

May 8, 2012

Mr. Edward Wallace, Senior Vice President
Regulatory Affairs
NuScale Power, LLC
1100 NE Circle Blvd, Suite 350
Corvallis, OR 97330

SUBJECT: FINAL SAFETY EVALUATION 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" (TAC NO. RX6242)

Dear Mr. Wallace:

By letter dated October 29, 2010, NuScale Power, Inc. (NuScale) submitted topical report (TR) NP-TR-1010-859-NP, Revision 0, "Quality Assurance Program Description for Design Certification of the NuScale Power Reactor," for U.S. Nuclear Regulatory Commission (NRC) staff review (Agencywide Documents Access and Management System (ADAMS) ML103210264). The topical report was submitted in accordance with the guidance of NUREG-0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description-Design Certification, Early Site Permit and New License Applicants."

By letter dated March 7, 2011 (ADAMS ML110670208), NuScale responded to the NRC staff's request for additional information (RAI) (ADAMS ML110410508). By letter dated September 16, 2011, NuScale provided responses (ADAMS ML112620083) to a second set of RAIs. By letter dated December 15, 2011, NuScale provided Revision 1 of Topical Report (TR) NP-TR-1010-859-NP (ADAMS ML120370093). By letter dated February 9, 2012, an NRC draft safety evaluation (SE) regarding our approval of NP-TR-1010-859-NP, Revision 1, was provided for you to identify any proprietary information and to clarify any factual inaccuracies (ADAMS ML120340493). By letter dated February 21, 2011, NuScale identified a document referenced inaccurately in the draft SE (ADAMS ML12053A030). The NRC staff has corrected the document reference in the final SE enclosed with this letter.

On the basis of its review, the NRC staff concludes that Revision 1 of the NuScale Quality Assurance Program (QAP) TR for the Design Certification of the NuScale Power Reactor, as documented in the referenced letters, adequately describes the NuScale QAP. Accordingly, the NRC staff finds that the NuScale QAP complies with the applicable NRC regulations and industry standards.

The enclosed SE defines the basis for acceptance of the TR. Our acceptance applies only to material provided and we do not intend to repeat our review of the acceptable material described in the TR. When the TR appears as a reference in regulatory applications, our review will ensure that the material presented applies to the specific application involved.

Licensing requests that deviate from this TR will be subject to a plant- or site-specific review in accordance with applicable review standards.

We request that NuScale publish the accepted version of this TR within 3 months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE after the title page. Also, the accepted version must contain historical review information, including NRC requests for additional information and your responses after the title page. The accepted versions shall include a "-A" (designating accepted) following the TR identification symbol.

As an alternative to including the RAIs and RAI responses behind the title page, if changes to the TR were provided to the NRC staff to support the resolution of RAI responses, and the NRC staff reviewed and approved those changes as described in the RAI responses, there are two ways that the accepted version can capture the RAIs:

1. The RAIs and RAI responses can be included as an Appendix to the accepted version.
2. The RAIs and RAI responses can be captured in the form of a table (inserted after the final SE) which summarizes the changes as shown in the approved version of the TR. The table should reference the specific RAIs and RAI responses which resulted in any changes, as shown in the accepted version of the TR.

If future changes to the NRC's regulatory requirements affect the acceptability of this TR, NuScale and/or licensee's referencing it will be expected to revise the TR appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact Greg Cranston at (301) 415-0546 or Mike Jones at (301) 415-0189.

Sincerely,

/RA/

Michael E. Mayfield, Director
Division of Advanced Reactors and Rulemaking
Office of New Reactors

Project No.: 0769

Enclosure:
Final Safety Evaluation

Licensing requests that deviate from this TR will be subject to a plant- or site-specific review in accordance with applicable review standards.

We request that NuScale publish the accepted version of this TR within 3 months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE after the title page. Also, the accepted version must contain historical review information, including NRC requests for additional information and your responses after the title page. The accepted versions shall include a "-A" (designating accepted) following the TR identification symbol.

