

17.0 QUALITY ASSURANCE (RELATED TO RG 1.206, SECTION C.III.1, CHAPTER 17, C.I.17, “QUALITY ASSURANCE AND RELIABILITY ASSURANCE”)

The quality assurance (QA) program for design, fabrication, construction, testing, and operation, the design reliability program, and the maintenance rule program are discussed in this chapter.

17.1 Quality Assurance During the Design and Construction Phases

17.1.1 Introduction

The QA program related to design and construction activities is discussed in this section. It addresses the QA program implemented during combined license (COL) application development, including site characterization activities, design and construction phases.

17.1.2 Summary of Application

Section 17.1, “Quality Assurance During the Design and Construction Phases,” of the William States Lee III Nuclear Station, Units 1 and 2 (WLS), COL Final Safety Analysis Report (FSAR), Revision 4, incorporates by reference Section 17.1 of the AP1000 Design Control Document (DCD), Revision 19.

In addition, in WLS COL FSAR Section 17.1, the applicant provided the following:

AP1000 COL Information Item

- WLS COL 17.5-1

The applicant provided additional information in WLS COL 17.5-1 to address COL Information Item 17.5-1. In WLS COL 17.5-1, the applicant addresses the quality assurance program under which the COL application was developed for the design and construction phases, which is applicable until COL issuance. Section 17.5, “Quality Assurance Program Description – New License Applicants,” of the WLS COL FSAR addresses the QA program for the remaining portion of the design and construction phases following COL issuance, which is described in the Duke Nuclear Plant Development (NPD) Quality Assurance Program Description (QAPD).

17.1.3 Regulatory Basis

The regulatory basis of the information incorporated by reference into WLS COL FSAR Section 17.1 is addressed in NUREG-1793, “Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design,” and its supplements.

In addition, the relevant requirements of the Commission regulations for the resolution of WLS COL 17.5-1 are established in Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, “Domestic licensing of production and utilization facilities,” Appendix B, “Quality assurance criteria for nuclear power plants and fuel reprocessing plants,” as required by 10 CFR 52.79(a)(25).

17.1.4 Technical Evaluation

The staff of the Nuclear Regulatory Commission (NRC) reviewed Section 17.1 of the WLS COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the COL application represents the complete scope of information relating to this review topic.¹ The NRC staff's review confirmed that the information in the application and incorporated by reference addresses the required information relating to QA during design and construction phases. The results of the NRC staff's evaluation of the information incorporated by reference in the WLS COL application are documented in NUREG-1793 and its supplements.

Section 1.2.3 of this safety evaluation report (SER) provides a discussion of the strategy used by the NRC to perform one technical review for each standard issue outside the scope of the design certification (DC) and use this review in evaluating subsequent COL applications. To ensure that the staff's findings on standard content that were documented in the SER for the reference COL application (Vogle Electric Generating Plant, Units 3 and 4 [VEGP]) were equally applicable to the WLS Units 1 and 2 COL application, the NRC staff undertook the following reviews:

- The staff compared the VEGP COL FSAR, Revision 5, to the WLS COL FSAR. In performing this comparison, the staff considered changes made to the WLS COL FSAR (and other parts of the COL application, as applicable) resulting from requests for additional information (RAIs).
- The staff confirmed that all responses to RAIs identified in the corresponding standard content evaluation were endorsed.
- The staff verified that the site-specific differences were not relevant.

The staff has completed its review and found the evaluation performed for the standard content to be directly applicable to the WLS COL application. This standard content material is identified in this SER by use of italicized, double-indented formatting. Section 1.2.3 of this SER provides an explanation of why the standard content material from the SER for the reference COL application (VEGP) includes evaluation material from the SER for the Bellefonte Nuclear Plant (BLN), Units 3 and 4 COL application. Any confirmatory items in the standard content material retain the numbers assigned in the VEGP SER.

The staff reviewed the following information in the WLS COL FSAR:

AP1000 COL Information Item

- WLS COL 17.5-1

The NRC staff reviewed the partial resolution of WLS COL 17.5-1 related to QA during the design and construction phases until COL issuance, which is included under Section 17.1 of the WLS COL FSAR. The remaining information for WLS COL 17.5-1 is included in Section 17.5 of

¹ See SER Section 1.2.2 for a discussion of the NRC staff's review related to verification of the scope of information to be included in a COL application that references a design certification (DC).

the WLS COL FSAR. The staff's review of WLS COL 17.5-1 is a combination of plant-specific evaluation and standard content evaluation.

Duke supplemented the information in AP1000 DCD Section 17.1 with new text to address the QA program requirements for design and construction activities implemented from COL application development through operations. Upon review of the additional text provided by the applicant, the NRC staff identified areas where additional information was needed.

In RAI 17.5-8, dated October 6, 2008, the NRC staff noted that WLS COL FSAR Section 17.1 states that the Duke Energy QA program and the Westinghouse Electric Company Quality Management System establish the QA requirements for design activities until the Duke NPD QAPD becomes effective. The staff requested clarification on the expected Duke Energy and Westinghouse Electric Company scope of work related to the applicant's COL application design activities from the time of docketing until the time the COL might be issued.

In its response letter, dated December 11, 2008, the applicant referenced a letter dated February 6, 2008, which provided a clarification to Section 17.1 of the WLS COL FSAR. Enclosure 1 of that letter revised the WLS COL FSAR to remove the reference to the Westinghouse Electric Company Quality Management System and clarified that the Duke QA program is applicable to design, procurement, and construction activities associated with WLS Units 1 and 2 that may occur before as well as after the COL is issued.

By letter dated December 17, 2010, Duke Energy submitted Revision 3 of the WLS COL FSAR. The staff reviewed Section 17.1 of the WLS COL FSAR and confirmed that the applicant had (1) adequately identified which QA programs applied to the design, procurement, and construction activities described in section 17.1 of the WLS COL FSAR, and (2) adequately described the expected scope of work related to the COL activities. Therefore, RAI 17.5-8 is closed.

In RAI 17.5-9, dated October 6, 2008, the NRC staff requested that the applicant confirm when the Duke NPD QAPD will become effective, as well as clarify the difference between the statements that "the Duke NPD QAPD will become effective at COL issuance," located in the WLS COL FSAR Section 17.1, and that "the QA Program - Operation will be implemented 30 days prior to initial fuel loading," located in WLS COL FSAR Table 13.4-201.

In its response letter, dated December 11, 2008, the applicant stated that the Duke NPD QAPD becomes effective at COL issuance, and establishes the QA program requirements for the remaining portion of the design and construction phases. However, full implementation of operations-related requirements is not expected until 30 days prior to fuel load, as indicated in FSAR Table 13.4-201. Accordingly, as part of its response to RAI 17.5-9, the applicant proposed to revise the last paragraph of Section 17.1 of the WLS COL FSAR to state:

Implementation of the applicable portions of the "Quality Assurance Program Description" (QAPD) discussed in Section 17.5 begins at COL issuance. The program establishes the QA program requirements for the remaining portion of the design and construction phases and for operations; full implementation of the operations related requirements will be no later than as indicated in Table 13.4-201.

By letter dated December 17, 2010, Duke Energy submitted Revision 3 of the WLS COL FSAR. The staff reviewed Section 17.1 of the WLS COL FSAR and confirmed that the applicant had

provided (1) an acceptable implementation schedule for the Duke NPD QAPD, and (2) an adequate description regarding implementation of the Duke NPD QAPD at COL issuance, and establishment of the appropriate QA program requirements for the remaining portion of the design and construction phases. Therefore, RAI 17.5-9 is closed.

The following portion of this section is reproduced from Section 17.1.4 of the VEGP SER:

In addition, the applicant proposed revisions to Appendix 1AA in its letter, dated August 19, 2008, in response to the NRC staff's RAI 1-5. In its response, the applicant proposed to change the exception statements to address the version of NQA-1 instead of addressing the QAPD included in Part 11 of the BLN COL application. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN COL FSAR for those RGs with QA requirements. RAI 1-5 is closed for all RGs that contain exception statement referencing NQA-1 (i.e., RG 1.28, 1.30, 1.38, 1.39, 1.94, and 1.116) except for RG 1.33.

*In RAI 1-11, dated December 16, 2008, the NRC staff requested that the applicant document the mechanism for incorporation of the requirements of RG 1.33 since these requirements are not covered by NQA-1. In its letter, dated January 27, 2009, the applicant stated that conformance with RG 1.33 will be supplemented in a future amendment to include a reference to Nuclear Energy Institute (NEI) 06-14A. The NRC staff has addressed this issue with NEI since NEI 06-14A does not commit to RG 1.33. This issue will remain open until closure is reached with NEI 06-14A or the applicant. This is identified as **Open Item 17.1-1**.*

Resolution of Standard Content Open Item 17.1-1

*In its letter, dated December 31, 2009, the applicant proposed to revise VEGP COL FSAR Section 1.9, Table 1.9-201, "Regulatory Guide/FSAR Section Cross-References," to document that RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2, is addressed in Section IV of the QAPD. Additionally, the applicant proposed to revise Appendix 1AA of the VEGP COL FSAR to document conformance to RG 1.33. Therefore, Open Item 17.1-1 is resolved for VEGP and the proposed revisions are identified as **Confirmatory Item 17.1-1**, pending formal revision of the VEGP COL FSAR.*

Resolution of Standard Content Confirmatory Item 17.1-1

Confirmatory Item 17.1-1 is an applicant commitment to revise its FSAR Table 1.9-201 and Appendix 1AA to document conformance to RG 1.33. The staff verified that the VEGP COL FSAR was appropriately updated. As a result, Confirmatory Item 17.1-1 is now closed.

WLS Resolution of Standard Content Open and Confirmatory Item 17.1-1

In a letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP. By letter dated December 17, 2010, the applicant provided Revision 3 of

the WLS COL FSAR and Revision 3 of the Duke NPD QAPD. In Revision 3 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.1-1. The NRC staff has confirmed through review of Revision 3 of the Duke NPD QAPD that (1) the applicant has incorporated the appropriate changes to Appendix 1AA of the WLS COL FSAR and Part IV, "Regulatory Commitments," of the Duke NPD QAPD, and (2) the applicant has adequately identified and specified conformance to RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2, consistent with the NRC-approved NEI 06-14A, Revision 7, guidance. This adequately addresses the issue outlined by Confirmatory Item 17.1-1; therefore, Standard Content Open Item 17.1-1 is resolved for the WLS COL application.

