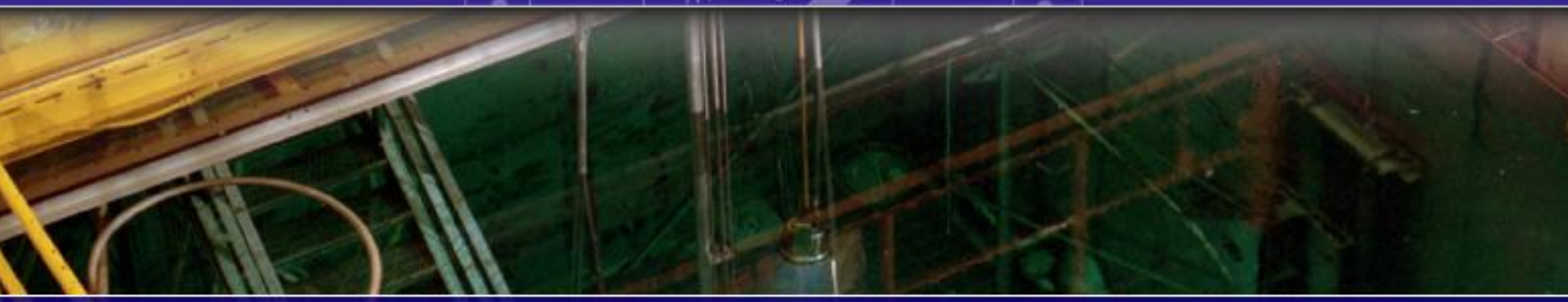
CNS

OFFICE OF THE UNDER SECRETARY



Strengthening Line Management Oversight and Federal Monitoring of Nuclear Facilities

Standard Review Plan

Commercial Grade Dedication (CGD)

August 2013

OFFICE OF ENVIRONMENTAL MANAGEMENT

Standard Review Plan (SRP)

Commercial Grade Dedication (CGD)

Applicability						
CD-0	**CD-1**	**CD-2**	**CD-3**	**CD-4**	**Operation**	**Post Operation**
	✓	✓	✓	✓	✓	✓

August 2013

Table of Contents

Objective

The objective of this Standard Review Plan (SRP) on Commercial Grade Dedication (CGD) is to provide guidance for a uniform review of the CGD activities for office of Environmental Management nuclear projects. It can be used for project reviews or verifying critical decision approval readiness.

Overview of Commercial Grade Dedication for Nuclear Facilities

Items or services that provide a safety function will be furnished by and/or performed under an ASME NQA-1 QA program, or be commercial grade dedicated to ASME NQA-1 requirements. This standard review plan module addresses the commercial grade dedication process required by ASME NQA-1 to ensure that a commercial grade service provider or a commercial grade item that performs a safety function provides the equivalent level of functionality as if provided by a vendor having with an ASME NQA-1 QA program. The goal of the CGD process is to provide reasonable assurance that the commercial grade item or service can perform its intended safety function. Reasonable assurance is based on facts, actions and observations[1]. The use of a supplier with an approved ASME NQA-1 program could still result in the need to perform CGD if items or services in support of a ASME NQA-1 procurement are provided by a commercial vendor or supplier.

Section 300 of the Introduction to Part I of ASME NQA-1 allows for specifying those QA requirements appropriately related to specific items and services. This approach for the use of commercial grade products and services is defined in ASME NQA-1, Requirement 7 - section 700 and in Part II - Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services. By applying the technical evaluation and dedication processes described in subpart 2.14, this judicious application of QA requirements allows for the use of items[2] or services produced in non ASME NQA-1 QA program environments, to be used to satisfy safety functions. This process is described graphically by Figure 1.

Once successfully dedicated by applying the ASME NQA-1 CGD process requirements, the dedicated item or service is considered to be a basic component[3] and is subject to the specified requirements of ASME NQA-1, Parts I and II.

[1] Reasonable Assurance is defined as a justifiable level of confidence based on objective and measurable facts, actions, or observations which infer adequacy; from EPRI Report TR-102260 *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items.*

[2] "Item" includes computer programs that are used in design analysis support, administrative, and embedded in hardware components. Refer to the full definition of "Item" in DOE O 414.1D

[3] See section 101 – Definitions of ASME NQA-1a-2009, Subpart 2.14

Requirements

1. DOE O 414.1D, Admin Chg1, *Quality Assurance*, May 2013
2. DOE O 413.3B, *Program and Project Management for the Acquisition of Capital Assets*, November 2010
3. ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*
4. ASME NQA-1a-2009, Addenda to ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*