As an alternative to including the RAIs and RAI responses behind the title page, if changes to the TR were provided to the NRC staff to support the resolution of RAI responses, and the NRC staff reviewed and approved those changes as described in the RAI responses, there are two ways that the accepted version can capture the RAIs:

1. The RAIs and RAI responses can be included as an Appendix to the accepted version.
2. The RAIs and RAI responses can be captured in the form of a table (inserted after the final SE) which summarizes the changes as shown in the approved version of the TR. The table should reference the specific RAIs and RAI responses which resulted in any changes, as shown in the accepted version of the TR.

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If you have any questions, please contact Greg Cranston at (301) 415-0546 or Mike Jones at (301) 415-0189.

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/RA/

Michael E. Mayfield, Director
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 Office of New Reactors

Project No.: 0769

Enclosure:
 Final Safety Evaluation

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NAME	GCranston	MVaaler (Kkavanagh for)	KKavanagh	SMagruder	SVrahoretis	MMayfield
DATE	03/8/2012	03/8/2012	03/8/2012	05/1/2012	04/26/2012	05/8/2012

FINAL SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS

REGARDING THE NUSCALE TOPICAL REPORT

NP-TR-1010-859-NP, REVISION 1, "QUALITY ASSURANCE PROGRAM DESCRIPTION

FOR DESIGN CERTIFICATION OF THE NUSCALE POWER REACTOR"

PROJECT NO.: PROJ0769

1.0 INTRODUCTION

By letter dated October 29, 2010 (Reference 1), NuScale Power, LLC, (NuScale), submitted for U.S. Nuclear Regulatory Commission (NRC, the Commission) staff review Topical Report NP-TR-1010-859-NP, Revision 0, "Quality Assurance Program Description for Design Certification of the NuScale Power Reactor," in accordance with the guidance of NUREG-0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants" (Reference 2). By letter dated March 7, 2011, NuScale responded to the NRC staff's request for additional information and provided Revision 1 of Topical Report NP-TR-1010-859-NP (Reference 3). By letter dated September 16, 2011 (Reference 4), NuScale provided additional responses to a second set of requests for additional information from the NRC staff. In addition, by letter dated December 15, 2011 (Reference 5), NuScale submitted Revision 1 of Topical Report NP-TR-1010-859-NP, incorporating updates to the "Organization" section of the document in order to reflect the recent corporate restructuring of NuScale Power, Inc.

The NuScale Quality Assurance Program Description (QAPD) topical report addresses the activities associated with the Design Certification (DC) of a NuScale Power Reactor. The QAPD is based on the applicable portions of both Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations*, Part 50 (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities," and American Society of Mechanical Engineers (ASME) NQA-1-2008, "Quality Assurance Program Requirements for Nuclear Facilities," with NQA-1a-2009 Addenda (Reference 6), as endorsed by NRC Regulatory Guide (RG) 1.28, Revision 4, "Quality Assurance Program Criteria (Design and Construction)" (Reference 7), relevant to the NuScale Power Reactor DC project.

2.0 REGULATORY EVALUATION

The Commission's regulatory requirements related to quality assurance programs are set forth in 10 CFR 52.47(a)(19) and Appendix B to 10 CFR 50 (Appendix B).

10 CFR 52.47(a) requires that a DC application contain the technically relevant information in a final safety analysis report (FSAR) 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) and of the facility as a whole. 10 CFR 52.47(a)(19) states that the FSAR must include a description of the quality assurance program to be applied to the design of the

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SSCs of the facility. 10 CFR 52.47(a)(19) further requires that the description of the quality assurance program for a nuclear power plant include a discussion of how the applicable requirements of Appendix B will be satisfied.

