



NuScale Topical Report: Quality Assurance Program Description for Design Certification of the NuScale Power Reactor

NP-TR-1010-859-NP

Deleted: ¶
NuScale Non-Proprietary

... [1]

NuScale Topical Report: Quality Assurance Program Description for Design Certification of the NuScale Power Reactor

March 2011

Deleted: October 2010¶

Revision 1

Deleted: 0

Nonproprietary

Deleted: NuScale Non-Proprietary¶

Prepared by/date:

Dan Ramey Quality Specialist

Deleted: R. M. Marshall . Senior

Reviewed by/date:

Frank Hood Quality Assurance Director

Deleted: C. A. Smioldo

Deleted: (Acting)

Approved by/date:

E. G. Wallace

Senior Vice President, Regulatory Affairs

NuScale Power, Inc.

Suite 10310
1000 NE Circle Blvd
Corvallis, Oregon 97330
www.nuscalepower.com

© Copyright 2011 NuScale Power, Inc

Deleted: 2010

DRAFT

NP-TR-1010-859-NP

Rev. 1

This page intentionally blank

NUSCALE POWER PROPRIETARY INFORMATION NOTICE

This document does not contain proprietary information.

COPYRIGHT NOTICE

This document bears a NuScale Power, Inc., copyright notice. No right to disclose, use, or copy any of the information in this document, other than by the U.S. Nuclear Regulatory Commission (NRC), is authorized without the express, written permission of NuScale Power, Inc.

The NRC is permitted to make the number of copies of the information contained in these reports that is needed for its internal use in connection with generic and plant-specific reviews and approvals, as well as the issuance, denial, amendment, transfer, renewal, modification, suspension, revocation, or violation of a license, permit, order, or regulation subject to the requirements of 10 CFR 2.390 regarding restrictions on public disclosure to the extent such information has been identified as proprietary by NuScale Power, Inc., copyright protection notwithstanding. Regarding nonproprietary versions of these reports, the NRC is permitted to make the number of additional copies necessary to provide copies for public viewing in appropriate docket files in public document rooms in Washington, DC, and elsewhere as may be required by NRC regulations. Copies made by the NRC must include this copyright notice in all instances and the proprietary notice if the original was identified as proprietary.

Revision History

Revision	Section(s) or Page (s)	Description of Change
0		Original Issue
1	All Pages	Revised revision number
	Cover Page	Revised document revision number, preparer, reviewer, and date
	Cover Page	Revised copyright date
	Page 4	Added revision history to document
	Abstract	Revised to indicate proper referencing of NQA-1
	1.1	Revised to indicate proper referencing of NQA-1
	1.1.1	Revised to indicate proper referencing of NQA-1
	2.1.2.2	Removed "document control system" as part of responsibility of Chief Engineer
	2.1.4.2	Revised per RAI 5452, 17.5-1a; Deleted extra words
	2.2	Revised to indicate proper referencing of NQA-1
	2.2.2	Revised wording to read "in this document" for consistency in document
	2.3	Revised per RAI 5452, 17.5-2; clarified statement for document review by Quality Assurance
	2.3.4	Revised to indicate proper referencing of NQA-1
	2.5	Revised wording to read "in this document" for consistency in document
	2.6.3	Revised per RAI 5452, 17.5-1c; Added number 6 indicate which requirement referring to
	2.7.2	Revised per RAI 5452, 17.5-5; Revised to indicate proper referencing of NQA-1
	2.11	Revised per RAI 5452, 17.5-7; Added Assurance to specify referring to Quality Assurance Program. Revised wording to read "in this document" for consistency in document.
	2.11.1	Revised to indicate proper referencing of NQA-1
	2.11.2	Revised to indicate proper referencing of NQA-1
	2.12	Revised per RAI 5452, 17.5-7; Added Assurance to specify referring to Quality Assurance Program
	2.15	Revised wording to read "in this document" for consistency in document
	2.16.2	Revised per RAI 5452, 17 5-1d; Added Section 100 to sentence
	2.17.1	Revised per RAI 5452, 17.5-1e; added NQA-1 to sentence so properly understood where appendix 17A is located
	2.18.1	Revised per RAI 5452, 17.5-1f; added "in this document" for consistency of document