In January 2011 the NRC staff conducted a limited scope inspection at the Duke Energy facility in Charlotte, North Carolina, as documented in inspection report numbers 05200018/2011-201 and 05200198/2011-201 dated March 16, 2011. The purpose of the NRC inspection was to verify that the QA processes and procedures were effectively implemented with regard to the WLS COL application. During this inspection, the NRC inspectors identified one violation and one non-cited violation of NRC requirements related to the WLS QA program. Duke Energy responded to the Notice of Violation in a letter dated April 15, 2011. Duke Energy identified its actions to correct and prevent recurrence of the violation and noted that full compliance was achieved. Based on this response, the staff does not intend to conduct a follow-up inspection as a part of the ongoing licensing process.

17.1.5 Post Combined License Activities

There are no post combined license activities related to this section.

17.1.6 Conclusion

The NRC staff reviewed the application and checked the referenced DCD. The NRC staff's review confirmed that the applicant addressed the required information relating to QA during the design and construction phase, and there is no outstanding information expected to be addressed in the WLS COL FSAR related to this section. The results of the NRC staff's technical evaluation of the information incorporated by reference in the WLS COL application are documented in NUREG-1793 and its supplements.

Based on the information provided by the applicant, the staff concludes that WLS COL 17.5-1 meets the applicable Appendix B to 10 CFR Part 50 and 10 CFR 52.79(a)(25) requirements.

17.2 Quality Assurance During the Operations Phase

Section 17.2, "Quality Assurance During the Operations Phase," of the WLS COL FSAR, Revision 4, incorporates by reference, with no departures or supplements, Section 17.2 of Revision 19 to the AP1000 DCD. The NRC staff reviewed the application and checked the referenced DCD to ensure that no issues relating to this section remained for review.¹ The review confirmed that there are no outstanding issues related to this section. The results of the NRC staff's technical evaluation of the information incorporated by reference into the WLS COL application are documented in NUREG-1793 and its supplements.

17.3 Quality Assurance During Design, Procurement, Fabrication, Inspection, and/or Testing of Nuclear Power Plant Items (Related to RG 1.206, Section C.III.1, Chapter 17, C.I.17.3, “Quality Assurance Program Description”)

Section 17.3, “Quality Assurance During Design, Procurement, Fabrication, Inspection, and/or Testing of Nuclear Power Plant Items,” of the WLS COL FSAR, Revision 4, incorporates by reference, with no departures or supplements, Section 17.3 of Revision 19 to the AP1000 DCD. The NRC staff reviewed the application and checked the referenced DCD to ensure that no issues relating to this section remained for review.¹ The review confirmed that there are no outstanding issues related to this section. The results of the NRC staff’s technical evaluation of the information incorporated by reference into the WLS COL application are documented in NUREG-1793 and its supplements.

17.4 Design Reliability Assurance Program (Related to RG 1.206, Section C.III.1, Chapter 17, C.I.17.4, “Reliability Assurance Program Guidance”)

17.4.1 Introduction

This reliability assurance program (RAP) provides reasonable assurance that a plant is designed, constructed, and operated in a manner that is consistent with the assumptions and risk insights related to structures, systems, and components (SSCs) that are identified as being significant contributors to plant safety as determined by using probabilistic, deterministic, or other methods of analysis. The information is obtained from sources such as the plant- and site-specific probabilistic risk assessment (PRA), industry operating experience, relevant component failure databases, and expert panels.

The RAP is implemented in two stages. The first stage, the design reliability assurance program (D-RAP), comprises the reliability assurance activities necessary to provide confidence that the plant is consistent with the certified design when fuel is loaded for the first time. The second stage comprises the operational phase reliability assurance activities (OPRAAs) that are to be integrated into other programs.

17.4.2 Summary of Application

Section 17.4, “Design Reliability Assurance Program,” of the WLS COL FSAR, Revision 4, incorporates by reference Section 17.4 of the AP1000 DCD, Revision 19.

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

Supplemental Information

- STD SUP 17.4-1

The applicant provided supplemental (SUP) information in standard (STD) SUP 17.4-1 regarding the QA requirements for nonsafety-related SSCs within the scope of the D-RAP.

17.4.3 Regulatory Basis

The regulatory basis of the information incorporated by reference into WLS COL FSAR Section 17.4 is addressed in NUREG-1793 and its supplements.

In addition, the acceptance criteria associated with the relevant requirements of the Commission regulations for the D-RAP are given in Section 17.4 of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants." SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems in Passive Plant Designs," states the following:

An application for advanced reactor DC or a COL must include: (1) the description of the RAP used during the design that includes, scope, purpose, and objectives; (2) the process used to evaluate and prioritize the SSCs in the design, based on their degree of risk significance; (3) a list of the SSCs designated as risk significant; and (4) for those SSCs designated as risk significant: (i) a process to determine dominant failure modes that considered industry experience, analytical models, and applicable requirements; and (ii) key assumptions and risk insights from probabilistic, deterministic, or other methods that considered operations, maintenance, and monitoring activities.

Each licensee that references the advanced reactor design must implement the design reliability assurance program approved by the NRC.

The Commission approved this position in the associated staff requirements memorandum (SRM) dated June 28, 1995.

Regulatory Guide (RG) 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," describes an acceptable way to satisfy these requirements.

17.4.4 Technical Evaluation

The NRC staff reviewed Section 17.4 of the WLS COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the COL application represents the complete scope of information relating to this review topic.¹ The NRC staff's review confirmed that the information in the application and incorporated by reference addresses the required information relating to the D-RAP. The results of the staff's evaluation of the information incorporated by reference in the WLS COL application are documented in NUREG-1793 and its supplements.

Section 1.2.3 of this SER provides a discussion of the strategy used by the NRC to perform one technical review for each standard issue outside the scope of the DC and use this review in evaluating subsequent COL applications. To ensure that the staff's findings on standard content that were documented in the SER for the reference COL application (VEGP Units 3 and 4) were equally applicable to the WLS Units 1 and 2 COL application, the NRC staff undertook the following reviews:

- The staff compared the VEGP COL FSAR, Revision 5, to the WLS COL FSAR. In performing this comparison, the staff considered changes made to the WLS COL FSAR (and other parts of the COL application, as applicable) resulting from RAIs.

- The staff confirmed that all responses to RAIs identified in the corresponding standard content evaluation were endorsed.
- The staff verified that the site-specific differences were not relevant.

The NRC staff has completed its review and found the evaluation performed for the standard content to be directly applicable to the WLS COL application. This standard content material is identified in this SER by use of italicized, double-indented formatting. Section 1.2.3 of this SER provides an explanation of why the standard content material from the SER for the reference COL application (VEGP) includes evaluation material from the SER for the BLN Units 3 and 4 COL application. Any confirmatory items in the standard content material retain the numbers assigned in the VEGP SER.

The following portion of this technical evaluation section is reproduced from Section 17.4.4 of the VEGP SER:

Supplemental Information

- *STD SUP 17.4-1*

The applicant provided supplemental information in STD SUP 17.4-1 to describe the QA requirements for nonsafety-related SSCs within the scope of D-RAP.

The following portion of this technical evaluation section is reproduced from Section 17.4.4 of the BLN SER:

No site specific structures, systems, and components (SSCs) have been added to the D-RAP. The applicant asserts that the AP1000 DCD and PRA bound all site specific hazards and associated risks. The staff's evaluation of the probabilistic methods used to reach this conclusion is documented in Chapter 19 of this safety evaluation. The staff concludes that the list of SSCs incorporated by reference to the DCD is an acceptable list for the BLN COL.

The staff noted that risk metrics may change with modifications to the plant design or other new information and requested additional information on how the applicant would address risk significant SSCs that are identified after the COL is issued (RAI 17.4-1). In its response dated September 17, 2008, the applicant stated that such changes would be captured and included in the appropriate OPRAAs in accordance with procedures developed under the QA program. In addition, the response states that the [Maintenance Rule] MR program is to be consistent with NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed under 10 CFR Part 52," which has been endorsed by the staff in a letter to NEI, dated January 24, 2008.

The Maintenance Rule program description calls for establishment of an expert panel prior to fuel load. As additional information is developed, such a panel alters the scope of OPRAAs as appropriate. Because this provides assurance

that changes will receive appropriate review, the staff finds it acceptable; therefore, RAI 17.4-1 is closed.

*However, the staff requested that the applicant supplement the BLN COL FSAR to describe the organizational and process aspects of the RAP that will be performed by the COL holder (RAI 17.4-2). In its response dated April 9, 2009, the applicant proposed to revise the BLN COL FSAR Section 17.4 to include a standard supplement identifying the quality assurance requirements for nonsafety-related SSCs within the scope of D-RAP. This is consistent with RG 1.206 and is therefore an acceptable method for meeting the Commission's policy for RAP. The staff identifies the need for a revision to the BLN COL FSAR as **Confirmatory Item 17.4-1**.*

Resolution of Standard Content Confirmatory Item 17.4-1

Confirmatory Item 17.4-1 required the applicant to update its FSAR to include a standard supplement identifying the QA requirements for nonsafety-related SSCs within the scope of D-RAP. The NRC staff verified that the VEGP COL FSAR was appropriately updated with STD SUP 17.4-1. As a result, Confirmatory Item 17.4-1 is resolved.

The NRC staff verified that the WLS COL FSAR was appropriately updated with STD SUP 17.4-1. As a result, Standard Content Confirmatory Item 17.4-1 is resolved.

17.4.5 Post Combined License Activities

There are no post combined license activities related to this section.

17.4.6 Conclusion

The NRC staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant addressed the required information relating to the D-RAP, and there is no outstanding information expected to be addressed in the WLS COL FSAR related to this section. The results of the staff's technical evaluation of the information incorporated by reference in the WLS COL application are documented in NUREG-1793 and its supplements.

The NRC staff concludes that the relevant information presented in Section 17.4 of the WLS COL FSAR is consistent with the guidance provided in SECY-95-132, as well as the requirements of 10 CFR 52.47(b)(1), and 10 CFR 52.80(a). Therefore, the WLS D-RAP described in Section 17.4 of the WLS COL FSAR is acceptable.

17.5 Quality Assurance Program Description – New License Applicants (Related to RG 1.206, Section C.III.1, Chapter 17, C.I.17.5, “Quality Assurance Program Guidance”)

17.5.1 Introduction

The QA program during the design, fabrication, construction, testing, and operation phases of a nuclear power plant is discussed in this section. Implementation of the applicable portions of

the QAPD referenced in Section 17.5, "Quality Assurance Program Description – New License Applicants," of the WLS COL FSAR begins at COL issuance with full implementation of the operations-related requirements consistent with the outline provided in WLS COL FSAR Table 13.4-201, "Operational Programs Required by NRC Regulations."

17.5.2 Summary of Application

In Part 11 of the WLS COL application, the applicant provided a QAPD to be in place during the design, construction, and operations phases of WLS Units 1 and 2. This QAPD will be incorporated by reference in Section 17.5 of the WLS COL FSAR upon resolution of WLS Confirmatory Item 17.5-1, as discussed in the technical section below.

In addition, in WLS COL FSAR Section 17.5, the applicant provided the following:

AP1000 COL Information Items

- WLS COL 17.5-1

The applicant provided additional information in WLS COL 17.5-1 to address COL Information Item 17.5-1. In WLS COL 17.5-1, the applicant addresses the quality assurance program under which the COL application was developed for the design and construction phases, which is applicable until COL issuance. Section 17.5 of the WLS COL FSAR addresses the QA program for the remaining portion of the design and construction phases following COL issuance, which is described in the Duke NPD QAPD.

- STD COL 17.5-2

The applicant provided additional information in STD COL 17.5-2 to address COL Information Item 17.5-2. STD COL 17.5-2 addresses QA programs for procurement, fabrication, installation, construction, and testing of SSCs in the plant.

- STD COL 17.5-4

The applicant provided additional information in STD COL 17.5-4 to address COL Information Item 17.5-4. STD COL 17.5-4 addresses the QA program for operations, and uses FSAR Table 13.4-201 to provide milestones for operational quality assurance program implementation.

- STD COL 17.5-8

The applicant provided additional information in STD COL 17.5-8 to address COL Information Item 17.5-8. STD COL 17.5-8 addresses operational RAP integration with the QA program.

17.5.3 Regulatory Basis

The acceptance criteria associated with the relevant requirements of the Commission regulations for the QAPD are given in Section 17.5 of NUREG-0800. The applicable regulatory requirements for the QAPD are as follows:

Appendix B to 10 CFR Part 50 requires that the application include a description of the QA program to be applied to the design, fabrication, construction, and testing of the SSCs of the facility and establishes QA requirements for the design, construction, and operation of those SSCs. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of the SSCs, including designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

Section 10 CFR 52.79(a)(17) requires that the application include information with respect to compliance with technically relevant positions of the Three Mile Island requirements of 10 CFR 50.34(f).

Section 10 CFR 52.79(a)(25) requires that the description of the QA program include a discussion of how the applicable requirements of Appendix B have been and will be satisfied, and also include a discussion of how the QA program will be implemented.

Further, 10 CFR 52.79(a)(27) requires that the application include information on the managerial and administrative controls to be used for a nuclear power plant and include a discussion of how the applicable requirements of Appendix B will be satisfied.

17.5.4 Technical Evaluation

The NRC staff reviewed Section 17.5 of the WLS COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the COL application represents the complete scope of information relating to this review topic.¹ The NRC staff's review confirmed that the information in the application and incorporated by reference addresses the required information relating to the QAPD. The results of the staff's evaluation of the information incorporated by reference in the WLS COL application are documented in NUREG-1793 and its supplements.

Section 1.2.3 of this SER provides a discussion of the strategy used by the NRC to perform one technical review for each standard issue outside the scope of the DC and use this review in evaluating subsequent COL applications. To ensure that the staff's findings on standard content that were documented in the SER for the reference COL application (VEGP Units 3 and 4) were equally applicable to the WLS Units 1 and 2 COL application, the NRC staff undertook the following reviews:

- The staff compared the VEGP COL FSAR, Revision 5, to the WLS COL FSAR. In performing this comparison, the staff considered changes made to the WLS COL FSAR (and other parts of the COL application, as applicable) resulting from RAIs.
- The staff confirmed that all responses to RAIs identified in the corresponding standard content evaluation were endorsed.
- The staff verified that the site-specific differences were not relevant.

The NRC staff has completed its review and found the evaluation performed for the standard content to be directly applicable to the WLS COL application. This standard content material is identified in this SER by use of italicized, double-indented formatting. Section 1.2.3 of this SER

provides an explanation of why the standard content material from the SER for the reference COL application (VEGP) includes evaluation material from the SER for the BLN Units 3 and 4 COL application. Any confirmatory items in the standard content material retain the numbers assigned in the VEGP SER.

Although the NRC staff concluded that the evaluation performed for the standard content is directly applicable to the WLS COL application, there were differences between the information provided by the WLS applicant and that provided by the VEGP applicant regarding details in the WLS COL FSAR and the Duke NPD QAPD. The resolutions of these differences for WLS are evaluated by the staff following the standard content material to which they apply.

The following portion of this technical evaluation section is reproduced from Section 17.5.4 of the VEGP SER:

The NRC staff reviewed Section 17.5 of the BLN COL FSAR and the QAPD provided in Part 11 of the BLN COL application. In RAI 17.5-9, dated May 12, 2008, the NRC staff requested that the applicant explain why the QAPD provided in Part 11 of the BLN COL application is not referenced or incorporated by reference in the BLN COL FSAR Section 17.5. In its letters, dated June 26, 2008, and October 16, 2008, the applicant proposed to revise Section 17.5 of the BLN COL FSAR to state that the QAPD is incorporated by reference. In addition, the applicant proposed to revise Section 17.5 of the BLN COL FSAR to provide the title of the QAPD that is incorporated by reference. The NRC staff has reviewed the proposed revisions to Section 17.5 and concluded that the proposed changes are responsive to RAI 17.5-9. The NRC staff has verified that the proposed revision was incorporated into Revision 1 of the BLN COL FSAR. RAI 17.5-9 is closed.

*The NRC staff has verified that the proposed revision to incorporate the QAPD by reference was incorporated into the VEGP COL FSAR. In its letter dated January 29, 2010, the applicant proposed to revise Section 17.5 of the VEGP COL FSAR to provide the title of the QAPD that is incorporated by reference. This item is identified as **Confirmatory Item 17.5-1**, pending formal revision of the VEGP COL FSAR.*

Resolution of Standard Content Confirmatory Item 17.5-1

Confirmatory Item 17.5-1 is an applicant commitment to revise its FSAR Section 17.5 to specify the title of the QAPD. The staff verified that the VEGP COL FSAR was appropriately updated. As a result, Confirmatory Item 17.5-1 is now closed.

WLS Resolution of Standard Content Confirmatory Item 17.5-1

In RAI 17.5-11, dated October 6, 2008, the NRC staff noted that WLS COL FSAR Section 17.5 does not either include or incorporate the Duke NPD QAPD by reference. In its response letter, dated December 11, 2008, the applicant proposed to revise Section 17.5 of the WLS COL FSAR to identify that the QAPD is included as Part 11 of the Lee COL application and is incorporated by reference.

By letter dated December 17, 2010, Duke Energy submitted Revision 3 of the WLS COL FSAR. The staff reviewed Section 17.5 of the WLS COL FSAR and confirmed that the applicant had (1) adequately identified which QA program is in place during the design, construction, and operations phases, as described by the Duke NPD QAPD, and (2) adequately identified that the QAPD is included as Part 11 of the Lee COL application and is incorporated by reference. Therefore, RAI 17.5-11 is closed.

In addition, by letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP in its letters dated January 29, 2010, and April 2, 2010, in reference to the BLN response to RAI 17.5-9 as standard, and proposed to incorporate the standard content in a future revision of the WLS COL FSAR. The applicant provided its commitment to incorporate the standard content material that consists of revising Section 17.5 of the WLS COL FSAR to incorporate the Duke NPD QAPD by reference and to provide the title of the QAPD that is incorporated by reference. By letter dated December 17, 2010, the applicant provided Revision 3 of the WLS COL FSAR. The NRC staff confirmed that Revision 3 included reference to the Duke NPD QAPD by title in Section 17.1 and 17.5 of the WLS COL FSAR; therefore, Standard Content Confirmatory Item 17.5-1 is resolved for the WLS COL application.

In RAI 17.5-1, dated October 6, 2008, the NRC staff noted that the Duke NPD QAPD, Part I, Section 1.1, "Scope / Applicability," states that the QAPD applies to COL / construction / pre-operation and/or operation activities, which is not consistent with the scope of the QAPD as stated in QAPD Part I, Section 1 or WLS COL FSAR Table 13.4-201, which lists the QA program as a required operational program. Accordingly, the staff requested that the applicant clarify the scope of the Duke NPD QAPD since it applies to all the stated activities.

In its response letter, dated December 11, 2008, the applicant stated that the Duke NPD QAPD will be revised to clarify that the scope of the Duke NPD QAPD applies to all stated activities. By letter dated December 17, 2010, Duke Energy submitted Revision 3 of the WLS COL FSAR as well as Revision 3 of the Duke NPD QAPD. The staff reviewed Part I, Section 1.1 of the QAPD and confirmed that the applicant had provided an acceptable scope for the activities addressed by the Duke NPD QAPD. Therefore, RAI 17.5-1 is closed.

In RAI 17.5-10, dated October 6, 2008, the NRC staff requested that the applicant provide an evaluation of the existing Duke Energy QA program against the applicable acceptance criteria in Section 17.5 of NUREG-0800, pursuant to the requirements of 10 CFR 52.79(a)(41), which requires that COL applicants must provide an evaluation of the facility against the SRP revision in effect six months before the docket date of the application.

In its response letter, dated December 11, 2008, the applicant stated that the Duke Energy Carolinas Topical Report, Quality Assurance Program, was reviewed and evaluated by the NRC and determined to meet the requirements of Appendix B to 10 CFR Part 50, utilizing the applicable acceptance criteria in NUREG-0800, Section 17.5. The applicant also stated that the QAPD described in Section 17.5 of the WLS COL FSAR, which will apply after COL issuance, has been evaluated for conformance to NUREG-0800, Section 17.5 and discussed in Table 1.9-202 of the WLS COL FSAR and found acceptable. The NRC staff has reviewed the response and determined that the applicant's response is acceptable. Therefore, RAI 17.5-10 is closed.

In RAI 17.5-2, dated October 6, 2008, the NRC staff requested that the applicant provide clarification of how WLS siting activities, as described in Duke NPD QAPD Part I, Section 1.1, would be subject to the provisions of the QAPD, since siting activities for WLS would be complete at the time of COL issuance.

In its response letter, dated December 11, 2008, the applicant stated that siting under the Duke NPD QAPD would not be applicable to WLS. However, the siting activity was included in the listing of activities to which the Duke NPD QAPD applies based on the development of the QAPD to serve as topical report for all potential future Duke Energy new nuclear plant development activities.

On the basis of the Duke Energy response, which clarified how siting activities discussed in the WLS COL FSAR would be subject to the Duke NPD QAPD described in Section 17.5 of the WLS COL FSAR, the NRC staff determined that the issue has been adequately resolved for the WLS COL application. Therefore, RAI 17.5-2 is closed.

The NRC staff reviewed the resolution of COL information items STD COL 17.5-2, STD COL 17.5-4, STD COL 17.5-8, and WLS COL 17.5-1, which are addressed in the Duke NPD QAPD. The Duke NPD QAPD is based on NEI 06-14A, "Quality Assurance Program Description," Revision 7, which was approved by the NRC staff using Section 17.5 of NUREG-0800. The staff's review of these four COL information items is a combination of plant-specific evaluation and standard content evaluation.

AP1000 COL Information Items

- STD COL 17.5-2, STD COL 17.5-4, STD COL 17.5-8 and WLS COL 17.5-1

The following portion of this section is reproduced from Section 17.5.4 of the VEGP SER:

The NEI 06-14A template provided generic information and format for QAPDs with bracketed areas for applicants to provide plant-specific information. The generic information in NEI 06-14A provides the information required for STD COL 17.5-2, 17.5-4, and 17.5-8. In its review of TVA QAPD, the NRC staff used Section 17.5 of NUREG-0800 and RG 1.206 as guidance. The NRC staff developed Section 17.5 of NUREG-0800 using American Society of Mechanical Engineers (ASME) standard ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as supplemented by additional regulatory and industry guidance for nuclear operating facilities.

Further NRC staff evaluation of the COL information items and the associated sections of the Duke NPD QAPD is provided in the following sections.

17.5.4.1 Organization

The following portion of this technical evaluation section is reproduced from Section 17.5.4.1 of the VEGP SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.A. 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 TVA management to size the QA organization commensurate with the duties and responsibilities assigned.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 1, and Supplement 1S-1.

WLS RAI 17.5-3 and RAI 17.5-4

During its review of the Duke NPD QAPD, the NRC staff identified several issues regarding QAPD Part II, Section 1, "Organization," that required further clarification.

In RAI 17.5-3, dated October 6, 2008, the NRC staff requested that the applicant restructure the Organization section of the Duke NPD QAPD as follows:

Clearly delineate (1) how the QA program is implemented during the period of construction and testing, and (2) how the QA program is implemented during the operations phase. The transition process during which the operational programs become effective should be described. Position descriptions, including roles, responsibilities, and lines of authority, should be included for applicable corporate and line positions that implement and verify elements of the QA program and the associated administrative controls.

In RAI 17.5-4, dated October 6, 2008, the NRC staff requested that the applicant provide (1) clarification regarding the inclusion of organizational charts in the Duke NPD QAPD, and (2) additional clarifications and expanded level of detail regarding organizational descriptions provided in Part II, Section 1, of the Duke NPD QAPD.

In its response letter, dated December 11, 2008, the applicant stated, in part, that Duke Energy will revise the Duke NPD QAPD to define the appropriate organizational structure, roles and responsibilities, and reporting relationships for the Duke Energy organizations that will implement the requirements of the QAPD for the development, construction, and operation of new nuclear generating plants. The organizational descriptions and organization charts contained within the Duke NPD QAPD, as revised, will define the corporate and Nuclear Generation Group organizations that implement the quality assurance requirements of the Duke NPD QAPD in support of the development, construction, and operation of the units.

Specifically, the response to RAI 17.5-4 provides descriptions of how the QA program is implemented during the construction and testing phases and during the operations phase, as well as the transition process. The response to RAI 17.5-4 also provides additional information on the QA program responsibilities, implementation, and administrative controls. In addition, the applicant noted that the basic implementation of the QA program is the same during construction and testing and operations; only the activities being implemented differ. However, the manager responsible for Quality Assurance and Oversight performs the independent oversight functions throughout all phases of QA program implementation.

Resolution of WLS RAI 17.5-3 and RAI 17.5-4

By letter dated December 17, 2010, Duke Energy submitted Revision 3 of the WLS COL FSAR as well as Revision 3 of the Duke NPD QAPD. The staff confirmed that Revision 3 of the Duke NPD QAPD incorporated a description of the WLS organization, including organizational charts, consistent with the applicant's RAI responses. Therefore, RAI 17.5-3 and RAI 17.5-4 are closed.

17.5.4.2 Quality Assurance Program

The following portion of this technical evaluation section is reproduced from Section 17.5.4.2 of the VEGP SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.B. 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 necessary to provide confidence that SSCs will perform their intended safety function, including certain nonsafety-related SSCs and activities that are significant contributors to plant safety, as described in the applicant's FSAR. The QA program requires that a list or system identifying SSCs and activities to which the QAPD applies be maintained.

The QAPD provides measures to assess the adequacy of the QAPD and to ensure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. 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 Section 17.5 of NUREG-0800, 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 backwards so that the interval prescribed for the performance of the activity is not exceeded.

The QAPD also follows the guidance of Section 17.5 of NUREG-0800, paragraphs II.S and II.T. The QAPD describes measures to 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 suitable proficiency. The plant's technical specifications delineate the minimum qualifications for plant and support staff. Personnel are required to complete the training for positions identified in 10 CFR 50.120, "Training and Qualification of Nuclear Power Plant Personnel," according to programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training. The QAPD also provides the minimum training requirements for managers responsible for QAPD implementation, in addition to the minimum training requirements for the individuals responsible for planning, implementing, and maintaining the QAPD.

The QAPD also follows Section 17.5 of NUREG-0800, paragraph II.W. The QAPD provides measures for establishing an independent review program for activities occurring during the operational phase. In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 2, and Supplements 2S-1, 2S-2, 2S-3, and 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, states that the organization designate those activities that require qualified inspectors and test personnel and establish written procedures for the qualification of these 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 the 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) and has at least 5 years of engineering work experience, with at least 2 years of this experience regarding nuclear facilities. The 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 of 10 CFR Part 50, Appendix B, Criterion II, "Quality Assurance Program," and NQA-1-1994, Supplement 2S-1. Therefore, the NRC 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. The NRC staff evaluated this proposed alternative and determined that it is consistent with inspection and test personnel initial qualification requirements specified in Section 17.5 of NUREG-0800, paragraph II.T.5. Therefore, the NRC 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 ASME Boiler and Pressure Vessel Code. 10 CFR 50.55a, "Codes and Standards," also requires the use of the latest Edition and Addenda of Sections III and XI of the ASME Code. The 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 NRC 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 provided in Section 17.5 of NUREG-0800, 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. The NRC staff evaluated this proposed alternative and determined that it is consistent with the regulation in 10 CFR Part 50, Appendix B, Criterion II. Therefore, the NRC staff concluded that this alternative is acceptable.*

*In RAI 17.5-5, dated May 12, 2008, the NRC staff requested that the applicant revise the TVA QAPD Part II, Section 2.5 to cite the correct regulation of 10 CFR 52.79(a)(27) versus 10 CFR 50.34(b)(6)(ii). In its response dated June 26, 2008, the applicant proposed to revise the TVA QAPD Part II, Section 2.5 consistent with the proposed wording in NEI Technical Report 06-14A, "Quality Assurance Program Description," Revision 5, dated May 2008. Revision 5 of NEI 06-14A has not been approved by the NRC staff; therefore, this issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-1**.*

Resolution of Standard Content Open Item 17.5-1

*Revision 7 of NEI 06-14A was approved by the NRC staff in a letter dated November 3, 2009, and adequately addressed RAI 17-5-5. In a letter dated December 31, 2009, the VEGP applicant provided a markup of Revision 9 of the SNC QAPD. The NRC staff has reviewed the markup of SNC QAPD, Revision 9, and determined that conforming changes have been proposed to Section 2.5 consistent with NEI 06-14A, Revision 7. On this basis, Open Item 17.5-1 is **Confirmatory Item 17.5-7** for the VEGP COL application.*

Resolution of Standard Content Confirmatory Item 17.5-7

Confirmatory Item 17.5-7 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-7 is now closed.

WLS Resolution of Standard Content Open Item 17.5-1 and Confirmatory Item 17.5-7

In a letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP. By letter dated December 17, 2010, the applicant provided Revision 3 of the WLS COL FSAR and Revision 3 of the Duke NPD QAPD. In Revision 3 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-1. The NRC staff has confirmed through review of Revision 3 of the Duke NPD QAPD that the applicant has incorporated the appropriate changes to Part II, Section 2.5, of the Duke NPD QAPD, which is consistent with the guidance contained in NRC-approved NEI 06-14A, Revision 7. This adequately addresses the issue outlined by Confirmatory Item 17.5-7; therefore, Standard Content Open Item 17.5-1 is resolved for the WLS COL application.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.2 of the VEGP SER:

*In RAI 17.5-6, the NRC staff requested that the applicant explain how the discussion of the Independent Review Committee responsibilities in Part II, Section 2.7 of the TVA QAPD is consistent with the requirements of American National Standards Institute (ANSI) N18.7. In its response dated June 26, 2008, the applicant proposed to revise the TVA QAPD Part II, Section 2.7 consistent with the proposed wording in NEI 06-14A, Revision 5. This issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-2**.*

Resolution of Standard Content Open Item 17.5-2

*NEI 06-14A, Revision 7, adequately addressed RAI 17.5-6. In a letter dated December 31, 2009, the applicant provided a markup of Revision 9 of the SNC QAPD. The NRC staff has reviewed the markup of SNC QAPD, Revision 9, and determined that conforming changes have been proposed to Section 2.7 consistent with NEI 06-14A, Revision 7. On this basis, Open Item 17.5-2 is **Confirmatory Item 17.5-8** for the VEGP COL application.*

Resolution of Standard Content Confirmatory Item 17.5-8

Confirmatory Item 17.5-8 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-8 is now closed.

WLS Resolution of Standard Content Open Item 17.5-2 and Confirmatory Item 17.5-8

In a letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP. By letter dated December 17, 2010, the applicant provided Revision 3 of the WLS COL FSAR and Revision 3 of the Duke NPD QAPD. In Revision 3 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-2. The NRC staff has confirmed through review of Revision 3 of the Duke NPD QAPD that the applicant has incorporated the appropriate changes to Part II, Section 2.7, of the Duke NPD QAPD, which is consistent with the guidance contained in NRC-approved NEI 06-14A,

Revision 7. This adequately addresses the issue outlined by Confirmatory Item 17.5-8; therefore, Standard Content Open Item 17.5-2 is resolved for the WLS COL application.

WLS RAI 17.5-5

During its review of the Duke NPD QAPD, the NRC staff identified several issues regarding QAPD Part II, Section 2, "Quality Assurance Program," that required further clarification.

In RAI 17.5-5, dated October 6, 2008, the NRC staff requested that the applicant revise the language in Part II, Section 2, of the Duke NPD QAPD, which 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 WLS COL FSAR. The revised language should include 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, as well as to the managerial and administrative controls to be used to assure safe operation. The NRC staff also requested that the applicant identify the corresponding WLS COL FSAR section(s) that describe safety-related SSCs or clarify the purpose of this statement in the Duke NPD QAPD.

In its response letter, dated December 11, 2008, the applicant stated that Duke Energy developed and prepared the Duke NPD QAPD consistent with NRC-approved template NEI 06-14A for the format and content of standard and site specific sections. Duke Energy committed to review and implement the appropriate standard and site specific text changes to Part II, Section 2 of the Duke NPD QAPD, in order to describe these programmatic controls within the QAPD, following approval of NEI 06-14, Revision 5, by the NRC. Since that time, the NRC staff has reviewed and approved NEI 06-14A, Revision 7, which has been adopted by the applicant as the foundation for the Duke NPD QAPD.

The applicant also noted that safety-related SSCs are appropriately described in the DCD and associated FSAR content consistent with RG 1.206; however, SSC requirements were included in Duke NPD QAPD Part II, Section 2, in order to allow the QAPD to be used for potential future new plant development activities. The NRC staff has reviewed the applicant's response to this portion of RAI 17.5-5 and determined that the applicant's response is acceptable.

By letter dated December 17, 2010, Duke Energy submitted Revision 3 of the WLS COL FSAR as well as Revision 3 of the Duke NPD QAPD. The staff confirmed that Revision 3 of the Duke NPD QAPD incorporated a description of the quality-related activities that involve the functions of safety-related activities of SSCs, consistent with the NRC-approved NEI 06-14A, Revision 7, description. Therefore, RAI 17.5-5 is closed.

WLS RAI 17.5-6

In RAI 17.5-6, dated October 6, 2008, the NRC staff requested that the applicant provide clarification of how the Duke NPD QAPD applies to Early Site Permit (ESP) applications / activities, which are referenced in QAPD Part II, Section 2, as well as elsewhere in the document, or remove these references from the QAPD.

In its response letter, dated December 11, 2008, the applicant stated that since Duke Energy did not execute an ESP for WLS, ESP requirements in the Duke NPD QAPD do not apply to the WLS site. WLS COL FSAR Section 17.1 clarifies the timing for and applicability of the QAPD to

activities for WLS. However, ESP requirements were included in the Duke NPD QAPD in order to allow the QAPD to be used for potential future new plant development activities.

On the basis of the Duke Energy response, which clarified how ESP activities discussed in the WLS COL FSAR would be subject to the Duke NPD QAPD described in Section 17.5 of the WLS COL FSAR, the NRC staff determined that the issue has been adequately resolved for the WLS COL application. Therefore, RAI 17.5-6 is closed.

WLS RAI 17.5-7

In RAI 17.5-7, dated October 6, 2008, the NRC staff requested that the applicant identify the site-specific design basis activities in Part II, Section 2.3, of the Duke NPD QAPD, consistent with the guidance of NEI 06-14A, Section 2.3, which states that the QAPD in the COLA will be annotated to identify these activities; or justify their omission. Section 2.3 of the Duke NPD QAPD states that this information will be maintained in a project planning document.

In its response letter, dated December 11, 2008, the applicant stated that the Duke NPD QAPD Part II, Section 2.3, addresses identification of QA controls for ESP and COL application development. The wording of QAPD Part II, Section 2.3, is intended to address the activities that would apply to any future ESP or COL application development, and is not intended to be a commitment for the applicant to develop or submit annotated outlines for the COL application. Since Duke Energy did not execute an ESP for WLS, and the COL application preparation was not performed under the Duke NPD QAPD, this requirement would not be applicable to WLS. The applicant committed to revise Duke NPD QAPD Part II, Section 2.3 for clarity.

By letter dated December 17, 2010, Duke Energy submitted Revision 3 of the WLS COL FSAR as well as Revision 3 of the Duke NPD QAPD. The staff confirmed that Revision 3 of the Duke NPD QAPD incorporated a description of the site specific safety-related design basis activities, consistent with the applicant's RAI response, as well as the applicable NRC-approved NEI 06-14A, Revision 7, description. Therefore, RAI 17.5-7 is closed.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.3 of the VEGP SER:

17.5.4.3 Design Control

The following portion of this technical evaluation section is reproduced from Section 17.5.4.3 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.C. The QAPD establishes the necessary measures to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. 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). In addition, the QAPD provides for individuals knowledgeable in QA principles to review design documents to ensure that they contain the necessary QA requirements.

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

The following portion of this technical evaluation section is reproduced from Section 17.5.4.4 of the VEGP SER:

17.5.4.4 Procurement Document Control

The following portion of this technical evaluation section is reproduced from Section 17.5.4.4 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.D. 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 Section 17.5 of NUREG-0800, 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") are invoked for procurement of items and services.

In the QAPD, TVA 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. The NRC staff evaluated this proposed alternative and determined that it is consistent with Appendix B, Criterion IV, "Procurement Document Control." Therefore, the NRC staff concluded that this alternative is acceptable.*
 - *As an alternative to this requirement, the QAPD proposes that procurement documents allow suppliers to work under TVA's QAPD, including implementing procedures, if suppliers do not have their own QA program. The NRC staff evaluated this proposed alternative and determined that TVA's QAPD follows the guidance in Section 17.5 of*

NUREG-0800, paragraph II.G, regarding "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 award of the contract. As an alternative to this requirement, the QAPD proposes to conduct the QA review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements, before contract award. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive QA review. The NRC staff evaluated this proposed alternative and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change. Therefore, the NRC staff concluded that this alternative is acceptable.*
- *In the QAPD, TVA commits that procurement documents prepared for commercial-grade items, procured as safety-related items, shall contain technical and quality requirements such that the procured item can be appropriately dedicated. The NRC staff evaluated this proposed commitment and determined that it is consistent with NRC staff guidance in Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989, and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991, as delineated in Section 17.5 of NUREG-0800, paragraphs II.U.1.d and II.U.1.e. Therefore, the NRC staff concluded that this commitment is acceptable.*

*In RAI 17.5-7, dated May 12, 2008, the NRC staff requested that the applicant revise TVA QAPD Part II, Section 4 to substitute "TVA's" for "licensee's" to make it clear that a supplier may work under TVA's approved QA program. In its response dated June 26, 2008, the applicant stated that current use of "licensee's" is consistent with the wording in NEI 06-14A, Revision 4, which has been approved by the NRC staff. In a letter, dated September 17, 2008, the NRC staff requested NEI to address this question as part of a future revision to NEI 06-14A. This issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-3**.*

Resolution of Standard Content Open Item 17.5-3

NEI 06-14A, Revision 7, adequately addressed RAI 17.5-7. In a letter dated December 31, 2009, the applicant provided a markup of Revision 9 of the SNC QAPD. The NRC staff has reviewed the markup of SNC QAPD, Revision 9, and

*determined that conforming changes have been proposed to Section 4 consistent with NEI 06-14A, Revision 7. On this basis, Open Item 17.5-3 is **Confirmatory Item 17.5-9** for the VEGP COL application.*

Resolution of Standard Content Confirmatory Item 17.5-9

Confirmatory Item 17.5-9 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-9 is now closed.

WLS Resolution of Standard Content Open Item 17.5-3 and Confirmatory Item 17.5-9

In a letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP. By letter dated December 17, 2010, the applicant provided Revision 3 of the WLS COL FSAR and Revision 3 of the Duke NPD QAPD. In Revision 3 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-3. The NRC staff has confirmed through review of Revision 3 of the Duke NPD QAPD that the applicant has incorporated the appropriate changes to Part II, Section 4, of the Duke NPD QAPD, which is consistent with the guidance contained in NRC-approved NEI 06-14A, Revision 7. This adequately addresses the issue outlined by Confirmatory Item 17.5-9; therefore, Standard Content Open Item 17.5-3 is resolved for the WLS COL application.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.5 of the VEGP SER:

17.5.4.5 Instructions, Procedures, and Drawings

The following portion of this technical evaluation section is reproduced from Section 17.5.4.5 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.E. 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, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 5, to establish procedural controls.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.6 of the VEGP SER:

17.5.4.6 Document Control

The following portion of this technical evaluation section is reproduced from Section 17.5.4.6 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.F. The QAPD establishes the necessary measures and governing procedures to control the preparation, review, approval, issuance, and changes

of documents that specify quality 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 Section 17.5 of NUREG-0800, paragraph II.F.8.

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

The following portion of this technical evaluation section is reproduced from Section 17.5.4.7 of the VEGP SER:

17.5.4.7 Control of Purchased Material, Equipment, and Services

The following portion of this technical evaluation section is reproduced from Section 17.5.4.7 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.G. 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 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 quality 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 acceptable quality, consistent with their effect on safety.

In the QAPD, TVA commits to comply with the quality standards 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 TVA), 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 TVA are not required to be evaluated or audited.*

The 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, TVA remains responsible for ensuring that procured items or services conform to its Appendix B program, applicable ASME Boiler and Pressure Vessel Code requirements, and other regulatory requirements and commitments. TVA 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 NRC staff determined that this exception is acceptable as documented in a previous SE.

- *Section 17.5 of NUREG-0800, 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 evaluation and selection measures not be required, provided 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):*
 - *National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology,*

- *American Association for Laboratory Accreditation (A2LA).*
- o *The accreditation encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."*
- o *The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.*

*The NRC staff evaluated and found to be acceptable the NVLAP and A2LA accreditation programs. In RAI 17.5-13, dated May 12, 2008, the NRC staff requested that the applicant justify the wording discrepancy between TVA QAPD Part II, Section 7.2 and Section 17.5 of NUREG-0800, Section II.L.8.c, regarding the NRC approved alternative for commercial grade calibration services. In its response dated June 24, 2008, the applicant stated that wording is consistent with the wording in NEI 06-14A, Revision 4, which has been approved by the NRC staff. In a letter, dated September 17, 2008, the NRC staff requested NEI to address this question as part of Revision 5 to NEI 06-14A. This issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-4**.*

Resolution of Standard Content Open Item 17.5-4

*NEI 06-14A, Revision 7, adequately addressed RAI 17.5-13. In a letter dated December 31, 2009, the VEGP applicant provided a markup of Revision 9 of the SNC QAPD. The NRC staff has reviewed the markup of SNC QAPD, Revision 9, and determined that conforming changes have been proposed to Section 7.2 consistent with NEI 06-14A, Revision 7. On this basis, Open Item 17.5-4 is **Confirmatory Item 17.5-10** for the VEGP COL application.*

Resolution of Standard Content Confirmatory Item 17.5-10

Confirmatory Item 17.5-10 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-10 is now closed.

WLS Resolution of Standard Content Open Item 17.5-4 and Confirmatory Item 17.5-10

In a letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP. By letter dated December 17, 2010, the applicant provided Revision 3 of the WLS COL FSAR and Revision 3 of the Duke NPD QAPD. In Revision 3 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-4. The NRC staff has confirmed through review of Revision 3 of the Duke NPD QAPD that the applicant has incorporated the appropriate changes to Part II, Section 7.2, of the Duke NPD QAPD, which is consistent with the guidance contained in NRC-approved NEI 06-14A, Revision 7. This adequately addresses the issue outlined by Confirmatory Item 17.5-10; therefore, Standard Content Open Item 17.5-4 is resolved for the WLS COL application.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.7 of the VEGP SER:

The following portion of this technical evaluation section is reproduced from Section 17.5.4.7 of the BLN SER:

- *NQA-1-1994, Supplement 7S-1, Section 8.1, states that documentary evidence that items conform to procurement documents shall be available at the nuclear facility site prior to installation or use. As an alternative to the requirement for procurement documentary evidence to be available at the nuclear facility site during construction. The QAPD proposes that documentary evidence may be stored in physical form or in electronic media, under the control of TVA or its supplier(s), 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 completion of construction, TVA will have sufficient documentary evidence to support operations. The NRC staff determined that implementation of this alternative would allow access to and review of the necessary procurement documentary evidence at the nuclear facility site, both before installation and use. Therefore, the NRC staff concluded that this alternative is acceptable.*
- *As an alternative to the requirements for the control of commercial-grade items and services in NQA-1-1994, Supplement 7S-1, Section 10, TVA commits in the QAPD to follow NRC guidance discussed in GL 89-02 and GL 91-05. In addition, TVA commits to establish and describe special quality verification requirements in applicable documents to assure that the commercially procured items will perform satisfactorily in service. In addition, the documents should provide for determining critical characteristics, technical evaluation, receipt requirements, and quality evaluation of the items to ensure that the items are suitable for their intended use. The NRC staff determined that this alternative will improve detection of counterfeit and fraudulently marked products and will improve the commercial-grade dedication programs. This alternative is consistent with the guidance of Section 17.5 of NUREG-0800, paragraphs II.U.1.d and II.U.1.e. Therefore, the NRC staff concluded that this alternative is acceptable.*
- *As an alternative to the requirements for the control of commercial-grade items and services in NQA-1-1994, Supplement 7S-1, Section 10, TVA commits to use other appropriate approved regulatory means and controls to support TVA commercial grade dedication activities. One example of this is NRC Regulatory Issue Summary (RIS) 2002-22, "Use of EPRI/NEI Joint Task Force Report, 'Guideline on Licensing Digital Upgrades: EPRI TR-102348, Revision 1, NEI 01-01: A Revision of EPRI TR-102348 to Reflect Changes to the 10 CFR 50.59 Rule.'" TVA will assume 10 CFR Part 21 reporting responsibility for all items that TVA dedicates as safety-related.*

In RAI 17.5-14, the NRC staff requested that the applicant provide an explanation as to how RIS 2002-22 represents an example of other approved regulatory means for

*commercial grade dedication activities. In its response dated June 24, 2008, the applicant stated that wording is consistent with the wording in NEI 06-14A, Revision 4, which has been approved by the NRC staff. In a letter, dated September 17, 2008, the NRC staff requested NEI to address this question as part of Revision 5 to NEI 06-14A. This issue will remain open until Revision 5 of NEI 06-14A is approved and TVA has incorporated the approved changes into the TVA QAPD. This is identified as **Open Item 17.5-5**.*

Resolution of Standard Content Open Item 17.5-5

*NEI 06-14A, Revision 7, adequately addressed RAI 17.5-14. In a letter dated December 31, 2009, the VEGP applicant provided a markup of Revision 9 of the SNC QAPD. The NRC staff has reviewed the markup of SNC QAPD, Revision 9, and determined that conforming changes have been proposed to Section 7.2 consistent with NEI 06-14A, Revision 7. On this basis, Open Item 17.5-5 is **Confirmatory Item 17.5-11** for the VEGP COL application.*

Resolution of Standard Content Confirmatory Item 17.5-11

Confirmatory Item 17.5-11 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-11 is now closed.

WLS Resolution of Standard Content Open Item 17.5-5 and Confirmatory Item 17.5-11

In a letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP. By letter dated December 17, 2010, the applicant provided Revision 3 of the WLS COL FSAR and Revision 3 of the Duke NPD QAPD. In Revision 3 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-5. The NRC staff has confirmed through review of Revision 3 of the Duke NPD QAPD that the applicant has incorporated the appropriate changes to Part II, Section 7.2, of the Duke NPD QAPD, which is consistent with the guidance contained in NRC-approved NEI 06-14A, Revision 7. This adequately addresses the issue outlined by Confirmatory Item 17.5-11; therefore, Standard Content Open Item 17.5-5 is resolved for the WLS COL application.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.8 of the VEGP SER:

17.5.4.8 Identification and Control of Materials, Parts, and Components

The following portion of this technical evaluation section is reproduced from Section 17.5.4.8 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.H. 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, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 8 and Supplement 8S-1, to establish provisions for identification and control of items.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.9 of the VEGP SER:

17.5.4.9 Control of Special Processes

The following portion of this technical evaluation section is reproduced from Section 17.5.4.9 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.I. The QAPD establishes programs, procedures, and processes to ensure that special processes requiring interim process controls to ensure 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, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 9 and Supplement 9S-1, to establish measures for the control of special processes.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.10 of the VEGP SER:

17.5.4.10 Inspection

The following portion of this technical evaluation section is reproduced from Section 17.5.4.10 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.J. The QAPD establishes the necessary measures to implement inspections that ensure 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 inspection, 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, TVA commits to comply with 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." 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." 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." 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 definition of safety systems equipment from IEEE Standard 603-1980 to appropriately implement NQA-1-1994, Subpart 2.4. In the QAPD, TVA 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 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 of NQA-1-1994, Subpart 2.4.

- *NQA-1-1994, Supplement 10S-1, Section 3.1, states that inspection personnel shall not report to the immediate supervisor who is 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 such inspections. The NRC staff determined that the use of this alternative is consistent with guidance provided in Section 17.5 of NUREG-0800, paragraph II.J.1. Therefore, the NRC staff concluded that this alternative is acceptable.*

*In a letter dated December 31, 2009, the VEGP applicant provided a markup of Revision 9 of the SNC QAPD that includes the alternative to NQA-1-1994, Supplement 10S-1, Section 3.1, discussed above. The NRC staff has reviewed the markup of SNC QAPD, Revision 9, and determined that the proposed changes are consistent with the alternative evaluated in the BLN SER. These items are identified as **Confirmatory Item 17.5-12**, pending NRC review of the revised QAPD as referenced in Section 17.5 of the VEGP COL FSAR.*

Resolution of Standard Content Confirmatory Item 17.5-12

Confirmatory Item 17.5-12 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-12 is now closed.

WLS Resolution of Standard Content Confirmatory Item 17.5-12

By letter dated July 29, 2011, the applicant provided Revision 4 of the WLS COL FSAR and Revision 4 of the Duke NPD QAPD. In Revision 4 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-12. The NRC staff has confirmed through review of Revision 4 of the Duke NPD QAPD that the applicant has incorporated the appropriate changes to Part II, Section 10.3, of the Duke NPD QAPD, which is consistent with the guidance contained in NRC-approved NEI 06-14A, Revision 7. This adequately addresses the issue outlined by Confirmatory Item 17.5-12; therefore, Standard Content Confirmatory Item 17.5-12 is resolved for the WLS COL application.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.11 of the VEGP SER:

17.5.4.11 Test Control

The following portion of this technical evaluation section is reproduced from Section 17.5.4.11 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.K. 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, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 11 and Supplement 11S-1, to establish provisions for testing.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Supplement 11S-2 and Subpart 2.7, to establish provisions to ensure that computer software used in applications affecting safety be prepared, documented, verified, tested, and used such that the expected outputs are obtained and configuration control maintained.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.12 of the VEGP SER:

17.5.4.12 Control of Measuring and Test Equipment

The following portion of this technical evaluation section is reproduced from Section 17.5.4.12 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.L. The QAPD establishes the necessary measures to control the calibration, maintenance, and use of measuring and test equipment that provide information important to safe plant operation.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 12 and Supplement 12S-1, to establish provisions for control of measuring and test equipment, 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 measuring and test equipment are found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. The NRC staff determined that the clarification for the out-of-calibration conditions is consistent with Supplement 12S-1. Therefore, the NRC 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. The NRC staff determined that this alternative is consistent with NRC staff guidance provided in Section 17.5 of NUREG-0800, paragraph II.L.3. Therefore, the NRC staff concluded that this alternative is acceptable.*

The following portion of this technical evaluation section is reproduced from Section 17.5.4.13 of the VEGP SER:

17.5.4.13 Handling, Storage, and Shipping

The following portion of this technical evaluation section is reproduced from Section 17.5.4.13 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.M. 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, TVA commits to comply with NQA-1-1994, Basic Requirement 13 and Supplement 13S-1, and to establish provisions for handling, storage, and shipping. In the QAPD, TVA also commits to comply with NQA-1-1994, Subparts 2.1 and 2.2 during the construction and pre-operations phase of the plant, as applicable, with the following alternative:

- *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 recording personnel access. However, the QAPD proposes to not consider these documents as quality records. As an alternative, SNC will retain these documents in accordance with plant administrative controls. The NRC staff determined*

that these records do not meet the classification of a quality record as defined in NQA-1-1994, Supplement 17S-1, Section 2.7. Therefore, the NRC 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 of items. The QAPD clarifies that the scope of Subpart 2.15 includes hoisting, rigging and transporting of 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.*

*NQA-1-1994, Subpart 3.2, Appendix 2.1, Section 3, provides cleaning recommendations and precautions. In a letter dated December 31, 2009, the VEGP applicant proposed a revision to the SNC QAPD to clarify that only the precautions in Section 3 are committed to in accordance with RG 1.37, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," Revision 1. The NRC staff has determined that this clarification is acceptable because commitment to Subpart 3.2, Appendix 2.1, Section 3 is consistent with Regulatory Position 3 of RG 1.37. These items are identified as **Confirmatory Item 17.5-13**, pending NRC review of the revised QAPD as referenced in Section 17.5 of the VEGP COL FSAR.*

Resolution of Standard Content Confirmatory Item 17.5-13

Confirmatory Item 17.5-13 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-13 is now closed.

WLS Resolution of Standard Content Confirmatory Item 17.5-13

By letter dated July 29, 2011, the applicant provided Revision 4 of the WLS COL FSAR and Revision 4 of the Duke NPD QAPD. In Revision 4 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-13. The NRC staff has confirmed through review of Revision 4 of the Duke NPD QAPD that the applicant has incorporated the appropriate changes to Part II, Section 13.2, of the Duke NPD QAPD, which is consistent with the guidance contained in NRC-approved NEI 06-14A, Revision 7. This adequately addresses the issue outlined by Confirmatory Item 17.5-13; therefore, Standard Content Confirmatory Item 17.5-13 is resolved for the WLS COL application.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.14 of the VEGP SER:

17.5.4.14 Inspection, Test, and Operating Status

The following portion of this technical evaluation section is reproduced from Section 17.5.4.14 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.N. The QAPD establishes the necessary measures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD to maintain personnel and reactor safety and avoid inadvertent operation of equipment.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 14, for identifying inspection, test, and operating status.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.15 of the VEGP SER:

17.5.4.15 Nonconforming Materials, Parts, or Components

The following portion of this technical evaluation section is reproduced from Section 17.5.4.15 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.O. The QAPD establishes the necessary measures to control items, including services that do not conform to specified requirements to prevent inadvertent installation or use. Nonconformances are evaluated for their impact on 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, 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, as applicable.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 15 and Supplement 15S-1, to establish measures for nonconforming material.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.16 of the VEGP SER:

17.5.4.16 Corrective Action

The following portion of this technical evaluation section is reproduced from Section 17.5.4.16 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.P. 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 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, TVA may delegate specific responsibility for the corrective action program, but TVA maintains responsibility for the program's effectiveness.

In addition, the QAPD provides for establishing the necessary measures to implement a reporting program in accordance with the requirements of 10 CFR Part 21.

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

The following portion of this technical evaluation section is reproduced from Section 17.5.4.17 of the VEGP SER:

17.5.4.17 Quality Assurance Records

The following portion of this technical evaluation section is reproduced from Section 17.5.4.17 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.Q. The QAPD establishes the necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable.

Concerning the use of electronic records storage and retrieval systems, the QAPD complies with the NRC guidance given in RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000, and associated Nuclear Information and Records Management Association (NIRMA) guidelines TG 11-1998, TG 15-1998, TG 16-1998 and TG 21-1998.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, to establish 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 an SER dated September 1, 2005 for Nuclear Management Company.*

The following portion of this technical evaluation section is reproduced from Section 17.5.4.18 of the VEGP SER:

17.5.4.18 Quality Assurance Audits

The following portion of this technical evaluation section is reproduced from Section 17.5.4.18 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.R. The QAPD establishes the necessary measures to implement audits to verify 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 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, conducted after placing the facility in operation, are performed with a frequency commensurate with safety significance 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. External audits determine the adequacy of a supplier's or contractor's QA program.

TVA ensures that audits are documented and reviews audit results. TVA responds to all audit findings and initiates appropriate corrective actions. In addition, where corrective actions are indicated, TVA documents follow-up of applicable areas through inspections, review, re-audits, or other appropriate means to verify implementation of assigned corrective actions.

In the QAPD, TVA commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1, to establish the independent audit program.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.19 of the VEGP SER:

17.5.4.19 Nonsafety-Related SSCs Quality Assurance Control

17.5.4.19.1 Nonsafety-Related SSCs - Significant Contributors to Plant Safety

The following portion of this technical evaluation section is reproduced from Section 17.5.4.19.1 of the BLN SER:

TVA's QAPD follows the guidance of Section 17.5 of NUREG-0800, paragraph II.V.1. The QAPD establishes program controls applied to nonsafety-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 SSC a significant contributor to plant safety consistent with applicable sections of the QAPD.

The Duke NPD QAPD incorporates the guidance of Section 17.5 of NUREG-0800, Paragraph II.V.1 that establishes specific, targeted program controls for nonsafety related SSCs, and is therefore acceptable to the staff.

17.5.4.19.2 Nonsafety-Related SSCs Credited for Regulatory Events

The Duke NPD QAPD follows the guidance of Section 17.5 of NUREG-0800, Paragraph II.V.2, to establish the quality requirements for nonsafety-related SSCs credited for regulatory events. In the QAPD, Duke Energy commits to comply with the following regulatory guidance:

- Duke Energy implements quality requirements 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.
- Duke Energy implements the quality requirements for anticipated transient without scram (ATWS) equipment in accordance with Part III, Section 1, of the Duke NPD QAPD.
- Duke Energy implements quality requirements for station blackout (SBO) equipment in accordance with Part III, Section 1, of the Duke NPD QAPD. Regulatory Guide 1.155, "Station Blackout," dated August 1988, is not applicable for the AP1000 design in accordance with the certified design as shown in the DCD, Appendix 1A. Regulatory Guide 1.155 relates to the availability of safety related functions supported by AC power. Since AC power is not required to support the availability of safety-related functions, the guidance is not applicable to the WLS COL application.

17.5.4.20 *Regulatory Commitments*

The Duke NPD QAPD follows the guidance of Section 17.5 of NUREG-0800, Paragraph II.U. The QAPD establishes QA program commitments. By letter dated December 17, 2010, Duke Energy submitted Revision 3 of the WLS COL FSAR as well as Revision 3 of the Duke NPD QAPD. In Part IV of the Duke NPD QAPD, Duke Energy commits to comply with the following NRC regulatory guides and other QA standards to supplement and support the QAPD:

- RG 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 3.
- RG 1.26, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," Revision 4.
- RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3.
- RG 1.29, "Seismic Design Classification," Revision 4.
- RG 1.33, "Quality Assurance Program Requirements (Operations)," Revision 2.
- RG 1.37, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Water-Cooled Nuclear Power Plants," Revision 1.
- ASME NQA-1-1994 Edition, Parts I, II, and III.

- Nuclear Information and Records Management Association, Inc. (NIRMA) technical guides, as described in Part II, Section 17 of the Duke NPD QAPD.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.20 of the VEGP SER:

In RAI 17.5-15 dated May 12, 2008, the NRC staff requested that the applicant revise the TVA QAPD Part IV to commit 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. In its response dated June 24, 2008, the applicant stated that Part IV of the TVA QAPD is consistent with Revision 4 of NEI 06-14A. In a letter, dated September 17, 2008, the NRC staff requested NEI to address this question as part of Revision 5 to NEI 06-14A. However, the applicant committed to RG 1.37, Revision 1, in Revision 1 of the BLN QAPD. RAI 17.5-15 is closed.

*In a letter dated December 31, 2009, the VEGP applicant provided a markup of Revision 9 of the SNC QAPD. The NRC staff has reviewed the markup of SNC QAPD, Revision 9, and determined that conforming changes have been proposed to Part IV consistent with NEI 06-14A, Revision 7. On this basis, the updating of the SNC QAPD for closure of standard content RAI 17.5-15 is **Confirmatory Item 17.5-16** for the VEGP COL application.*

Resolution of Standard Content Confirmatory Item 17.5-16

Confirmatory Item 17.5-16 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-16 is now closed.

WLS Resolution of Standard Content Confirmatory Item 17.5-16

In a letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP. By letter dated December 17, 2010, the applicant provided Revision 3 of the WLS COL FSAR and Revision 3 of the Duke NPD QAPD. In Revision 3 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-16. The NRC staff has confirmed through review of Revision 3 of the Duke NPD QAPD that the applicant has incorporated the appropriate changes to Part IV of the Duke NPD QAPD, which is consistent with the guidance contained in NRC-approved NEI 06-14A, Revision 7. This adequately addresses the issue outlined by Confirmatory Item 17.5-16; therefore, Standard Content Confirmatory Item 17.5-16 is resolved for the WLS COL application.

The following portion of this technical evaluation section is reproduced from Section 17.5.4.20 of the VEGP SER:

The NRC staff also reviewed Appendix 1AA of the BLN COL FSAR, which lists BLN's conformance with NRC RGs and provides any exceptions to conformance with those RGs. In RAI 17.5-17, the NRC staff requested that the applicant explain how the QAPD provides an acceptable exception to the RGs described in

*Appendix 1AA. In its response (ML081780171), the applicant stated that Part IV of the TVA QAPD is consistent with Revision 4 of NEI 06-14A. Additionally, the applicant provided further information addressing these RGs in response to RAIs 17.5-15 and 17.5-17. The response to RAI 17.5-15 proposed revisions to Appendix 1AA and Parts II and IV of the QAPD, whereas the response to RAI 17.5-17 provided further justification. The applicant provided a response to RAI 1-5 in a letter dated August 19, 2008, to address the discrepancies between the revisions of the RGs addressed in Appendix 1AA and those addressed in Westinghouse DCD Appendix 1A. The information in this letter appears to have superseded the changes that were proposed and acceptable to the NRC staff in the applicant's June 24, 2008 letter, thereby reopening the issue identified in RAI 17.5-17. This is identified as **Open Item 17.5-6**.*

Resolution of Standard Content Open Item 17.5-6

*In a letter dated July 29, 2009, the VEGP applicant stated that the revisions to the COL application identified in the referenced TVA August 19, 2008, letter do supersede the changes identified in the referenced TVA June 24, 2008, letter, as shown in Revision 1 of the BLN COL application. In a letter dated December 31, 2009, the VEGP applicant proposed additional changes to FSAR Chapter 1, Appendix 1AA to address conformance to RG 1.33, Revision 2. The NRC staff has reviewed the proposed changes to VEGP COL FSAR Chapter 1, Appendix 1AA, and determined that the changes are responsive to RAI 17.5-17. On this basis, Open Item 17.5-6 is **Confirmatory Item 17.5-17** for the VEGP COL application.*

Resolution of Standard Content Confirmatory Item 17.5-17

Confirmatory Item 17.5-17 is an applicant commitment to revise its FSAR Appendix 1AA. The staff verified that the VEGP COL FSAR was appropriately updated. As a result, Confirmatory Item 17.5-17 is now closed.

WLS Resolution of Standard Content Open Item 17.5-6 and Confirmatory Item 17.5-17

In a letter dated November 4, 2010, the applicant endorsed the standard content material provided by VEGP. By letter dated December 17, 2010, the applicant provided Revision 3 of the WLS COL FSAR and Revision 3 of the Duke NPD QAPD. In Revision 3 of the Duke NPD QAPD, the applicant addressed the information related to Standard Content Open Item 17.5-6, in regard to applicability of the RGs identified in Part IV of the Duke NPD QAPD and Appendix 1AA of the WLS COL FSAR.

