SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

REGARDING TOPICAL REPORT MN-122626, REVISION 1,

"NUSCALE POWER, LLC QUALITY ASSURANCE PROGRAM DESCRIPTION"

1.0 INTRODUCTION

By letter dated November 4, 2022 (Reference 1), NuScale Power, LLC, (NuScale), submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Topical Report (TR) MN-122626, Revision 0, "NuScale Power, LLC Quality Assurance Program Description" (QAPD). NuScale prepared the QAPD TR in accordance with the guidance of 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 (Reference 2), and the NRC-endorsed Nuclear Energy Institute (NEI) 11-04A, Revision 0, "Nuclear Generation Quality Assurance Program Description," issued September 2012 (Reference 3).

The NRC staff held a teleconference with NuScale on March 27, 2023 (Reference 4), to ask clarifying questions. Following this teleconference, NuScale submitted Revision 1 of the QAPD, MN-122626, by letter dated July 11, 2023 (Reference 5).

NuScale's QAPD addresses quality activities associated with the NuScale US460 Power Plant Standard Design Approval (SDA) application and customer contracts. The QAPD is based on the applicable portions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." Additionally, NuScale's QAPD commits to the applicable requirements of the American Society of Mechanical Engineers (ASME) NQA-1-2008, "Quality Assurance Requirements For Nuclear Facility Applications," dated March 14, 2008 (Reference 6), and NQA-1a-2009 Addenda, dated August 11, 2009 (Reference 7), as endorsed by NRC Regulatory Guide (RG) 1.28, Revision 4, "Quality Assurance Program Criteria (Design and Construction)," issued June 2010 (Reference 8).

2.0 REGULATORY EVALUATION

The regulatory requirements related to quality assurance (QA) programs are, in part, set forth in 10 CFR 52.137(a) and Appendix B to 10 CFR Part 50. Specifically, 10 CFR 52.137(a) requires that an SDA application describe the QA program applied to the design of the structures, systems, and components (SSCs) of the facility. Additionally, 10 CFR 52.137(a)(19) requires that the QAPD discuss how the applicable requirements of Appendix B to 10 CFR Part 50 have been satisfied.

Appendix B to 10 CFR Part 50 sets forth the requirements for quality assurance programs for nuclear power plants, and establishes QA 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, including designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

3.0 TECHNICAL EVALUATION

In evaluating the compliance of NuScale's QAPD with applicable requirements, the NRC staff utilized the guidance contained in SRP Section 17.5, Revision 1, which outlines an acceptable QA program template for design certification, early site permit, combined license, construction permit, and operating license applicants. SRP Section 17.5, Revision 1, describes regulatory and industry guidance determined to be acceptable methods for satisfying the requirements of Appendix B to 10 CFR Part 50.

3.1 Quality Assurance Program Overview

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's QA program implementation. Based on its review, the NRC staff finds that NuScale's QAPD establishes independence between the organization that performs oversight functions related to the QA program and the organization responsible for performing the functions to be evaluated. In addition, the NuScale QAPD provides for applicable management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. The QAPD clearly describes and defines the responsibility and authority for planning, establishing, and implementing an effective overall QA program.

The NuScale QAPD provides the authority and responsibility to stop work immediately in accordance with approved procedures whenever personnel safety or SSC integrity may be jeopardized.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 1, Section 100 through 300, without further clarifications or exceptions. As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are considered acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale's organization, as detailed above, complies with the requirements of Criterion I, "Organization," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

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 QA program to ensure that activities affecting the quality and performance of items and services provided by NuScale supporting the SDA and customer contracts (such as designing, procuring, fabricating, cleaning, inspecting, receiving, handling, shipping, storing, testing, and training) are in accordance with the governing regulations and license requirements. The QA program applies to those quality-related activities that involve the functions of safety-related SSCs associated with the design, fabrication, and testing of the NuScale Power Plant activities, and to the managerial and administrative controls to be used to provide assurance that the NuScale Power Plant design complies with applicable regulatory requirements. Examples of the SDA program's 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.

NuScale maintains a list or system identifying the SSCs and activities to which the NuScale Quality Assurance Program applies. NuScale may delegate all or part of the activities for which they are responsible to others but retains overall responsibility for the QA 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.10, the NuScale QAPD allows for the application of a grace period of 90 days to activities that must be performed on a periodic basis. Consistent with an alternative approved by the NRC in 2020 (Reference 9), during exigent conditions, the NuScale QAPD applies an extension of the audit or survey interval of up to 25 percent of the periodicity for audits and surveys to be performed. Section 2.7.2 of the QAPD and Section 3.1.7 of this safety evaluation (SE) contain additional information on audit extensions performed during exigent conditions.