Primary References

- Office of Environmental Management, *Guidance for Commercial Grade Dedication*, September 20, 2011
- ASME NQA-1-2008, *American Society of Mechanical Engineers Quality Assurance Requirements for Nuclear Facility Applications*
- ASME NQA-1a-2009, Addenda to ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*
- DOE O 413.3B, *Program and Project Management for the Acquisition of Capital Assets*
- *Standard Review Plan Handbook, Capital and Major Construction Projects Critical Decision*
- NRC Information Notice 2011-01: *Commercial-Grade Dedication Issues Identified During NRC Inspections*
- EPRI, TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items*
- EPRI, NP-5652,*Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)*

Commercial Grade Dedication Process Flow Diagram

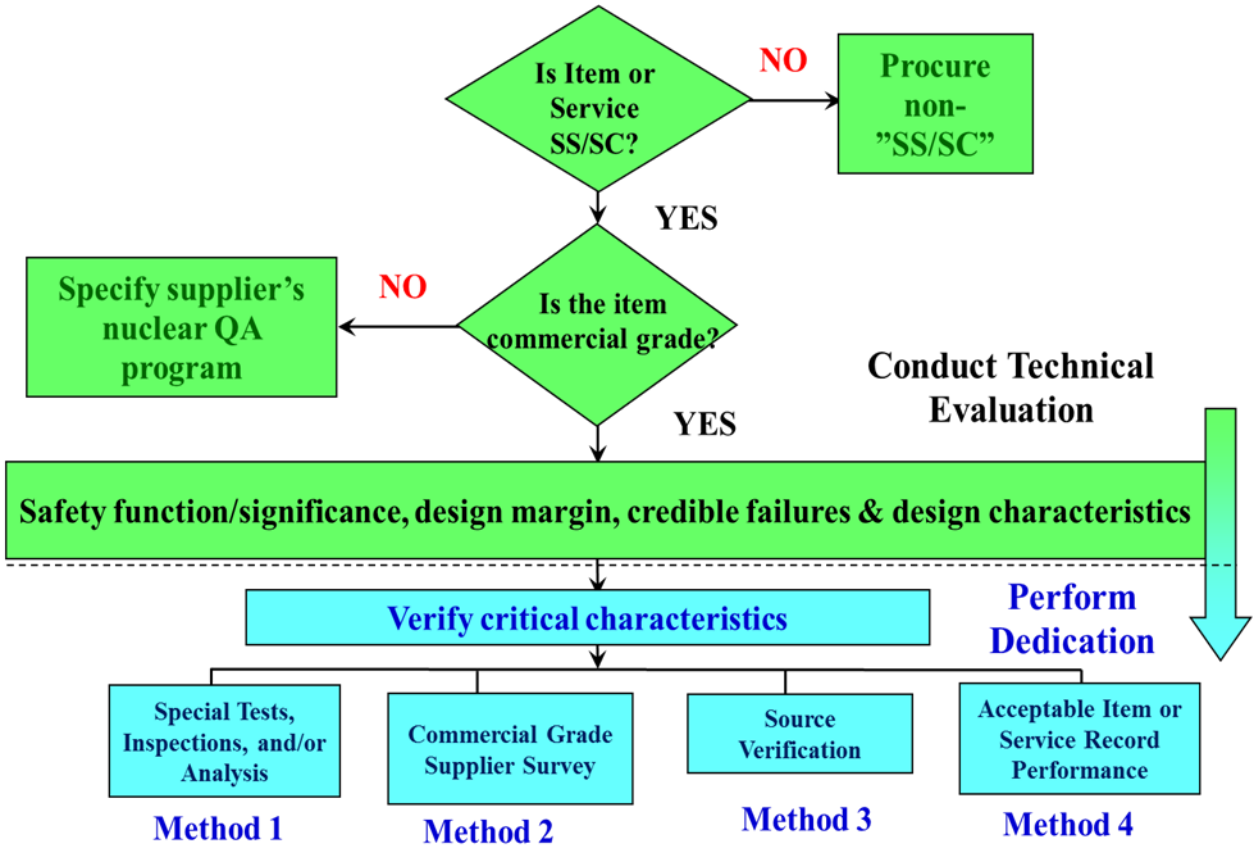


Figure 1, Commercial Grade Dedication Process Flow Diagram

Review Scope and Criteria

General

This review plan was written using requirements from ASME NQA-1-2008 with the NQA-1a-2009 addenda.

The specific requirements or lines of inquiry were not included in this standard review plan because they would be taken directly from ASME NQA-1. This would duplicate ASME NQA-1 and could be considered a copy right violation. Program reviewers are expected to develop their lines of inquiry based on ASME NQA-1 requirements.

A plan for all CGD activities that describes the identification of critical characteristics and the dedication methods should be developed and used. Deficiencies identified during dedication activities should be adequately addressed. CGD Method 4 should be used in conjunction with other dedication methods.

Commercial grade dedication activities should not be employed as a method for accepting commercial grade items or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's own specified processes and controls.

