

SAFETY EVALUATION OF THE
NUSCALE TOPICAL REPORT: QUALITY ASSURANCE PROGRAM
DESCRIPTION FOR DESIGN CERTIFICATION
OF THE NUSCALE SMALL MODULAR REACTOR
NP-TR-1010-859-NP, REVISION 3

1.0 INTRODUCTION

By letter dated May 8, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No ML120680132) (Ref. 1), the U.S. Nuclear Regulatory Commission (NRC or Commission) issued a Final Safety Evaluation, concluding that Revision 1 of the NuScale Power, LLC (NuScale) Topical Report, "Quality Assurance Program Description for Design Certification of the NuScale Power Reactor," complies with the applicable NRC regulations and industry standards. By letter and enclosures dated May 20, 2015 (ADAMS Accession Numbers ML15142A469, ML15142A470, and ML15142A471) (Ref. 2, 3, and 4, respectively), NuScale submitted Revision 2 of the NuScale Topical Report, "Quality Assurance Program Description for Design Certification of the NuScale Power Plant" (NuScale QAPD) for the NRC staff's review. By e-mail dated December 8, 2015 (ADAMS Accession No. ML15342A445) (Ref. 5), the NRC transmitted a request for additional information (RAI). By letter dated February 4, 2016 (ADAMS Accession No. ML16035A524) (Ref. 6), NuScale responded to the NRC's RAI with a redline version of the QAPD Revision 3, showing the changes resulting from the RAI and other editorial corrections. By letter dated March 24, 2016 (ADAMS Accession No. ML16084B004) (Ref. 7), NuScale provided a clean version of the QAPD Revision 3, which incorporates the redline changes submitted as part of NuScale's RAI response.

2.0 REGULATORY BASIS

The Commission's regulatory requirements related to quality assurance (QA) programs for design certification applications are set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) 52.47(a)(19) (Ref. 8).

Under 10 CFR 52.47(a), a design certification application must contain information in a final safety analysis report that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components (SSCs) of the facility as a whole. In addition, 10 CFR 52.47(a)(19) states that the final safety analysis report must include a description of the QA Program (QAP) to be applied to the design of the SSCs of the facility and requires that the description of the QAP for a nuclear power plant discuss how the QAP will satisfy the applicable requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (Ref. 9).

In Appendix B to 10 CFR Part 50, the NRC established QA requirements for the design, fabrication, construction, and testing of 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 SSCs.

3.0 EVALUATION

NuScale's QAPD, NP-TR-1010-859-NP, Revision 3, includes (1) changes in the organization and titles of positions of NuScale Power Corporation, along with some corrections and other editorial changes throughout the document; and (2) noneditorial revisions to QAPD Sections 2.4.1, 2.7.2, 2.8, 2.9, 2.10, 2.11, 2.12, 2.13, 2.14, and 3.1.

The NRC staff's evaluation of NuScale QAPD Revision 3 followed the guidance contained in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP), Section 17.5, Revision 1, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," issued August 2015 (ADAMS Accession No. ML15037A441) (Ref. 10). The SRP provides acceptance criteria for QAP descriptions for applicants for a design certification.

3.1 Organization/Title/Editorial Changes and Corrections

The NRC staff determined that NuScale QAPD, NP-TR-1010-859-NP, Revision 3, continues to meet the requirements of Appendix B to 10 CFR Part 50. Specifically, the staff concluded that the revised NuScale QAPD continues to ensure that persons and organizations performing QA functions have the required authority and organizational freedom, and remain sufficiently independent from cost and schedule when opposed to safety considerations. The other changes were minor and grammatical or editorial in nature.

3.2 Revision of NuScale QAPD Procurement Document Control, Section 2.4.1 "NQA-1-2008 Commitment/Exceptions"

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Procurement Document Control, Section 2.4.1, "NQA-1-2008 Commitment/Exceptions," to (1) allow services performed by a supplier to be performed under the NuScale QAP, including implementing procedures, in lieu of the supplier having its own QAP, and (2) specify that procurement documents of commercial-grade items NuScale procured for use as safety-related items must contain technical and quality requirements so the procured item can be dedicated in accordance with the NuScale QAPD, Section 7, "Control of Purchased Material, Equipment and Services."

The NRC staff reviewed the NuScale QAPD, using the guidance of SRP Section 17.5, paragraph II.D, for establishing the necessary administrative controls and processes to ensure that procurement documents include or reference the applicable regulatory, technical, and QA program requirements.

With regard to service performed by a supplier, NuScale revised its procurement documents to allow the supplier to work under the NuScale QAP, including implementing procedures, in lieu of the supplier having its own QAP. The NRC staff determined this clarification to be acceptable because it meets the acceptance criteria in SRP Section 17.5, paragraph II.D.2.d, and, therefore, satisfies the requirements of Criterion IV of Appendix B to 10 CFR Part 50.