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraphs II.S and II.T, by providing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD to ensure that suitable proficiency is achieved and maintained. The NuScale QAPD provides the minimum training qualification for all personnel responsible for implementation of NuScale's QA program.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 2, Sections 100 through 500, with the following clarification for lead auditors:

- NuScale considers that prospective Lead Auditors, with comparable industry experience, may satisfy the Lead Auditor qualification requirement of participating in a minimum of five QA audits within a period of 3 years prior to the date of qualification by alternatively demonstrating the ability to properly implement the audit process, effectively organize and report results, and participate in at least one nuclear audit within the year preceding the date of qualification, subject to review and acceptance by the responsible QA organization.

The NRC staff notes that this clarification has been documented as a regulatory position in RG 1.28, Revision 5, issued October 2017 (Reference 10), and, therefore, is considered acceptable.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale's QA program, as detailed above, complies with the requirements of Criterion II "Quality Assurance Program" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.3 Design Control

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.C, 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 QAPD design process includes provisions to control design inputs, outputs, changes, interfaces,

records, and organizational interfaces within NuScale and with suppliers. These provisions ensure that the design inputs (such as design bases and the performance, regulatory, quality and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification. 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 QA requirements.

Consistent with SRP Section 17.5, Paragraph II.C, the NuScale QAPD design processes provide for design verification to ensure that items and activities subject to the provisions of the QA program are suitable for their intended application and are consistent with their effect on safety. Design changes are subject to these controls, which include verification measures commensurate with those applied to the 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 non-safety-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 NuScale QAPD states that 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 in NQA-1-2008, and NQA-1a-2009 Addenda, Part II Subpart 2.7 “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications” and Subpart 2.14 “Quality Assurance Requirements for Commercial Grade Items and Services” without further clarifications or exceptions. As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale’s Design Control, as detailed above, complies with the requirements of Criterion III “Design Control” of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.4 Procurement Document Control

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.D, for establishing the necessary measures and governing procedures for preparing and reviewing procurement documents to ensure that the documents include or reference applicable regulatory, technical, and QA program requirements. The NuScale QAPD ensures that relevant personnel develop and review the procurement documents and that changes are subject to the same degree of control as that used in preparing the original documents.

The NuScale QAPD states that applicable technical, regulatory, administrative, quality, and reporting requirements (such as those in specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21, "Reporting of Defects and Noncompliance,") 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 10 CFR part 50, Appendix B. Alternatively, the QAPD allows the supplier to work under NuScale's approved QA program.

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

- With regard to service performed by a supplier, NuScale procurement documents may allow the supplier to work under the NuScale QA program, including implementing procedures, in lieu of the supplier having its own QA program.

The NRC staff evaluated this proposed exception and determined that it provides adequate control for establishing and executing the responsibilities for the QA program because it is consistent with SRP Section 17.5, Paragraph II.D.1. In addition, Criterion IV, "Procurement Document Control," of Appendix B to 10 CFR Part 50, requires suppliers to have a QA program consistent with the regulations. Therefore, the NRC staff determined that the exception is acceptable.

- Sections 300 and 400 of Requirement 4 require the review of technical and QA program requirements of procurement documents prior to award of a contract and for procurement document changes (respectively). NuScale may satisfy this requirement through the review of procurement specifications when the specification contains the technical and QA requirements of the procurement.

The NRC staff evaluated this proposed clarification and determined that it provides adequate QA review of procurement documents before awarding the contract and after any change to the contract because it is consistent with SRP Section 17.5, Paragraph II.D.3. Therefore, the NRC staff determined that the clarification is acceptable.

- Procurement documents for commercial grade items that will be procured by NuScale for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated in accordance with Section 2.7 of the NuScale QAPD.

The NRC staff evaluated this proposed clarification and determined that it is consistent with NRC staff guidance provided in RG 1.164, Revision 0, "Dedication of Commercial Grade Items for use in Nuclear Power Plants," issued June 2017 (Reference 21). The proposed clarification is also consistent with Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989 (Reference 26), and GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (Reference 27), as delineated in SRP Section 17.5, Paragraphs II.V.1.d and II.V.1.e.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale's Procurement Document Control, as detailed above, complies with the requirements of Criterion IV, "Procurement Document Control" of Appendix B to 10 CFR Part 50, and, therefore, 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 that, where applicable, include quantitative or qualitative acceptance criteria to implement the QA program.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 5, Section 100, without further clarifications or exceptions. As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale's Instructions, Procedures, and Drawings, as detailed above, complies with the requirements of Criterion V, "Instructions, Procedures and Drawings" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

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, Section 100 through 300, without further clarifications or exceptions. As stated in RG 1.28. Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale's Document Control, as detailed above, complies with the requirements of Criterion VI, "Document Control" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

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 NuScale QAPD 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 NuScale 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. Qualified suppliers are audited on a triennial basis. The NuScale QAPD provides for using audits conducted by outside organizations for supplier qualification if the scope and adequacy of the audits meet NuScale requirements. NuScale will also perform annual evaluations of qualified suppliers to document that these suppliers continue to provide acceptable products and 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. In addition, the QAPD establishes controls for the selection, determination of suitability for intended use (i.e., critical characteristics), evaluation, receipt, and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.

