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.

<u>Understanding the use of Graded Approach in implementation of the question</u> 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