EFCOG White Paper:

Tailoring of NQA-1 Quality Requirements for Procurement

By the

Energy Facilities Contractors Group

Safety Working Group

Quality Assurance

Procurement Engineering Quality Task Team

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Introduction

This document is intended for use by DOE contractors required to implement ASME NQA-1, *Quality Assurance Requirements for Nuclear Applications*. For these contractors, the procurement of safety related items or services must satisfy NQA-1 requirements. The maximum implementation would be to flow down all requirements in NQA-1 Part I Requirements and Part II Subparts in the procurement. A "tailored" approach chooses only the needed requirements to satisfy the work associated with the procurement. Below is a discussion on the "tailored" approach and examples of its implementation.

Purpose

The purpose of this document is to provide the basis and examples for using a tailored approach in flowing down NQA-1 requirements for procurement of goods and services. The document is based on NQA-1 2008 with the 2009 Addenda but the concepts are applicable to other editions.

Tailoring Description

In many procurements made by entities working to ASME NQA-1, only applicable sections of NQA-1 need to be flowed down to ensure quality of the procurement scope. This approach is referred to as "Tailoring" of NQA-1 requirements. Flowing down only the applicable sections of NQA-1 is an acceptable practice as described in NQA-1, DOE Order 414.1D, Quality Assurance, and previous EFCOG Guidance as discussed below.

NQA-1 Tailoring Basis

NQA-1 provides guidance for tailoring NQA-1 requirement to match the procurement scope of work. In Part 1 Introduction, Para 300 Responsibility section:

> *The organization invoking this Part shall be responsible for specifying which requirements, or portions thereof, apply, and appropriately relating them to specific items and services. The organization implementing this Part, or portions thereof, shall be responsible for complying with the specific requirements to achieve quality results.*

This provides organizations invoking ASME NQA-1 the latitude to specify only those requirements applicable to their specific situation. The implementing organization is then responsible for addressing those specified requirements within their prime contract scope as well as in procurements they execute.

NQA-1, Part III, Subpart 3.1, "NONMANDATORY APPENDIX 4A-1 Guidance on Procurement Document Control" Section 500, provides general logic considerations for determining the quality assurance requirements that should be applied for various procurements. Factors that may be used in determining the extent of QA include:

a. Importance of Malfunction or Failure of the item to Plant Safety
b. Complexity or Uniqueness of the Item
c. Need for Special Controls and Surveillance Over Processes and Equipment
d. Degree to Which Functional Compliance Can Be Demonstrated by Inspection and Test
e. Quality History and Degree of Standardization of the Item

Within this guidance in the Subpart, Para 700 articulates the approach to tailoring the quality program flow down using terminology “Unique Order Method.” This para also provides the following example:

> *(b) Unique Order Method. The Purchaser may incorporate into the procurement documents selected portions of a quality assurance standard, such as Part 1, that are unique to the items or services being procured. For example, when the Purchaser's order is limited to design work only, Requirements 1, 2, 3, 5, 6, 16, 17, and 18 of Part I could be applied.*

This non-mandatory subpart includes further discussion and a flowchart for using the Unique Order Method for tailoring the needed quality program attributes for a particular scope of work. A more detailed example of using the Unique Order Method is included in para 702 of the Subpart where tailored NQA-1 flow down approach for a specification to perform a design review and performance test of a supplied piece of equipment.

NQA-1 also provides Part IV, Subpart 4.2, *Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development (R&D)*, for tailoring NQA-1 requirements for Research and Development applications. This tailoring would be applicable to a subcontract approach for R&D activities as well as a site self-performing these activities.