Fully remote source verification may be conducted during exigent conditions due to restricted access or travel to a supplier providing the source verification is conducted in accordance with Electric Power Research Institute (EPRI) Technical Report 3002019436, "Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance," issued October 2020 (Reference 11).

The NuScale QAPD allows for the extension of audit or survey intervals up to 25 percent under exigent conditions. This unique grace period can be applied if exigent conditions exist including, but not limited to the following:

a. a severe local or national public health concern,
b. natural disaster, severe localized or national weather conditions, or
c. a declaration of a national emergency.

Under these exigent conditions, the grace period clock reset, as described in Section 2.2 of the NuScale QAPD, does not apply; the audit performed within this extension period resets the triennial clock. The 25 percent grace period extension is applicable to domestic and international suppliers. The NuScale QAPD requires that, under these exigent conditions, NuScale will evaluate the supplier's program to provide reasonable assurance that the quality of items and services will continue to be maintained during this extension period.

The NRC staff notes that the Coronavirus Disease 2019 (COVID-19) related public health emergency expired on May 11, 2023; therefore, the provisions for audit extension and remote source verification under exigent conditions, as described above, can no longer be used unless new exigent conditions exist.

In establishing procurement verification controls and commercial grade item requirements, 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 and Subpart 2.14 with the following clarifications and exceptions:

- NuScale considers that other 10 CFR Part 50 licensees, Authorized Nuclear Inspection [ANI] agencies, National Institute of Standards and Technology [NIST], or other State

and Federal agencies, that may provide items or services to NuScale, are not required to be evaluated or audited.

The NRC staff has documented its current regulatory position regarding this exception in safety evaluation (SE) Section 3.1.7.1 of the Tennessee Valley Authority (TVA) New Nuclear QAPD, dated December 12, 2023 (Reference 12). The NRC staff verified that the NuScale QAPD provided the same commitments associated with supplier oversight activities as those provided in the TVA New Nuclear QAPD. Therefore, the NRC staff's position associated with this exception, as documented in the TVA New Nuclear QAPD SE, would apply to the NuScale QAPD. The NRC staff concludes that the requested exception regarding audit and evaluation, as described above, is acceptable subject to the limitations described in the TVA New Nuclear QAPD SE, as identified in Section 5.0 of this SE, for control of purchased material, equipment, and services.

- NuScale will implement the guidance from NEI 14-05A, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," issued September 2020 (Reference 13), for using the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) accreditation process in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process.

The NRC staff evaluated this proposed clarification and determined that it is consistent with the NRC staff's current regulatory position, documented in RG 1.28, Revision 6, issued September 2023 (Reference 14). In this RG, the NRC staff concluded that NEI 14-05A, Revision 1, provides an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50. This NEI document relates to using laboratory accreditation by Accreditation Bodies that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procuring calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA. Therefore, the NRC staff concluded that this clarification is acceptable.

- NuScale will assume 10 CFR Part 21 reporting responsibility for commercial items and services that NuScale dedicates for use in safety-related applications.

Under 10 CFR Part 21, 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 that could create a substantial safety hazard, must immediately notify the Commission of such failure to comply or such defect, unless they have actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

The NRC staff evaluated this clarification and determined that it ensures that 10 CFR Part 21 reportability requirements encompass all items that are dedicated as safety-related and does not remove the supplier's responsibilities under 10 CFR Part 21. Therefore, the NRC staff concluded that this clarification is acceptable.

- In establishing a program for remote source verification during exigent conditions, NuScale commits to compliance with the screening process described in EPRI Technical Report 3002019436-A, “Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance,” (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20300A386), Section 4, to determine whether remote source verification is appropriate prior to conducting the activity remotely.