Appendix B establishes quality assurance requirements for the design, fabrication, construction, and testing of SSCs for 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

In evaluating the adequacy of the NuScale QAPD, the NRC staff utilized the guidance contained in NUREG-0800 (SRP), Section 17.5, which provides an outline of an acceptable quality assurance program template for design certification, early site permit, combined operating license, construction permit, and operating license applicants. Section 17.5 of the SRP is based on ASME standard NQA-1-1994 Edition, as supplemented by additional regulatory and industry guidance for nuclear operating facilities. ASME standard NQA-1-2008 and the NQA-1a-2009 Addenda, upon which the NuScale QAPD is based, incorporates the supplemental guidance into a single document, and is therefore in alignment with Section 17.5 of the SRP. In addition, NQA-1-2008 and the NQA-1a-2009 Addenda are endorsed by NRC Regulatory Guide 1.28, Revision 4.

3.1 Quality Assurance Program Overview

Topical Report NP-TR-1010-859-NP, Revision 1, provides for the control of NuScale activities affecting the quality and performance of SSCs related to the design certification of the NuScale Power Reactor.

3.1.1 Organization

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.A, for providing an organizational description that includes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying NuScale quality assurance program implementation. The NuScale QAPD establishes independence between the organization performing checking functions related to the QAP and the organization responsible for performing the function. In addition, the NuScale QAPD provides for applicable management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. Finally, responsibility and authority for planning, establishing, and implementing an effective overall quality assurance program are clearly described and defined.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 1, Sections 100 through 300, without further clarifications or exceptions.

3.1.2 Quality Assurance Program

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.B, for establishing the necessary measures to implement a quality assurance program in order to ensure that the design of the NuScale Power Reactor is in accordance with governing regulations and license

requirements. The quality assurance program applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design of the NuScale Power Reactor, and to the managerial and administrative controls to be used to assure the NuScale Power Reactor design complies with applicable regulatory requirements. Examples of design certification program safety-related activities include, but are not limited to, basic, applied, and developmental research; determination of SSC safety class; design configuration management; and document control.

A list or system identifying the SSCs and activities to which the NuScale QAPD applies is maintained for the design certification project. NuScale may delegate all or part of the activities for which they are responsible to others, but retains overall responsibility for quality assurance program effectiveness. The NuScale QAPD provides for measures to assess the adequacy of the quality assurance program and to ensure its effective implementation, at least once each year or at least once during the life of the activity, whichever is shorter. In addition, consistent with SRP Section 17.5, Paragraph II.B.8, the NuScale quality assurance program applies a grace period of 90 days to activities that must be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backwards by performing the activity early.

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the quality assurance program to assure that suitable proficiency is achieved and maintained. The NuScale QAPD provides the minimum training requirements for all personnel responsible for implementation of the NuScale quality assurance program.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 2, Sections 100 through 500, without further clarifications or exceptions.

3.1.3 Design Control

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.C.1, for establishing the necessary measures to control the design, design verification, and analysis activities of safety-related items and services that are subject to the provisions of the QAPD. The NuScale quality assurance program design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces. These provisions ensure that the design inputs (such as design bases, performance and regulatory requirements, and codes and standards) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions). In addition, the NuScale QAPD provides for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary quality assurance requirements.

Consistent with SRP Section 17.5, Paragraph II.C.2, the NuScale design processes provide for design verification to ensure that items and activities subject to the provisions of the quality assurance program are suitable for their intended application and consistent with their effect on safety. Design changes are subject to these controls, which include verification measures commensurate with those applied to original plant design. The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with

previously proven designs. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing.

The NuScale QAPD governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. NuScale and its suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The QAPD states that the procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, and NQA-1a-2009 Addenda, Requirement 3, Sections 100 through 900, as well as the standards for computer software contained in NQA-1-2008, and NQA-1a-2009 Addenda, Subpart 2.7, without further clarifications or exceptions.

3.1.4 Procurement Document Control

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.D, for establishing the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QA program requirements are included or referenced in procurement documents.

Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, "Reporting of Defects and Noncompliance" (10 CFR 21)) are invoked for the procurement of items and services.

To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of Appendix B, as appropriate to the circumstances of procurement (or the supplier may work under the NuScale approved QA program). The scope of procurement includes engineering, design, and testing services, as well as the procurement of safety-related software. No equipment or components are being procured as part of the NuScale Power Reactor design certification project.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 4, Sections 100 through 400, with the following exception:

- As an alternative to NQA-1-2008, Requirement 4, Section 300, which requires procurement documents to be reviewed before award of the contract, the NuScale QAPD proposes to conduct the QA review of procurement documents through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to bid or award of contract. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive a QA review.