2014 EFCOG White Paper on NQA-1 Tailoring

The EFCOG Guidance document, *EFCOG White Paper Application of NQA-1 interpretation QA12-007 for Flow-down of QA Requirements to Subcontractors of Prime Contractors to DOE*, (Attachment 1) provides further perspectives on this topic. This report was initially written to address situations where sites were overly specifying quality program requirements. A short excerpt from this report includes:

> *DOE Order 413.3 defines Tailoring as “an element of the acquisition process and must be appropriate considering the risk, complexity, visibility, cost, safety, security, and schedule of the project. Tailoring does not imply the omission of essential elements in the acquisition process or other processes that are appropriate to a specific project's requirements or conditions.”*
>
> *Tailoring may occur within individual requirements as well as identifying an entire requirement that is not applicable. Tailoring relates to applicability of the scope of work. Grading relates to the degree of rigor and control required for that requirement.*
>
> *For example, if the supplier is not designing the product, Requirement 3 and Sub-Requirements would not apply. Or if no special processes are involved, Requirement 9 and its Sub-Requirements would not apply. A third example would be if no Nondestructive Examination will be performed then Sub-Requirement 301 from Requirement 2 would not apply but other portions of Requirement 2 would apply.*

A tailored approach should be used when making procurements to avoid the unnecessary costs associated with requiring suppliers to meet non-applicable or extraneous requirements.

For further information on this document, see Attachment 1.

DOE Order 414.1D, *Quality Assurance*

The overall strategy of applying only those requirements applicable to a task DOE Order 414.1D defines Graded Approach in part as follows:

> *The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with:*
> *(1) the relative importance to safety, safeguards, and security;*
> *(2) the magnitude of any hazard involved;*
> *(3) the life-cycle stage of a facility or item;*
> *(4) the programmatic mission of a facility;*
> *(5) the particular characteristics of a facility or item;*
> *(6) the relative importance to radiological and non-radiological hazards; and,*
> *(7) any other relevant factors. (10 C.F.R. § 830.3)*

Therefore, DOE Orders, NQA-1, and past EFCOG information provides clear basis and expectations for tailoring quality program flow down to the scope of work being requested. Not all NQA-1 criteria, either in total or at the paragraph levels may be applicable to a particular scope of work.

NQA-1 Part II Subpart Considerations

Many of the NQA-1 Part II Subparts are intended to invoke quality requirements for on-site operations or construction activities and may not be applicable quality program elements at some sites based on site DOE approved quality management plans. Some are typically utilized by sites for program execution such as Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services,* and Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications,* as directly invoked by Part I requirements. Also, even if a subpart is topically pertinent to a scope of work such as Part II Subpart 2.2., *Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants*, direct flow down may not be necessary or applicable to a particular procurement. This flow down should be very critically reviewed for necessity as many nuclear grade vendors such as those for engineered equipment items and service do not directly consider these subparts to be applicable to their activities. For the purposes of this white paper, the examples in the attachments will be based on a strategy of applying any subpart that potentially could be applicable to the scope for conservative tailoring approach.

EFCOG Guidance Document

In 2016, EFCOG issued E-SG-QA-QA-2016-01 R0, *Guidance Document for Selecting Applicable Quality Assurance Requirements for Department of Transportation Packaging*.

The purpose E-SG-QA-QA-2016-01 R0 was to establish a process to show how a DOE contractor could tailor the applicable quality assurance requirements being flowed down to the Department of Transportation (DOT) packaging supplier for a specific DOT packaging procured.

The scope of the document is limited to the procurement of UN Performance-Oriented Packaging used to ship solids and liquid hazardous waste, substances, and materials. This packaging may also meet the requirements of DOT Specification 7A, Type A used to ship solid radioactive materials.

Tailored Examples of NQA-1 Flow Down for Safety Related Procurements

Four examples of safety related procurements flowing down applicable ASME NQA-1 requirements are provided below.
- Construction/Fabrication and Design Work (see Attachment 2)
- Construction/Fabrication Work Only (see Attachment 3)
- Design Services Only (see Attachment 4)
- Software (see Attachment 5)

The Supplier QA Procurement Requirements (SQAPR) must identify the applicable NQA-1 requirements (See attached examples)

Tailored Examples of NQA-1 Flow Down for Non-Safety Related Procurements

See Attachment 6 for a tailored flow down of requirements for procurement of a non-safety engineered item. The Quality requirements are generic and not specifically tied to NQA-1 to allow for suppliers not familiar with NQA-1 to bid on the procurement.