In an SE, dated July 7, 2020 (Reference 15), the NRC staff evaluated Energy Northwest’s request to implement guidance found in EPRI Technical Report 3002019436-A for performing remote source verification when a pandemic or a similar state of emergency has been declared restricting access or travel to and/or from those locations affected by the declaration. As documented in that SE, the NRC staff has determined that the implementation of EPRI Technical Report 3002019436-A, as outlined in Energy Northwest’s submittal, will continue to meet the requirements of Criterion VII, “Control of Purchased Material, Equipment, and Services,” of Appendix B to 10 CFR Part 50, and, therefore, was acceptable. The NRC staff evaluated NuScale’s proposed clarification and determined that it is consistent with the SE, dated July 7, 2020, and is, therefore, acceptable. However, the NRC staff notes that the conditions included in that SE must be met before implementing the guidance in EPRI Technical Report 3002019436-A. As stated above, the COVID-19 related public health emergency expired on May 11, 2023; therefore, the provisions for audit extension and remote source verification under exigent conditions can no longer be used unless new exigent conditions exists.

- In establishing a program for remote audits or surveys during exigent conditions, NuScale commits to only utilize these provisions for previously qualified suppliers to renew their qualifications, and to use the screening process in EPRI Technical Report 3002020796, “Remote Assessment Techniques: Planning and Conducting Audits and Surveys Using Remote Techniques During Exigent Conditions,” to determine whether remote audits or surveys are appropriate and can be effectively applied to the activities, and the applicable quality and technical requirements of interest can be reviewed and or verified.

In an SE dated June 22, 2021 (Reference 16), the NRC staff evaluated a Southern Nuclear Operating Company, Inc. (SNC), request to revise the SNC QAPD TR to expand the allowances for performing fully remote and provisional remote audits and commercial-grade surveys during times of extenuating circumstances (e.g., pandemics). As documented in that SE, the NRC staff determined that the implementation of EPRI Technical Report 3002020796 will continue to meet the requirements of Criterion VII of Appendix B to 10 CFR Part 50, and, therefore, was acceptable. The NRC staff evaluated NuScale’s proposed clarification and determined that it is consistent with the SE dated June 22, 2021, and is, therefore, acceptable. However, the NRC staff notes that the conditions included in that SE must be met before implementing the guidance in EPRI Technical Report 3002020796. As stated above, the COVID-19 public health emergency expired on May 11, 2023; therefore, the provisions for audit extension and remote source verification under exigent conditions can no longer be used unless new exigent conditions exist.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review and subject to the limitations in Section 5.0 of this safety evaluation, the NRC staff finds that NuScale’s description of the controls for purchased material, equipment, and services, as detailed above, complies

with the requirements of Criterion VII, of Appendix B to 10 CFR Part 50, and therefore, is acceptable.

3.1.8 Identification and Control of Materials, Parts, and Components

The NuScale QAPD follows the guidance of SRP Section 17.5, Subsection II.H, for establishing the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or nonconforming items. Identification and control measures include controls for consumable materials and items with a limited shelf-life. Identification of items is maintained throughout fabrication, erection, installation, and use so that the materials, parts, or components can be traced back to their documentation, consistent with the item's effect on safety. The location and identification methods are selected so the function or quality of the item being identified is not affected.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 8, Section 100 through 300, with the clarification that the necessary measures and governing procedures shall be established before initiating the activities defined in this section.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that NuScale's description of identification and control of materials, parts, and components, with the included clarification, as detailed above, complies with the requirements of Criterion VIII, "Identification and Control of Materials, Parts, and Components" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.9 Control of Special Processes

The NuScale QAPD follows the guidance of SRP Section 17.5, Subsection II.I, for establishing the necessary measures and governing procedures to provide assurance that special processes that require interim process controls to assure quality, such as welding, heat treating, and non-destructive examination are controlled. Special processes are accomplished by qualified personnel using qualified procedures and equipment, and in accordance with applicable codes, standards, specifications, criteria, or other special requirements.

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

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale's control of special processes, with the included clarification, as detailed above, complies with the requirements of Criterion IX "Control of Special Processes" of Appendix B to 10 CFR Part 50, and therefore, is acceptable.

3.1.10 Inspection

The NuScale QAPD follows the guidance of SRP Section 17.5, Subsection II.J, for establishing the necessary measures and governing procedures to implement inspections that provide assurance that items, services, and activities affecting safety meet established requirements

and conform to applicable documented specifications, instructions, procedures, and design documents. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection. These types of inspections will be performed by properly qualified personnel independent of those who performed or directly supervised the work, and the inspection results will be documented.