The NRC staff evaluated this proposed alternative and determined that it provides for adequate QA review of procurement documents and the associated requirements before awarding the contract and after any change, which is consistent with the intent of NQA-1-2008, Requirement 4, Section 300, and Criterion IV of Appendix B. Therefore, the NRC staff concluded that this alternative is acceptable.

3.1.5 Instructions, Procedures, and Drawings

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAPD.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 5, Section 100, without further clarifications or exceptions.

3.1.6 Document Control

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.F, for establishing the necessary measures and governing procedures to control the preparation, review, approval, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled. Measures are provided to assure that documents, including revisions or changes (other than those defined in implementing procedures as minor changes), are reviewed and approved by the same organization that performed the original review and approval, unless other organizations are specifically designated. A list of all controlled documents, identifying the current approved revision or date, is maintained so personnel can determine the appropriate document for use.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 6, Sections 100 through 300, without further clarifications or exceptions.

3.1.7 Control of Purchased Material, Equipment, and Services

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The program provides measures for source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services. The QAPD establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity, and frequency of procurement.

The NuScale QAPD provides measures for evaluating prospective suppliers and selecting only qualified suppliers, as well as auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services. The scope of procurement includes engineering, design and testing services, as well as the procurement of safety-related software. No equipment or components are being procured as part of the NuScale Power Reactor design certification project. Therefore, the controls associated with this section of the NuScale QAPD are limited to the control of applicable services.

The NuScale QAPD also outlines acceptance actions, such as source verification, receipt inspection, certificates of conformance, and review of documentation

(e.g., Certified Material Test Reports/Certificates) to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, and NQA-1a-2009 Addenda, Requirement 7, Sections 100 through 800, with the following clarifications and exceptions:

- The NuScale QAPD proposes that other 10 CFR 50 licensees, 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 NuScale during the design certification phase are not be required to be evaluated or audited.

The NRC staff acknowledges that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the NIST, and other State and Federal agencies perform work under acceptable quality programs, and no additional audit or evaluation is required. The NRC staff determined that this exception is acceptable as documented in a letter to the Edwin Hatch Nuclear Power Station on March 20, 2000 (Reference 8).

However, NuScale is still responsible for ensuring that the items or services procured conform to the applicable Appendix B criteria, ASME Boiler and Pressure Vessel Code requirements, and other regulatory requirements and commitments. NuScale is also responsible for ensuring that procured items or services are suitable for the intended application, as well as for documenting the associated evaluation. To this extent and on this basis, the NRC staff finds the proposed exception acceptable.

- The NuScale QAPD includes provisions 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 from a calibration laboratory. The NuScale QAPD proposes not to require procurement source evaluation and selection measures provided each of the following conditions are met:
 - a. Purchase documents impose additional technical and administrative requirements as necessary, to comply with the NuScale quality assurance program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment and standard used.
 - b. Purchase documents require reporting as-found calibration data when calibrated items are found to be out of tolerance.
 - c. A documented review of the supplier's accreditation will be performed and will include a verification of the following:
 - 1. The calibration laboratory holds a domestic accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement:
 - i. National Voluntary Laboratory Accreditation Program, administered by NIST

- ii. American Association for Laboratory Accreditation
 - iii. ACLASS Accreditation Services
 - iv. International Accreditation Service
 - v. Laboratory Accreditation Bureau
 - vi. Other NRC-recognized laboratory accrediting bodies
2. The accreditation is based on ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
 3. The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.

The NRC staff has approved the use of calibration laboratories that hold a domestic accreditation approved by certain accrediting bodies. This method for qualifying a calibration supplier and accepting its calibration services is applicable only to dedicating commercial-grade calibration services as defined by 10 CFR 21. The current regulatory position regarding the acceptability of procuring commercial-grade calibration services from NRC-recognized calibration laboratories is documented in SRP Section 17.5, Paragraph II.L.8, as well as associated letters to the NRC-recognized laboratories. On this basis, the NRC staff finds the proposed exception acceptable.

