June 24, 2019 Docket No. PROJ0769

U.S. Nuclear Regulatory Commission
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SUBJECT: NuScale Power, LLC Submittal of "NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant," TR-1010-859-NP, Revision 4

REFERENCES:
1. Letter from NuScale Power, LLC to Nuclear Regulatory Commission, "NuScale Power LLC, Submittal of the Accepted Version of NuScale Licensing Topical Report NP-TR-1010-859-NP-A, 'Quality Assurance Program Description for the NuScale Power Plant,' Revision 3 (TAC No. RN6630)," dated December 12, 2016 (ML16347A405)

NuScale Power, LLC (NuScale) hereby submits Revision 4 of the "NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant" (NP-TR-1010-859-NP).

Substantive changes to the previously accepted NP-TR-1010-859-NP-A, Revision 3 (Reference 1) and NP-TR-1010-859-NP Revision 4 are limited to organization executive level reporting of testing activities. NP-TR-1010-859-NP Revision 4 Section 2.1.4.1 identifies the following responsibilities under the "Engineering" organization that had previously been under the "Technology" organization in NP-TR-1010-859-NP Revision 3 Section 2.1.3:

- Design certification testing and code development.
- Testing responsibilities include ensuring that test personnel are qualified and that test service providers develop facilities and test programs capable of providing accurate data defining the operating characteristics of the NuScale design.
- Code development responsibilities include the development of thermal hydraulic software code and the qualification and modification of existing analytical software codes.

This change is not a reduction in commitments of the NRC accepted NP-TR-1010-859-NP-A, Revision 3. This determination is based on the following considerations:

- The revision does not change any QA requirements or commitments. The same activities and same QA program requirements apply to the testing activities, and the same QA department audit oversight applies. The only change is in the organizational reporting of the testing and code development activities from the Manager responsible for "Technology," to the Manager responsible for "Engineering."
- The revision does not have any safety implications because there is no change to QA commitments, codes, or standards. QA program requirements are implemented by the same line organizations with a change in executive reporting.
- The change does not affect any licensing obligations identified in the NuScale FSAR and the change is not affecting any commitments related to notices of violation.

In accordance with 10 CFR 52.47(a)(19), the forthcoming Revision 3 of the NuScale design certification application will continue to identify NP-TR-1010-859-NP as the "description of the quality assurance program applied to the design of the structures, systems, and components of the facility." Because NuScale does not anticipate subsequent revisions of NP-TR-1010-859-NP or the design certification application, Revision 3 of the NuScale design certification application will cite NP-TR-1010-859-NP Revision 4, which is submitted herein to support completion of design certification.

This letter makes no regulatory commitments and no revisions to any existing regulatory commitments.

If you have any questions, please feel free to contact Rebecca Norris at 541-602-1260 or at rnorris@nuscalepower.com if you have any questions.

Sincerely,

Zackary W. Rad
Director, Regulatory Affairs
NuScale Power, LLC

Distribution: Samuel Lee, NRC, OWFN-8H12
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Enclosure: "NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant," TR-1010-859-NP, Revision 4

Enclosure 1:

"NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant," TR-1010-859-NP, Revision 4

Licensing Topical Report

NuScale Topical Report: Quality Assurance Program Description for the NuScale Power Plant

April, 2017

Revision 4

Docket: PROJ0769

Nonproprietary

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Licensing Topical Report

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Abstract

This topical report provides a description of the NuScale Power, LLC (NuScale) Quality Assurance Program (QAP) for the NuScale Power Plant. For ease of reference, this topical report is referred to as the Quality Assurance Program Description (QAPD). The QAPD has been prepared in accordance with the requirements of Title 10, Part 50 of the Code of Federal Regulations (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and ASME NQA-1-2008 and NQA-1a-2009 addenda, "Quality Assurance Program Requirements for Nuclear Facilities" as endorsed by Regulatory Guide 1.28, Revision 4, "Quality Assurance Program Criteria (Design and Construction)." This report was prepared consistent with the guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants" and Nuclear Energy Institute (NEI) 11-04A Revision 0, "Quality Assurance Program Description (QAPD)" template.

The topical report is divided into four parts: 1.0 Introduction; 2.0 Quality Assurance Program Description (QAPD) Details; 3.0 Nonsafety-Related Structures, Systems, and Components (SSC) Quality Control; and 4.0 Regulatory Commitments.

Consistent with common licensing practice, most of the application text is written in the present tense, active voice. It should be understood, however, that statements regarding the processes typically address activities that may have not yet been performed and will not be performed until it is reasonable and appropriate to do so.

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Policy Statement

NuScale Power, LLC (NuScale) shall design nuclear plants in a manner that will assure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations, the applicable Nuclear Regulatory Commission (NRC) licensing requirements, and applicable laws and regulations of state and local governments.

The NuScale Quality Assurance Program (QAP) is described in this document, the Quality Assurance Program Description (QAPD), and the associated implementing documents, which include policies, plans, and procedures. Together, they provide for control of NuScale activities that affect the quality of safety-related nuclear plant structures, systems, and components (SSCs) 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 QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents NuScale's overall philosophy regarding achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define the organizational interfaces involved in conducting activities within the scope of the QAP. Senior management establishes overall expectations for obtaining the desired end result. Compliance with the QAPD and its implementing documents is mandatory for NuScale personnel directly or indirectly associated with the implementation of the QAPD.

Signed

John Hopkins

Chief Executive Officer

NuScale Power, LLC

Date: April 13, 2017

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1.0 Part I—Introduction

1.1 General

NuScale Power's (NuScale) Quality Assurance Program Description (QAPD) is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for nuclear power plant activities conducted by or for NuScale. The QAPD describes the methods and establishes quality assurance and administrative control requirements that meet 10 CFR 50, Appendix B, 10 CFR 52, and 10 CFR 21. The QAPD is based on the requirements and recommendations of ASME NQA-1-2008 and NQA-1a-2009 addenda, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, with specific reference to selected sections in Part III and IV, as specified in this document.