Occasionally services or items providing safety functions are procured that do not meet ASME NQA-1 QA requirements. In these situations commercial grade dedication may be used to provide a reasonable assurance that the service or item will perform its intended safety function. Because the commercial grade dedication process may not confirm that a service or item is acceptable; using CGD after an item or service has been procured as a corrective action may involve significant project cost and schedule risk. Review of CGD activities should be done during the entire facility life cycle, beginning in the Critical Decision stages and through post operations[4.]

Preparation for Review

Reviewers of CGD actions must be familiar with ASME NQA-1: sections 200 and 700 of Requirement 7 - Control of Purchased Items and Service; sections 100, 201, 202, 301, 302 and 303 of Requirement 8 - Identification and Control of Items; sections 302 and 303 of Subpart 2.7 - Quality Assurance Requirements for Computer Software for Nuclear Facility Applications, and Subpart 2.14 - Quality Assurance Requirements for Commercial Grade Items and Services, in its entirety. Reviewers must also be familiar with the definitions in DOE O 414.1D and Subpart 2.14 of NQA-1a-2009.

Review Topic CD-0, Project Approval of Mission Need

Activities supporting the development of a potential project mission and need do not include planning for or performing CGD.

Review Topic CD-1, Approval of Alternative Selection and Cost Range

This review topic focuses on the project documents and activities prior to CD-1 - Approval of Alternative Selection and Cost Range. The review areas include: Conceptual Design Report preparation; Acquisition Strategy preparation; Preliminary Project Execution Plan preparation; selection of the Federal Project Director (FPD); establishment of the Integrated Project Team (IPT); and preparation of safety documents.

[4] Post operations activities include facility deactivation, long-term surveillance and maintenance, and decommissioning.

Some alternative analyses may require the use of service suppliers that do not have fully compliant ASME NQA-1 QA programs. The use of computer programs or services that contribute to the safety design or accident analyses and not having an ASME NQA-1 QA program should be evaluated to determine if these computer programs or services can be procured as commercial grade and still meet its intended safety function, prior to use. Because acquiring items or services requiring CGD is usually more expensive than acquiring from suppliers with a compliant ASME NQA-1 QA program, the possible cost impact of CGD activities should be part of the pre-CD-1 review[5]. The CGD review should also verify that procedures for conducting CGD activities address specified DOE requirements.

Review Topic CD-2, Approval of Performance Baseline

This review topic focuses on the project documents and activities prior to CD-2-Approval of Performance Baseline. The review areas include: Earned Value Management System preparation; design documents preparation, QAP preparation; safety documents preparations; and National Environmental Policy Act activities.

Acquisition of processes or systems that include software may be initiated in this phase. Services that do not have ASME NQA-1 QA programs or computer programs not developed under an ASME NQA-1 QA program may be used in the safety design or accident analyses. These service and computer programs need to be evaluated using the CGD process to verify their ability to provide the intended safety function, prior to their use.

This review should also examine the extent design documents define safety systems in sufficient detail that CGD activities can be planned and included in the performance baseline. Because CGD activities consume time and resources, the review should examine the extent that CGD activities have been included in the cost and schedule elements of the performance baseline.[3] If long lead procurements from a commercial supplier are initiated, are CGD activities started early enough that they could be completed before the service or material will be used?
The CGD review should also verify that procedures for conducting CGD activities address specified DOE requirements.

Review Topic CD-3, Approval of Start of Construction

This review topic focuses on the project documents and activities to adequately address activities prior to CD-3 - Approval Prior to Start of Construction. The review areas include: final design documents, preparation; safety documents preparation; initiation of long lead procurements, and updating of project management documents.

Detailed design of a nuclear facilities, structures, systems and components (SSCs) occurs after CD-2 is issued. These design activities may involve the use of an engineering service provider that does not have, or computer programs not developed under compliant ASME NQA-1 QA programs. These services, computer programs, and other commercial grade items used to satisfy safety requirements need to be evaluated using the CGD process to determine their ability to provide their intended safety functions, prior to their use.

[5] The Office of Environmental Management, *Guidance for Commercial Grade Dedication* suggests that prior to initiating the CGD process an estimate of the cost to perform the CGD process be completed.

Reviews during this phase should also evaluate the implementation of the project's CGD procedures.

Review Topic CD-4, Approval of Start of Operations and Project Completion

This review topic focuses on the project documents and activities to adequately address activities prior to CD-4 - Approval of Start of Operations and Project Completion.

