

July 13, 2010

Mr. Russell J. Bell, Director
New Plant Licensing
Nuclear Generation Division
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington, DC 20006-3708

SUBJECT: FINAL SAFETY EVALUATION FOR TECHNICAL REPORT NEI 06-14,
"QUALITY ASSURANCE PROGRAM DESCRIPTION," REVISION 9

Dear Mr. Bell:

By letter dated February 19, 2010, the Nuclear Energy Institute (NEI) submitted Revision 8 to NEI 06-14 for staff review and approval. NEI 06-14 provides a Quality Assurance Program Description (QAPD) template for applicants of 10 CFR Part 52 permits or licenses to use in meeting the requirements of 10 CFR Parts 50 and 52. Revision 8 to NEI 06-14 was submitted to the U.S. Regulatory Commission (NRC) to address NRC comments made during a public meeting on December 11, 2009 and to provide an acceptable alternative for a commitment to Regulatory Guide (RG) 1.33, "Quality Assurance Program Requirements (Operation)," Revision 2, February 1978, in the QAPD. The NRC staff reviewed NEI 06-14, Revision 8, in accordance with the provisions of Section 17.5, "Quality Assurance Program Description-Design Certification, Early Site Permit and New License Applicants," of NUREG 0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants."

Based on the results of its review, the NRC staff held another public meeting on NEI 06-14 on April 27, 2010. The purpose of the meeting was to discuss the proposed changes to the QAPD template and its compliance with the applicable quality assurance requirements for the operations phase. By letter dated May 12, 2010, NEI submitted NEI 06-14, Revision 9, that incorporates NEI responses to NRC staff comments on NEI 06-14, Revision 8, provided in the April 27, 2010, public meeting.

The Quality and Vendor Branches have reviewed the NEI submittal and supporting documentation. On the basis of its review, the staff concludes that the QAPD template can be used by applicants of 10 CFR Part 52 permits or licenses, as applicable, for establishing a quality assurance program that complies with Appendix B to Title 10 of the *Code of Federal Regulations* 10 CFR Part 50 requirements.

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 06-14 to determine if the applicant adequately followed the guidance provided in the QAPD template and has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in SRP Section 17.5. Key areas that an applicant is required to address include:

- The organizational description addressed in Part II, Section 1 of NEI 06-14.
- Record retention criteria addressed in Part II, Section 17.1 of NEI 06-14.
- Regulatory commitments addressed in Part IV of NEI 06-14.

To ensure all quality assurance requirements for the operations phase are addressed, an applicant must either demonstrate that its QAPD has incorporated all of the administrative controls not included in ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," by explicitly addressing the provisions in NEI 06-14, Revision 9, Attachment 4, or otherwise by including a commitment to RG 1.33 in Part IV of the QAPD.

Enclosed is the NRC staff's SER which defines the basis for acceptance of NEI 06-14, Revision 9. The NRC staff finds that for COL applications, NEI 06-14, Revision 9, provides an acceptable template for describing a quality assurance program.

Our acceptance applies only to material provided in NEI 06-14, Revision 9. We do not intend to repeat our review of the acceptable material described in the NEI 06-14, Revision 9. When NEI 06-14, Revision 9 appears as a reference in COL applications, our review will ensure that the material presented applies to the specific application involved. Licensing requests that deviate from NEI 06-14, Revision 9, will be subject to a plant-specific or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that NEI publish the accepted version of NEI 06-14A, Revision 2 within 3 months of receipt of this letter. The accepted version should incorporate this letter and the enclosed SER. The accepted version should also contain historical review information, including NRC RAIs and your responses. The accepted versions shall include a "-A" (designating accepted) following the report identification symbol.

If future changes to the NRC's regulatory requirements affect the acceptability of NEI 06-14A, NEI will be expected to revise NEI 06-14A appropriately, or justify its continued applicability for subsequent referencing.

R. J. Bell

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If you have any questions, please contact Sheryl A. Burrows at (301) 415-6086 or via email at Sheryl.Burrows@nrc.gov.