The Quality Assurance Program (QAP) described in this report consists of the QAPD and associated implementing documents, which include policies, plans, and procedures. Quality Assurance Program Description requirements are defined by Regulatory Guide 1.28, Revision 4, which endorses NQA-1-2008 and NQA-1a-2009 addenda, which in turn describes the required Quality Assurance (QA) elements. Procedures and instructions that control activities will be developed prior to commencement of those activities. Policies establish high-level responsibilities and authority for carrying out important administrative functions that are outside the scope of the QAPD.

Procedures establish practices for certain activities that are common to all NuScale organizations performing those activities so that the activity is controlled and carried out in a manner that meets QAPD requirements. Procedures specific to an organization or group establish detailed implementation requirements and methods and may be used to implement policies or be unique to particular functions or work activities.

1.2 Scope/Applicability

The QAPD applies to the following activities affecting the quality and performance of safety-related structures, systems, and components (SSCs), in support of design certification activities

- designing
- procuring
- fabricating
- cleaning
- inspecting
- receiving
- handling
- shipping
- storing
- testing

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- training

Safety-related SSCs, subject to the requirements of the QAPD, are identified in design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QA requirements for activities within their scope.

The policy of NuScale is to assure a high degree of availability and reliability of a nuclear plant(s) while ensuring the health and safety of its workers and the public. To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other Nuclear Regulatory Commission (NRC) guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

The definitions provided in NQA-1a-2009 addenda, Part I, Section 400 apply to select terms as used in this document.

1.3 Abbreviations

Table 1-1. Abbreviations

Term	Definition
ATWS	anticipated transient without scram
CEO	chief executive officer
CFR	Code of Federal Regulations
COO/CNO	chief operating officer/chief nuclear officer
DC	design certification
FSAR	final safety analysis report
ILAC	International Laboratory Accreditation Cooperation
M&TE	Measuring and Test equipment
MRA	Mutual Recognition Arrangement
NRC	Nuclear Regulatory Commission
NEI	Nuclear Energy Institute
NIRMA	Nuclear Information and Records Management Association
NRC	Nuclear Regulatory Commission
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
RG	(NRC) Regulatory Guide
SBO	station blackout
SSCs	structures, systems, and components
TG	technical guide

Table 1-2. Definitions

Term	Definition
Applied research	Research intended to solve a specific problem or meet a practical

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Term	Definition
	need.
Basic research	Research conducted to acquire new knowledge of a theoretical or experimental nature.
Design certification (DC)	The process of research and design activities that develop and support an application to the NRC for certification of a standard design nuclear power plant.
Design process	Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.
Developmental research	Activities associated with the application of proven theory and experimental results and their extension to its end use, e.g., use in a design environment.
NuScale Power Plant	A modular, scalable nuclear power plant consisting of 50 Megawatts electrical light water reactors developed and designed by NuScale Power, LLC.
Quality Assurance Program (QAP)	The QA Program (QAP) described in this report consists of the QAPD and associated implementing documents, which include policies, plans, and procedures.
Quality Assurance Program Description (QAPD)	The document that describes the policies, scope, organizations, objectives, processes, and methods that constitutes the NuScale QAP relative to U.S. domestic licensing requirements for nuclear power plants. The QAPD document is entitled "Quality Assurance Topical Report" NP-TR-1010-859-NP, "Quality Assurance Program Description for the NuScale Power Plant." The QAPD is the top level policy document establishing the quality objectives and methods of NuScale Power, LLC.
Research and Development support activities	Activities that are conventional in nature to the advancement of knowledge and development of technology but allow the primary purpose of the work to be accomplished in a credible manner (e.g., calibration of measuring and test equipment).
Sub-tier implementing documents	Procedures, instructions, drawings, forms, and other forms of communicating prescribed methods, processes, sequences, authorization/authentication, quantitative /qualitative acceptance criteria, and required documentation necessary to assure and provide documented evidence of the quality of NuScale end products and services.

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2.0 Part II—Quality Assurance Program Description Details

2.1 Organization

This section describes the NuScale functional organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying QAPD implementation. The functional organizational structure includes corporate and support functions, including interface responsibilities for multiple organizations that perform quality-related functions. Implementing documents assign more specific responsibilities and duties, and they define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent, and effects of organizational structure changes.

The NuScale quality assurance function is responsible to size the quality assurance staff commensurate with the duties and responsibilities assigned.

Design, engineering, and testing services are provided to NuScale by qualified contractors in accordance with their QA programs or by contractors working under the NuScale QA program. These contractors are evaluated and approved prior to performing safety-related work.

The following sections describe the reporting relationships, functional responsibilities, and authorities for organizations implementing and supporting the NuScale QAP. The NuScale functional organization is shown in Figure 2-1.

2.1.1 Chief Executive Officer

The NuScale chief executive officer (CEO) is responsible for all aspects of design of the NuScale Power Plant. The CEO is also responsible for all technical and administrative support activities provided by NuScale and its contractors. The CEO directs the business systems function, the chief operating officer (COO)/chief nuclear officer (CNO), and the technology function in the fulfillment of their responsibilities. The CEO reports to the NuScale Board of Directors with respect to all company matters.

2.1.2 Business Systems

The Manager responsible for business systems reports to the NuScale CEO and, in addition to normal financial functions customarily managed, is responsible for other company-wide administrative functions, including the integration of company information technology controls and infrastructure, the development of company-wide system of policies and procedures, and the document control and record management system.

2.1.3 Technology

The Manager responsible for technology reports to the NuScale CEO, and is responsible for technology development and research collaboration.

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2.1.4 Chief Operating Officer/Chief Nuclear Officer

The NuScale chief operating officer/chief nuclear officer (COO/CNO) has overall responsibility for ensuring the effective functioning of all areas of engineering, operations, regulatory affairs, supply chain, safety analysis, corrective action program, human resources, and project management through their functional managers, consistent with regulatory requirements and procedural guidance. The COO/CNO is responsible for ensuring through the respective functional managers, that all functional groups understand the implementing procedures, that their direct reports are adequately trained and qualified to those procedures prior to performing assigned tasks, and that those direct reports develop their respective work products consistent with the requirements established by those procedures. The COO/CNO reports to the CEO. The COO/CNO is also responsible for leading the development of an effective company-wide Safety Culture/Safety Conscious Work Environment (SCWE) Program.