	3.1.11	Revised wording to read "in this document" for consistency in document
	3.1.11	Revised per RAI 5452, 17.5-7; added Assurance to specify referring to Quality Assurance Program
	3.1.12	Revised per RAI 5452, 17.5-7; added Assurance to specify referring to Quality Assurance Program
	Standards	Revised to indicate proper referencing of NQA-1. Revised wording to read "in this document" for consistency in document

CONTENTS

Abstract.....	9
1.0 Part I - Introduction	15
1.1 General	15
1.1.1 Scope/Applicability	15
2.0 Part II – Quality Assurance Program Description Details	17
2.1 Organization	17
2.1.1 Chief Executive Officer.....	17
2.1.2 Chief Operating Officer	17
2.1.3 Chief Technology Officer	18
2.1.4 Senior Vice President, Regulatory Affairs	18
2.1.5 Vice President, Supply Chain	19
2.1.6 Authority to Stop Work	19
2.1.7 Quality Assurance Organizational Independence.....	19
2.1.8 NQA-1-2008 Commitment	20
2.2 Quality Assurance Program	22
2.2.1 Responsibilities	23
2.2.2 Delegation of Work.....	23
2.2.3 Periodic Review of the Quality Assurance Program	23
2.2.4 Issuance and Revision to Quality Assurance Program.....	23
2.2.5 Personnel Qualifications	23
2.2.6 NQA-1-2008 Commitment and Exceptions.....	24
2.3 Design Control	25
2.3.1 Design Verification	25
2.3.2 Design Records.....	26
2.3.3 Computer Application and Digital Equipment Software	26
2.3.4 NQA-1-2008, and NQA-1a-2009 addenda, Commitment	26
2.4 Procurement Document Control	27
2.4.1 NQA-1-2008 Commitment / Exceptions.....	27
2.5 Instructions, Procedures, and Drawings	28
2.5.1 Procedure Adherence	28
2.5.2 Procedure Content.....	28
2.5.3 NQA-1-2008 Commitment	28
2.6 Document Control	29
2.6.1 Review and Approval of Documents	29
2.6.2 Changes to Documents	29
2.6.3 NQA-1-2008 Commitment	30
2.7 Control of Purchased Material, Equipment, and Services	30
2.7.1 Acceptance of Item or Service	30
2.7.2 NQA-1-2008, and NQA-1a-2009, Commitment / Exceptions	31
2.8 Identification and Control of Materials, Parts, and Components	33
2.9 Control of Special Processes	34
2.10 Inspection.....	35
2.10.1 Inspection Program	35
2.10.2 Inspector Qualification	35
2.10.3 NQA-1-2008 Commitment / Exceptions.....	36
2.11 Test Control.....	37
2.11.1 NQA-1a-2009 addenda, Commitment	37
2.11.2 NQA-1-2008, and NQA-1a-2009 addenda, Commitment for Computer Program	37

	Testing	37
2.12	Control of Measuring and Test Equipment	38
	2.12.1 NQA-1-2008 Commitment / Exceptions	38
2.13	Handling, Storage, and Shipping	39
2.14	Inspection, Test, and Operating Status	40
2.15	Nonconforming Materials, Parts, or Components	41
	2.15.1 Interface with the Reporting Program	41
	2.15.2 NQA-1-2008 Commitment	41
2.16	Corrective Action	42
	2.16.1 Interface with the Reporting Program	42
	2.16.2 NQA-1-2008 Commitment	42
2.17	Quality Assurance Records	43
	2.17.1 Record Retention	43
	2.17.2 Electronic Records	43
	2.17.3 NQA-1-2008 Commitment and Exceptions	43
2.18	Audits	44
	2.18.1 Performance of Audits	44
	2.18.2 Internal Audits	44
	2.18.3 NQA-1-2008 Commitment	45
3.0	Part III - Nonsafety-Related Structure, System, and Component Quality Control	46
3.1	Nonsafety-Related Structure, System, and Components - Significant Contributors to Plant Safety	46
	3.1.1 Organization	46
	3.1.2 Quality Assurance Program	46
	3.1.3 Design Control	46
	3.1.4 Procurement Document Control	46
	3.1.5 Instructions, Procedures, and Drawings	46
	3.1.6 Document Control	46
	3.1.7 Control of Purchased Items and Services	47
	3.1.8 Identification and Control of Purchased Items	47
	3.1.9 Control of Special Processes	47
	3.1.10 Inspection	47
	3.1.11 Test Control	47
	3.1.12 Control of Measuring and Test Equipment	47
	3.1.13 Handling, Storage, and Shipping	48
	3.1.14 Inspection, Test, and Operating Status	48
	3.1.15 Control of Nonconforming Items	48
	3.1.16 Corrective Action	48
	3.1.17 Records	48
	3.1.18 Audits	48
3.2	Nonsafety-Related Structure, System, and Components Credited for Regulatory Events	48
4.0	Part IV - Regulatory Commitments	49
4.1	Nuclear Regulatory Commission Regulatory Guides and Quality Assurance Standards	49