NuScale's inspection program establishes requirements for planning the inspections, such as measures for (1) the identification of the group or discipline responsible for performing the inspection, (2) the application of hold points that require witnessing or inspecting, (3) the acceptance criteria for inspection, (4) the frequency of inspections, and (5) the identification of special tools required to perform the inspection. Inspection plans are based on, at minimum, (1) the importance of the item to safety, (2) the complexity of the item, (3) the technical requirements to be met, and (4) the design specifications. Inspection information and results, such as rejection, acceptance criteria, reinspection results, and the person(s) performing the inspection, are documented. The documentation of this information is the responsibility of the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings. Inspections are carried out by properly qualified persons, independent of those who performed or directly supervised the work.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 10, Sections 100 through 800, and Part II, Subparts 2.5, and 2.8 with the clarification that the necessary measures and governing procedures shall be established before initiating activities defined in this section.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that NuScale's description of inspection controls, with the included clarification, as detailed above, complies with the requirements of Criterion X, "Inspection" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.11 Test Control

The NuScale QAPD follows the guidance of SRP Section 17.5, Subsection II.K, for establishing the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in-service. Test programs include criteria for determining when testing is required to demonstrate that performance of plant systems is in accordance with design. Tests are performed according to applicable procedures that include, consistent with the effect on safety, (1) instructions and prerequisites to perform the tests, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to ensure that the test requirements have been satisfied. If acceptance criteria are not met, re-testing is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure. Personnel who perform or evaluate tests are qualified in accordance with the requirements established in Section 2.2 of the QAPD.

For non-computer program testing, NuScale's QAPD commits to implement the quality standards described in NQA-1a-2009 Addenda, Requirement 11, Sections 100 through 300, 500, 600 and 601 without further clarifications or exceptions.

For computer program testing, NuScale's QAPD commits to implement the quality standards described in NQA-1a-2009 Addenda, Requirement 11, Sections 100, 200, 400, 600 and 602, and Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1-2008, Requirement 3, without further clarifications or exceptions.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that NuScale's description of testing controls, as detailed above, complies with the requirements of Criterion XI, "Test Control" of Appendix B to 10 CFR Part 50, and therefore, is acceptable.

3.1.12 Control of Measuring and Test Equipment

The NuScale QAPD follows the guidance of SRP Section 17.5, Subsection II.L, for establishing the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides data to verify acceptance criteria are met for information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and non-destructive examination equipment.

NuScale's QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 12, Section 100 through 400, with the following clarification and exception.

- The NuScale QAPD clarifies that the out-of-calibration conditions described in NQA-1-2008, Requirement 12, Section 303.2, refer to cases in which the M&TE is found to be out of the required accuracy limits (i.e., out of tolerance) during calibration and not overdue for calibration.

The NRC staff finds 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, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50, 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.

- The NuScale QAPD clarifies that M&TE is not required to be marked with the calibration status, as described in NQA 1 2008, Requirement 12, Section 303.6, where it is impossible or impractical due to equipment size or configuration (e.g., the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-2008, Subpart 2.4 (See Section 7.2.1 of American National Standards Institute/Institute of Electrical and Electronics Engineers Standard 336-1985, "IEEE Standard Installation, Inspection and Testing Requirements for Power, Instrumentation, and Control equipment at Nuclear Facilities").

The NRC staff finds this exception is consistent with the overall objective of NQA-1-2008, Requirement 12, Section 303.6, and Criterion XII of Appendix B to 10 CFR Part 50, 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.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that NuScale's description of M&TE controls, with the included clarifications, as detailed above, complies with the requirements of Criterion XII, of Appendix B to 10 CFR Part 50, and therefore, is acceptable.

3.1.13 Handling, Storage, and Shipping

The NuScale QAPD follows the guidance of SRP Section 17.5, Subsection II.M, for establishing the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration. Items are appropriately marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the item's integrity and provide indication of the needs for special controls. Any special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required. In addition, the procurement documents identify any special or additional handling, storage, shipping, cleaning, and preservation requirements. Special handling tools and equipment are controlled to ensure safe and adequate handling. These special tools and handling equipment are inspected and tested in accordance with procedures at specified time intervals or before use. Operators of special handling and lifting equipment are experienced or trained in the use of the equipment. Where required, NuScale complies with applicable hoisting, rigging, and transportation regulations and codes. NuScale's QAPD establishes housekeeping practices to account for conditions or environments that could affect the quality of SSCs.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 13, Sections 100 through 600.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that NuScale's description of handling, storage, and shipping controls, as detailed above, complies with the requirements of Criterion XIII, "Handling, Storage and Shipping" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.14 Inspection, Test, and Operating Status

The NuScale QAPD follows the guidance of SRP Section 17.5, Subsection II.N, for establishing the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Measures are provided for the verification of inspections, tests, and operating status to preclude the bypassing of inspections or tests, or to preclude inadvertent operation. These measures require the inspection, test, or operating status to be verified before release, fabrication, receipt, installation, test, or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels. Temporary modifications will be controlled by procedures that incorporate the applicable requirements for independent verification and status tracking.