- The NuScale QAPD commits to the requirements of the NQA-1a-2009 Addenda, Requirement 7, Section 700, and Subpart 2.14, "Quality Assurance Requirements for Commercial Grade Items and Services," for establishing commercial-grade item requirements. These sections implement controls for the selection, determination of suitability of intended use (critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to ensure they will perform satisfactorily in service. The NuScale QAPD also specifies that NuScale will hold its commercial suppliers accountable for quality requirements in the procurement documents, including the reporting of defects. As such, the NRC staff finds the proposed clarification acceptable.
- As an alternative to NQA-1a-2009 Addenda, Requirement 7, Section 700, the NuScale QAPD proposes that NuScale will assume 10 CFR 21 reporting responsibility for all commercial items and services that NuScale dedicates for use in safety related applications.

The purpose of 10 CFR 21 states that any individual director or responsible officer of a firm constructing, owning, operating, or supplying the components of any licensed or regulated facility or activity, who obtains information reasonably indicating: (a) that the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards; or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, must immediately notify the Commission of

such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

Therefore, the alternative proposed in the NuScale QAPD, which ensures that 10 CFR 21 reportability requirements encompass all safety-related activities for the NuScale Power Reactor design certification project, would continue to meet the intent of this requirement and is, therefore, acceptable to the NRC staff.

3.1.8 Identification and Control of Materials, Parts, and Components

This element is not applicable to the NuScale Power Reactor design certification application and has not been reviewed or approved by the NRC staff.

3.1.9 Control of Special Processes

This element is not applicable to the NuScale Power Reactor design certification application and has not been reviewed or approved by the NRC staff.

3.1.10 Inspection

The NuScale QAPD states that NuScale does not perform inspection activities as part of the development of the NuScale Power Reactor design certification. However, the NuScale QAPD describes the requirements for suppliers who perform inspection activities associated with the NuScale Power Reactor design certification. These requirements include measures to assure that items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents.

In addition, the NuScale QAPD states that inspection may also be applied to items, services, and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results are adequately documented.

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.J, by committing to require NuScale's suppliers and subcontractors to implement the quality standards described in NQA-1-2008, Requirement 10, Sections 100 through 800, without clarifications or exceptions.

3.1.11 Test Control

The NuScale QAPD states that NuScale does not perform testing activities as part of the development of the NuScale Power Reactor design certification, except for computer software testing. However, the NuScale QAPD describes the requirements for suppliers who perform testing activities associated with the NuScale Power Reactor design certification. These requirements include a provision that the supplier either have a test control program meeting the applicable QA requirements or conduct testing under the NuScale quality assurance program.

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.K, by committing to implement the quality standards described in the NQA-1a-2009 Addenda, Requirement 11,

Sections 100 through 600, as they relate to establishing the provisions for testing, without further clarifications or exceptions.

In establishing provisions to ensure that the computer software used in applications affecting safety is prepared, documented, verified, tested, and used such that the expected outputs are obtained and configuration control maintained, the NuScale QAPD commits to implement the quality standards described in the NQA-1a-2009 Addenda, Requirement 11, Section 400, and NQA-1a-2009 Addenda, Subpart 2.7, without clarifications or exceptions.

3.1.12 Control of Measuring and Test Equipment

The NuScale QAPD states that NuScale will not control measuring and test equipment (M&TE) as part of the development of the NuScale Power Reactor design certification. However, the NuScale QAPD describes the requirements for organizations that control measurement and test equipment associated with design verification of the NuScale Power Reactor design certification application. These requirements include a provision that the M&TE organization either have an M&TE control program meeting the applicable QA requirements or conduct M&TE control activities under the NuScale quality assurance program.