TABLES

Table 1-1. Abbreviations 10

Table 1-2. Definitions..... 11

FIGURES

Figure 2-1. NuScale organization 21

Abstract

This topical report provides the NuScale Power, Inc. Quality Assurance Program Description (QAPD) for the design certification (DC) of the NuScale Power Reactor. The QAP 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) 06-14A, Revision 7, "Quality Assurance Program Description (QAPD)" template.

Adaptations from the NEI reference were necessary to conform to the most recent Nuclear Regulatory Commission endorsed version of NQA-1-2008, and NQA-1a-2009 addenda. The report scope is limited to the program activities associated with DC.

The topical report is divided into four parts: 1.0 Introduction and Scope; 2.0 Quality Assurance Program Description (QAPD) Details; 3.0 Nonsafety-Related Structure, System, 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, including discussions of processes associated with advanced stages of the DC process. It should be understood, however, that statements regarding these 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.

Deleted: Part

Deleted: (with a2009 Addenda)"

Deleted: with a2009

Deleted:).

Table 1-1. Abbreviations

Term	Abbreviation
ATWS	anticipated transients without scram
CEO	chief executive officer
CFR	code of federal regulations
COO	chief operating officer
CTO	chief technology officer
DC	design certification
FSAR	Final Safety Analysis Report
M&TE	measuring and test equipment
MWe	Megawatts electric
NEI	Nuclear Energy Institute
NRC	Nuclear Regulatory Commission
PEP	Project Execution Plan
PMP	Project Management Plan
PQAM	project quality assurance manager
PQP	Project Quality Plan

Term	Abbreviation
QAD	quality assurance director
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
QMP	Quality Management Plan
RG	Regulatory Guide
SBO	station blackout
SSC	structures, systems, and components

Table 1-2. Definitions

The following definitions apply to the use of these terms in this report.

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

Term	Definition
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 Reactor	A modular, scalable nuclear power plant consisting of 45 MWe light water reactors developed and designed by NuScale Power, Inc.
Project Execution Plan (PEP)	The PEP defines work tasks, products and schedules, and deliverables as well as performance data generation and tracking requirements.
Project Management Plan (PMP)	It establishes the Project scope, objectives, organizational structure, management interfaces, basic R2A2s (i.e., roles, responsibilities, authorities, and accountabilities), strategies, and performance measurements parameters and methods
Project Quality Plan (PQP)	The primary, project specific quality assurance document that defines project scope; organizations; governing regulations, codes, and standards; processes; and methods applicable to control activities affecting the quality of the project's product or service.
Quality Assurance Program (QAP)	The NuScale quality assurance program as a whole, including the QMP, PQP, and all applicable sub-tier implementing documents.
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 Design Certification of the NuScale Power Reactor."
Quality Management Plan (QMP)	The top level policy document establishing the quality objectives and methods of NuScale Power, Inc.
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.

Term	Definition
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.

NuScale Power

Policy Statement

NuScale Power (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 Design Certification Quality Assurance Program Description (QAPD) delineates the policies, processes, and controls established by the NuScale Quality Management Plan (QMP) and associated implementing documents relative to U.S. domestic licensing requirements for nuclear power plants. Together, the Quality Assurance Program (QAP) documents defined in this QAPD 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 QAP 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 QMP 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 QMP. Compliance with the QMP and implementing documents is mandatory for NuScale Power personnel.

Signed

Paul Lorenzini

Chief Executive Officer

NuScale Power, Inc.

Date:

1.0 Part 1 - Introduction

1.1 General

NuScale Power's (NuScale) Quality Management Plan (QMP) is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for nuclear power reactor design certification (DC) activities conducted by or for NuScale. The QMP describes the methods and establishes quality assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QMP 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, as specified in this document.