2.1.4.1 Engineering

The Manager responsible for engineering reports to the COO/CNO and is responsible for the design of the NuScale Reactor Module, Safety-Related Structures, Systems, and Components as the Design Authority, and is responsible for ensuring the NuScale Power Plant is designed for safe, simple, and reliable operation. The position oversees a group of engineering managers and other direct reports to ensure assigned work is performed in accordance with applicable NuScale procedures and practices and regulatory requirements. Engineering is responsible to issue and control drawings, specifications, calculations, and other documents that define the NuScale design, accept such documents from others for incorporation into the NuScale design, and delegate such authority to others. In this capacity, Engineering provides the fully integrated suite of engineering, design, safety analysis products and processes necessary to define the design (and to support associated procuring, fabricating, testing, and training) of the NuScale Power Plant to the requisite technical, safety, performance, and quality standards. Engineering is also responsible for design certification testing and code development. Testing responsibilities include ensuring that test personnel are qualified and that test service providers develop facilities and test programs capable of providing accurate data defining the operating characteristics of the NuScale design. Code development responsibilities include the development of thermal hydraulic software code and the qualification and modification of existing analytical software codes.

2.1.4.2 Operations

The Manager responsible for operations reports to the COO/CNO and is responsible for performing the functions necessary to inform the NuScale design from an operations and maintenance perspective. Operations is responsible for developing a plant services business to provide services for the effective startup and operation of NuScale power plants.

2.1.4.3 Program Management

The Manager responsible for program management reports to the COO/CNO and is responsible to effectively and efficiently execute projects across the company in a consistent manner. Program Management has the responsibility to develop and deploy

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integrated project schedules, with associated budget and project management controls. This is achieved through the development of project plans; scope; and budgets and schedules by working in coordination with internal services, support organizations and contract resources; problem anticipation, identification, and resolution; and defining and delivering reports on project performance.

2.1.4.4 Regulatory Affairs

The Manager responsible for regulatory affairs reports to the COO/CNO and is responsible for licensing activities associated with the NuScale Power Plant and standard plant design and development. Regulatory Affairs develops, implements, and monitors the NuScale Licensing Plan and provides licensing recommendations to senior management. This function is the single point of contact with regulatory agencies for effective communications and is responsible for 1) administration of the 10 CFR 21 evaluation and reporting program and 2) ensuring that licensing-related requirements and commitments are addressed and controlled in an effective manner.

2.1.4.5 Supply Chain

The Manager responsible for supply chain activities reports to the COO/CNO and is responsible for the development, evaluation, and administration of the NuScale supply chain. Responsibilities include interfacing with engineering and quality assurance functions to ensure that suppliers of safety-related services are evaluated prior to award and all applicable technical and quality requirements are effectively communicated through procurement documents.

2.1.4.6 Human Resources

The Manager responsible for human resources reports to the COO/CNO and is responsible for all personnel decisions regarding recruitment and retention.

2.1.4.7 Quality Assurance

The Manager responsible for quality assurance is responsible for independently planning and performing activities to verify the development and effective implementation of the NuScale QAPD, including, but not limited to, NuScale Power Plant engineering, document control, corrective action program, and procurement processes.

Quality assurance reports to the COO/CNO. Quality Assurance is responsible for development, implementation, and maintenance of the QAPD and is responsible for verifying that activities are in compliance with applicable regulatory, code, and industry standard requirements. If Quality Assurance disagrees with actions taken by the NuScale organization and is unable to obtain resolution, Quality Assurance shall inform the COO/CNO and has the authority to directly bring the matter to the attention of the CEO for final disposition.

Quality Assurance is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; for monitoring organization processes to ensure conformance to commitments and licensing document requirements; and for ensuring that suppliers providing quality services, parts, and

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materials to NuScale are meeting the requirements of 10 CFR 50, Appendix B through NuScale supplier evaluations, surveillances, and audits. Quality Assurance has sufficient independence from other priorities to bring forward issues affecting safety and quality and to make judgments regarding quality in all areas necessary regarding NuScale activities.

The Manager responsible for QA is at the same or higher organizational level as the highest line manager directly responsible for performing the activities affecting quality (i.e. engineering, procurement, operations) and is sufficiently independent from cost and schedule for the conduct of Quality Assurance activities by reporting to the COO/CNO.

2.1.5 Authority to Stop Work

Quality assurance and inspection personnel have the authority, and the responsibility, to stop work in progress that is not being performed in accordance with approved procedures where safety or SSC integrity may be jeopardized. This extends to off-site work performed by suppliers that furnish safety-related items and services to NuScale.

2.1.6 Quality Assurance Organizational Independence

Independence shall be maintained between the organizations performing the checking (quality assurance and control) functions and the organizations performing the functions. Independence for design reviews and verifications is described in Section 2.3.1.

2.1.7 NQA-1-2008 Commitment

In establishing its organizational structure, NuScale commits to compliance with NQA-1-2008, Requirement 1, Sections 100 through 300.