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.L, by committing to implement the quality standards described in NQA-1-2008, Requirement 12, Sections 100 through 400, with the following clarification:

- The NuScale QAPD clarifies that the out-of-calibration conditions described in NQA-1-2008, Requirement 12, Section 303.2, and the subsequent requirements to evaluate the validity of previous M&TE results, refer to cases where the measuring and test equipment is found to be out of the required accuracy limits (i.e., out of tolerance) during calibration versus simply overdue for calibration. The latter situation is addressed by NQA-1-2008, Requirement 12, Section 303, and assumes that an overdue calibration does not automatically equate to an inaccurate measurement or test.

The NRC staff determined that the clarification for out-of-calibration conditions is consistent with the overall objective of NQA-1-2008, Requirement 12, Section 303.2, and Criterion XII of Appendix B, which require that M&TE used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits. Therefore, the NRC staff concluded that this clarification is acceptable.

3.1.13 Handling, Storage, and Shipping

This element is not applicable to the NuScale Power Reactor design certification application and has not been reviewed or approved by the NRC staff.

3.1.14 Inspection, Test, and Operating Status

This element is not applicable to the NuScale Power Reactor design certification application and has not been reviewed or approved by the NRC staff.

3.1.15 Nonconforming Materials, Parts, or Components

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.O, for establishing the necessary measures and governing procedures to control items, including services that do not conform to specified requirements, in order to prevent inadvertent use. Controls provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming items, and notification to affected organizations. Controls are also provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release.

Nonconformances are evaluated for impact on the operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements which are dispositioned “repair” or “use-as-is” are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with NuScale procedures, regulatory requirements, and industry standards.

In addition, the NuScale QAPD provides for establishing the appropriate interfaces between the quality assurance program for identification and control of nonconforming materials, parts, or components, and the non-QA reporting program in order to satisfy the requirements of 10 CFR Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants (10 CFR Part 52) and 10 CFR 21.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 15, Sections 100 through 400, without further clarifications or exceptions.

3.1.16 Corrective Action

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.P, for establishing the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD provides for procedures to ensure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards.

The NuScale QAPD also 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 and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken. In the case of suppliers working on safety-related activities, or other similar situations, NuScale may delegate specific responsibilities for corrective actions, but NuScale maintains overall responsibility for the effectiveness of corrective action measures and the corrective action program.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 16, Section 100, without further clarifications or exceptions.

3.1.17 Quality Assurance Records

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.Q, for establishing the necessary measures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for NuScale and include requirements for records administration including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

The NuScale QAPD establishes measures to ensure that sufficient records of completed items and activities affecting quality are appropriately stored. The records and retention times are based on Regulatory Position C.1 of Regulatory Guide 1.28, Revision 4, and NQA-1-2008, and NQA-1a-2009 Addenda, Non-mandatory Appendix 17A-1, Section 200, as applicable for the NuScale Power Reactor design certification project. In all cases where state, local, or other agencies have more restrictive requirements for record retention, the NuScale QA provides that those more restrictive requirements will be met

When using electronic records storage and retrieval systems, the NuScale QAPD provides for compliance with the NRC guidance contained in NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks (Reference 9)," Regulatory Issue Summary (RIS) 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media (Reference 10)," and the associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG), including TG 11-1998, "Authentication of Records and Media," TG 15-1998, "Management of Electronic Records," TG 16-1998, "Software Configuration Management and Quality Assurance," and TG 21-1998, "Electronic Records Protection and Restoration."

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 17, Sections 100 through 800, without further clarifications or exceptions.

3.1.18 Audits

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.R, for establishing the necessary measures and governing procedures to implement audits in order to verify that activities covered by the quality assurance program are performed in conformance with the requirements established. The audit programs are also themselves reviewed for effectiveness as part of the overall NuScale audit process.

The NuScale QAPD provides for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of program and procedures, as well as to determine if they are meaningful and comply with the overall NuScale quality assurance program. Internal audits are performed (1) with a frequency commensurate with the safety significance of the activity and in a manner which assures that audits of safety-related activities are completed; and/or (2) with a frequency that ensures that an audit of all applicable quality assurance program elements is completed within a period of once per calendar year or at least once during the life of the activity, whichever is shorter.

External audits determine the adequacy of supplier or contractor quality assurance programs. The scope of the audit is determined by the quality status and safety importance of the activities

being performed. These audits are conducted by trained personnel not having direct responsibility in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the NuScale quality assurance director.

The NuScale QAPD provides for all audit results to be documented and reviewed by responsible management. Management responds to all audit findings and initiates corrective actions where indicated. In addition, where corrective action measures are determined necessary, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means, is conducted to verify the implementation and effectiveness of the assigned corrective actions.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 18, Sections 100 through 800, without further clarifications or exceptions.

3.2 Nonsafety-Related SSC Quality Control

3.2.1 Nonsafety-Related SSCs - Significant Contributors to Plant Safety

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.V.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 is not applicable.

The NuScale QAPD applies specific controls to such items in a selected manner, targeted toward those characteristics or critical attributes that render the SSC a significant contributor to plant safety, consistent with applicable sections of the NuScale quality assurance program.

The NRC staff has determined that this approach, as described in the NuScale QAPD, is acceptable to maintain alignment with SRP Section 17.5, Paragraph II.V.1.

3.2.2 Nonsafety-Related SSCs Credited for Regulatory Events

In establishing the quality requirements for nonsafety-related SSCs credited for regulatory events, the NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.V.2, and NuScale commits to implement the following regulatory guidance:

- The quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, Revision 2, "Fire Protection for Operating Nuclear Power Plants (Reference 11)," dated October 2009.
- The quality requirements for anticipated transient without scram (ATWS) equipment in accordance with NRC Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related (Reference 12)," dated January 16, 1985.
- The quality requirements for station blackout (SBO) equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for

Non-Safety Systems and Equipment," in Regulatory Guide 1.155, "Station Blackout (Reference 13)," dated August 1988.

The NRC staff has determined that this approach, as described in the NuScale QAPD, is acceptable to maintain alignment with SRP Section 17.5, Paragraph II.V.2.

3.3 Regulatory Commitments

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.U, for establishing QA program commitments. Furthermore, NuScale commits to comply with the following NRC Regulatory Guides and other quality assurance standards to supplement and support the quality assurance program:

- Regulatory Guide 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants (Reference 14)," dated May 2000. Regulatory Guide 1.8 provides guidance regarding qualifications and training for nuclear power plant personnel.
- Regulatory Guide 1.26, Revision 4, "Quality Group Classification and Standards for Water, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants (Reference 15)," dated March 2007. Regulatory Guide 1.26 defines classification of systems and components.
- Regulatory Guide 1.28, Revision 4, "Quality Assurance Program Requirements (Design and Construction)," dated June 2010. Regulatory Guide 1.28 describes a method acceptable to the NRC for complying with the provisions of Appendix B with regard to establishing and implementing the requisite QA program for the design of nuclear power plants.
- Regulatory Guide 1.29, Revision 4, "Seismic Design Classification (Reference 16)," dated March 2007. Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).
- ASME NQA-1-2008, and NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described above in Sections 3.1.1 through 3.1.18 of this safety evaluation.
- Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides, as described in Section 3.1.17 of this safety evaluation.

4.0 CONCLUSION

The NuScale QAPD delineates the policies, processes, and controls established by NuScale and associated implementing documents relative to U.S. domestic licensing requirements for nuclear power plants. Together, the quality assurance program documents defined in the QAPD provide for control of NuScale activities that affect the quality of safety-related nuclear plant structures, systems, and components and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service.

The QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements.