With regard to specifying that procurement documents for commercial-grade items that NuScale will procure for use as safety-related items must contain technical and quality requirements so the procured item can be appropriately dedicated in accordance with the NuScale QAPD, Section 7, the NRC staff determined that this alternative is consistent with SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d, and staff guidance in the following generic letters (GLs):

- GL 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989 (Ref. 11)
- GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (Ref. 12)

3.3 Revision of NuScale QAPD Control of Purchased Material, Equipment, and Services, Section 2.7.2, "NQA-1-2008 and NQA-1a-2009 Commitment/Exceptions"

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Control of Purchased Material, Equipment, and Services, Section 2.7.2, "NQA-1-2008 and NQA-1a-2009 Commitment/Exceptions," to use Nuclear Energy Institute (NEI) 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1. NEI 14-05, Revision 1, provides a method by which NuScale can use laboratory accreditation by accreditation bodies that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (hereafter referred to as the ILAC accreditation process) in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC accreditation process.

The NRC staff reviewed the NuScale QAPD, using the guidance of SRP Section 17.5, paragraph II.L.8, for the procurement of commercial-grade calibration and testing services for safety-related applications for establishing the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QA program requirements are included. The NRC staff reviewed the NuScale QAPD to ensure the conditions specified in NEI 14-05 were met and to determine that the NRC's safety evaluation for NEI 14-05 (ADAMS Accession No. ML14322A535) (Ref. 13) was applicable to the NuScale QAPD.

The NRC staff determined that the provisions of this exception are consistent with the regulatory guidance provided in SRP Section 17.5, paragraph II.L.8, for the procurement of commercial-grade calibration services for safety-related applications, meet the conditions specified in NEI 14-05, and are acceptable as documented in the NRC's previous safety evaluation for NEI 14-05.

3.4 Revision of NuScale QAPD Section 2.8, "Identification and Control of Materials, Parts, and Components"

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Section 2.8, "Identification and Control of Materials Parts, and Components," to be applicable to NuScale and follow the guidance of SRP Section 17.5, paragraph II.H, for establishing the necessary measures and governing procedures for the identification and control of items such as materials, including consumables and items with limited shelf life, parts, components, and partially fabricated subassemblies. Identification of such items is maintained throughout fabrication, erection, installation, and use so that the item is traceable to its documentation.

The NuScale QAPD commits to implement the quality standards described in Requirement 8, Sections 100 through 300, of NQA-1-2008, "Quality Assurance Program Requirements for Nuclear Facilities" (with 2009 Addenda), dated March 14, 2008 (Ref. 14), with the clarification that the necessary measures and governing procedures shall be established before initiating the activities defined in this section.

The NRC staff determined that the NuScale QAPD with the included clarification is consistent with the acceptance criteria provided in SRP Section 17.5, paragraph II.H, because it commits to implementing the quality standards described in NQA-1-2008, Requirement 8, Sections 100 through 300, with the clarification, before initiating activities requiring these controls. Therefore, it satisfies the requirements of Criterion VIII of Appendix B to 10 CFR Part 50.

3.5 Revision of NuScale QAPD Section 2.9, "Control of Special Processes"

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Section 2.9, "Control of Special Processes," to be applicable to NuScale and follow the guidance of SRP Section 17.5, paragraph II.I, for establishing and implementing 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 controlled in accordance with applicable codes, specifications, and standards for the specific application.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 9, Sections 100 through 400, with the clarification that the necessary measures and governing procedures shall be established before initiating activities defined in this section.

The NRC staff determined that the NuScale QAPD with the included clarification is consistent with the acceptance criteria provided in SRP Section 17.5, paragraph II.I, because it commits to implementing the quality standards described in NQA-1-2008, Requirement 9, Sections 100 through 400, with the clarification, before initiating activities requiring these controls. Therefore, it satisfies the requirements of Criterion IX of Appendix B to 10 CFR Part 50.

3.6 Revision of NuScale QAPD Section 2.10, "Inspection"

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Section 2.10, "Inspection," from being applicable to only suppliers to being applicable to both suppliers and NuScale. The NuScale QAPD follows the guidance of SRP Section 17.5, paragraph II.J, for establishing the necessary measures and governing procedures to ensure that inspection of activities affecting quality (i.e., source, in-process, final, receipt, maintenance, modification, inservice, and operations) is established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Properly qualified persons independent of those who performed or directly supervised the work will carry out and document the inspections.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 10, Sections 100 through 800, with no exceptions or clarifications.

The NRC staff determined that the NuScale QAPD is consistent with the acceptance criteria provided in SRP Section 17.5, paragraph II.J, because it commits to implementing the quality standards described in NQA-1-2008, Requirement 10, Sections 100 through 800, with no

exceptions or clarifications. Therefore, it satisfies the requirements of Criterion X of Appendix B to 10 CFR Part 50.