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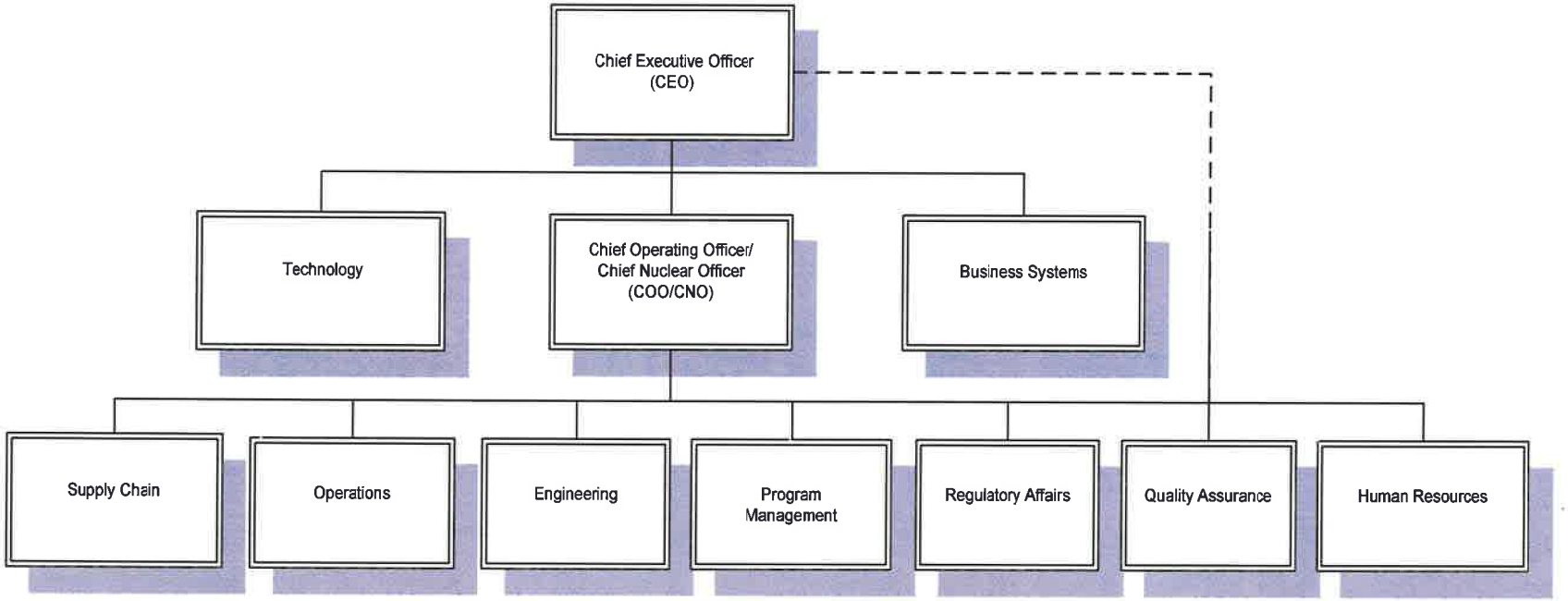

Figure 2-1. NuScale Organization

2.2 Quality Assurance Program

NuScale has established the necessary measures and governing procedures to implement the QAP as described in the QAPD. NuScale is committed to implementing the QAP in all aspects of work that are important to the safety of the nuclear plant(s) as described and to the extent delineated in the QAPD. The QAP shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities important to safety are performed satisfactorily. Further, NuScale ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. Senior management is regularly apprised of the adequacy of implementation of the QAP through the audit functions described in Section 2.18 in this document.

The objective of the QAP is to assure that NuScale Power Plants are designed in accordance with governing regulations and requirements. The program is based on the requirements of ASME NQA-1-2008 and NQA-1a-2009 addenda, "Quality Assurance Requirements for Nuclear Facility Applications," as further described in this document. The QAP 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 and to the managerial and administrative controls to be used to assure the NuScale Power Plant design complies with applicable regulatory requirements. Examples of 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 that identifies SSC and activities to which this program applies is maintained at NuScale. Cost and scheduling challenges must be addressed; however, they do not prevent proper implementation of the QAP.

As described in Section 3.0 of the QAPD, specific program controls are applied to nonsafety-related SSCs, for which 10 CFR 50, Appendix B is not applicable, but that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner and targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

Delegated responsibilities may be performed under a supplier's or principal contractor's QAP, provided the supplier or principal contractor has been approved as a supplier in accordance with the NuScale QAP. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principal contractor's QAPD and implementing procedures. In addition, routine interfaces with the supplier's personnel provide added assurance that quality expectations are met.

In general, the program requirements specified herein are detailed in implementing procedures that are either NuScale implementing procedures or supplier implementing procedures governed by a supplier quality assurance program.

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis, unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90-day general period could be applied. The grace period does not allow the "clock" for a particular activity to be reset

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forward. The "clock" for an activity is reset backwards by performing the activity early. Audit schedules are based on the month in which the audit starts.

2.2.1 Responsibilities

Personnel who work directly or indirectly for NuScale are responsible for achieving acceptable quality in the work covered by the QAPD. This includes the activities delineated in Section 1.1. NuScale personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAPD are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate to the activity's complexity and effect on safety. Instructions, procedures, and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate to the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity and to ascertain that such documents are being used. The NuScale quality assurance function is responsible to verify that processes and procedures comply with the QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2.2 Delegation of Work

NuScale retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in Section 2.1 in this document may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but they retain the responsibility for the program's effectiveness. Decisions affecting safety are made at the level appropriate for its nature and effect and with any necessary technical advice or review.

2.2.3 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program, or portions thereof, assess the adequacy of that part of the program for which they are responsible to assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter.

2.2.4 Issuance and Revision to Quality Assurance Program

Administrative control of the QAPD is in accordance with 10 CFR 50.55(f). Changes to the QAPD are evaluated by the NuScale quality assurance organization to ensure that such changes do not degrade previously approved quality assurance controls specified in the QAPD. This document shall be revised, as appropriate, to incorporate additional QA commitments that may be established over time. New revisions to the document will be reviewed, at a minimum, by the NuScale quality assurance organization and approved by the COO/CNO.

2.2.5 Personnel Training and Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end, NuScale establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing

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activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained. The indoctrination, training, and qualification programs are commensurate with scope, complexity, and importance of the activities; and include or address the following, as appropriate:

- Education, experience, and proficiency of the personnel receiving training
- General criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements
- On-the-job training, if direct hands-on applications or experience is needed to achieve and maintain proficiency

Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable NuScale procedures. Indoctrination includes administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed. Records of personnel training and qualification are maintained.