The NuScale QAPD follows the NRC guidance contained within, and conforms to the format of, SRP Section 17.5. The NRC staff used the acceptance criteria of SRP Section 17.5 as the basis for evaluating the acceptability of the NuScale quality assurance program in conformance with the provisions of 10 CFR 52.47(a)(19) and Appendix B to 10 CFR 50. On the basis of its review of the NuScale QAPD, the NRC staff concludes that:

- The NuScale QAPD adequately describes the authority and responsibility of management and supervisory personnel, performance and verification personnel, and self-assessment personnel, in relation to activities to which the NuScale quality assurance program is applicable.
- The NuScale QAPD adequately provides for organizations and personnel to perform verification and self-assessment functions related to NuScale activities that affect the quality of safety-related nuclear plant SSCs, as well as select nonsafety-related SSCs, with these organizations and personnel having the authority and independence to conduct activities without undue influence from those directly responsible for costs and schedules.
- The NuScale QAPD adequately applies to activities and items that are important to safety.
- The NuScale QAPD adequately establishes controls that, when properly implemented, comply with the requirements of 10 CFR 52, Appendix B to 10 CFR 50, and 10 CFR 21, consistent with the criteria contained in SRP Section 17.5, as well as the relevant regulatory guidance.

On the basis of its review, the NRC staff determined that the NuScale QAPD adequately describes the NuScale quality assurance program. Accordingly, the NRC staff concludes that the NuScale quality assurance program complies with the applicable NRC regulations and industry standards and can be used by NuScale for design certification activities associated with the NuScale Power Reactor.

5.0 REFERENCES

1. Letter from Edward G. Wallace, NuScale Power, Inc., to the NRC Document Control Desk, "NuScale Power Submittal of NuScale Quality Assurance Program Description (QAPD) for Design Certification of the NuScale Power Reactor - Non-Proprietary (NRC Project No. 0769)," dated October 29, 2010 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML103210264)
2. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," dated March 2007 (ADAMS Accession No. ML063190019)

3. Letter from Edward G. Wallace, NuScale Power, Inc., to the NRC Document Control Desk, "Request for Additional Information No. 5452 (NRC Project 0769)," dated March 7, 2011 (ADAMS Accession No. ML110670208)
4. Letter from Edward G. Wallace, NuScale Power, Inc., to the NRC Document Control Desk, "Request for Additional Information No. 5892 (NRC Project 0769)," dated September 16, 2011 (ADAMS Accession No. ML112620083)
5. Letter from Edward G. Wallace, NuScale Power, Inc., to the NRC Document Control Desk, "NuScale Power Submittal of NuScale Quality Assurance Program Description (QAPD) Revision 1 for Design Certification of the NuScale Power Reactor - Non-Proprietary (NRC Project No. 0769)," dated December 15, 2011 (ADAMS Accession No. ML120370407)
6. American Society of Mechanical Engineers (ASME) NQA-1-2008, "Quality Assurance Program Requirements for Nuclear Facilities" (with a2009 Addenda), New York, NY, dated March 14, 2008
7. Regulatory Guide 1.28, Revision 4, "Quality Assurance Program Criteria (Design and Construction)," dated June 2010 (ADAMS Accession No. ML100160003)
8. Letter from NRC to Southern Nuclear Operating Company, Edwin I. Hatch Nuclear Power Station, Units 1 and 2, "RE: Approval of Relief Request RR-27, Third 10-Year Interval Inservice Inspection Program (TAC NOS. MA6163 and MA6164)," dated March 20, 2000 (ADAMS Accession No. ML003693241)
9. NRC Generic Letter 1988-18, "Plant Record Storage on Optical Disks," dated October 20, 1988
10. Regulatory Issue Summary 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media," dated October 23, 2000 (ADAMS Accession No. ML003739359)
11. Regulatory Guide 1.189, Revision 2, "Fire Protection for Operating Nuclear Power Plants," dated October 2009 (ADAMS Accession No. ML092580550)
12. NRC Generic Letter 1985-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," dated January 16, 1985
13. Regulatory Guide 1.155, "Station Blackout," dated August 1988
14. Regulatory Guide 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants," dated May 2000 (ADAMS Accession No. ML003706932)
15. Regulatory Guide 1.26, Revision 4, "Quality Group Classification and Standards for Water, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," dated March 2007 (ADAMS Accession No. ML070290283)

16. Regulatory Guide 1.29, Revision 4, "Seismic Design Classification," dated March 2007 (ADAMS Accession No. ML070310052)