Administrative procedures will also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. Review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 14, Section 100. As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that NuScale's description of inspection, test, and operating status controls, as detailed above, complies with the requirements of Criterion XIV, "Inspection, Test, and Operating Status" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

3.1.15 Nonconforming Materials, Parts, or Components

The NuScale QAPD follows the guidance of SRP Section 17.5, Subsection 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 installation or use. Controls provide for the identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming items, and notification to affected organizations. Controls are also provided to address the conditional release of nonconforming items for use on an at-risk basis before resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release.

Nonconforming items are evaluated for impact on the operability of quality SSCs to provide assurance that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements that 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 reported to designated management. Significant trends are reported to management in accordance with NuScale's procedures, regulatory requirements, and industry standards.

The NuScale QAPD provides for establishing the appropriate interfaces between the QAP for identification and control of nonconforming items, including services, and the reporting programs in order to satisfy the requirements of 10 CFR Part 50, 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," and 10 CFR Part 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. As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that NuScale's description of controls for nonconforming materials, parts, or components, as detailed above, complies with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

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, correct, and verify conditions adverse to quality. The NuScale 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 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 or contractors 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 provides for establishing appropriate links between the implementing procedures of the QA program for corrective actions and the reporting procedures to satisfy the requirements of 10 CFR Part 50, 10 CFR Part 52, and 10 CFR Part 21.

The NuScale QAPD commits to implementing the quality standards described in NQA-1-2008, Requirement 16, Section 100, without further clarifications or exceptions. As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale's Corrective Action program complies with the requirements of Criterion XVI, "Corrective Action" of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

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 (e.g., design, engineering, procurement, inspection, test, and audits) of completed items and activities affecting quality are appropriately stored. The records and retention times are based on Regulatory Position C.1 of RG 1.28, Revision 4, and NQA-1a-2009 Addenda, Part III, Subpart 3.1 for Non-mandatory Appendix 17A-1, Section 200, as applicable for the QAPD. In all cases in which State, local, or other agencies have more restrictive requirements for record retention, the NuScale QAPD provides that those more restrictive requirements will be met.

When using optical disks for electronic records storage and retrieval systems, the NuScale QAPD complies with the NRC guidance contained in NRC GL 88-18, "Plant Record Storage on Optical Disks dated October 20, 1988 (Reference 32)."

The NuScale QAPD commits to implement the quality standards described in NQA-1-2008, Requirement 17, Sections 100 through 800, with the following clarification.

- NuScale manages the storage of QA Records in electronic media consistent with the intent of Regulatory Issue Summary (RIS) 2000-18 “Guidance on Managing Quality Assurance Records in Electronic Media,” dated October 23, 2000 (Reference 17), and associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs), including TG 11-2011, “Authentication of Records and Media” (Reference 28), TG 15-2011, “Management of Electronic Records,” (Reference 29), TG 16-2011, “Software Configuration Management and Quality Assurance,” (Reference 30), and TG 21-2011, “Electronic Records Protection and Restoration” (Reference 31).

The NRC staff has approved the NIRMA TGs identified above, as documented in Regulatory Position C.3.b in RG 1.28, Revision 5, and therefore, NuScale’s reliance on RIS 2000-18 and the cited TGs is considered acceptable.

As stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale’s QA Records complies with the requirements of Criterion XVII, “Quality Assurance Records,” of Appendix B to 10 CFR Part 50 and, therefore, is acceptable.

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 to verify that activities covered by the QA program are performed in conformance with the requirements established. NuScale also reviews the audit programs for effectiveness as part of the overall audit process.

The NuScale QAPD provides for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures, as well as to determine whether they are meaningful and comply with the overall NuScale QA program. Internal audits of all applicable QA program elements should be completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter.

External audits determine the adequacy of supplier and contractor QA programs, and NuScale QAPD Section 2.7 describes additional controls for external audits.

The scope of the audits is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities 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 NuScale QA management.

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 when determined necessary. In addition, if 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. As

stated in RG 1.28, Revision 4, NQA-1-2008 and NQA-1a-2009 Addenda are editions considered to be acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50. Based upon its review, the NRC staff finds that the description of NuScale's audits complies with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, and, therefore, is acceptable.

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.U.1, for establishing specific program controls to be applied to non-safety-related SSCs that are significant contributors to plant safety, but for which the requirements of Appendix B to 10 CFR Part 50 are 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 the applicable sections of the NuScale QAPD.

Based upon its review, the NRC staff has determined that this approach, as described in the NuScale QAPD, is consistent with SRP Section 17.5, Paragraph II.U.1, and, therefore, is acceptable.

3.2.2 Nonsafety-Related SSCs Credited for Regulated Events

In establishing the quality requirements for non-safety-related SSCs credited for regulatory events, the NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.U.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 RG 1.189, Revision 3, "Fire Protection for Operating Nuclear Power Plants," issued February 2018 (Reference 18).