Deleted: with ASME

The QA Program (QAP) described in this report consists of the QMP, the Project Quality Plan (PQP), and associated implementing documents. It is defined by Regulatory Guide 1.28, Revision 4, which endorses NQA-1-2008, ~~and NQA-1a-2009 addenda~~, which in turn describes the required QA elements. Procedures and instructions that control DC 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 QMP.

Deleted: (with

Deleted:),

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 QMP 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.

1.1.1 Scope/Applicability

The QMP applies to nuclear DC activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

- designing
- procuring
- receiving
- testing
- licensing
- training

Safety-related SSCs, under the control of the QMP, 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 QMP 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 nuclear plant(s) while ensuring the health and safety of its workers and the public. To this end, selected elements of the QMP 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.

Deleted: ASME NQA-1, 2008 with ASME

2.0 Part II – Quality Assurance Program Description Details

2.1 Organization

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

The NuScale quality assurance director 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 QAPs, or by contractors working under the NuScale QMP. 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 DC QAP. The NuScale 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 Reactor. The CEO is also responsible for all technical and administrative support activities provided by NuScale and its contractors. The CEO directs the Chief Operating Officer (COO), the Chief Technology Officer (CTO), the Senior Vice President of Regulatory Affairs, and the Vice President of Supply Chain in the fulfillment of their responsibilities. The CEO reports to the NuScale Board of Directors with respect to all company matters.

2.1.2 Chief Operating Officer

The NuScale chief operating officer (COO) is responsible for all areas of engineering, safety analysis, and project management consistent with regulatory requirements and procedural guidance. The COO is responsible for ensuring that engineering functional and project managers understand the implementing procedures, that their direct reports are adequately trained to those procedures, and that those direct reports develop their respective work products consistent with the requirements established by those procedures. The COO has the responsibility to develop and deploy integrated project schedules with associated budget and project management controls. The COO reports to the CEO.

2.1.2.1 Project Manager

The project manager reports to the COO and is responsible for the development and implementation of the Project Management Plan (PMP) including, but not limited to, assuring that necessary resources are provided, that personnel are adequately trained and qualified prior to performing assigned activities, that specified procedures are available and implemented, and that project activities and deliverables are in compliance with applicable codes, standards, and regulatory requirements.

2.1.2.2 Chief Engineer

The chief engineer reports to the COO and is responsible for providing technical guidance and resolution of design issues between disciplines and interfacing external organizations, establishing and maintaining engineering technical standards, providing technical guidance and oversight of external organizations to ensure compliance with project requirements, chairing the design change board, providing technical oversight of the design change process, and managing the iENG work process.

Deleted: and document control system

2.1.2.3 Engineering Manager

The engineering manager reports to the COO and is responsible for development and implementation of the Project Execution Plan (PEP), including project engineering resource allocation, management of the design process, development of design documents (i.e., calculations, drawings, procedures, specifications), interface task coordination, design verification processes, and ensuring compliance with technical and quality objectives.

2.1.2.4 Safety Analysis Manager

The safety analysis manager reports to the COO and is responsible for managing the conduct of design basis and beyond design basis safety analyses, including the development of software codes and methods to support analyses in the areas of thermal hydraulics, severe accidents, core neutronics, dose consequence, and probabilistic risk assessment. Responsibilities also include planning, developing, and managing programs to develop and maintain computer codes, models, and experimental databases for evaluating nuclear reactor and plant systems transient behavior under normal, abnormal, and accident conditions.

2.1.3 Chief Technology Officer

The chief technology officer (CTO) reports to the NuScale CEO and is responsible for aspects of research associated with the development of the conceptual design of the NuScale Power Reactor. This includes conduct of engineering studies and collection of test data used to confirm plant performance.

2.1.4 Senior Vice President, Regulatory Affairs

The Senior Vice President of Regulatory Affairs reports to the CEO, is responsible for the quality assurance organization as more fully described in Section 2.1.4.1, and is responsible for licensing activities associated with the NuScale Power Reactor development. The licensing organization develops, implements, and monitors the NuScale licensing plan and provides licensing recommendations to senior management. This position is the single-point-of-contact with regulatory agencies for effective communications and ensures that licensing-related requirements and commitments are addressed and controlled in an effective manner.