Attachment 7 provides NQA-1, Section 100 requirements typically used for non-safety related procurements. The applicable requirements are determined through collaboration between Engineering and QA for the particular item being procured. The requirements from subsequent sections may also be added if additional rigor is determined to be needed.

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Attachment 1: EFCOG White Paper Application of NQA-1 interpretation QA12-007 for Flow-down of QA Requirements to Subcontractors of Prime Contractors to DOE

EFCOG White Paper Application of NQA-1 interpretation QA12-007 for Flow-down of QA Requirements to Subcontractors of Prime Contractors to DOE

October, 2014

EFCOG White Paper on NQA-I Interpretation QA12-007

Introduction

In 2011 the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Committee issued an interpretation regarding the flow down of "100 Sections" of NQA-1 and the ability to credit the quality assurance (QA) program as being one that meets NQA-1. This interpretation was narrow in scope due to the specific language used in the question posed to the NQA-1 committee. As a result there have been cases where the interpretation is being used as a basis to overly prescribe QA requirements into subcontracts such that unnecessary requirements are being flowed down that are not consistent with the work scope.

Purpose

This white paper is written to provide context to the interpretation and to provide rationale for the appropriate tailoring of QA requirements for the procured item or service.

Background

In 2011, the following question QA12-007 was posed by the Defense Nuclear Facility Safety Board (DNFSB) and interpretation was provided by the ASME Committee:

"Interpretation:
Subject: NQA-1-2000 and more recent editions through NQA-1b-2011

Date Issued: March 22, 2012

Question: For an implementer, is choosing to apply only paragraph 100 of applicable requirements of Parts I and II of the standard an appropriate and sufficient method to implement a NQA-1 based Quality Assurance program?

Response: No. With the exception of the Part I requirement areas: 5, Instructions, Procedures and Drawings; 14; Inspection, Test and Operating Status; and 16 Corrective Action, paragraph 100 is a summary and introductory paragraph for additional mandatory criteria contained in the requirement area.

The application of only section 100 by an implementing organization is insufficient to claim credit for implementing Part I or Part II of an NQA-1 based Quality Assurance program. It is also insufficient for an invoking organization to invoke only section 100 of Part I or Part II and expect results equivalent to specifying all of Parts I or II.

This response is applicable to NQA-1-2000, NQA-1-2004, NQA-1-2008 and the NQA-1b-2011 Addenda."

Discussion

The NQA-1 Interpretation is wholly consistent for the stipulated case posed and it would be inappropriate to be assured of a subcontractors QA program meeting detailed NQA-1 requirements needed in the subsections when only sections 100 were flowed down.

The recommendation of the EFCOG QA working group provided below needs to be understood within the context of several influences, which include:

- "Tailoring"
- "Graded Approach"
- Use of a disciplined procurement

Understand the use of Tailoring in Procurement Activities

DOE Order 413.3 defines Tailoring as "an element of the acquisition process and must be appropriate considering the risk, complexity, visibility, cost, safety, security, and schedule of the project. Tailoring does not imply the omission of essential elements in the acquisition process or other processes that are appropriate to a specific project's requirements or conditions."

Tailoring may occur within individual requirements as well as identifying an entire requirement that is not applicable. Tailoring relates to applicability of the scope of work. Grading relates to the degree of rigor and control required for that requirement.

For example, if the supplier is not designing the product, Requirement 3 and Sub-Requirements would not apply. Or if no special processes are involved, Requirement 9 and its Sub-Requirements would not apply. A third example would be if no Nondestructive Examination will be performed then Sub-Requirement 301 from Requirement 2 would not apply but other portions of Requirement 2 would apply.