Sincerely,

/RA/

William F. Burton, Chief
Rulemaking and Guidance Development Branch
Division of New Reactor Licensing
Office of New Reactors

Project No. 689

Enclosure:
Safety Evaluation Report

cc w/encl: See next page

R. J. Bell

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cc w/encl: See next page

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SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS

TECHNICAL REPORT NEI-06-14,

"QUALITY ASSURANCE PROGRAM DESCRIPTION" REVISION 9

1. INTRODUCTION

By letter dated October 19, 2006 (Ref. 1), the Nuclear Energy Institute (NEI) submitted an industry quality assurance program description (QAPD) template for review and approval by the U.S. Nuclear Regulatory Commission (NRC) staff. In its letter dated January 7, 2007, NEI revised the QAPD template in technical report NEI 06-14, "Quality Assurance Program Description," that provides a generic template for use by early site permit (ESP) and combined license (COL) applicants to implement NRC regulatory requirements related to quality assurance (QA) programs. NEI 06-14 is based on ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as supplemented by quality assurance and administrative control requirements specific to the operations phase. NEI 06-14 provides a common format for applicants when making commitments to comply with Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," (Appendix B), and 10 CFR Part 52 requirements.

The QAPD template was initially released in May 2008 as NEI 06-14A, Revision 0, the 'A' denoting NRC staff approval as documented by NRC safety evaluation dated April 25, 2007 (Ref. 4). Subsequent to issuance of NEI 06-14A, NEI submitted NEI 06-14, Revision 5 by letter dated May 7, 2008 (Ref. 9), to address generic QA program issues that had been identified during NRC staff review of COL applications. By letter dated June 24, 2008, NEI submitted NEI 06-14, Revision 7 (Ref. 12) and incorporated NEI responses to NRC Requests for Additional Information (RAI) dated April 30, 2009 (Ref. 10), and September 17, 2008 (Ref. 7). The NRC staff approved the use of NEI 06-14, Revision 7, in the safety evaluation dated September 16, 2009 (Ref. 13).

In response to the public meeting held on December 11, 2009, NEI submitted Revision 8, by letter dated February 19, 2010 (Ref. 14), to incorporate changes necessary to address operational conditions in accordance with American National Standards Institute (ANSI) N18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants" and Regulatory Guide (RG) 1.33 "Quality Assurance Program Requirements (Operation)," Revision 2, February 1978. By letter dated May 12, 2010 (Ref. 17), NEI submitted NEI 06-14, Revision 9, that incorporates NEI responses to NRC staff comments on NEI 06-14 provided in a public meeting conducted on April 27, 2010. This safety evaluation report documents the basis for the NRC staff's acceptance of NEI 06-14, Revision 9, as an acceptable basis for developing a QAPD that meets Appendix B to 10 CFR Part 50 requirements.

2. BACKGROUND

The QAPD template provides guidance for establishing a top-level policy document that defines Quality Assurance (QA) policy and assigns major QA program functional responsibilities. This QAPD template can be used for ESP, COL, construction, preoperational and/or operation activities, as applicable, affecting the quality and performance of safety-related SSCs.

The QAPD template includes brackets throughout the document to allow for user-specific text for statements that are scope dependent; are not applicable to COL applications with an approved ESP, or are applicable only to ESP applications. In addition, the QAPD template uses brackets to provide guidance to users on how to address areas that are specific to the application. Brackets are also used to provide the user with different alternatives that satisfy Appendix B to 10 CFR Part 50 requirements.

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 06-14 to determine if the applicant has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR Part 50, consistent with the criteria contained in SRP Section 17.5.

3. DISCUSSION AND EVALUATION

3.1 REGULATORY EVALUATION

The Commission's regulatory requirements related to quality assurance programs are set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." Appendix B establishes QA requirements for the design, fabrication, construction, and testing of the structures, systems and components (SSCs) of the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

10 CFR Part 52, Section 52.79 establishes the technical information requirements for COL applications. Section 52.79(a)(25) requires that COL applications provide a description of the QA program applied to the design, and to be applied to the fabrication, construction, and testing of the SSCs of the facility. Further, 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.

10 CFR Part 52, Section 52.17 establishes the technical information requirements for ESP applications. Section 52.17(a)(1)(xi) requires that ESP applications provide a description of the QA program applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site.

Finally, 10 CFR 52.79(a)(27) requires that the application contain information on the managerial and administrative controls to be used to assure safe operation consistent with Appendix B to 10 CFR Part 50 requirements and to include a discussion of how such requirements will be satisfied.

3.2 EVALUATION

In evaluating the adequacy of the QAPD template, the staff followed SRP 17.5 (Ref. 5), which provides guidance to NRC staff for evaluating QA program descriptions submitted under 10 CFR Part 52. SRP 17.5 is based on ASME NQA-1-1994; Regulatory Guide (RG) 1.8, "Qualification and Training of Personnel for Nuclear Power Plants," Revision 3; RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3; and RG 1.33, "Quality Assurance Program Requirements (Operation), Revision 2." An evaluation of conformance with these regulatory guides is included in Part IV of the QAPD template.