2.1.4.1 Quality Assurance

The NuScale quality assurance organization is responsible for independently planning and performing activities to verify the development and effective implementation of the NuScale Quality Management Plan (QMP) and Project Quality Plans (PQP) including, but not limited to, NuScale Power Reactor engineering, document control, corrective action program, and procurement that support the DC process.

2.1.4.1.1 Quality Assurance Director

The quality assurance director (QAD) reports to the Senior Vice President of Regulatory Affairs. The QAD is responsible for development, implementation, and maintenance of the QMP and is responsible for verifying that activities are in compliance with applicable regulatory, code, and industry standard requirements.

2.1.4.1.2 Project Quality Assurance Manager

The NuScale project quality assurance manager (PQAM) reports to the NuScale QAD and is responsible for the development and verification of implementation of the PQP described in this document. The PQAM 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 vendors providing quality services, parts, and materials to NuScale are meeting the requirements of 10 CFR 50, Appendix B, through NuScale vendor evaluations, surveillances, and audits. The PQAM has sufficient independence from other DC priorities to bring forward issues affecting safety and quality, and to make judgments regarding quality in all areas necessary regarding NuScale's DC activities. If the PQAM disagrees with actions taken by the project organization and is unable to obtain resolution, the PQAM shall inform the QAD and Senior Vice President of Regulatory Affairs and bring the matter to the attention of the CEO for final disposition.

2.1.4.2 Licensing Manager

The Licensing Manager reports to the Senior Vice President of Regulatory Affairs and is responsible for developing, implementing, and monitoring the NuScale licensing plan, including coordination and evaluation of licensing activities to ensure regulatory requirements and commitments are effectively addressed in licensing submittal documents.

2.1.5 Vice President, Supply Chain

The Vice President of Supply Chain reports to the CEO and is responsible for 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.

2.1.6 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 or where safety or SSC integrity may be jeopardized. This extends to off-site work performed by suppliers that furnish safety-related materials and services to NuScale.

2.1.7 Quality Assurance Organizational Independence

For the DC phase, independence shall be maintained between the organization and organizations performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review verification.