The minimum qualifications of the individual in charge of quality assurance are that he or she holds an engineering or related science degree and a minimum of four years of related experience, including two years of nuclear power plant experience, and one year of supervisory or management experience, with one year of that experience performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements are not eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of the individuals responsible for planning, implementing, and maintaining the programs of the QAPD are that each has a high school diploma, or equivalent, and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

2.2.6 NQA-1-2008 Commitment and Exceptions

In establishing qualification and training programs, NuScale commits to compliance with NQA-1-2008, Requirement 2, Sections 100 through 500.

2.3 Design Control

NuScale has established and implements a process to control the design and design changes of items that are subject to the provisions of the QAPD. The design process

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includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces within NuScale and with suppliers. These provisions assure that 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. Design change processes and the division of responsibilities for design-related activities are detailed in NuScale and supplier procedures. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. Design changes and disposition of nonconforming items as "use as is" or "repair" are reviewed and approved by the NuScale design organization or by other organizations so authorized by NuScale.

Design documents are reviewed by individuals knowledgeable and qualified in QA through education, experience, and training to ensure the documents contain the necessary QA requirements.

2.3.1 Design Verification

NuScale design processes provide for design verification to ensure that items, computer programs, and activities subject to the provisions of the QAPD are suitable for their intended application and consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.

Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator's supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator's supervisor, the justification of the need is documented and approved in advance by management.

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. This includes design inputs, design outputs, and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the item's intended use.

NuScale normally completes design verification activities before the design outputs are used by other organizations for design work and before they are used to support other

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activities such as procurement or testing. Procedures are established that require identification and control of any portion of the design where verification has not been completed. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

2.3.2 Design Records

NuScale maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as records of the important design steps (e.g., calculations, analyses, and computer programs) and the sources of input that support the final output.

Plant design drawings reflect the properly reviewed and approved configuration of the plant.

2.3.3 Computer Application and Digital Equipment Software

The 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. Computer program acceptability is pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs are controlled using a software configuration management process. NuScale and suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto is documented and approved by authorized personnel. The QAP is also applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAP requirements such as QA records.

2.3.4 NQA-1-2008 and NQA-1a-2009 addenda, Commitment

In establishing its program for design control and verification, NuScale commits to compliance with NQA-1-2008 and NQA-1a-2009 addenda, Requirement 3, Sections 100 through 900, and the standards for computer software in NQA-1-2008 and NQA-1a-2009 addenda, Part II, Subpart 2.7 and Subpart 2.14 for Quality Assurance requirements for commercial grade items and services.

2.4 Procurement Document Control

NuScale has established the necessary measures and governing procedures to assure that purchased items, computer programs, and services are subject to appropriate quality and technical requirements. Procurement documents (e.g., statements of work to be included in contracts), and any changes thereto shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include the following provisions:

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- If original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit, and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.
- Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating, and reporting shall be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for 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 50, Appendix B as appropriate to the circumstances of procurements (or the supplier may work under NuScale's approved QA program).

Reviews of the technical and quality requirements for inclusion in procurement documents shall be performed by personnel who have access to pertinent information and who have an adequate understanding of those requirements and their intent.

2.4.1 NQA-1-2008 Commitment/Exceptions

In establishing controls for procurement, NuScale commits to compliance with NQA-1-2008, Requirement 4, Sections 100 through 400, with the following clarifications and exceptions:

- With regard to service performed by a supplier, NuScale procurement documents may allow the supplier to work under the NuScale QAP, including implementing procedures, in lieu of the supplier having its own QAP.
- Sections 300 and 400 of Requirement 4 require the review of technical and Quality Assurance 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 specification when the specification contains the technical and quality assurance requirements of the procurement.
- 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 the NuScale QAPD, Section 2.7, "Control of Purchased Material, Equipment and Services."

2.5 Instructions, Procedures, and Drawings

NuScale has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with, instructions, procedures, or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP as described in this document. Such documents are prepared and

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controlled according to Section 2.6 in this document. In addition, means are provided to disseminate to the staff instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

2.5.1 Procedure Adherence

NuScale's policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Section 2.6 in this document. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require

- the written procedure to be present and followed step-by-step while the task is being performed.
- the user to have committed the procedure steps to memory.
- verification of completion of significant steps by initials or signatures or use of check-off lists.

Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks are infrequently performed, and tasks where steps must be performed in a specified sequence.

2.5.2 Procedure Content

The established measures address the applicable content of procedures as described in the introduction to Part II of NQA-1-2008. In addition, procedures governing tests, inspections, operational activities, and maintenance will include, as applicable, initial conditions and prerequisites for the performance of the activity.

2.5.3 NQA-1-2008 Commitment

In establishing procedural controls, NuScale commits to compliance with NQA-1-2008, Requirement 5, Section 100.

2.6 Document Control

NuScale has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control systems (including electronic systems used to make documents available) are documented and provide for the following:

- identification of documents to be controlled and their specified distribution
- a method to identify the correct document (including revision) to be used and control of superseded documents

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- identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents
- review of documents for adequacy, completeness, and correctness prior to approval and issuance
- a method for providing feedback from users to continually improve procedures and work instructions
- coordinating and controlling interface documents and procedures

The types of documents to be controlled include

- drawings, such as design
- engineering calculations
- design specifications
- purchase orders and related documents
- vendor-supplied documents
- audit, surveillance, and quality verification/inspection procedures
- inspection and test reports
- instructions and procedures for activities covered by the QAP
- technical specifications
- nonconformance reports and corrective action reports

2.6.1 Review and Approval of Documents

Documents are reviewed for adequacy by qualified persons other than the preparer. Procedures for design and installation are also reviewed by the quality group to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence. Prior to issuance or use, documents including revisions thereto, are approved by the designated authority. A listing of all controlled documents identifying the current approved revision or date is maintained so personnel can readily determine the appropriate document for use.

2.6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated. The reviewing organization has access to pertinent background data or information upon which to base their approval. Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval, and the persons who can authorize such a classification shall be clearly delineated in implementing procedures.

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2.6.3 NQA-1-2008 Commitment

In establishing provisions for document control, NuScale commits to compliance with NQA-1-2008, Requirement 6, Sections 100 through 300.