- the quality requirements for anticipated transient without scram (ATWS) equipment in accordance with NRC GL 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," issued April 16, 1985 (Reference 19).

- 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 RG 1.155, "Station Blackout," issued August 1988 (Reference 20).

Based upon its review, the NRC staff has determined that this approach, as described in the NuScale QAPD, is consistent with SRP Section 17.5, Paragraph II.U.2, and, therefore, is acceptable.

3.3 Regulatory Commitments

The NuScale QAPD follows the guidance of SRP Section 17.5, Paragraph II.V, for establishing QA program commitments. Furthermore, NuScale commits to comply with the following NRC

RGs and other QA standards to supplement and support the QA program:

- RG 1.164, Revision 0 (Reference 21), on methods acceptable to the NRC staff for complying with the regulatory requirements for dedication of commercial-grade items and services used in nuclear power plants.

- RG 1.231, Revision 0, “Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Safety-Related Applications for Nuclear Power Plants,” issued January 2017 (Reference 22). RG 1.231 on methods acceptable to the NRC staff for complying with the regulatory requirements for acceptance and dedication of commercial-grade design and analysis computer programs used in safety-related applications for nuclear power plants.

- RG 1.234, Revision 0, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21,” issued April 2018 (Reference 23), on methods acceptable to the NRC staff for complying with the provisions of 10 CFR Part 21.

- RG 1.26, Revision 6, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” issued December 2021 (Reference 24), defines classification of systems and components.

- RG 1.28, Revision 4 (Reference 8), on a method acceptable to the NRC staff for complying with the provisions of Appendix B to 10 CFR Part 50 regarding establishing and implementing the requisite QA program for the design of nuclear power plants.

- RG 1.29, Revision 6, "Seismic Design Classification," issued July 2021 (Reference 25), defines systems required to withstand a safe shutdown earthquake (SSE).

- ASME NQA-1-2008, and NQA-1a-2009 Addenda (References 6 and 7), Part I and Part II (as described in Sections 3.1.1 through 3.1.18 of this SE, and Part III (only as specifically noted in Section 2.0 of the QAPD).

- Commitments consistent with GL 89-02 (Reference 26) and GL 91-05 (Reference 27), as described in Section 3.1.4 of this SE.

- NIRMA TG (References 28-31), as described in Section 3.1.17 of this SE.

- ISO/IEC 17025, 2017 Edition, “General requirements for the competence of testing and calibration laboratories.”

- EPRI Technical Report 3002019436-A, as described in Section 3.1.7 of this SE.

- EPRI Technical Report 3002020796, as described in Section 3.1.7 of this SE.

Based upon its review, the NRC staff has determined that this approach, as described in the NuScale QAPD, is consistent with SRP Section 17.5, Paragraph II.V, and, therefore, is acceptable.

4.0 CONCLUSION

The NRC staff concludes that the NuScale QAPD delineates the policies, processes, and controls and the implementing documents associated with NuScale's activities that affect the quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service.

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

The NRC staff finds that 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 QAPD in conformance with the provisions of 10 CFR 52.137(a)(19) and Appendix B to 10 CFR Part 50. Based on its review of the NuScale QAPD, the NRC staff concludes the following:

- The NuScale QAPD adequately describe 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 provide 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 non-safety 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 apply to activities and items that are important to safety.

- The NuScale QAPD adequately establishes controls that, when properly implemented, and subject to the limitations in Section 5.0 of this SE, comply with the requirements of 10 CFR Part 52, Appendix B to 10 CFR Part 50, and 10 CFR Part 21, consistent with the criteria contained in SRP Section 17.5, as well as the relevant regulatory guidance.

Based on its review, the NRC staff has determined that the NuScale QAPD, Revision 1, adequately describes the NuScale QA program. Further, the staff concludes that the NuScale QA program complies with applicable NRC regulations and industry standards and can be used by NuScale for activities affecting the quality and performance of items and services supporting the SDA and customer contracts.

5.0 LIMITATIONS AND CONDITIONS

This NuScale QAPD is specific to activities affecting the quality and performance of items and services supporting the SDA and customer contracts. Any other application referencing the approved revision of the NuScale QAPD, Revision 1 (MN-122626), shall provide a description in its QAPD that meets Appendix B to 10 CFR Part 50 and associated regulatory requirements.

As referenced in section 3.1.7 of this SE, the following limitations on the use of this QAPD apply:

- The exception to not perform audit or evaluation for procurements from other Part 50 licensees only applies when NuScale procures from other 10 CFR Part 50 power reactor licensees.

- When NuScale procures from manufacturing licensees where inspections during the fabrication or manufacturing process are required to assure quality, NuScale must establish measures for source verification for these procurements, as required by Criterion VII of Appendix B to 10 CFR Part 50.