Comment [drr1]: RAI 5452 17.5-1a

Deleted: Insert into document. Delete DCD Project Manager section

2.1.8 NQA-1-2008 Commitment

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

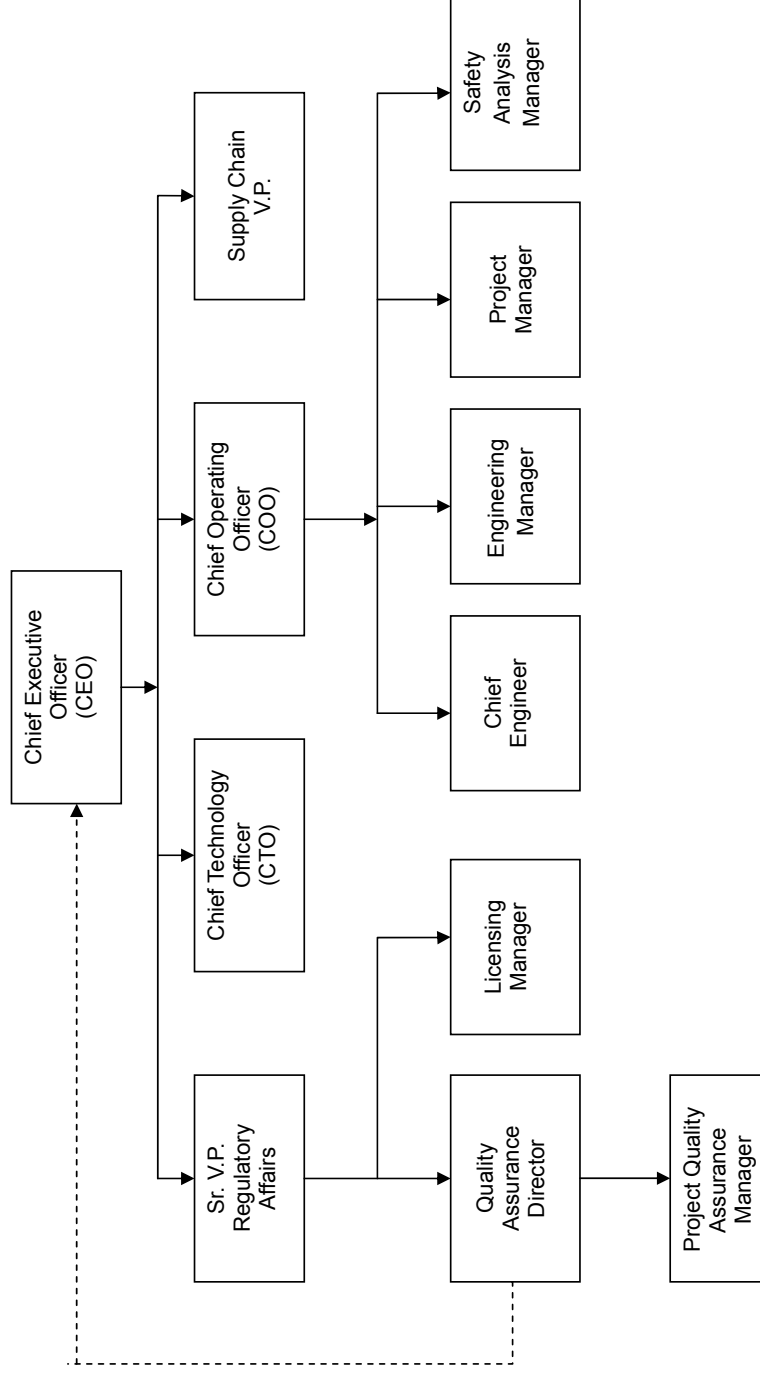


Figure 2-1. NuScale organization

Deleted: NuScale Non Proprietary Rev. 01

2.2 Quality Assurance Program

NuScale has established the necessary measures and governing procedures to implement the QAP as described in this ~~document~~. 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 this ~~document~~. 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~~.

Deleted: QAPD

Deleted: QAPD

Deleted: of

Deleted: QAPD.

The objective of the QAP is to assure that NuScale's nuclear generating plants are designed in accordance with governing regulations and DC 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 structures, systems, and components associated with the design of the NuScale Power Reactor, and to the managerial and administrative controls to be used to assure the NuScale Power Reactor design complies with applicable regulatory requirements. Examples of DC program safety-related activities include, but are not limited to, basic, applied, and developmental research; determination of SSC safety class; design configuration management; and document control. A list or system that identifies SSCs and activities to which this program applies is maintained at NuScale. Regulatory Guide 1.26 is used as the basis for this list or system. Cost and scheduling functions do not prevent proper implementation of the QAP.

Deleted: with ASME

Deleted: , including DC activities,

As described in Section 3.0 of this ~~document~~, specific program controls are applied to nonsafety-related SSCs, 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 QAP are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

Deleted: QAPD

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 QAP. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier's or principal contractor's QAP 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 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 QAP. 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 QAP are performed as directed by documented instructions, procedures, and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures, and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for 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 Director is responsible for verifying that processes and procedures comply with the QMP 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 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.

Deleted: of

Deleted: QAPD

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 QMP is in accordance with 10 CFR 50.55(f). Changes to the QMP are evaluated by the NuScale Quality Assurance Director to ensure that such changes do not degrade previously approved quality assurance controls. This document shall be revised, as appropriate, to incorporate additional QA commitments that may be established during the DC application process. New revisions to the document will be reviewed, at a minimum, by the NuScale Quality Assurance Director and approved by the Senior Vice President of Regulatory Affairs.

2.2.5 Personnel Qualifications

Personnel assigned to implement elements of the QAP 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 activities within the scope of the QAP to assure that suitable proficiency is achieved and maintained. 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 QAP elements to be employed. Records of personnel training and qualification are maintained.

The minimum qualifications of the Quality Assurance Director 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, one year of supervisory or management experience, and one year of the experience is in 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 QAP 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, with the following clarification.

NQA-1-2008, Requirement 2, Section 303.3

The requirement that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years is replaced by the following: "The prospective lead auditor shall demonstrate his or her ability to properly implement the audit process, as implemented by NuScale, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification."

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 QAP. The design process 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 documents are reviewed and approved by the NuScale design organization or by other organizations so authorized by NuScale.