3.7 Revision of NuScale QAPD Section 2.11, “Test Control”

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Section 2.11, “Test Control,” from being applicable only to computer software testing and suppliers to being applicable to computer software testing, nonsoftware testing, for both suppliers and NuScale. The NuScale QAPD follows the guidance of SRP Section 17.5, paragraph II.K, for establishing the necessary measures and governing procedures to ensure that qualified personnel identify and perform all testing required to demonstrate that SSCs will perform satisfactorily in service in accordance with written test procedures that incorporate the requirements and acceptance limits contained in applicable design documents.

In establishing provisions to ensure that qualified personnel prepare, document, verify, test, and use the computer software used in applications affecting safety such that the expected outputs are obtained and configuration control maintained, the NuScale QAPD commits to implement the quality standards described in NQA-1a-2009 Addenda, Requirement 11, Section 400, and NQA-1a-2009 Addenda, Subpart 2.7, without clarifications or exception.

For nonsoftware testing, the NuScale QAPD commits to implement the quality standards described in NQA-1a-2009 Addenda, Requirement 11, Sections 100 through 300 and Sections 500 through 602, with no exceptions or clarifications.

The NRC staff determined that the NuScale QAPD is consistent with the acceptance criteria provided in SRP Section 17.5, paragraph II.K, because it commits to implementing the quality standards described in NQA-1a-2009, Requirement 11, Sections 100 through 602, and NQA-1a-2009 Addenda, Subpart 2.7, with no exceptions or clarifications. Therefore, it satisfies the requirements of Criterion XI of Appendix B to 10 CFR Part 50.

3.8 Revision of NuScale QAPD Section 2.12, “Control of Measuring and Test Equipment”

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Section 2.12, “Control of Measuring and Test Equipment,” from being applicable only to suppliers to being applicable to both suppliers and NuScale. The NuScale QAPD follows the guidance of SRP Section 17.5, paragraph II.L, for establishing the necessary measures and governing procedures to ensure that qualified personnel properly control, calibrate, and adjust tools, gages, instruments, and other measuring and testing devices used in quality-affecting activities at specified periods to maintain accuracy within necessary limits.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 12, Sections 100 through 400, with the clarification that the calibration conditions described in Section 303.2 refer to cases when the measuring and test equipment is found to be out of the required accuracy limits (i.e., out of tolerance) during calibration.

The NRC staff determined that the NuScale QAPD is consistent with the acceptance criteria provided in SRP Section 17.5, paragraph II.L, because it commits to implementing the quality standards described in NQA-1-2008, Requirement 12, Sections 100 through 400. In its safety evaluation for Revision 1 of the QAPD, the NRC staff determined that the clarification that the calibration conditions described in Section 303.2 refer to cases when the measuring and test

equipment is found to be out of the required accuracy limits (i.e., out of tolerance) during calibration is consistent with the overall objective of NQA-1-2008, Requirement 12. Therefore it satisfies the requirements of Criterion XII of Appendix B to 10 CFR Part 50.

3.9 Revision of NuScale QAPD Section 2.13, "Handling Shipping and Storage"

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Section 2.13, "Handling Shipping and Storage," to be applicable to NuScale and follow the guidance of SRP Section 17.5, paragraph II.M, for establishing necessary measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 13, with the clarification that the necessary measures and governing procedures shall be established before initiating activities defined in this section.

The NRC staff determined that the NuScale QAPD with the clarification is consistent with the acceptance criteria provided in SRP Section 17.5, paragraph II.M, because it commits to implementing the quality standards described in NQA-1-2008, Requirement 13, with the clarification, before initiating activities requiring these controls. Therefore, it satisfies the requirements of Criterion XIII of Appendix B to 10 CFR Part 50.

3.10 Revision of NuScale QAPD Section 2.14, "Inspections, Test, and Operating Status"

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Section 2.14, "Inspections, Test, and Operating Status," to be applicable to NuScale and follow the guidance of SRP Section 17.5, paragraph II.N, for establishing necessary measures to identify the inspection, test, and operating status of items and components within the scope of the QAPD to maintain personnel and reactor safety and avert inadvertent operation of equipment.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 14, Section 100, with the clarification that the necessary measures and governing procedures shall be established before initiating activities defined in this section.

The NRC staff determined that the NuScale QAPD with the clarification is consistent with the acceptance criteria provided in SRP Section 17.5, paragraph II.N, because it commits to implementing the quality standards described in NQA-1-2008, Requirement 14, with the clarification, before initiating activities requiring these controls. Therefore, it satisfies the requirements of Criterion XIV of Appendix B to 10 CFR Part 50.

3.11 Revision of NuScale QAPD Section 3.1, "Nonsafety-Related Structures, Systems, and, Components—Significant Contributors to Plant Safety"

NuScale revised QAPD, NP-TR-1010-859-NP, Revision 3, Section 3.1, "Nonsafety-Related Structures, Systems, and, Components—Significant Contributors to Plant Safety," to add requirements for "Identification and Control of Purchased Items," "Control of Special Processes," "Inspection," "Test Control," "Control of Measuring and Test Equipment," "Handling Shipping and Storage," and "Inspection, Test and Operating Status." The NuScale QAPD follows the acceptance criteria of SRP Section 17.5, paragraph II.U.1, for establishing specific program controls to be applied to nonsafety-related SSCs that are significant contributors to plant safety but for which Appendix B to 10 CFR Part 50 is not applicable.

The approach, as described in the NuScale QAPD, is consistent with the SRP section 17.5, paragraph II.U.1, therefore the NRC staff determined it is acceptable.

4.0 CONCLUSION

The NRC staff used the acceptance criteria of NUREG-0800, Section 17.5, as the basis for evaluating the acceptability of NuScale's QAPD, NP-TR-1010-859-NP, Revision 3, for conformance with the applicable requirements of Appendix B to 10 CFR Part 50. The NRC staff concludes that NuScale's QAPD, NP-TR-1010-859-NP, Revision 3, follows the NRC guidance contained within and conforms to the format of NUREG-0800, Section 17.5; complies with Appendix B to 10 CFR Part 50 requirements for the QA program; and is therefore acceptable.

1.0 REFERENCES

1. "Final Safety Evaluation Report Regarding the Review of NuScale Topical Report NP-TR-1010-859-NP, Revision 1, 'Quality Assurance Program Description for Design Certification of the NuScale Power Reactor,'" U.S. Nuclear Regulatory Commission, dated May 8, 2012 (ADAMS Accession No. ML120680132).
2. Letter from Zackary Rad, NuScale Power, LLC., to the NRC Document Control Desk, "NuScale Power, LLC Submittal of Revision 2 to NuScale Power, LLC, Quality Assurance Program Description (QAPD) (NRC Project No. 0769)," dated May 20, 2015 (ADAMS Accession No. ML15142A469).
3. Enclosure 2 of letter from Zackary Rad, NuScale Power, LLC., to the NRC Document Control Desk, "NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant," (QAPD) Revision 2 (ADAMS Accession Numbers ML15142A470)
4. Enclosure 1 of letter from Zackary Rad, NuScale Power, LLC., to the NRC Document Control Desk, "NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant," (QAPD) Revision 2, Redline version (ADAMS Accession Numbers ML15142A471)
5. Letter from Gregory Cranston, U.S. Nuclear Regulatory Commission, to Thomas Bergman, NuScale Power, "Request for Additional Information Letter No. 02 for The Review of NuScale Topical Report, NP-TR-1010-859-NP, Revision 2, 'Quality Assurance Program Description for Design Certification of the NuScale Power Reactor' (TAC No. RN6330)," dated December 8, 2015 (ADAMS Accession No. ML15342A445).
6. Letter from Zackary Rad, NuScale Power, LLC., to the NRC Document Control Desk, "NuScale Power, LLC Submittal of Response to Request for Additional Information Letter No. 02 for the Review of "NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant," NP-TR-1010-859-NP, Revision 2 (TAC No. RN6330)," dated February 4, 2016 (ADAMS Accession No. ML16035A524).
7. Letter from Thomas Bergman, NuScale Power, LLC., to the NRC Document Control Desk, "NuScale Power, LLC Submittal of Revision 3 to NuScale Topical Report: Quality

Assurance Program Description for the NuScale Power Plant (TAC No. RN6330),” dated March 24, 2016 (ADAMS Accession No. ML16084B004).

8. *Code of Federal Regulations*, Title 10, *Energy*, Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.”
9. *Code of Federal Regulations*, Title 10, *Energy*, Part 50, “Domestic Licensing of Production and Utilization Facilities.”
10. NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” Section 17.5, Revision 1, “Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants,” U.S. Nuclear Regulatory Commission, August 2015 (ADAMS Accession No. ML15037A441).
11. Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products,” U.S. Nuclear Regulatory Commission, March 21, 1989.
12. Generic Letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs,” U.S. Nuclear Regulatory Commission, April 9, 1991.
13. “Final Safety Evaluation for Technical Report NEI 14-05, ‘Guidelines for the Use of Accreditation in lieu of Commercial Grade Survey for Procurement of Laboratory Calibration and Test Services,’ Revision 1,” U.S. Nuclear Regulatory Commission, February 9, 2015 (ADAMS Accession No. ML14322A535).
14. NQA-1-2008, “Quality Assurance Program Requirements for Nuclear Facilities” (with 2009 Addenda), American Society of Mechanical Engineers, New York, NY, March 4, 2008.