- STD SUP 17.6-2

The applicant addressed the COL information by describing the Maintenance Rule Program relationship with reliability assurance activities in FSAR Section 17.6.3.

- STD SUP 17.6-3

The applicant stated that the correct reference to design reliability assurance program (DRAP) in the NEI 07-02A, paragraph 17.6.1.1.b, will then be "(DRAP, See FSAR Section 17.4)".

17.6.3 Regulatory Basis

The regulatory basis for the information incorporated by reference is addressed in the FSER for TR NEI. The regulatory basis for acceptance of the Maintenance Rule program is established in 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants" and 10 CFR 52.79(a) (15), which requires that a COL FSAR contain a description of the program and its implementation for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.

17.6.4 Technical Evaluation

NRC staff reviewed Section 17.6 of the North Anna 3 COL FSAR and checked the referenced TR NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," Revision 0, to ensure that the combination of TR NEI 07-02A and the information in the COL represent the complete scope of information relating to this review topic.. The review confirmed that the applicant has addressed required information relating to theand no outstanding information is expected to be addressed in the COL FSAR related to the Maintenance Rule program.

The staff issued the SER on TR NEI 07-02A and approved the template for the Maintenance Rule program (Ref. 17.4-2).

The staff reviewed the relevant information in the COL FSAR:

COL Items

- STD COL 17.4-1-H Operation Reliability Assurance Activities

The Maintenance Rule program supports the operation RAP. The applicant incorporated by reference NEI 07-02A, as an acceptable method for satisfying the acceptance criteria in SRP Section 17.6. The staff finds that this approach is acceptable.

Supplemental Information

- STD SUP 17.6-1

The applicant stated that the text of the template provided in NEI 07-02A is generically numbered as "17.X." When the template is incorporated by reference into this section, numbering will change from "17.X," to "17.6."

- STD SUP 17.6-2

The applicant described the Maintenance Rule program relationship with the reliability assurance activities in FSAR Section 17.6.3. The applicant states that the reliability of SSCs during the operations phase is assured through the implementation of operational programs, including, the Maintenance Rule program, the QAP, the ISI program, the IST program, technical specifications surveillance requirements, and maintenance programs.

- STD SUP 17.6-3

The applicant action in changing the phrase in paragraph 17.6.1.1.b in NEI 07-02A template from "(DRAP –See FSAR Section 17.Y)" to "(See Section 17.4)," is of editorial in nature, (see also the evaluation under STD SUP 17.6.1).

17.6.5 Post Combined License Activities

The applicant has committed to implement a process for integrating reliability assurance activities for risk-significant SSCs into operational programs (e.g., Maintenance Rule, surveillance testing, maintenance programs and QA) to meet the objectives of the RAP during plant operation. Consistent with this commitment, the following item was identified as the responsibility of the COL holder:

- STD COL 17.4-1-H Operation Reliability Assurance Activities

17.6.6 Conclusion

The staff concludes that the topical report incorporated by reference and supplemental provided in the FSAR are acceptable and meets the requirements of 10 CFR 50.65 with respect to a Maintenance Rule program. This conclusion is based on the following:

- The staff issued the SER on TR NEI 07-02A and approved the template for the Maintenance Rule program (Ref. 17.4-2)

- STD COL 17.4-1-H is acceptable because it appropriately references NEI 07-02A as the template used by the applicant for developing its Maintenance Rule program.

- STD SUP 17.6-1 is acceptable because it appropriately conforms the section numbering of NEI 07-02 when incorporated by reference.

- STD SUP 17.6-2 is acceptable because the reliability of SSCs during the operations phase is assured through the implementation of operational programs, including, the Maintenance Rule program, the QAP, the ISI program, the IST program, technical specifications surveillance requirements, and maintenance programs.

- STD SUP 17.6-3 is acceptable because it incorporates an appropriate reference change.

17.7 References

17.4.-1 NUMARC 93-01, "Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 2, Nuclear Energy Institute, April, 1996.

17.4-2 Nuclear Energy Institute, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52", NEI 07-02A, March 2008.

17.5-1. U.S. Nuclear Regulatory Commission, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," NUREG–0800, March 2007.

17.5-2. American Society of Mechanical Engineers. "Quality Assurance Requirements for Nuclear Facility Applications" ANSI/ASME Standard NQA-1-1994, Washington DC.

17.5-3. Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21,1989

17.5-4. Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991.

17.5-5. U.S. NRC, Office of Nuclear Reactor Regulation, "Approval of Nuclear Management Company Quality Assurance Topical Report (TAC Nos. MC1309, MC1310, MC1311, MC1312. MC1313. MC1314, MC1315, MC1316)"," (ADAMS Accession No. ML050700416), March 24, 2005.

17.5-6. U.S. NRC, Office of Nuclear Reactor Regulation, "Palo Verde Nuclear Generating Station, Units 1, 2, and 3 – Approval of Change To Quality Assurance Program (Commercial-Grade Calibration Services) (TAC Nos. MA4402, MC4403, and MA4404)," (ADAMS Accession No. ML052710224), September 28, 2005.

17.5-7. U.S. NRC, Office of Nuclear Reactor Regulation, Letter of Recognition of ACLASS Accreditation Services, "Reply to Your Letter Dated September 26, 2007, Seeking Agency Assistance in Accepting ACLASS Accreditation Services," (ADAMS Accession No. ML ML073440472), December 19, 2007.

17.5-8. U.S. NRC, Office of Nuclear Reactor Regulation, Letter of Recognition of Laboratory Accreditation Bureau (L-A-B), "Reply to Your Letter Dated February 29, 2008, Seeking Assistance in Accepting Laboratory Accreditation Bureau," (ADAMS Accession No ML081140564), April 22, 2008.

17.5-9. U.S. NRC, Office of Nuclear Reactor Regulation, Letter of Recognition of International Accreditation Services, "Reply to Your Letter Dated March 3, 2008, Seeking Assistance in Accepting International Accreditation Services, INC," (ADAMS Accession No ML081330253), May 14, 2008.

17.5-10. Institute of Electrical and Electronic Engineers (IEEE) Standard 336-1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities."

17.5-11. Institute of Electrical and Electronic Engineers (IEEE) Standard 498-1985, "IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities."

17.5-12. Institute of Electrical and Electronic Engineers (IEEE) Standard 603-1980, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations."

17.5-13. U.S. NRC, Office of Nuclear Reactor Regulation, Safety Evaluation of the Proposed Change to the Quality Assurance Program, "Approval of Nuclear Management Company Quality Assurance Topical Report," (ADAMS Accession No. ML052360625), August 26, 2005.

17.5-14 Nuclear Energy Institute, "Template for Quality Assurance Program Description", NEI 06-14, April 2007.

Chapter 17-Call Outs

QA	RAI
FASR	NQA
ESP	NEI
COLA	ASME
ESBWR	NIST
DCD	NVLAP
NAPS	ILAC
SUP	ALLA
SSAR	ACLACS
FSER	IAS
SER	L-A-B
NRC	MRA
STD	IEEE
QAPD	M&TE
SSCs	NIRMA
DOM	ATWS
SRP	SBO
RG	