~~The development of quality-related procedures shall be reviewed and concurred by QA personnel before they are issued for implementation to ensure documents include the necessary QA requirements.~~

Deleted: Design documents are

Deleted: individuals knowledgeable in

Comment [drr2]: RAI 5452 17.5-2

Deleted: the

Deleted: contain

2.3.1 Design Verification

NuScale design processes provide for design verification to ensure that items and activities subject to the provisions of the QAP 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 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 QAP governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. NuScale and 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.

Deleted: with

2.4 Procurement Document Control

NuScale has established the necessary measures and governing procedures to assure that purchased items 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:

- Where 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:

- NQA-1-2008, Requirement 4
 - Section 203 requires QAP requirements to be specified in procurement documents. 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.

With regard to services 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.
 - Section 300 requires procurement documents to be reviewed prior to award of contract. The quality assurance review of procurement documents is satisfied through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to award of contract. Procurement document changes (e.g., scope, technical, or quality requirements) will also receive the quality assurance review.

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 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.

Deleted: the QAPD.

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
- 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. 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.

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.

Comment [drr3]: RAI 5452 17.5.1c

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, during DC activities. 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 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 during the DC phase are not required to be evaluated or audited.
 - When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed, provided each of the following conditions are met:
 - a) The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the NuScale QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment and standard used.
 - b) The purchase documents require reporting as-found calibration data when calibrated items are found to be out of tolerance.
 - c) A documented review of the supplier's accreditation will be performed and will include a verification of the following:
 - The calibration laboratory holds a domestic (United States) accreditation by any one of the following accrediting bodies that are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).
 - National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology
 - American Association for Laboratory Accreditation (A2LA)
 - ACLASS Accreditation Services (ACCLASS)
 - International Accreditation Service (IAS)
 - Laboratory Accreditation Bureau (L-A-B)
 - Other NRC-approved laboratory accrediting body
 - The accreditation encompasses ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
 - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.

Deleted: with

Comment [drr4]: RAI 5452 17.5-5

Deleted: NQA-1a, 2009, Sections

- NQA-1-2008, Requirement 7, Section 501

- For Section 501, NuScale considers documents that may be stored in approved electronic media under NuScale or vendor controls not physically located on the plant site but are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. The NuScale records management system will provide for timely retrieval of necessary records.

Deleted: NQA-1a, 2009,

- NQA-1a-2009 **addenda**, Requirement 7, Section 700

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

Deleted: NQA-1-2008,

2.8 Identification and Control of Materials, Parts, and Components

This section is not applicable at this time (DC Application).

2.9 Control of Special Processes

This section is not applicable at this time (DC Application).

2.10 Inspection

NuScale does not perform inspection activities during the DC phase. Suppliers will be required to perform this activity, where required by contract, as indicated in this section.

Suppliers shall establish the necessary measures and governing procedures 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.
- for final acceptance of fabricated and/or installed items involved in design development (e.g., test fixture configuration).
- 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, and 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.

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

NuScale commits to requiring suppliers and subcontractors to establish inspection requirements in accordance with NQA-1-2008, Requirement 10, Sections 100 through 800.

2.11 Test Control

NuScale does not perform test activities in the DC phase, except for computer software testing described in Section 2.11.2 ~~in~~ this document. Suppliers may perform testing services in support of DC phase activities such as applied and developmental research and where required by contract, and will be required to either have a test control program meeting the following requirements or conduct testing under the ~~NuScale Quality Assurance Program (QAP).~~

Deleted: of

Comment [drr5]: RAI 5452 17.5-7

NuScale has established the necessary measures and governing procedures to demonstrate that design concepts 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 according to 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, re-testing 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 QAP. 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

Deleted: NQA-1-2008 with

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

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

Deleted: with

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, Section 400, and ~~NQA-1-2008, and NQA-1a-2009 addenda~~, Subpart 2.7 to establish the appropriate provisions.

Deleted: 1-2008, with NQA-

2.12 Control of Measuring and Test Equipment

NuScale does not perform control of measuring and test equipment (M&TE) activities in the DC phase. Suppliers will perform M&TE controls in support of DC phase activities such as applied and developmental research and where required by contract, and will be required to either have an M&TE control program meeting the following requirements or conduct M&TE control activities under the NuScale Quality Assurance Program (QAP).