Understanding the use of Graded Approach in implementation of the question requirements

DOE Order 414.1D defines Graded Approach in part as "The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with:
(1) the relative importance to safety, safeguards, and security;
(2) the magnitude of any hazard involved;
(3) the life-cycle stage of a facility or item;
(4) the programmatic mission of a facility;
(5) the particular characteristics of a facility or item;
(6) the relative importance to radiological and non-radiological hazards; and,
(7) any other relevant factors. (10 C.F.R. § 830.3) "
For example, if an item will be used in a Safety Class an actual Chemical and Mechanical Test Report (CMTR) may be required whereas if the item will be used in a non-safety application a Certification of Conformance (C of C) may be sufficient. Caution should be exercised when

using C of Cs ensuring the requirements of ASME NQA-1, Requirement 7, Control of Purchased Items and Services, Sub-requirement 503 are met. Another example would be a high risk activity may require prior approval of NDE procedures and qualifications of staff as well as the final inspection reports whereas a lower risk activity would require the final inspection reports only.

ASME NQA-1-2008 supporting the idea of a graded approach in Part 1 Introduction by stating "*The organization invoking this Part shall be responsible for specifying which requirements, or portions thereof, apply, and appropriately relating them to specific items and services. The organization implementing this Part, or portions thereof, shall be responsible for complying with the specific requirements to achieve quality results." This provides organizations invoking ASME NQA-1the latitude to specify only those requirements applicable to their specific situation. The implementing organization is then responsible for addressing those specified requirements.*

Evaluation of Suppliers Capability vs an "NQA-1 Supplier"

Qualification of a supplier to provide specific items or services in accordance with ASME NQA-1 does not infer or imply the ability to provide other items or services without further evaluation (See Requirement 7, paragraph 200 of ASME NQA-1) of the scope of work and applicability of requirements. Therefore, the use of the terms "ASME NQA-1 qualified supplier" does not imply a certification similar to ISO-certification. Further, NQA-1 procurement processes do not result in a supplier being declared "NQA-1 qualified" but rather that the procurement agent has performed an evaluation of the supplier's capability to meet the requirements of the procurement, which includes adequacy of processes, facilities, resources, etc. Better terminology for an evaluated supplier's quality program may be an ASME NQA-1 compliant program.

Summary Recommendations:

In context of the NQA-1 interpretation, identification of appropriate requirements is a "tailoring" activity and is not considered a "graded approach" activity. However, as various levels of procurement represent varying levels of risk and consequence, many procurement processes have a "graded approach" built in to them such that minimal requirements for low risk/low consequence procurements can be applied and additional requirements (including exceeding NQA-1 requirements) can be applied for high risk/high consequence procurements (See EM Graded Approach for Procurement Document posted on the Quality Assurance Corporate Board web page).

DOE Contractors should use their procurement process, as described in their approved QA program, to identify and document how QA requirements are stipulated in the procurement documents. During procurement document development, identification of the appropriate requirements is done within context of the development of the scope of work, and depending on how much reliance is needed on the suppliers QA program, varying levels of specificity (partial or complete portions of requirements section).

ASME NQA-1 provides requirements for applying QA requirements applicable to the scope of work. Careful consideration of these activities is a disciplined process used to ensure the correct technical and quality requirements are selected for the particular scope of work to provide the contracting entity reasonable assurance that the item or service procured will meet the project or program's needs, which is consistent with the ASME Committee interpretation.

Credits/Contacts:
The above was developed by the Energy Facility Contractors Group Quality Assurance Policies and Procedures task group.
QAWG Chair: Mike Hassell, CHPRC
QA P&P TG Chair: Robert Thompson, ICP

Attachment 2: Safety Construction/Fabrication and Design Work

Scope of work was for labor, materials, and services required for the design, fabrication, inspection, testing and delivery of the assembly. The NQA-1 quality requirements were tailored to the work. The applicable version of NQA-1 was 2008 with 2009 Addenda.