6.0 REFERENCES

1. Letter from Mark W. Shaver, NuScale Power, LLC, to the NRC Document Control Desk, “NuScale Power, LLC Submittal of Topical Report “NuScale Power, LLC Quality Assurance Program Description,” MN-122626, Revision 0,” dated November 4, 2022 (ML22308A151).

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 August 2015 (ML15037A441).

3. Bell, R. J., Nuclear Energy Institute, to the U.S. NRC, “NEI Technical Report 11-04, Nuclear Generation Quality Assurance Program Description, Revision 0," September 13, 2012 (ML12258A358).

4. NRC Staff Clarification call with NuScale held on March 27, 2023 (Non-public) (ML23104A444).

5. Letter from Mark W. Shaver, NuScale Power, LLC, to the NRC Document Control Desk, “NuScale Power, LLC Submittal of Topical Report “NuScale Power, LLC Quality Assurance Program Description,” MN-122626, Revision 1,” dated July 11, 2023 (ML23192A280).

6. American Society of Mechanical Engineers (ASME) NQA-1-2008, “Quality Assurance Program Requirements for Nuclear Facilities Applications,” dated March 14, 2008.

7. American Society of Mechanical Engineers (ASME) NQA-1a-2009, “Addenda to ASME NQA-1-2008, Quality Assurance Program Requirements for Nuclear Facilities Applications,” dated August 11, 2009.

8. Regulatory Guide 1.28, Revision 4, “Quality Assurance Program Criteria (Design and Construction),” dated June 2010 (ML100160003).

9. Letter from Mahesh Chawla, USNRC, to Fadi Diya, Ameren Missouri, “Callaway Plant, Unit 1 – Operating Quality Assurance Manual Change Revision 34b,” dated August 6, 2020 (ML20216A681).

10. Regulatory Guide 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 5, dated October 2017 (ML17207A293).

11. EPRI Technical Report 3002019436 “Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance,” dated October 2020 (ML20300A386).

12. SE by the Office of Nuclear Reactor Regulation Regarding the Topical Report on the Quality Assurance Program Description for the Tennessee Valley Authority New Nuclear Program,” dated December 12, 2023 (ML23254A050).

13. Revision 1 of NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated September 2020 (ML20259B731).

14. Regulatory Guide 1.28, “Quality Assurance Program Criteria (Design and Construction),” Revision 6, dated September 2023 (ML23177A002).

15. SER by the Office of Nuclear Reactor Regulation “Columbia Generating Station – Reduction in Commitment to Operational Quality Assurance Program Description,” dated July 7, 2020 (ML20181A445).

16. SER by the Office of Nuclear Reactor Regulation for the SNC Fleet “Reduction in Commitment to the Quality Assurance Topical Report,” dated June 22, 2021 (ML21161A201).

17. Regulatory Issue Summary 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” dated October 23, 2000 (ML003739359).

18. Regulatory Guide 1.189, Revision 3, "Fire Protection for Nuclear Power Plants," dated February 2018 (ML17340A875).

19. NRC Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," dated April 16, 1985 (ML031140390).

20. Regulatory Guide 1.155, "Station Blackout,” dated August 1988 (ML003740034).

21. Regulatory Guide 1.164, Revision 0, “Dedication of Commercial-Grade Items for use in Nuclear Power Plants,” dated June 2017 (ML17041A206).

22. Regulatory Guide 1.231, Revision 0, “Acceptance of Commercial-Grade Design and Analysis Computer Programs used in Safety-Related Applications for Nuclear Power Plants,” dated January 2017 (ML16126A183).

23. Regulatory Guide 1.234, Revision 0, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21,” dated April 2018 (ML17338A072).

24. Regulatory Guide 1.26, Revision 6, "Quality Group Classification and Standards for Water, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” dated December 2021 (ML21232A142).

25. Regulatory Guide 1.29, Revision 6, "Seismic Design Classification," dated July 2021 (ML21155A003).

26. NRC, Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products,” dated March 21, 1989 (ML031140060).

27. NRC, Generic Letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs,” dated April 9, 1991 (ML031140508).

28. Nuclear Information and Records Management Association (NIRMA), “Authentication of Records and Media,” TG 11-2011, New York, NY.

29. NIRMA, “Management of Electronic Records,” TG 15-2011, Windham, NH.

30. NIRMA, “Software Configuration Management and Quality Assurance,” TG 16-2011, Windham, NH.

31. NIRMA, “Electronic Records Protection and Restoration,” TG 21-2011, Windham, NH.

32. NRC Generic Letter 88-18, “Plant Record Storage on Optical Disks”, dated October 20, 1988.