Comment [drr6]: RAI 5452 17.5-7

NuScale has established the necessary measures and governing procedures to control the calibration, maintenance, and use of M&TE that provides information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gages, 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 302 refers to when the M&TE is found out of the required accuracy limits (i.e., out of tolerance) during calibration.
- Measuring and test equipment are not required to be marked with the calibration status (as stated in Section 303.6) where it is impossible or impractical due to equipment size or configuration (such as when the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device.

2.13 Handling, Storage, and Shipping

This section is not applicable at this time (DC Application).

2.14 Inspection, Test, and Operating Status

This section is not applicable at this time (DC Application).

2.15 Nonconforming Materials, Parts, or Components

NuScale has established the necessary measures and governing procedures to control items, including services, which 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 ~~in 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.

Deleted: of

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 quality 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 materials, parts, or components and the non-QA reporting program to satisfy the requirements of 10 CFR 52 and 10 CFR 21 during the DC phase.

2.15.2 NQA-1-2008 Commitment

In establishing measures for nonconforming materials, parts, or components, 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, and correct 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 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 during the DC phase.

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 |

Comment [drr7]: RAI 5452 17.5-1d

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-1-2008, and NQA-1a-2009 addenda**, Nonmandatory Appendix 17A-1, Section 200 as applicable for the DC project. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

Comment [drr8]: RAI 5452 17.5-1e

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.

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 QAP are performed in conformance with the requirements established. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

2.18.1 Performance of Audits

Internal audits of selected aspects of the DC project activities are performed with a frequency commensurate with the safety significance of the activity and in a manner which assures that audits of safety-related activities are completed. During the early portions of DC activities, audits will focus on areas including, but not limited to, design, document control, procurement, 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 record keeping.

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.

The results of each audit are reported in writing to the senior vice president of regulatory affairs or designee, 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, review, re-audits, or other appropriate means is conducted to verify implementation and effectiveness of corrective actions.

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

Comment [drr9]: RAI 5452 17.5-1f

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 QAP. 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 record keeping.

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.

3.0 Part III - Nonsafety-Related Structure, System, and Component Quality Control

3.1 Nonsafety-Related Structure, System, and Components - Significant Contributors to Plant Safety

Specific program controls are applied to nonsafety-related SSCs, 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 QAP are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QAP to the nonsafety-related SSCs and related activities, including the identification of exceptions to the QAP described in Sections 2.1 through 2.18 in this document, taken for nonsafety-related SSCs.

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 QMP 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.

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

This section is not applicable at this time (DC Application).

3.1.9 Control of Special Processes

This section is not applicable at this time (DC Application).

3.1.10 Inspection

NuScale does not perform inspection activities during the DC phase. Suppliers will be required to perform this activity, where required in contracts, as indicated in this section.

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 does not perform test activities in the DC phase, except for computer software testing described in Section 2.11.2 ~~in~~ this document. Suppliers may perform testing services in support of DC phase activities such as applied and developmental research and where required in contracts. ~~Suppliers shall be required to either have a test control program meeting the following requirements or conduct testing under the NuScale Quality Assurance Program (QAP).~~

Deleted: of

Comment [drr10]: RAI 5452 17.5-7

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 does not perform control of measuring and test equipment (M&TE) activities in the DC phase. Suppliers will perform M&TE controls in support of DC phase activities such as applied and developmental research and will be required, where required in contracts, to either have an M&TE control program meeting the following requirements or conduct M&TE control activities under the NuScale Quality Assurance Program (QAP).

Comment [drr11]: RAI 5452 17.5-7

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

3.1.13 Handling, Storage, and Shipping

This section is not applicable at this time (DC Application).

3.1.14 Inspection, Test, and Operating Status

This section is not applicable at this time (DC Application).

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 Structure, System, 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:

- 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."

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. See Final Safety Analysis Report (FSAR) Chapter 1 of the NuScale DC application for a full evaluation of conformance with the guidance in NRC RG 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.

1. 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 Reactor 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.

2. 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.

3. 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 (SSE).

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

Standards:

1. 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.
2. NuScale commits to NQA-1-2008, ~~and NQA-1a-2009 addenda~~, Parts I and II as described in Section 2.0 ~~in this document~~.
3. Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs).
4. NuScale commits to NIRMA TGs as described in Section 2.17 ~~in this document~~.

Deleted: with ASME

Deleted: with

Deleted: of

NuScale Non-Proprietary