Verifying that CGD activities were effectively implemented early during construction reduces the schedule and cost risk associated with ineffective CGD activities. The CGD review for CD-4 approval should examine the conduct of CGD activities. The examination should examine if:

- CGD plans developed and followed,
- CGD procedures followed,
- CGD critical characteristics for acceptance identified,
- dedication activities appropriate, and
- CGD activity records processed as QA records and are they .retrievable

Review Topic, Operations and Post-Operations

During facility operations and post-operations, safety related items may have to be replaced with commercial grade items, facility designs may change and re-analysis of the safety basis may be necessary.

CGD reviews should examine if operating procedures address the CGD requirements for the use of commercial grade facility design change services and replacement items, and are they adequately implemented.

APPENDIX A: CGD Lines of Inquiry

Purpose

The purpose of this Appendix is to provide a breakdown of the key requirements and deliverables for projects as identified in DOE O 413.3B, Program and Project Management for the Acquisition of Capital Assets. The Lines of Inquiry (LOIs) provided in this section are organized by CD phase as described in DOE O 413.3B. A section on operations and post operations is also included because CGD may be necessary for replacement items, to support design changes, and maintaining an adequate safety basis. Each of the key deliverables for each section is identified and the adequacy of the specific deliverable is defined in the Performance Objectives and Criteria.

Application

This Appendix can be applied in a variety of ways; however, its structure is particularly focused on reviews prior to, and the approval of the particular CD decision point.

	Lines of Inquiry (LOI)	Reference
CD-1 Approval of Alternative Selection and Cost Range		
1	Has an Integrated Project Team been established and chartered to include a responsibility assignment matrix? Does the IPT include personnel knowledgeable in CGD?	DOE O 413.3B, Appendix A Table 2.1 DOE O 414.1D, Attachment 2 Section 2.a
2	Does the preliminary cost estimate include CGD activities[6]? Note: The cost range provided at CD-1 is the preliminary estimate for the selected alternative.	DOE O 413.3B, Appendix A, Section 4b
3	Do procedures for conducting CGD activities adequately address the specified DOE requirements?	DOE O 414.1D, Attachment 2 Section 4.a
4	If engineering services or developers of computer software were employed in the alternative analysis that did not have a compliant ASME NQA-1 QA program, was CGD utilized to verify the acceptability of these services and computer programs, prior to their use?	ASME NQA-1a-2009, Requirement 7, Section 700

[6] The Office of Environmental Management, *Guidance for Commercial Grade Dedication* suggests that prior to initiating the CGD process an estimate of the cost to perform the CGD process be completed.

	Lines of Inquiry (LOI)	Reference
5	Did the CGD plans capture the required activities?	ASME NQA-1a-2009, Subpart 2.14, Section 300
6	Were the CGD plans and procedures implemented effectively?	ASME NQA-1-2008, Requirement 5, Section 100
7	Were the CGD activities adequately captured and processed as QA records?	ASME NQA-1-2008, Requirement 17, Section 100
CD-2 Approval of Performance Baseline		
8	Approve an updated Acquisition Strategy Does the acquisition strategy address the possible acquisition of items or services requiring CGD?	DOE O 413.3B, Appendix A, Table 2.2
9	Establish a Performance Baseline Does the performance baseline include CGD activities? Are they planned, scheduled and are adequate resources allocated[7]?	DOE O 413.3B, Appendix A, Table 2.2
10	Determine that the Quality Assurance Program is acceptable and continues to apply Does the Quality Assurance Program include CGD activities?	DOE O 413.3B, Appendix A, Table 2.2
11	Do procedures for conducting CGD activities adequately address the specified DOE requirements?	DOE O 414.1D, Attachment 1, Section 1 EM-QA-001, Rev. 1, Section 3
12	If engineering services or developers of computer software were employed in developing the performance baseline that did not have a compliant ASME NQA-1 QA program, was CGD utilized to verify the acceptability of these services and computer programs, prior to their use?"	ASME NQA-1a-2009, Requirement 7, Section 700
13	If long lead procurements from a commercial supplier are initiated, were CGD activities started early enough that they could be completed before the service or material will be used?	DOE O 413.3B, Appendix A, Table 2.2 ASME NQA-1a-2009, Requirement 7, Section 700
14	Did the technical evaluation adequately identify critical characteristics?	ASME NQA-1a-2009, Subpart 2.14, Section 401

[7] The Office of Environmental Management, *Guidance for Commercial Grade Dedication* suggests that prior to initiating the CGD process an estimate of the cost to perform the CGD process be completed.

	Lines of Inquiry (LOI)	Reference
15	Did dedication activities adequately verify implementation of critical characteristics?	ASME NQA-1a-2009, Subpart 2.14, Section 600
16	Were the technical evaluation and verification of the critical characteristics properly documented, approved, and maintained as QA records?	ASME NQA-1-2008, Requirement 17, Section 100
17	Have the item or service deficiencies identified during CGD dedication activities been adequately addressed?	ASME NQA-1a-2009, Subpart 2.14, