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, design reliability program, and Maintenance Rule (MR) 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 of the Levy Nuclear Plant (LNP) COL Final Safety Analysis Report (FSAR), Revision 9, incorporates by reference Section 17.1 of the AP1000 Design Control Document (DCD), Revision 19.

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

AP1000 COL Information Item

- LNP COL 17.5-1

The applicant provided additional information in LNP COL 17.5-1 to address COL Information Item 17.5-1. In LNP COL 17.5-1, the applicant addresses the Quality Assurance Program Description (QAPD) under which the COL application was developed for the design and construction phases up until COL issuance. Section 17.5 of the LNP COL FSAR addresses the QA program for the remaining portion of the design and construction phases following COL issuance.

17.1.3 Regulatory Basis

The regulatory basis of the information incorporated by reference 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 LNP 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 Nuclear Regulatory Commission (NRC) staff reviewed Section 17.1 of the LNP 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 LNP 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 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 (Vogtle Electric Generating Plant [VEGP], Units 3 and 4) were equally applicable to the LNP Units 1 and 2 COL application, the staff undertook the following reviews:

- The staff compared the VEGP COL FSAR, Revision 5 to the LNP COL FSAR. In performing this comparison, the staff considered changes made to the LNP 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 LNP 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. Confirmatory items that are first identified in this SER section have a LNP designation (e.g., Confirmatory Item LNP 17.1-1).

The staff reviewed the information in the LNP COL FSAR:

AP1000 COL Information Item

- LNP COL 17.5-1

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

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

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

The applicant replaced information in the 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 17.5-6, dated February 27, 2009, the NRC staff requested that the applicant identify which QA program applied to design, procurement, and construction activities associated with the LNP Units 1 and 2 COL application before the COL is issued. In addition, the NRC staff requested clarification on the expected scope of work related to Levy Nuclear Plant COL application design and procurement activities from the time of docketing until the time the COL might be issued.

In letters dated March 31, 2009, and May 4, 2010, the applicant responded to the staff's RAI and stated, in part, that a revision to Section 17.1 of the COL application will be made to clarify the applicability of the applicant's QA program to design, procurement, and construction activities associated with Levy Nuclear Plant Units 1 and 2 that may occur before as well as after the COL is issued. By letter dated October 4, 2010, the applicant submitted Revision 2 of the LNP COL FSAR. The staff reviewed Section 17.1 of the LNP COL FSAR and Section 2 of the LNP QAPD 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 LNP COL FSAR, and (2) adequately described the expected scope of work, consistent with the NEI 06-14A text, related to the COL activities; therefore, RAI 17.5-6 is closed.

In RAI 17.5-8, dated February 27, 2009, the NRC staff requested that the applicant provide an evaluation of the applicant's existing QA program against the applicable acceptance criteria in the Standard Review Plan, pursuant to the requirements of 10 CFR 52.79(a)(41).

By letter dated March 31, 2009, the applicant responded to the staff's RAI and stated, in part, that it is implementing its existing QA program for the activities associated with the LNP COL application prior to issuance of the LNP COL. The applicant's existing nuclear QA program has been reviewed and determined to meet the requirements of Appendix B to 10 CFR Part 50 by the NRC utilizing the acceptance criteria in NUREG-0800, Sections 13 and 17, respectively. The applicant also stated that the QAPD described in Section 17.5 of the LNP COL FSAR to be applied after COL issuance has been evaluated and discussed in Table 1.9-202 of the LNP COL FSAR for conformance to NUREG-0800, Section 17.1. The NRC staff has reviewed the response and determined that the applicant's response is acceptable; therefore, RAI 17.5-8 is closed.

In RAI 17.5-12, dated February 27, 2009, the NRC staff requested that the applicant provide references in Section 17.8 of the LNP COL FSAR for several documents referred to in Section 17.1 of the LNP COL FSAR.

By letter dated March 31, 2009, the applicant responded to the staff's RAI and stated, in part, that the LNP COL FSAR will be revised to address the references, and the applicant provided a proposed LNP COL FSAR revision to reflect these additions. By letter dated July 25, 2013, the applicant submitted Revision 6 of the LNP COL FSAR. The staff reviewed Section 17.1 and 17.8 of the LNP COL FSAR and confirmed that the applicant had adequately identified the documents referenced in Section 17.1 of the LNP COL FSAR; therefore, RAI 17.5-12 is closed.

The NRC staff also reviewed Appendix 1AA of the LNP COL FSAR which lists LNP's conformance with NRC regulatory guides (RGs) and provides any exceptions to conformance with those RGs. In RAI 17.5-13, dated February 27, 2009, the NRC staff requested that the applicant explain how Appendix 1AA addresses its existing nuclear QA program's conformance to the applicable RGs since this QA program is being used for activities associated with the LNP COL application prior to issuance of the LNP COL. In its letter dated March 31, 2009, the applicant stated, in part, that Chapter 17.1 of the Levy Nuclear Power Plant Units 1 and 2 FSAR, will be revised to clarify that its existing Nuclear Quality Assurance Program Description identifies the quality assurance requirements that will be in effect until the QAPD provided in Part 11 of the COL application is implemented. Included in its Nuclear Quality Assurance Program Description (Reference 201) is Chapter 1.8 which describes the conformance with NRC Regulatory Guides and any NRC approved exceptions or alternatives taken. The applicant's Nuclear Plant Development activities performed prior to implementation of the QAPD provided in Part 11 of the COL application are performed in accordance with these existing quality assurance program requirements. The applicant developed NGGM-PM-0030, Quality Assurance Plan for New Nuclear Plant Development and Construction Activities to identify the appropriate programs and procedures that implement existing nuclear commitments. By letter dated July 25, 2013, the applicant submitted Revision 6 of the LNP COL FSAR. The staff reviewed Section 17.1 of the LNP COL FSAR and confirmed that the applicant had adequately identified the applicability of its existing nuclear QA program and the associated RGs that apply to the LNP COL application prior to the issuance of the LNP COL; therefore, RAI 17.5-13 is closed.

The following portion of this technical evaluation 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 01-11, 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.*

LNP Resolution of Standard Content Open Item 17.1-1 and Associated Confirmatory Item 17.1-1

In a letter dated September 23, 2010, the applicant endorsed the standard content material provided by VEGP. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. In Revision 9 of the LNP Units 1 and 2 QAPD, the application addressed the information related to standard content Open Item 17.1-1. The NRC staff has confirmed through review of Revision 9 of the LNP Units 1 and 2 QAPD that the applicant has incorporated changes to Appendix 1AA of the LNP COL FSAR and Part IV, "Regulatory Commitments," of the LNP Units 1 and 2 QAPD. The staff confirmed that the applicant had adequately identified and specified exceptions to RG 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2; consistent with the NRC-approved NEI 06-14A, Revision 7 guidance, and incorporated specific changes into Part IV, "Regulatory Commitments," of the LNP Units 1 and 2 QAPD, Revision 9 that adequately addresses the issue. The staff's review of this information is provided in Section 17.5.4.20 of the staff's SER. Therefore, standard content Open Item 17.1-1 and associated Confirmatory Item 17.1-1 are resolved for the LNP COL application.

In April 2010, the NRC staff conducted a limited scope inspection at the applicant's facility in Raleigh, North Carolina, as documented in inspection report numbers 05200029/2010-201 and 05200030/2010-201 dated July 11, 2010. The purpose of the NRC inspection was to verify that the QA processes and procedures were effectively implemented with regards to the LNP COL application. In this inspection, the NRC inspectors did not identify any violations of NRC requirements related to the QA program. Based on the results of the inspection, the staff does not intend to conduct a follow-up inspection as part of licensing.

17.1.5 Post Combined License Activities

There are no post-COL activities related to this section.

17.1.6 Conclusion

The NRC staff reviewed the application and checked the referenced DCD. The 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 LNP COL FSAR related to this section. The results of the NRC staff's technical evaluation of the information incorporated by reference in the LNP COL application are documented in NUREG-1793 and its supplements.

Based on the information provided by the applicant which addresses the QA program requirements for design and construction activities, as well as endorsement of the standard content material provided by VEGP, the staff concludes that LNP COL 17.5-1 meets Appendix B to 10 CFR Part 50 and 10 CFR 52.79(a)(25) requirements regarding the identification of and description for quality assurance criteria for nuclear power plants.

17.2 Quality Assurance During the Operations Phase

Section 17.2 of the LNP COL FSAR, Revision 9, incorporates by reference, with no departures or supplements, Section 17.2 of Revision 19 of the AP1000 DCD. The NRC staff reviewed the application and checked the referenced DCD to ensure that no issue relating to this section remained for review.[1] The NRC staff's review confirmed that there is no outstanding issue related to this section. The results of the NRC staff's technical evaluation of the information incorporated by reference in the LNP 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 of the LNP COL FSAR, Revision 9, incorporates by reference, with no departures or supplements, Section 17.3 of Revision 19 of the AP1000 DCD. The NRC staff reviewed the application and checked the referenced DCD to ensure that no issue relating to this section remained for review.[1] The NRC staff's review confirmed that there is no outstanding issue related to this section. The results of the NRC staff's technical evaluation of the information incorporated by reference in the LNP 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 providing 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 of the LNP COL FSAR, Revision 9, incorporates by reference Section 17.4 of the AP1000 DCD, Revision 19.

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

Supplemental (SUP) Information

- STD SUP 17.4-1

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

- LNP SUP 17.4-1

The applicant provided plant-specific supplemental information in LNP SUP 17.4-1 related to inclusion of the safety-related, roller-compacted concrete bridging basemat in the D-RAP.

17.4.3 Regulatory Basis

The regulatory basis of the information incorporated by reference 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. 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.

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 LNP 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 NRC staff's evaluation of the information incorporated by reference in the LNP 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 LNP Units 1 and 2 COL application, the staff undertook the following reviews:

- The staff compared the VEGP COL FSAR, Revision 5 to the LNP COL FSAR. In performing this comparison, the staff considered changes made to the LNP 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 has completed its review and found the evaluation performed for the standard content to be directly applicable to the LNP 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.

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 MR 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 non-safety-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 non-safety-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.

- LNP SUP 17.4-1

In RAI 19-75, the staff requested plant-specific supplemental information related to inclusion of the safety-related, roller-compacted concrete bridging basemat in the RAP. One part of the request was the capacity of the basemat to withstand earthquakes, expressed as the peak ground acceleration in the free field at which there is high confidence in low probability of failure (HCLPF) value.

In a letter dated November 17, 2011, and Revision 4 of the LNP COL FSAR, the applicant reported that the bridging basemat controls the plant HCLPF value for LNP. Because of its importance in the plant-specific seismic margin analysis, the structure has been added to the RAP. This is consistent with RG 1.206.

17.4.5 Post Combined License Activities

There are no post-COL activities related to this section.

17.4.6 Conclusion

The NRC staff reviewed the application. For the information incorporated by reference to the DCD, the NRC 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 LNP COL FSAR related to this section. The results of the NRC staff's technical evaluation of the information incorporated by reference in the LNP COL application are documented in NUREG-1793 and its supplements.

The staff concludes that the plant specific information presented in Section 17.4 of the LNP COL FSAR is consistent with the guidance provided in SECY-95-132, and the requirements of 10 CFR 52.47(b)(1), "Contents of applications; technical information," and 10 CFR 52.80(a) "Contents of applications; additional technical information." Therefore, the LNP D-RAP 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 begins at COL issuance with full implementation of the operations-related requirements consistent with LNP COL FSAR Table 13.4-201, "Operational Programs Required by NRC Regulations."

17.5.2 Summary of Application

In Part 11 of the LNP COL application, the applicant provided a QAPD to be in place during the design, construction, and operations phases. This QAPD is incorporated by reference in Section 17.5 of the LNP COL FSAR.

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

AP1000 COL Information Items

- LNP COL 17.5-1

The applicant provided additional information in LNP COL 17.5-1 to address COL Information Item 17.5-1. LNP COL 17.5-1 addresses the QA program in place during the design, construction, and operations phases.

- 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.

- 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 regulatory requirements for the QAPD include the following:

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

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 LNP Units 1 and 2 COL application, the staff undertook the following reviews:

- The staff compared the VEGP COL FSAR, Revision 5 to the LNP COL FSAR. In performing this comparison, the staff considered changes made to the LNP 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 staff has completed its review and found the evaluation performed for the standard content to be directly applicable to the LNP 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. Confirmatory items that are first identified in this SER section have a LNP designation (e.g., Confirmatory Item LNP 17.5-1).

Although the staff concluded that the evaluation performed for the standard content is directly applicable to the LNP COL application, there were differences between the information provided by the LNP applicant and that provided by the VEGP applicant regarding details in the LNP COL FSAR and the LNP Units 1 and 2 QAPD. The resolutions of these differences for LNP 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.*
>
> *Resolution of Standard Content Open Item 17.5-9*
>
> *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.*

LNP Resolution of Standard Content Open Item 17.5-9 and Associated Confirmatory Item 17.5-1

In a letter dated September 23, 2010, the applicant endorsed the standard content material provided by VEGP in its letters dated January 29, 2010, and April 02, 2010, with reference to BLN response to RAI 17.5-9 as standard, and proposed to incorporate the standard content in a future revision of the LNP COL FSAR. The applicant provided its commitment to incorporate the standard content material that consists of revising Section 17.1 of the LNP COL FSAR to incorporate the LNP Units 1 and 2 QAPD by reference and to provide the title of the QAPD that is incorporated by reference. The NRC staff reviewed the applicant's proposed commitment to incorporate the standard content with reference to the LNP Units 1 and 2 QAPD and determined the proposed commitment to be acceptable. By letter dated July 25, 2013, the applicant provided Revision 6 of the LNP COL FSAR. The staff confirmed that Revision 6 included reference to the LNP Units 1 and 2 QAPD by title in Section 17.1 and 17.5 of the LNP COL FSAR; therefore, standard content Open Item 17.5-9 and associated Confirmatory Item 17.5-1 are resolved for the LNP application.

In RAI 17.5-7, dated February 27, 2009, the NRC staff requested that the applicant clarify when the LNP Units 1 and 2 QAPD discussed in Section 17.5 of the LNP COL FSAR will be implemented.

By letter dated March 31, 2009, the applicant responded to the staff's RAI and stated, in part, that the LNP Units 1 and 2 QAPD discussed in LNP COL FSAR Section 17.5, will become effective on approval of the LNP COL and it will establish the QA program requirements for the remaining portion of the design, construction, and operational phases for the new nuclear reactors. Specifically, 30 days following the issuance of the LNP 1 and 2 COL, or prior to the initiation of quality related activities following COL issuance, whichever is later, the licensee will implement the QAPD discussed in FSAR Section 17.5. In addition, full implementation of specific operation related requirements will occur no later than 30 days prior to the scheduled date of initial fuel load. By letter dated July 25, 2013, the applicant provided Revision 6 of the LNP COL FSAR. The staff confirmed that Revision 6 incorporated a description of the implementation schedule for LNP Units 1 and 2 QAPD consistent with the applicant's RAI responses; therefore, RAI 17.5-7 is closed.

In RAI 17.5-9 dated February 27, 2009, the NRC staff requested that the applicant clarify how siting activities discussed in Section 1.1 of the LNP Units 1 and 2 QAPD in Attachment 11 would be subject to the provisions of the QAPD.

By letter dated March 31, 2009, the applicant responded to the staff's RAI and stated, in part, that the siting activity was included in the listing of activities to which the LNP Units 1 and 2 QAPD applies based on the development of the QAPD to serve as a topical report for all future applicant new nuclear plant development activities. For LNP site characterization, services were procured in accordance with the applicant's existing Quality Assurance Program Requirements.

On the basis of the applicant's response, which clarified how siting activity discussed in the LNP COL FSAR would be subject to the QAPD described in LNP COL FSAR Section 17.5, the NRC staff determined that the issue has been adequately resolved; therefore, RAI 17.5-9 is closed.

In RAI 17.5-10 dated February 27, 2009, the NRC staff requested that the applicant clarify how the organizational charts provided in Chapter 13 of the LNP COL FSAR describe the specific functions and responsibilities for various departments and organizations as well as ensuring that these descriptions are consistent with the organization described in the LNP Units 1 and 2 QAPD.

By letter dated March 31, 2009, the applicant responded to the staff's RAI 17.5-10, and stated, in part, that it will revise the LNP Units 1 and 2 QAPD and LNP COL FSAR Chapter 13 to address these concerns. The applicant also referred to their response to RAI 17.5-2 for details regarding the specific changes to be incorporated into the LNP COL FSAR and LNP Units 1 and 2 QAPD. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. The staff confirmed that Revision 9 of the LNP Units 1 and 2 QAPD incorporated a description of the LNP organization, including organizational charts, consistent with the applicant's RAI responses. In addition, the staff confirmed that the applicant had incorporated changes to Section 13, "Conduct of Operations," of the LNP COL FSAR to reflect that changes to the organization are reviewed under the provisions of 10 CFR 50.54(a) to ensure that any reduction in commitments in the QAPD are submitted to and approved by the NRC prior to implementation; therefore, RAI 17.5-7 is closed.

In addition, 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 LNP COL 17.5-1, which are addressed in the LNP QAPD. The LNP Units 1 and 2 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 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 LNP COL 17.5-1

The following portion of this technical evaluation 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 review items and the LNP 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.*

During its review of the LNP Units 1 and 2 QAPD, the NRC staff identified an issue in the Organization Section of the LNP Units 1 and 2 QAPD that required further clarification. In RAI 17.5-2, dated February 27, 2009, the NRC staff requested that the applicant provide clarification

regarding the inclusion of organizational charts in the LNP Units 1 and 2 QAPD, and additional clarifications regarding organizational descriptions provided in Part II, of Section I of the LNP Units 1 and 2 QAPD. By letter dated March 31, 2009, the applicant responded to RAI 17.5-2 and stated, in part, that it has defined the organizational structure; roles and responsibilities; and reporting relationships for the its organizations that will implement the requirements of this QAPD for the development, construction and operation of new nuclear generating plants. The organizational descriptions and organization charts contained within the QAPD define the corporate and Nuclear Generation Group organizations that implement the quality assurance requirements in the QAPD in support of the development, construction and operation of the units. The operational phase organization chart provided in the QAPD is representative of the typical site organizational structure identifying the various reporting relationships that implement the quality assurance requirements including Nuclear Oversight functions. The applicant elects to describe the detailed organization responsible for the operation of the new nuclear generating plants within the respective sites' FSAR Chapter 13. This detailed description is incorporated by reference into the QAPD, and changes to this organization are reviewed under the provisions of 10 CFR 50.54(a) to ensure that any reduction in commitments contained in the QAPD (as accepted by the NRC) are submitted to and approved by the NRC prior to implementation.

By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. The staff confirmed that Revision 9 of the LNP Units 1 and 2 QAPD incorporated a description of the LNP organization, including organizational charts, consistent with the applicant's RAI responses. In addition, the staff confirmed that the applicant had incorporated changes to Section 13, "Conduct of Operations," of the LNP COL FSAR to reflect that changes to the organization are reviewed under the provisions of 10 CFR 50.54(a) to ensure that any reduction in commitments in the QAPD are submitted to and approved by the NRC prior to implementation; therefore, RAI 17.5-2 is 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 non-safety-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.*

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

> *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.*

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

In a letter dated September 23, 2010, the applicant endorsed the standard content material provided by VEGP. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. In Revision 9 of the LNP Units 1 and 2 QAPD, the application addressed the information related to standard content Open Item 17.5-1. The NRC staff has confirmed through review of the Revision 9 of the LNP Units 1 and 2 QAPD that the applicant has incorporated changes to Section 2.5 of the LNP Units 1 and 2 QAPD, which is consistent with the NRC-approved NEI 06-14A, Revision 7 guidance, that adequately addresses the issue; therefore, standard content Open Item 17.5-1 and associated Confirmatory Item 17.5-7 are resolved for the LNP 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.*

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

By letters dated April 26, 2010, and September 23, 2010, the applicant provided responses to address concurrence with standard content Open Item 17.5-2 in response to requests for information. With respect to standard content Open Item 17.5-2, regarding the Independent Review Committee, the applicant noted that Part II Section 2.7 of NEI 06-14A provides two different acceptable options for implementing the required activities associated with the Independent Review Process. Option II is implemented by the R-COL application QAPD, while the LNP COL applicant elected to implement Option I. Since the R-COL application implements Option II, the changes to Option II incorporated into NEI 06-14A Revision 7 are addressed in the standard response to NRC SER Open Item 17.05-02. Option I is not addressed or impacted by this standard response. The R-COL application standard response is not applicable to the LNP S-COL applications because the LNP COL applicant does not implement Option II in its QAPD. Therefore, the LNP COL applicant's QAPD is not impacted by the standard response to NRC SER Open Item 17.05-02. The staff has reviewed the applicant's response and finds that it adequately addresses the issue; therefore Standard Content RAI 17.5-2 and associated Confirmatory Item 17.5-8 are resolved for the LNP application. By letter dated June 19, 2013, the applicant provided Revision 9 of the LNP Units 1 and 2 QAPD, which provided a change to Section 2.7, "Independent Review," which relocated the description of the independent review function to Section V, "Additional Quality Assurance and Administrative Controls for the Plant Operational Phase," of the QAPD. This revision was to maintain consistency with the NRC-approved NEI 06-14A, Revision 7 guidance. The staff's review of this information is provided in Section 17.5.4.21 of the staff's SER.

In RAI 17.5-3, dated February 27, 2009, the NRC staff requested that the applicant provide a revision to the QAPD Part II, Section 2, which states that the LNP Units 1 and 2 QAPD applies to those quality-related activities that involve the functions of safety-related activities of structures, systems, and components SSCs as described in the COL FSAR consistent with Appendix B to 10 CFR Part 50 which requires, in part, that Part 52 applicants include in the FSAR a description of the quality assurance [program] applied to the design, and to be applied to the fabrication, construction, and testing of the SSCs of the facility and to the managerial and administrative controls to be used to assure safe operations.

In letter dated March 31, 2009, the applicant responded to RAI 17.5-3 and stated, in part, that: it developed and prepared the LNP Units 1 and 2 QAPD consistent with the NRC approved template NEI 06-14A, Revision 4, for the format and content of standard and site specific sections. The applicant committed to review and implement the appropriate standard and site specific text changes to Section 2 describing these programmatic controls within the QAPD following approval of NEI 06-14, Revision 5 by the NRC. Since that time the NRC has reviewed and approved NEI 06-14A, Revision 7 which has been adopted by the applicant as the foundation for the LNP Units 1 and 2 QAPD. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. The staff confirmed that Revision 9 of the LNP Units 1 and 2 QAPD incorporated a description of the quality-related activities, consistent with the NRC-approved NEI 06-14A, Revision 7 description; therefore RAI 17.5-3 is closed.

In RAI 17.5-4, dated February 27, 2009, the NRC staff requested that the applicant identify the site-specific design basis activities consistent with the guidance in NEI 06-14A, Section 2.3, or justify its omission. In letter dated March 31, 2009, the applicant responded to RAI 17.5-4 and stated, in part, that the section from NEI 06-14A was erroneously omitted during the preparation of the LNP Units 1 and 2 QAPD, and that the LNP Units 1 and 2 QAPD will be revised to include the site specific text contained within Section 2.3 of NEI 06-14A. Since that time the NRC has reviewed and approved NEI 06-14A, Revision 7 which has been adopted by the applicant as the foundation for the LNP Units 1 and 2 QAPD. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. The staff confirmed that Revision 9 of the LNP Units 1 and 2 QAPD incorporated a description of the site specific safety-related design basis activities, consistent with the NRC-approved NEI 06-14A, Revision 7 description; therefore RAI 17.5-4 is closed.

In RAI 17.5-5, dated February 27, 2009, the NRC staff requested that the applicant revise the LNP QAPD to include a description consistent with NEI 06-14A regarding the applicability of the QAPD to “those [Nuclear Development] and [CA] activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those characteristics.”

In a letter dated March 31, 2009, the applicant responded to RAI 17.5-5 and stated, in part, that the paragraph from NEI 06-14A was erroneously omitted during the preparation of the LNP Units 1 and 2 QAPD, and that the QAPD will be revised to be consistent with the NRC approved standard text contained within Section 2 of NEI 06-14A. Since that time the NRC has reviewed and approved NEI 06-14A, Revision 7 which has been adopted by the applicant as the foundation for the LNP Units 1 and 2 QAPD. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. The staff reviewed Section 2 of the LNP QAPD and confirmed that the applicant had adequately described those activities that can affect the safety-related site characteristics or analysis of those characteristics expected scope of work, consistent with the NRC- approved NEI 06-14A guidance, related to the COL; therefore, RAI 17.5-5 is closed.

The following portion of this technical evaluation section is reproduced from Section 17.5.4 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.

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.

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

In a letter dated September 23, 2010, the applicant endorsed the standard content material provided by VEGP. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. In Revision 9 of the LNP Units 1 and 2 QAPD, the application addressed the information related to the standard content Open Item 17.5-3. The NRC staff has confirmed, through review of Revision 9 of the LNP Units 1 and 2 QAPD, that the applicant has incorporated changes to Section 4 of the LNP Units 1 and 2 QAPD, consistent with the NRC-approved NEI 06-14A, Revision 7 guidance that adequately addresses the issue; therefore, standard content Open Item 17.5-3 and associated Confirmatory Item 17.5-9 are resolved for the LNP COL application.

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.

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.

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).*

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

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

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

In a letter dated September 23, 2010, the applicant endorsed the standard content material provided by VEGP. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. In Revision 9 of the LNP Units 1 and 2 QAPD, the application addressed the information related the standard content Open Item 17.5-4. The NRC staff has confirmed through review of the Revision 9 of the LNP Units 1 and 2 QAPD that the applicant has incorporated changes to Section 7 of the LNP Units 1 and 2 QAPD, consistent with the NRC-approved NEI 06-14A, Revision 7 guidance that adequately addresses the issue; therefore, standard content Open Item 17.5-4 and associated Confirmatory Item 17.5-10 are resolved for the LNP COL application.

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.*

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

In a letter dated September 23, 2010, the applicant endorsed the standard content material provided by VEGP. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. In Revision 9 of the LNP Units 1 and 2 QAPD, the application addressed the information related to the standard content Open Item 17.5-5. The NRC staff has confirmed through review of Revision 9 of the LNP Units 1 and 2 QAPD that the applicant has incorporated changes to Section 7 of the LNP Units 1 and 2 QAPD, consistent with the NRC-approved NEI 06-14A, Revision 7 guidance that adequately addresses the issue; therefore, standard content Open Item 17.5-5 and associated Confirmatory Item 17.5-11 are resolved for the LNP COL application.

The following portion of this technical evaluation section is reproduced from Section 17.5.4 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.

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.

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.

The following portion of this technical evaluation section is reproduced from Section 17.5.4 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.

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.*

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.

By letter dated June 19, 2013, the applicant provided Revision 9 of the LNP Units 1 and 2 QAPD. In Revision 9 of the LNP Units 1 and 2 QAPD, the application revised Section 13, "Handling, Storage, and Shipping," to reflect the NRC-approved NEI 06-14A, Revision 7 guidance on the subject. The staff has completed its review of this revised material as documented herein.

The LNP Units 1 and 2 QAPD follows the guidance of Section 17.5 of NUREG-0800, Paragraph II.M. The LNP Units 1 and 2 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 LNP Units 1 and 2 QAPD, the applicant 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 LNP Units 1 and 2 QAPD, the applicant 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 clarifications and exceptions:

- NQA-1-1994, Subpart 2.1, Sections 3.1 and 3.2 establish criteria for classifying items into cleanliness classes and requirements for each class. Instead of using the cleanliness level system of Subpart 2.1, the applicant may establish cleanliness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. The LNP Units 1 and 2 QAPD establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure. The NRC staff determined that this alternative is consistent with previous NRC-approved QAPD changes for operating reactors (Approval of Nuclear Management Company Quality Assurance Topical Report, dated March 24, 2005 (Agencywide Documents Access and Management System (ADAMS) Accession Number ML050700416)) and applicable to the LNP Units 1 and 2 QAPD during the operational phase of the LNP Units 1 and 2. Therefore, the NRC staff concluded that this alternative is acceptable.

- NQA-1-1994, Subpart 2.2, Section 2.2 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, the applicant may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function. The NRC staff determined that this alternative is consistent with previous

NRC-approved QAPD changes for operating reactors (Refer to ADAMS Accession Number ML050700416) and is applicable to the LNP Units 1 and 2 QAPD during the operational phase of the LNP Units 1 and 2. Therefore, the NRC staff concluded that this alternative is acceptable.

- 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 LNP Units 1 and 2 QAPD establishes the necessary measures to document personnel authorized to access storage areas and recording personnel access. However, the LNP Units 1 and 2 QAPD proposes to not consider these documents as quality records. As an alternative, the applicant will retain these documents in accordance with plant administrative controls. The NRC staff determined that these records do not meet the classification of a 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 LNP Units 1 and 2 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 2.3, Section 2.3 provides for the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, the applicant may base its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The LNP Units 1 and 2 QAPD states that the controls are implemented through procedures or instructions which, in the case of maintenance or modification work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control, and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. The NRC staff determined that this alternative is consistent with previous NRC-approved QAPD changes for operating reactors (Refer to ADAMS Accession Number ML050700416) and is applicable to the LNP Units 1 and 2 QAPD during the operational phase of the LNP Units 1 and 2. Therefore, the NRC staff concluded that this alternative is acceptable.

- NQA-1-1994, Subpart 3.2, Appendix 2.1. The LNP Units 1 and 2 QAPD clarifies that only Section 3 precautions are being committed to in accordance with RG 1.37. In addition, a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels. The NRC staff has determined that this clarification is acceptable because it is consistent with the precautions and recommendations contained in RG 1.37.

The following portion of this technical evaluation section is reproduced from Section 17.5.4 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.

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.

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.

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.*

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.

By letter dated June 19, 2013, the applicant provided Revision 9 of the LNP Units 1 and 2 QAPD. In Revision 9 of the LNP Units 1 and 2 QAPD, the application revised Section 18, "Audits," to reflect the NRC-approved NEI 06-14A, Revision 7 guidance on the subject. The staff has completed its review of this revised material as documented herein.

The LNP Units 1 and 2 QAPD follows the guidance of Section 17.5 of NUREG-0800, Paragraph II.R. The LNP Units 1 and 2 QAPD establishes the necessary measures to implement audits to verify that activities covered by the LNP Units 1 and 2 QAPD are performed in conformance with documented requirements. The audit program is reviewed for effectiveness as part of the overall audit process.

The LNP Units 1 and 2 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 LNP Units 1 and 2 QAPD. Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QAP elements is completed for each functional area at least once each year or at least once during the life of the

activity, whichever is shorter. 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 QAP elements are completed for each functional area within a period of two years. External audits determine the adequacy of a supplier's or contractor's QAP.

This section of the LNP Units 1 and 2 QAPD states that the applicant is to ensure that audits are documented and that it reviews audit results. The applicant is to respond to all audit findings and initiates appropriate corrective actions. In addition, where corrective actions are indicated, the applicant is to document follow-up of applicable areas through inspections, review, re-audits, or other appropriate means to verify implementation of assigned corrective actions.

In the LNP Units 1 and 2 QAPD, the applicant 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 non-safety-related SSCs that are significant contributors to plant safety and to which Appendix B does not apply. The QAPD applies specific controls to these items in a selected manner, targeting the characteristics or critical attributes that render the SSC a significant contributor to plant safety consistent with applicable sections of the QAPD.

In RAI 17.5-7, dated November 25, 2008, the NRC staff requested that the applicant provide additional description for SNC simultaneous and similar processes and the qualifications for personnel performing these inspections. In its response, dated December 17, 2008, the applicant stated that conforming changes to the SNC QAPD will be made consistent with NEI 06-14A after the revision has been formally approved by the NRC. In a letter dated December 31, 2009, the applicant proposed a markup of Revision 9 of the SNC QAPD. The NRC staff has verified that the SNC QAPD, Revision 9, markup has deleted the language. These items are identified as ***Confirmatory Item 17.5-14****, pending NRC review of the revised QAPD as referenced in Section 17.5 of the VEGP COL FSAR.*

Resolution of Standard Content Confirmatory Item 17.5-14

Confirmatory Item 17.5-14 is an applicant commitment to revise its QAPD. The staff verified that the VEGP COL application was appropriately updated. As a result, Confirmatory Item 17.5-14 is now closed.

17.5.4.19.2 *Nonsafety-Related SSCs Credited for Regulatory Events*

The LNP Units 1 and 2 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, the applicant commits to comply with the following regulatory guidance:

- The applicant 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," as identified in FSAR Chapter 1.

- The applicant implements the quality requirements for anticipated transient without scram (ATWS) equipment in accordance with Part III, Section 1. The applicant implements quality requirements for station blackout (SBO) equipment in accordance with Part III, Section 1. Regulatory Guide 1.155, is not applicable for the AP1000 design in accordance with the certified design as shown in 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.

17.5.4.20 *Regulatory Commitments*

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.

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*.

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

In a letter dated September 23, 2010, the applicant endorsed the standard content material provided by VEGP. By letters dated July 25, 2013, and June 19, 2013, the applicant provided Revision 6 of the LNP COL FSAR and Revision 9 of the LNP Units 1 and 2 QAPD, respectively. In Revision 9 of the LNP Units 1 and 2 QAPD, the application addressed the information related to the standard content Open Item 17.5-6 regarding applicability of the RGs identified in Part IV of the LNP Units 1 and 2 QAPD and in Appendix 1AA of the LNP COL FSAR. The NRC staff has confirmed through review of the Revision 9 of the LNP Units 1 and 2 QAPD and Appendix 1AA of the LNP COL FSAR that the applicant had identified conformance with and exceptions to RGs 1.8, 1.26, 1.29, and 1.33, 1.37, and 1.54. 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, III in lieu of a commitment to RG 1.28 for the remaining scope of work, consistent with the NRC-approved NEI 06-14A, Revision 7 guidance. With respect to RG 1.33, the applicant identifies an alternative to commitment to RG 1.33, based on incorporation of the NRC-approved NEI 06-14A, Revision 7, guidance (Refer to ADAMS Accession Number ML070510300) into Revision 9 of the LNP Unit 1 and 2 QAPD and the addition of Section V, "Additional Quality Assurance and Administrative Controls for the Plant Operational Phase," to address the regulatory guidance of ANSI N18/7-1976/ANS-3.2. The

staff determined that these revisions to the LNP Units 1 and 2 QAPD and Appendix 1AA of the LNP COL FSAR adequately address the issues associated with each RG as described below. Therefore, standard content Open Item 17.5-6 and associated Confirmatory Item 17.5-17 are resolved for the LNP COL application.

1) RG 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants," issued May 2000. In the LNP Units 1 and 2 QAPD, the applicant states that LNP Units 1 and 2 complies with the applicable regulatory guidance with the following exception as identified in LNP COL FSAR, Appendix AA, "Conformance with Regulatory Guides." The exception is:

   (a) Qualification requirements for licensed personnel cannot be met prior to operations (Section 4 of ANSI/ANS 3.1-1993). As a further alternative to the selection and qualification requirements for licensed operators contained in ANSI-3.1-1993, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants," the requirements for NEI 06-13A, Revision 1, may be used for cold-licensing of operators. The staff has reviewed this exception and found it is acceptable on the basis that it is consistent with the SRP 17.5 criteria and the programmatic guidance described in NEI 06-13A, Revision 1 that has been previously reviewed and approved by the NRC staff.

2) RG 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," issued March 2007. In the LNP Units 1 and 2 QAPD, the applicant states that LNP complies with the applicable regulatory guidance provided in this RG as identified in the LNP COL FSAR Appendix AA, "Conformance with Regulatory Guides."

3) RG 1.28, Revision 3, "Quality Assurance Program Requirements (Design and Construction)," issued August 1985. In the LNP Units 1 and 2 QAPD, the applicant states that LNP complies with the applicable regulatory guidance with exceptions as identified in the LNP COL FSAR Appendix AA, "Conformance with Regulatory Guides." These exceptions are:

   (a) This RG endorses the basic and supplementary requirements in ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants," and the ANSI/ASME NQA-1a-1983 Addenda along with the regulatory positions for the establishment and execution of QAPs during the design and construction phases of nuclear power plants. The LNP Units 1 and 2 QAPD provides adequate guidance for establishing a QAP that complies with Appendix B to 10 CFR Part 50 by using ASME NQA Standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance as clarified in Parts II, IV, and V of the LNP Units 1 and 2 QAPD. The staff has reviewed this exception and found it is acceptable on the basis that it is consistent with the SRP 17.5, the NEI 06-14A, Revision 7, guidance that has been previously reviewed and approved by the NRC staff (Refer to ADAMS Accession Number ML070510300), and with previous NRC-approved QAPD

changes for operating reactors (Refer to ADAMS Accession Number ML023440300).

4) RG 1.29, Revision 4, "Seismic Design Classification," issued March 2007. In the LNP Units 1 and 2 QAPD, the applicant states that LNP complies with the applicable regulatory guidance without exceptions as identified in as identified in the LNP COL FSAR Appendix AA, "Conformance with Regulatory Guides." The staff has reviewed the applicant's evaluation and found it is acceptable on the basis that it is consistent with the SRP 17.5, and the NEI 06-14A, Revision 7, guidance that has been previously reviewed and approved by the NRC staff (ADAMS Accession Number ML070510300).

5) RG 1.33, Revision 2, "Quality Assurance Program Requirements (Operations)," issued February 1978. In the LNP Units 1 and 2 QAPD, the applicant states that the applicant complies with the applicable regulatory guidance with clarification as identified in the LNP COL FSAR Appendix AA, "Conformance with Regulatory Guides." The applicant has chosen to follow the guidance provided in Section 3.2.3.1, "Alternative for Commitment to RG 1.33," of the staff's SER regarding the QAPD template (NEI 06-14, Revision 9) (ADAMS Accession Number ML101800497), which was subsequently incorporated into the NRC-approved NEI 06-14A, Revision 7, guidance (Refer to ADAMS Accession Number ML070510300). In addressing this issue, the applicant has revised Revision 6 of the LNP Unit 1 and 2 QAPD to add Section V, "Additional Quality Assurance and Administrative Controls for the Plant Operational Phase," to address the regulatory guidance of ANSI N18/7-1976/ANS-3.2.

   Consistent with the staff's SER on the QAPD template, the NRC staff requested that the applicant provide the information described Appendix 1 to NEI 06-14A, Revision 7, in addition to the incorporation Part V into the LNP Units 1 and 2 QAPD. By letter dated March 21, 2013, the applicant submitted the requested information described in Appendix 1 to NEI 06-14A. The staff reviewed the information and confirmed that each regulatory position in RG 1.33 was adequately addressed and specifically identified in the LNP Units 1 and 2 QAPD.

6) RG 1.37, Revision 1, "Quality Assurance Requirements for Cleaning Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants," issued March 2007. In the LNP Units 1 and 2 QAPD, the applicant states that LNP complies with the applicable regulatory guidance without exceptions as identified in LNP COL FSAR, Appendix AA, "Conformance with Regulatory Guides." The staff has reviewed the applicant's evaluation and found it is acceptable on the basis that it is consistent with the SRP 17.5, and the NEI 06-14A, Revision 7, guidance that has been previously reviewed and approved by the NRC staff (Refer to ADAMS Accession Number ML070510300).

7) RG 1.54, Revision 1, July 2000 - Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants. In the LNP Units 1 and 2 QAPD, the applicant states that LNP complies with the applicable regulatory guidance without exceptions as identified in LNP COL FSAR, Appendix AA, "Conformance with Regulatory Guides." The staff has reviewed the applicant's evaluation and found it is acceptable on the basis that it is consistent with the SRP 17.5, and the NEI 06-14A, Revision 7, guidance that has been

previously reviewed and approved by the NRC staff (ADAMS Accession Number ML070510300).

8) ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I, II, and III are described in Parts II and V of the LNP Units 1 and 2 QAPD. The staff has reviewed the applicable portions of the LNP Units 1 and 2 QAPD to confirm adequate incorporation of the guidance, and found it is acceptable on the basis that it is consistent with the SRP 17.5, and the NEI 06-14A, Revision 7, guidance that has been previously reviewed and approved by the NRC staff (Refer to ADAMS Accession Number ML070510300).

9) NIRMA technical guides, as described in Part II, Section 17 of the LNP Units 1 and 2 QAPD. The staff has reviewed the applicable portions of the LNP Units 1 and 2 QAPD to confirm adequate incorporation of the guidance, and found it is acceptable on the basis that it is consistent with the SRP 17.5, and the NEI 06-14A, Revision 7, guidance that has been previously reviewed and approved by the NRC staff (Refer to ADAMS Accession Number ML070510300).

17.5.4.21 *Additional Quality Assurance and Administrative Controls for the Plant Operational Phase*

The LNP Units 1 and 2 QAPD follows the guidance of Section 17.5 of NUREG-0800 for establishing quality and administrative controls for plant operation. Part V of the LNP Units 1 and 2 QAPD provides measures to assess the adequacy of review activities affecting safe plant operation. The LNP Units 1 and 2 QAPD provides a description of the on-site operational organization review program which includes measures for establishing an independent review program for activities occurring during the operational phase. The LNP Units 1 and 2 QAPD describes the independent review activities, establishes the scope of the independent review program, roles and responsibilities of the Operations Review Committee, and minimum qualifications for members of that committee.

The LNP Units 1 and 2 QAPD provides measures to establish and control operational phase procedures and follows the guidance in Appendix A to RG 1.33 in identifying the types of activities that should have procedures or instructions to control the activity. Each procedure shall be sufficiently detailed for a qualified individual to perform the required function without direct supervision, but need not provide a complete description of the system or plant process. The LNP Units 1 and 2 QAPD identified each type of procedure to be established, provides a description of the purpose for each type of procedure, and identifies the format and content requirements, as appropriate, for the development of plant operational procedures.

The LNP Units 1 and 2 QAPD provides measures to establish and control systems and equipment during the operational phase. Permission to release systems and equipment for maintenance or modification is controlled by designated operating personnel and documented. Measures, such as installation of tags or locks and releasing stored energy, are used to ensure personnel and equipment safety. Administrative procedures require the designated operating personnel to verify that the system or equipment can be released and determine the length of time it may be out of service. When systems or equipment are ready to be returned to service,

designated operating personnel control placing the items in service and document its functional acceptability. Independent verifications, where appropriate, are used to ensure that the necessary measures have been implemented correctly.

The LNP Units 1 and 2 QAPD provides measures to establish and control plant maintenance during the operational phase. The applicant establishes controls for the maintenance or modification of items and equipment subject to this QAPD to ensure quality at least equivalent to that specified in original design bases and requirements, such that safety-related structures, systems and components are maintained in a manner that assures its ability to perform its intended safety function(s).

Maintenance activities (both corrective and preventive) are scheduled and planned so as not to unnecessarily compromise the safety of the plant. In establishing controls for plant maintenance, the applicant commits to compliance with NQA-1-1994, Subpart 2.18, with the following clarifications:

- Where Subpart 2.18 refers to the requirements of ANS-3.2, it shall be interpreted to mean the applicable standards and requirements established within the QAPD.

- Section 2.3 requires cleanliness during maintenance to be in accordance with Subpart 2.1. The commitment to Subpart 2.1 is described in the QAPD, Part II, Section 13.2.

The staff has reviewed the description of the QA and administrative controls for plant operations contained in Part V, “Additional Quality Assurance and Administrative Controls for the Plant Operational Phase,” of the LNP Units 1 and 2 QAPD, and has confirmed that it provides an adequate description of the programmatic controls for the plant operational phase consistent with the guidance in RG 1.33, and the description provided in the previously NRC-approved QAPD template (ADAMS Accession Number ML101800497), and is, therefore, acceptable.

17.5.5 Post Combined License Activities

There are no post-COL activities related to this section.

17.5.6 Conclusion

The NRC staff used the requirements of 10 CFR Part 50, Appendix B and the guidance of Section 17.5 of NUREG-0800 as the basis for evaluating the acceptability of the LNP Units 1 and 2 QAPD and concludes that:

- The QAPD provides adequate guidance for the applicant to describe the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.

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

- The QAPD provides adequate guidance for the applicant to establish controls that, when properly implemented, comply with 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 LNP Units 1 and 2 QAPD addresses LNP 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, the staff concludes that Section 17.5 of the LNP COL FSAR and the LNP Units 1 and 2 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 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 staff in RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 2. 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 staff. NEI 07-02A provides a template for presenting this information that has also been endorsed by the staff in a letter to NEI, dated January 24, 2008.

17.6.2 Summary of Application

In Section 17.6 of the LNP COL FSAR, Revision 9, the applicant provided the following:

Supplemental Information

- STD SUP 17.6-1

The applicant provided additional information which incorporates, by reference, NEI 07-02A. The applicant also identified where operational programs are described in the LNP COL FSAR, including a description of and milestones for the MR program.

- STD SUP 17.6-2

The applicant provided additional information to incorporate condition monitoring of underground or inaccessible cables into the MR 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 MR 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 staff reviews this part of the application in accordance with Section 17.6 of NUREG-0800.

The regulatory basis of the information incorporated by reference is addressed in NUREG-1793 and its supplements. The NRC's Safety Evaluation for topical report NEI 07-02A includes additional regulatory information and was transmitted to NEI by letter, 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 [ITAAC]," identifies schedule requirements and proposes a license condition to be satisfied by COL holders.

17.6.4 Technical Evaluation

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 LNP Units 1 and 2 COL application, the staff undertook the following reviews:

- The staff compared the VEGP COL FSAR, Revision 5 to the LNP COL FSAR. In performing this comparison, the staff considered changes made to the LNP 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 staff has completed its review and found the evaluation performed for the standard content to be directly applicable to the LNP 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.

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 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 Office of New Reactors (NRO) 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 program has been fully implemented.

17.6.6 Conclusion

The NRC staff reviewed the application and confirmed that the applicant addressed the required information relating to the MR program. STD SUP 17.6-1 incorporated NEI 07-02A by reference; identified where operational programs are described in the LNP 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 inaccessible or

underground cables into the MR program. The staff concludes that the relevant information presented in Section 17.6 of the LNP COL FSAR meets the requirements of 10 CFR 50.65 and 10 CFR 52.79(a)(15) and is, therefore, acceptable.