2.7 Control of Purchased Material, Equipment, and Services

NuScale has established the necessary measures and governing procedures to control the procurement of items and services to assure conformance with specified requirements. Such control provides for the following, as appropriate: source evaluation and selection; evaluation of objective evidence of quality furnished by the supplier; source inspection, audit, and examination of items or services.

2.7.1 Acceptance of Item or Service

NuScale 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. Verification actions include testing, as appropriate. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of, or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. NuScale may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet NuScale requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs such as those applied by ASME are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third-party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate). Acceptance actions and documents are established by the purchaser with appropriate input from the supplier and are completed to ensure that procurement, inspection, and test requirements, as

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applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and acceptance of commercial grade services or items to assure they will perform satisfactorily in service in safety-related applications.
- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

2.7.2 NQA-1-2008 and NQA-1a-2009, Commitment/Exceptions

- In establishing procurement verification controls, NuScale commits to compliance with NQA-1-2008 and NQA-1a-2009 addenda, Requirement 7, Sections 100 through 800, with the following clarifications and exceptions:
- NQA-1-2008, Sections 200 & 503(f)
  - NuScale considers that other 10 CFR 50 licensees, authorized nuclear inspection agencies, National Institute of Standards and Technology, or other state and federal agencies that may provide items or services to NuScale are not required to be evaluated or audited.
  - When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), commercial grade surveys need not be performed provided each of the following conditions are met:
    - A documented review of the supplier's accreditation is performed and includes a verification of the following:
      - The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."
      - For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
      - For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services, including test methodology and tolerances/uncertainty.
    - The purchase documents require that
      - The service be provided in accordance with their accredited ISO/IEC-17025:2005 program and scope of accreditation.
      - As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only).

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  - The equipment/standards used to perform the calibration must be identified in the certificate of calibration (for calibration services only).
  - The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
  - Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
- It is validated, at receipt inspection, that the laboratory's documentation certifies that
  - The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 program and has been performed within their scope of accreditation.
  - The purchase order requirements are met.

- In establishing commercial grade items requirements, NuScale commits to compliance with NQA-1a-2009, Requirement 7, Section 700, and Subpart 2.14.
- NuScale will assume 10 CFR Part 21 reporting responsibility for commercial items and services that NuScale dedicates for use in safety-related applications.

2.8 Identification and Control of Materials, Parts, and Components

Prior to initiating the activities defined in this section, necessary measures and governing procedures will be established to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. The identification of items is maintained throughout fabrication, erection, installation and use so that the item can be traced to its documentation, consistent with the item's effect on safety. Identification locations and methods are selected so as not to affect the function or quality of the item.

In establishing provisions for identification and control of items, NuScale commits to compliance with NQA-1-2008, Requirement 8, Sections 100 through 300.

2.9 Control of Special Processes

Prior to initiating the activities defined in this section, necessary measures and governing procedures will be established to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria, or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

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2.9.1 NQA-1-2008 Commitment

In establishing provisions for control of special processes, NuScale commits to compliance with NQA-1-2008, Requirement 9, Sections 100 through 400.

2.10 Inspection

Prior to initiating the activities defined in this section, necessary measures and governing procedures will be established to implement inspections that assure items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. 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 documented.

2.10.1 Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary, to verify quality

- at the source of supplied items or services
- in-process during fabrication at a supplier's facility or at a NuScale facility
- for final acceptance of fabricated and/or installed items
- upon receipt of items involved in design development testing

The inspection program establishes requirements for planning inspections, including the identification of the group or discipline responsible for performing the inspection, establishing inspection hold points, determining applicable acceptance criteria, determining the frequency of inspection to be applied, and identifying any special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and may include qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections and documenting required inspection information such as rejection, acceptance, re-inspection results, and the person(s) performing the inspection.

Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

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2.10.2 Inspector Qualification

NuScale, suppliers and subcontractors shall, where applicable, establish a qualification program for personnel performing quality inspections. The qualification program requirements are described in Section 2.2 in this document. These qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

2.10.3 NQA-1-2008 Commitment/Exceptions

In establishing inspection requirements, NuScale commits to compliance with NQA-1-2008, Requirement 10, Sections 100 through 800 and Subparts 2.4, 2.5, and 2.8 for establishing appropriate inspection requirements.

2.11 Test Control

NuScale has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service. These measures and governing procedures include criteria for determining when testing is required to demonstrate that performance of plant systems is in accordance with design. Tests are performed in accordance with applicable procedures that include, consistent with the effect on safety,

- instructions and prerequisites to perform the test
- use of proper test equipment
- acceptance criteria
- 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 assure that the test requirements have been satisfied. If acceptance criteria are not met, retesting is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

Tests are performed and results documented in accordance with applicable technical and regulatory requirements, including ensuring appropriate retention of test data in accordance with the records requirements of the QAPD. Personnel who perform or evaluate tests are qualified in accordance with the requirements established in Section 2.2 in this document.

2.11.1 NQA-1a-2009 addenda, Commitment for non-Computer Program Testing

In establishing provisions for testing, NuScale commits to compliance with NQA-1a-2009 addenda, Requirement 11, Sections 100 through 300, 500, 600 and 601.

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2.11.2 NQA-1-2008 and NQA-1a-2009 addenda, Commitment for Computer Program Testing

NuScale establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified, tested, and used such that the expected output is obtained and configuration control maintained. To this end, NuScale commits to compliance with the requirements of 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.

2.12 Control of Measuring and Test Equipment

NuScale has established the necessary measures and governing procedures to control the calibration, maintenance, and use of Measuring and Test equipment (M&TE) that provides 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 nondestructive examination equipment. The suppliers of commercial grade calibration services are controlled as described in Section 2.7 in this document.

2.12.1 NQA-1-2008 Commitment/Exceptions

In establishing provisions for control of measuring and test equipment, NuScale commits to compliance with NQA-1-2008, Requirement 12, Sections 100 through 400, with the following clarification and exception:

- The out of calibration conditions described in Section 303.2 refers to when 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.
- Measuring and test equipment are not required to be marked with the calibration status, as described in Section 303.6, where it is impossible or impractical due to equipment size or configuration (such as 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 ANSI/IEEE Std. 336-1985).