The NRC staff has confirmed through review of Revision 3 of the Duke NPD QAPD and Appendix 1AA of the WLS COL FSAR that the applicant has identified and conforms to Regulatory Guides 1.8, 1.26, 1.29, 1.33, and 1.37. With respect to RG 1.28, the applicant identifies conformance with RG 1.28 for the DCD scope of work, and commits to ASME NQA-1-1994, Parts I, II, and III, in lieu of a commitment to RG 1.28 for the remaining scope of work. This is consistent with the guidance contained in NRC-approved NEI 06-14A, Revision 7. The NRC staff determined that the revisions to the Duke NPD QAPD and Appendix 1AA of the WLS COL FSAR adequately address the issue outlined by Confirmatory Item 17.5-17;

therefore, Standard Content Open Item 17.5-6 and Confirmatory Item 17.5-17 are resolved for the WLS COL application.

17.5.5 Post Combined License Activities

There are no post combined license activities related to this section.

17.5.6 Conclusion

The NRC staff used the requirements of Appendix B to 10 CFR Part 50 and the guidance of Section 17.5 of NUREG-0800 as the basis for evaluating the acceptability of the Duke NPD QAPD and concludes that:

- The QAPD provides adequate guidance for Duke Energy to describe the authority and responsibility of management and supervisory personnel, performance / verification personnel, and self-assessment personnel.
- The QAPD provides adequate guidance for Duke Energy to provide for organizations and persons to perform verification and self-assessment functions with the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.
- The QAPD provides adequate guidance for Duke Energy to apply a QAPD to activities and items that are important to safety.
- The QAPD provides adequate guidance for Duke Energy to establish controls that, when properly implemented, comply with the requirements of 10 CFR Part 52; Appendix B to 10 CFR Part 50; 10 CFR Part 21; and 10 CFR 50.55(e), with the acceptance criteria associated with Section 17.5 of NUREG-0800, and with the commitments to applicable regulatory guidance.

The Duke NPD QAPD addresses WLS COL 17.5-1, STD COL 17.5-2, STD COL 17.5-4, and STD COL 17.5-8.

Based on the information provided by the applicant and the evaluation above, the staff concludes that Section 17.5 of the WLS COL FSAR and the Duke NPD QAPD meet the requirements of Appendix B to 10 CFR Part 50; 10 CFR 52.79(a)(17); 10 CFR 52.79(a)(25); and 10 CFR 52.79(a)(27).

17.6 Maintenance Rule Program (Related to RG 1.206, Section C.III.1, Chapter 17, C.I.17.6, "Description of the Applicant's Program for Implementation of 10 CFR 50.65, The Maintenance Rule")

17.6.1 Introduction

This section addresses the program for maintenance rule (MR) implementation. It is based on the requirements of 10 CFR Part 52 and the guidance provided to the industry by the Nuclear Management and Resources Council (NUMARC) and its successor, the NEI. NUMARC 93-01, "Industry Guidance for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," is

endorsed by the NRC in RG 1.160, "Design Response Spectra for Seismic Design of Nuclear Power Plants." Section 11.0 of NUMARC 93-01 was later revised; the revision, as modified by RG 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants," is also endorsed by the NRC. NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," provides a template for presenting this information that has also been endorsed by the NRC staff in a letter addressed to NEI dated January 24, 2008.

17.6.2 Summary of Application

In Section 17.6, "Maintenance Rule Program," of the WLS COL FSAR, the applicant provided the following:

AP1000 COL Information Items

- STD COL 3.8-5

The applicant provided additional information in STD COL 3.8-5 to address COL Information Item 3.8-5. STD COL 3.8-5 addresses the inspection program for structures.

Supplemental Information

- STD SUP 17.6-1

The applicant provided additional information in STD SUP 17.6-1 to incorporate by reference NEI 07-02A. The applicant also identified where operational programs are described in the WLS COL FSAR, including a description of and milestones for the maintenance rule program.

- STD SUP 17.6-2

The applicant provided additional information in STD SUP 17.6-2 to incorporate condition monitoring of underground or inaccessible cables into the maintenance rule program.

License Condition

- Part 10, License Condition 6, "Operational Program Readiness"

This license condition states that the COL holder shall provide an operational program schedule to support NRC inspections.

17.6.3 Regulatory Basis

Commission regulations for the maintenance rule program include the requirements of 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," and 10 CFR 52.79(a)(15). The acceptance criteria associated with the relevant requirements of the NRC regulations for the MR are given in Section 17.6 of NUREG-0800.

The regulatory basis of the information incorporated by reference into WLS COL FSAR Section 17.6 is addressed in NUREG-1793 and its supplements for topical report NEI 07-02, Revision 3, which was transmitted to NEI in a letter from the NRC staff dated January 24, 2008.

SECY-05-0197, "Review of Operational Programs in a Combined License Application and Generic Emergency Planning Inspections, Tests, Analyses, and Acceptance Criteria," identifies schedule requirements and proposes a license condition to be satisfied by COL holders.

17.6.4 Technical Evaluation

The NRC staff reviewed Section 17.6 of the WLS COL FSAR and checked the referenced DCD to ensure that the combination of the DCD and the COL application represents the complete scope of information relating to this review topic.¹ The NRC staff's review confirmed that the information in the application and incorporated by reference addresses the required information relating to the MR. The results of the staff's evaluation of the information incorporated by reference in the WLS COL application are documented in NUREG-1793 and its supplements.

Section 1.2.3 of this SER provides a discussion of the strategy used by the NRC to perform one technical review for each standard issue outside the scope of the DC and use this review in evaluating subsequent COL applications. To ensure that the staff's findings on standard content that were documented in the SER for the reference COL application (VEGP Units 3 and 4) were equally applicable to the WLS Units 1 and 2 COL application, the NRC staff undertook the following reviews:

- The staff compared the VEGP COL FSAR, Revision 5, to the WLS COL FSAR. In performing this comparison, the staff considered changes made to the WLS COL FSAR (and other parts of the COL application, as applicable) resulting from RAIs.
- The staff confirmed that all responses to RAIs identified in the corresponding standard content evaluation were endorsed.
- The staff verified that the site-specific differences were not relevant.

The NRC staff has completed its review and found the evaluation performed for the standard content to be directly applicable to the WLS COL application. This standard content material is identified in this SER by use of italicized, double-indented formatting. Section 1.2.3 of this SER provides an explanation of why the standard content material from the SER for the reference COL application (VEGP) includes evaluation material from the SER for the BLN Units 3 and 4 COL application. Any confirmatory items in the standard content material retain the numbers assigned in the VEGP SER.

AP1000 COL Information Items

- STD COL 3.8-5

The NRC staff reviewed STD COL 3.8-5 in WLS COL FSAR Section 17.6 related to the inspection program for structures. The staff's review of this program is documented in Section 3.8 of this SER.

The following portion of this technical evaluation section is reproduced from Section 17.6.4 of the VEGP SER:

The NRC staff reviewed conformance of Section 17.6 of the BLN COL FSAR, including the COL standard information item identified in Subsection 17.6.2, with the guidance in NUREG-0800, Section 17.6. The staff also compared it with RG 1.206, Section C.III.1, Chapter 17, C.I.17.6, "Description of the Applicant's Program for Implementation of 10 CFR 50.65, the Maintenance Rule."

In addition, the NRC staff reviewed the COL standard information item identified in Subsection 17.6.2 above. In its review, the staff used NUREG-0800, Section 17.6, "Maintenance Rule," as guidance.

Supplemental Information

- *STD SUP 17.6-1, which incorporated NEI 07-02A and identified where operational programs are described in the BLN COL FSAR, including a description of the MR program*

The applicant added the following text to Section 17.6 of the BLN COL FSAR:

This section incorporates by reference NEI 07-02A, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed under 10 CFR Part 52," with the following supplemental information. See Table 1.6-201.

Table 13.4-201 provides milestones for maintenance rule [MR] program implementation.

The applicant indicated where, in the BLN COL FSAR, the programs listed in Subsection 17.X.3 of NEI 07-02A are described:

- *MR program (Section 17.6)*
- *QA program (Section 17.5)*
- *inservice inspection program (Sections 5.2 and 6.6)*
- *inservice testing program (Section 3.9)*
- *technical specifications surveillance test program (Chapter 16)*

The NRC staff endorsed NEI 07-02A, stating that it provides an acceptable method:

- *for complying with the requirement in 10 CFR 52.79(a)(15) that FSARs contain a description of the program and its implementation*
- *for monitoring the effectiveness of maintenance to meet the requirements of Section 50.65*
- *for satisfying the acceptance criteria of NUREG-0800, Section 17.6*

Because STD SUP 17.6-1 incorporates NEI 07-02A by reference and identifies the relevant operational programs and milestones, the staff finds that the applicant has provided sufficient information to fully describe the maintenance rule program. This provides reasonable assurance that the program, when implemented, satisfies the requirements of 10 CFR 50.65.

- STD SUP 17.6-2

In response to RAI 8.2-14, the applicant incorporated cable monitoring into its maintenance rule program. The program will monitor the condition of inaccessible or underground cables, including all those that support SSCs within the scope of 10 CFR 50.65. The staff documented its evaluation of the cable monitoring program in SER Section 8.2.4.

License Condition

- Part 10, License Condition 6

The applicant proposed a license condition to provide a schedule to support NRC inspection of operational programs including the MR program. The proposed license condition is consistent with the policy established in SECY-05-0197 and is acceptable.

17.6.5 Post Combined License Activities

For the reasons discussed in the technical evaluation section above, the NRC staff finds the following license condition acceptable:

- License Condition (17-1) – No later than 12 months after issuance of the COL, the licensee shall submit to the Director of the Office of New Reactors, a schedule that supports planning for and conduct of NRC inspections of the Maintenance Rule (MR) program. The schedule shall be updated every 6 months until 12 months before scheduled fuel loading, and every month thereafter until the MR has been fully implemented.

17.6.6 Conclusion

The NRC staff reviewed the application and checked the referenced DCD. The NRC staff's review confirmed that the applicant addressed the required information relating to the MR program. The results of the NRC staff's technical evaluation of the information incorporated by reference in the WLS COL application are documented in NUREG-1793 and its supplements.

STD SUP 17.6-1 incorporated NEI 07-02A by reference, identified where operational programs are described in the WLS COL FSAR, including a description of the MR program, and provided a schedule for implementation of the MR program. STD SUP 17.6-2 incorporated condition monitoring of underground or inaccessible cables into the maintenance rule program.

Based on its evaluation, the NRC staff concludes that the relevant information presented in Section 17.6 of the WLS COL FSAR meets the requirements of 10 CFR 50.65 and 10 CFR 52.79(a)(15), and is, therefore, acceptable.