NQA-1 Part I Requirement	Applies	Basis for not applying
1 – Organization	Y	NA
2 – Quality Assurance Program	Y	NA
3 – Design Control	Y	Section 800 does not apply, No software design activities
4 – Procurement Document Control	Y	NA
5 – Instructions, Procedures, and Drawings	Y	NA
6 – Document Control	Y	NA
7 – Control of Purchased Items and Services	Y	NA
8 – Identification and Control of Items	Y	NA
9 – Control of Special Processes	Y	NA
10 – Inspection	Y	Section 700, Design and fabricate only. No Operation related activities.
11 – Test Control	Y	NA
12 – Control of Measuring and Test Equipment	Y	NA
13 – Handling, Storage, and Shipping	Y	NA
14 – Inspection, Test, and Operating Status	Y	NA
15 – Control of Nonconforming Items	Y	NA
16 – Corrective Actions	Y	NA
17 – Quality Assurance Records	Y	NA
18 - Audits	Y	NA
NQA-1 Part II, Subpart		
2.1 - Cleaning of Fluid Systems and Associated Components	Y	NA
2.2 – Packaging, Shipping, Receiving, Storage, and Handling of Items	Y	NA
2.3 – Housekeeping	N	No housekeeping required.
2.4 – Installation, Inspection, and Testing of Power Equipment and Control Equipment	N	Work does not require any Power Equipment and Control Equipment.
2.5 – Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations	N	Work performed does not require any Structural Concrete, Structural Steel, Soils or Foundation.
2.7 – Computer Software	N	Satisfied in Part I.
2.8 – Installation. Inspection, and Testing of Mechanical Equipment and Systems	N	Work does not include any Mechanical Equipment or Systems.
2.14 – Commercial Grade Items and Services	Y	NA
2.15 – Hoisting, Rigging, and Transporting of Items	Y	NA
2.16 – Calibration and Control of Measuring and Test Equipment	N	Satisfied by Part I Requirement 12
2.18 – Maintenance	N	No Maintenance work required
2.20 – Subservice Investigations	N	No Subsurface work required
2.21 – Decommissioning	N	No Decommission work required

Attachment 3: Safety Construction/Fabrication Work Only

Scope of work was for excavation, erosion control, foundation, steel structure, architectural, electrical, security systems, control systems, communication systems, remote handling, radiation monitoring, process (glovebox), construction inspection and testing, and temporary office trailer installation. The NQA-1 quality requirements were tailored to the work. The applicable version of NQA-1 was 2008 with 2009 Addenda.

NQA-1 Part I Requirement	Applies	Basis for not applying
1 – Organization	Y	NA
2 – Quality Assurance Program	Y	NA
3 – Design Control	N	No design activities required in work scope
4 – Procurement Document Control	Y	NA
5 – Instructions, Procedures, and Drawings	Y	NA
6 – Document Control	Y	NA
7 – Control of Purchased Items and Services	Y	NA
8 – Identification and Control of Items	Y	NA
9 – Control of Special Processes	Y	NA
10 – Inspection	Y	NA
11 – Test Control	Y	NA
12 – Control of Measuring and Test Equipment	Y	NA
13 – Handling, Storage, and Shipping	Y	NA
14 – Inspection, Test, and Operating Status	Y	NA
15 – Control of Nonconforming Items	Y	NA
16 – Corrective Actions	Y	NA
17 – Quality Assurance Records	Y	NA
18 - Audits	Y	NA
NQA-1 Part II, Subpart		
2.1 - Cleaning of Fluid Systems and Associated Components	Y	NA
2.2 – Packaging, Shipping, Receiving, Storage, and Handling of Items	Y	Sections 202.1, 302.1 and 304.2 not required
2.3 – Housekeeping	Y	Section 202, Zone 1 and Zone II not required
2.4 – Installation, Inspection, and Testing of Power Equipment and Control Equipment	Y	NA
2.5 Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations	Y	NA
2.7 – Computer Software	N	No use or development of software in work scope
2.8 – Installation. Inspection, and Testing of Mechanical Equipment and Systems	Y	NA
2.14 – Commercial Grade Items and Services	Y	NA
2.15 – Hoisting, Rigging, and Transporting of Items	Y	Sections 202.1 and 701 not required
2.16 – Calibration and Control of Measuring and Test Equipment	N	Satisfied by Part I Requirement 12
2.18 – Maintenance	N	No Maintenance work required
2.20 – Subservice Investigations	N	No Subsurface work required
2.21 – Decommissioning	N	No Decommission work required

Attachment 4: Design Services Only

Scope of work was for research, analysis and development of engineering documents and record documents by preparing initial system level documents (such as Piping and Instrument Diagrams, Control Logic Diagrams, Electrical Single Lines, Pump Sizing Calculations, etc.). The NQA-1 quality requirements were tailored to the work. The applicable version of NQA-1 was 2008 with 2009 Addenda.

NQA-1 Part I Requirement	Applies	Basis for not applying
1 – Organization	Y	NA
2 – Quality Assurance Program	Y	NA
3 – Design Control	Y	NA
4 – Procurement Document Control	Y	NA
5 – Instructions, Procedures, and Drawings	Y	NA
6 – Document Control	Y	NA
7 – Control of Purchased Items and Services	Y	NA
8 – Identification and Control of Items	N	No Items are procured or fabricated
9 – Control of Special Processes	N	No Special Processes are required
10 – Inspection	N	No Inspections are required
11 – Test Control	Y	Section 300 not required, only software testing
12 – Control of Measuring and Test Equipment	N	No M&TE is required
13 – Handling, Storage, and Shipping	N	No Handling, Storage or Shipping of items is required
14 – Inspection, Test, and Operating Status	N	No Inspection, Testing or Operation of items is required
15 – Control of Nonconforming Items	N	No Nonconforming Items
16 – Corrective Actions	Y	NA
17 – Quality Assurance Records	Y	NA
18 - Audits	Y	NA
NQA-1 Part II, Subpart		
2.1 - Cleaning of Fluid Systems and Associated Components	N	No items procured, only documents
2.2 – Packaging, Shipping, Receiving, Storage, and Handling of Items	N	No items procured, only documents
2.3 – Housekeeping	N	No items procured, only documents
2.4 – Installation, Inspection, and Testing of Power Equipment and Control Equipment	N	No items procured, only documents
2.5 – Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations	N	No items procured, only documents
2.7 – Computer Software	Y	NA
2.8 – Installation. Inspection, and Testing of Mechanical Equipment and Systems	N	No items procured, only documents
2.14 – Commercial Grade Items and Services	N	No items procured, only documents
2.15 – Hoisting, Rigging, and Transporting of Items	N	No items procured, only documents
2.16 – Calibration and Control of Measuring and Test Equipment	N	No items procured, only documents
2.18 – Maintenance	N	No items procured, only documents
2.20 – Subservice Investigations	N	No Subsurface work required
2.21 – Decommissioning	N	No Decommission work required

Attachment 5: Safety Software

Scope of work is for the procurement of Safety Software. The NQA-1 quality requirements were tailored to the work. The applicable version of NQA-1 was 2008 with 2009 Addenda.

NQA-1 Part I Requirement	Applies	Basis for not applying
1 – Organization	Y	Section 400 is not needed
2 – Quality Assurance Program	Y	Sections 301 and 302 do not apply, Section 400 applicable to Lead Auditor only
3 – Design Control	Y	Sections 200, 300, 500 and 600 do not apply to this procurement
4 – Procurement Document Control	Y	Possible if software is purchased
5 – Instructions, Procedures, and Drawings	Y	NA
6 – Document Control	Y	NA
7 – Control of Purchased Items and Services	Y	Possible if software is purchased
8 – Identification and Control of Items	N	Does not apply to software
9 – Control of Special Processes	N	Does not apply to software
10 – Inspection	N	Does not apply to software
11 – Test Control	Y	Section 300 does not apply
12 – Control of Measuring and Test Equipment	N	Does not apply to software
13 – Handling, Storage, and Shipping	N	Does not apply to software
14 – Inspection, Test, and Operating Status	N	Does not apply to software
15 – Control of Nonconforming Items	N	Does not apply to software
16 – Corrective Actions	Y	NA
17 – Quality Assurance Records	Y	NA
18 - Audits	Y	NA
NQA-1 Part II, Subpart		
2.1 - Cleaning of Fluid Systems and Associated Components	N	Does not apply to software
2.2 – Packaging, Shipping, Receiving, Storage, and Handling of Items	N	Does not apply to software
2.3 – Housekeeping	N	Does not apply to software
2.4 – Installation, Inspection, and Testing of Power Equipment and Control Equipment	N	Does not apply to software
2.5 – Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations	N	Does not apply to software
2.7 – Computer Software	Y	Applicable Sections
2.8 – Installation. Inspection, and Testing of Mechanical Equipment and Systems	N	Does not apply to software
2.14 – Commercial Grade Items and Services	N	Does not apply to software
2.15 – Hoisting, Rigging, and Transporting of Items	N	Does not apply to software
2.16 – Calibration and Control of Measuring and Test Equipment	N	Does not apply to software
2.18 – Maintenance	N	Does not apply to software
2.20 – Subservice Investigations	N	Does not apply to software
2.21 – Decommissioning	N	Does not apply to software

Attachment 6: Non-Safety Related Procurement

Scope of work is for labor and materials to design, procure, fabricate, inspect, test, document and deliver a mixing pump. The NQA-1 Part I Requirements were tailored for the procurement and are shown generically below for suppliers not familiar with NQA-1.

QA Requirement	Supplier Specific Document / Criteria
Quality Assurance Program	A documented quality assurance program shall be planned, implemented, and maintained. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities. The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems. The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and maintained. Management shall regularly assess the adequacy and effective implementation of the quality assurance program.
Design Control	The design shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.
Control of Purchased Items and Services	The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control shall provide 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 upon delivery or completion.
Identification and Control of Items	Controls shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.
Control of Special Processes	Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.
Inspection	Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.
Test Control	Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.

Control of Measuring and Test Equipment	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.
Quality Assurance Records	The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Record control requirements and responsibilities for these activities shall be documented.

Attachment 7: NQA-1 Part I Requirements, Section 100 Only

QA Requirement	Supplier Specific Document / Criteria
Organization	Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.
Quality Assurance Program	A documented quality assurance program shall be planned, implemented, and maintained. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities. The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems. The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and maintained. Management shall regularly assess the adequacy and effective implementation of the quality assurance program.
Design Control	The design shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.
Procurement Document Control	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 quality assurance program.
Instructions/Procedures/ Drawings	Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment and worker proficiency and capability (education, training, experience).
Document Control	The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

Control of Purchased Items/Services	The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control shall provide 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 upon delivery or completion.
Identification and Control of Items	Controls shall be established to assure that only correct and accepted items are used or installed. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.
Control of Special Processes	Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.
Inspection	Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.
Test Control	Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.
Control of M&TE	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.
Handling, Storage, and Shipping	Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.
Inspection, Test, and Operating Status	The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of

	systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.
Control of Nonconforming Items	Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.
Corrective Action	Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined, and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.
Quality Assurance Records	The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Record control requirements and responsibilities for these activities shall be documented.
Audits	Audits shall be performed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.