2.13 Handling, Storage, and Shipping

Prior to initiating the activities defined in this section, necessary measures and governing procedures will be established to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration. These provisions include specific procedures, when required to maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling and storage to identify, maintain, and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are provided when required to maintain acceptable quality.

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Special or additional handling, storage, shipping, cleaning and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment are used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedure at specified time intervals, or prior to use.

Operators of special handling and lifting equipment are experienced or trained in the use the equipment. Where required, NuScale complies with applicable hoisting, rigging, and transportation regulations and codes.

2.13.1 Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems, and components. This includes control of cleanliness of facilities and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, and protection of equipment. Housekeeping practices help assure that only proper materials, equipment, processes, and procedures are used and that the quality of items is not degraded. Necessary procedures or work instructions are developed and used.

2.13.2 NQA-1 Commitment/Exceptions

In establishing provisions for handling, storage, and shipping, NuScale commits to compliance with NQA-1-2008, Requirement 13.

2.14 Inspection, Test, and Operating Status

Prior to initiating the activities defined in this section, necessary measures and governing procedures will be established 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. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test, or operating status 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.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers and lifted wires, and temporary trip-point settings, will be controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications, 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.

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2.14.1 NQA-1 Commitment

In establishing measures for control of inspection, test, and operating status, NuScale commits to compliance with NQA-1-2008, Requirement 14, Section 100.

2.15 Nonconforming Materials, Parts, or Components

NuScale has established the necessary measures and governing procedures to control items, including services that do not conform to specified requirements to prevent inadvertent use. Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Section 2.16 of this document. Controls provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming items, and notification to affected organizations. Controls are 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.

Conditional release of nonconforming items requires the approval of management. Nonconformances are corrected or resolved before relying on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of safety-related (Q) structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements, 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.

2.15.1 Interface with the Reporting Program

NuScale has appropriate interfaces between the QAP for identification and control of nonconforming items, including services, and the non-QA reporting programs to satisfy the requirements of 10 CFR 52 and 10 CFR 21.

2.15.2 NQA-1-2008 Commitment

In establishing measures for nonconforming items, including services, NuScale commits to compliance with NQA-1-2008, Requirement 15, Sections 100 through 400.

2.16 Corrective Action

NuScale has established the necessary measures and governing procedures to promptly identify, control, document, classify, correct and verify conditions adverse to quality. NuScale procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. NuScale procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, NuScale documents

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establish the requirements for documentation and timely evaluation of the issue. 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 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 responsibility for the effectiveness of corrective action measures.

2.16.1 Interface with the Reporting Program

NuScale has appropriate interfaces between the QAP for corrective actions and the non-QA reporting program to satisfy the requirements of 10 CFR 52 and 10 CFR 21.

2.16.2 NQA-1-2008 Commitment

In establishing provisions for corrective action, NuScale commits to compliance with NQA-1-2008, Requirement 16, Section 100.

2.17 Quality Assurance Records

NuScale has the necessary measures and governing procedures 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.

2.17.1 Record Retention

Measures are established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Records of activities for design, engineering, procurement, inspection, test, and audits and their retention times are defined in appropriate procedures. The records and retention times are based on Regulatory Position C.1 of Regulatory Guide 1.28, Revision 4, and NQA-1a-2009 addenda, Nonmandatory Appendix 17A-1, Section 200 as applicable. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

2.17.2 Electronic Records

When using optical disks for electronic records storage and retrieval systems, NuScale complies with the NRC guidance in Generic Letter 88-18, "Plant Record Storage on Optical Disks." NuScale manages the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG 11-1998, TG15-1998, TG16-1998, and TG21-1998.

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2.17.3 NQA-1-2008 Commitment and Exceptions

In establishing provisions for records, NuScale commits to compliance with NQA-1-2008, Requirement 17, Sections 100 through 800.

2.18 Audits

NuScale has established the necessary measures and governing procedures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established. The audit programs are reviewed for effectiveness as a part of the overall audit process.

2.18.1 Performance of Audits

Internal audits of selected aspects of the project activities are performed with a frequency commensurate with the safety significance of the activity and in a manner that assures that audits of safety-related activities are completed. During the early portions of project activities, audits will focus on areas including, but not limited to design, document control, procurement, testing and corrective action. Functional areas of an organization's QA program for auditing include, at a minimum, verification of compliance and effectiveness of implementation of internal rules and procedures (e.g., design, procurement, surveillance, test); regulations; programs for training, retraining, and personnel qualification; and corrective actions, including associated recordkeeping.

The audits are scheduled on a formal, preplanned audit schedule. The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities. Additional audits may be performed as deemed necessary by management. 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 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 the NuScale QAD.

The NuScale QAD is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures (by representative sampling), and to determine if they are meaningful and comply with the overall QAP. External audits determine the adequacy of supplier and contractor quality assurance programs and are issued to the management of the audited organization and applicable management.

The results of each audit are reported in writing to the COO/CNO and responsible functional manager, as appropriate. Additional internal distribution is provided to responsible management levels.

Management responds to all audit findings and initiates corrective action when determined necessary. When corrective action measures are determined to be necessary, documented follow-up of applicable areas through inspections, reviews, re-audits, or other appropriate means is conducted to verify implementation and effectiveness of corrective actions.

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Audits of suppliers of safety-related components and/or services are conducted as described in Section 2.7.1 in this document.

2.18.2 Internal Audits

Internal audits should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter.

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QAPD. These include regulations; provisions for training, retraining, qualification, and performance of personnel performing activities covered by the QAP; and observation of the performance of activities including associated recordkeeping.

2.18.3 NQA-1-2008 Commitment

In establishing the independent audit program, NuScale commits to compliance with NQA-1-2008, Requirement 18, Sections 100 through 800.