3.2.1 Organizational Description

The QAPD template provides guidance for applicants to describe functional responsibilities and position descriptions during the construction, preoperational and operations phases, as well as characterizing control and transitions between phases.

In addition, the QAPD template commits an applicant using it to the QA standards described in NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

Information in Part II, Section 1 of NEI 06-14, Revision 9, is applicant-specific and will be reviewed and approved by the NRC staff on a case-by-case basis.

3.2.2 Record Retention Criteria

The NRC staff will evaluate the adequacy of records retention times as applicant-specific information when an ESP or COL applicant submits their application. Regulatory position C.2 of RG 1.28, Revision 3 provides record retention times for lifetime and nonpermanent records. The QAPD template provides guidance to ESP and COL applicants to base record retention times on Regulatory Position C.2 and Table 1 of Regulatory Guide 1.28, Revision 3 or by including their specific table in the QAPD.

The QAPD template commits an applicant using it to complying with the quality standards described in NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the following clarification and exception:

- As an alternative to the NQA-1-1994, Supplement 17S-1, Section 4.2(b), requirements for records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers, the QAPD template proposes that hard 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. In a previous safety evaluation (Ref. 13), the staff determined that this proposed alternative is acceptable.

3.2.3 Regulatory Commitments

Commitments to NRC regulatory guides (RGs) identified in COL and ESP applications are listed in Chapter 1 of the Final Safety Analysis Report (FSAR). An applicant must specifically evaluate conformance to the following RGs related to an applicant's QA program. These RGs are typically identified in Chapter 1 of the FSAR and their inclusion is consistent with RG 1.206, section C.I.1.9:

- RG 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants," issued May 2000.
- 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.
- RG 1.28, Revision 3, "Quality Assurance Program Requirements (Design and Construction)," issued August 1985.

- RG 1.29, Revision 4, “Seismic Design Classification,” issued March 2007.
- RG 1.33, Revision 2, “Quality Assurance Program Requirements (Operations),” issued February 1978. (Exception to RG 1.33 see Section 3.2.3.1 of SER)
- 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.

Applicants using the template must address conformance to the RGs identified in Part IV of the QAPD template, in the bracketed text, by either including a commitment to the regulatory guides or by providing an alternative or exception to be reviewed for adequacy by the NRC staff. The NRC staff will review the adequacy of commitments to these RGs on an applicant-specific basis.

3.2.3.1 Alternative for Commitment to RG 1.33

RG 1.33, Revision 2, conditionally endorses ANSI N18.7-1976 as an acceptable method to the NRC staff for complying with the Commission's regulations with regard to the overall quality assurance program requirements for the operation phase of nuclear power plants. ANSI N18.7-1976 provisions for administrative controls during the operation phase of nuclear power plants are addressed in Part V of the NEI 06-14, Revision 9. Therefore, in order to satisfy Appendix B to Part 50 requirements during the operations phase, an applicant using the template must demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-1994 by either of the following methods:

- Explicitly addressing the provisions in NEI 06-14, Revision 9, Attachment 4 (Ref. 15), while also completing Part V of the QAPD template or,
- Including an explicit commitment to RG 1.33 in Part IV of the QAPD.

The NRC staff will review the adequacy of alternatives for commitment to RG 1.33 on an applicant-specific basis.

4. CONCLUSION

Based on its review of NEI 06-14, Revision 9, in accordance with the guidance of SRP 17.5, the NRC staff concludes that the QAPD template provides an acceptable format and adequate guidance for establishing a QA program that complies with Appendix B to 10 CFR Part 50. The QAPD template is based on ASME NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance applicable to administrative and quality controls during nuclear power plant operation. Accordingly, the staff concludes that the QAPD template can be used, by applicants of 10 CFR Part 52 permits or licenses, as applicable, for establishing a QA program description required by the provisions of 10 CFR 52.17(a)(1)(xi) for an ESP application and 10 CFR 52.79(a)(25) for a COL application.

When an applicant submits the QAPD as part of a licensing request, the staff will review applicant-specific information substituted for the bracketed text in NEI 06-14 to determine if the applicant adequately followed the guidance provided in the QAPD template and has established the necessary controls to comply with the applicable requirements of Appendix B to 10 CFR

Part 50, consistent with the acceptance criteria contained in SRP Section 17.5. Key areas that an applicant is required to address include:

- The organizational description addressed in Part II, Section 1 of NEI 06-14.
- Record retention criteria addressed in Part II, Section 17.1 of NEI 06-14.
- Regulatory commitments addressed in Part IV of NEI 06-14.