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3.0 Part III—Nonsafety-Related Structures, Systems, and Components Quality Control

3.1 Nonsafety-Related Structures, Systems, and, Components—Significant Contributors to Plant Safety

Specific program controls are applied to nonsafety-related SSC, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner and targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the nonsafety-related SSC and related activities, including the identification of exceptions to the QA Program for nonsafety-related SSC that are described in Sections 2.1 through 2.18 of this document.

3.1.1 Organization

The verification activities described in this section may be performed by the NuScale line organization. The QA organization described in Section 2.1 is not required to perform these functions.

3.1.2 Quality Assurance Program

NuScale QA requirements for nonsafety-related SSCs are established in the QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures. A new or separate QA program is not required.

3.1.3 Design Control

NuScale has design control measures to ensure that the established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer's work.

3.1.4 Procurement Document Control

Procurement documents for items and services obtained by or for NuScale include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

3.1.5 Instructions, Procedures, and Drawings

NuScale provides documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders to direct the performance of activities affecting quality. The method of instruction employed provides an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

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3.1.6 Document Control

NuScale controls the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

3.1.7 Control of Purchased Items and Services

NuScale employs measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

3.1.8 Identification and Control of Purchased Items

NuScale employs measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf life restrictions for the items.

3.1.9 Control of Special Processes

NuScale employs process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

3.1.10 Inspection

NuScale requires use of documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by knowledgeable personnel in the line organization. Knowledgeable personnel can be from the same discipline and have experience related to the work being inspected.

3.1.11 Test Control

NuScale employs measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

3.1.12 Control of Measuring and Test Equipment

NuScale employs measures to control M&TE use, calibration, and adjustment at specific intervals or prior to use.

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3.1.13 Handling, Storage, and Shipping

NuScale employs measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

3.1.14 Inspection, Test, and Operating Status

NuScale employs measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

3.1.15 Control of Nonconforming Items

NuScale employs measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

3.1.16 Corrective Action

NuScale employs measures to ensure that failures, malfunctions, deficiencies, deviations, and nonconformances are properly identified, reported, and corrected.

3.1.17 Records

NuScale employs measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

3.1.18 Audits

NuScale employs measures for line management to periodically review and document the adequacy of processes, including taking any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this section (Section 3.0) are implemented by the same programs, processes, or procedures as the comparable activities of Section 2.0, the audits performed under the provisions of Section 2.0 may be used to satisfy the review requirements of this section (Section 3.1.18).

3.2 Nonsafety-Related Structures, Systems, and Components Credited for Regulatory Events

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related:

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- NuScale implements quality requirements for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189 Revision 2, October 2009, "Fire Protection for Operating Nuclear Power Plants."
- NuScale implements the quality requirements for ATWS equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."
- NuScale implements quality requirements for 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 Nonsafety Systems and Equipment," in Regulatory Guide 1.155 Revision 0 August 1988, "Station Blackout."

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4.0 Part IV—Regulatory Commitments

4.1 Nuclear Regulatory Commission Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards that have been selected to supplement and support the NuScale QAP. NuScale complies with these standards to the extent described or referenced in the Scope/Applicability Section 1.2, as they apply to Design Certification activities. See Final Safety Analysis Report (FSAR) Chapter 1 of the NuScale DC application for a full evaluation of conformance with the guidance in NRC RGs in effect six months prior to the submittal date of the application. Commitment to a particular RG or standard does not constitute a commitment to other RGs or standards that may be referenced therein.

Regulatory Guides

4.1.1 U.S Nuclear Regulatory Commission, "Qualification and Training of Personnel for Nuclear Power Plants," Regulatory Guide 1.8, Revision 3, ADAMS Accession No. ML003706932.

Regulatory Guide 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel.

NuScale identifies conformance and exceptions for the applicable regulatory position guidance provided in this regulatory guide in FSAR Chapter 1.

4.1.2 U.S Nuclear Regulatory Commission, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," Regulatory Guide 1.26, Revision 4, ADAMS Accession No. ML070290283.

Regulatory Guide 1.26 defines classification of systems and components.

The NuScale Power Plant design is unique in configuration and safety feature functions. The design includes components not found in existing standard design reactors (e.g., containment pressure vessel) and does not include some components found in existing standard designs. Examples of features not found in the NuScale design include, but are not limited to, reactor coolant pumps, cold legs, hot legs, pressurizer surge line, core make-up tanks and piping, direct vessel injection lines, passive residual heat removal heat exchangers, in-containment storage tanks, and hydrogen recombiners. These unique design features and the equivalence of their design safety functions, including application to committed regulatory guidance, will be detailed in Chapter 3 of the FSAR.

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4.1.3 NuScale identifies conformance and exceptions for the applicable regulatory position guidance as indicated in the NuScale DC FSAR, Chapter 1, U.S. Nuclear Regulatory Commission, "Quality Assurance Program Requirements (Design and Construction)," Regulatory Guide 1.28, Revision 4, ADAMS Accession No. ML100160003.

Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design of nuclear power plants.

NuScale commits to the applicable regulatory position guidance as indicated in the NuScale DC FSAR, Chapter 1.

- U.S. Nuclear Regulatory Commission, "Seismic Design Classification," Regulatory Guide 1.29, Revision 4, ADAMS Accession No. ML070310052.
- Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake.
- NuScale commits to the applicable regulatory position guidance as indicated in the NuScale DC FSAR, Chapter 1.

Standards

4.1.4 American Society of Mechanical Engineers, "Quality Assurance Requirements for Nuclear Facility Applications," ASME NQA-1-2008 and NQA-1a-2009 addenda, Edition, New York, NY.

NuScale commits to NQA-1-2008 and NQA-1a-2009 addenda, Parts I and II as described in Section 2.0 in this document with specific identification of exceptions or clarification. NuScale commits to NQA-1-2008 with NQA-1a-2009 addenda, Part III only as specifically noted in Section 2.0 of this document.

4.1.5 Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs).

4.1.6 NuScale commits to NIRMA TGs as described in Section 2.17 in this document.

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