To ensure all quality assurance requirements for the operations phase are addressed, an applicant must either demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-1994 by explicitly addressing the provisions in NEI 06-14, Revision 9, Attachment 4 (Ref. 15), or otherwise by including a commitment to RG 1.33 in Part IV of the QAPD.

5. REFERENCES

1. Heymer, A. P., Nuclear Energy Institute, to the U.S. NRC, "NEI Technical Report on Template for an Industry Quality Program Description," October 19, 2006. (ADAMS Accession No. ML062990149)
2. Heymer, A. P., Nuclear Energy Institute, to the U.S. NRC, "NEI Technical Report 06-14, *Template for an Industry Quality Program Description*, Request for Additional Information (RAI) Responses," January 4, 2007. (ADAMS Accession No.:ML070470234)
3. Heymer, A. P., Nuclear Energy Institute, to the U.S. NRC, "NEI Technical Report 06-14, *Template for an Industry Quality Program Description*, Revision 3," February 13, 2007. (ADAMS Accession No: ML070600650)
4. U.S. NRC, Office of New Reactors, Final Safety Evaluation for Technical Report NEI 06-14, "Quality Assurance Program Description," April 25, 2007. (ADAMS Accession No. ML070510300)
5. NUREG-0800, "Standard Review Plan," Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," March 2007. (ADAMS Accession No. ML06310019)
6. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "NEI Technical Report 06-14, *Quality Assurance Program Description*, Revision 5," May 7, 2008. (ADAMS Accession No. ML081350560)
7. U.S. NRC, Office of New Reactors, to the NEI, "Request for Additional Information Regarding Nuclear Energy Institute Technical Report 06-14A, Quality Assurance Program Description, Revision 5," dated September 17, 2008, (ML0824607713,) and enclosure: Request for Additional Information Regarding the Nuclear Energy Institute Quality Assurance Program Description Topical Report No. NEI-06-14A, Revision 5. (ADAMS Accession No.: ML0824607831)
8. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "Response to September 17, 2008, Request for Additional Information on NEI 06-14A, Revision 5, "Quality Assurance Program Description," and "Revised NEI 06-14A for NRC Endorsement," dated

November 14, 2008. (ADAMS Accession No.: ML083380308)

9. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "Supplemental Response to NRC's September 17, 2008, Request for Additional Information on NEI 06-14A, *Quality Assurance Program Description*, Revision 5," November 20, 2008. (ADAMS Accession No. ML083380335)
10. U.S. NRC, Office of New Reactors, to the NEI, "Supplemental Request for Additional Information Regarding Nuclear Energy Institute Technical Report 06-14A, *Quality Assurance Program Description*, Revision 6," dated April 30, 2009. (ADAMS Accession No. ML091140483)
11. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "Response to April 30, 2009 Request for Additional Information on NEI 06-14A, Revision 6, *Quality Assurance Program Description*," dated June 12, 2009, (ADAMS Accession No. ML091800447) and enclosure: NEI response to NRC's Request for Additional Information Regarding the Nuclear Energy Institute *Quality Assurance Program Description* Topical Report No.: NEI-06-14A, Revision 5. (ADAMS Accession No.: ML091800448)
12. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "Submittal of NEI 06-14, Revision 7, *Quality Assurance Program Description*," dated June 24, 2009.
13. U.S. NRC, Office of New Reactors, Safety Evaluation of NEI 06-14, "Quality Assurance Program Description," Revision 7, September 16, 2009. (ADAMS Accession No.: ML092390016)
14. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "Submittal of NEI 06-14, Revision 8, *Quality Assurance Program Description*," dated February 19, 2010.
15. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "Submittal of NEI 06-14, Revision 8, *Quality Assurance Program Description*," dated February 19, 2010.
Attachment 4: Table of where RG 1.33 and ANSI N18.7-1976 requirements are addressed by NQA-1-1994 and/or NEI 06-14
16. U.S. NRC, Office of New Reactors, December 12, 2010 Summary of Meeting with Industry to Discuss Technical Report 06-14 "*Quality Assurance Program Description*" January 13, 2010: (ADAMS Accession No. ML100130690)
17. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, "Submittal of NEI 06-14, Revision 9, *Quality Assurance Program Description*," dated May 12, 2010.
18. U.S. NRC, Office of New Reactors, April 27, 2010 Summary of Meeting with Industry to Discuss Technical Report 06-14 "*Quality Assurance Program Description*" May 10, 2010. (ADAMS Accession No.: ML101270249)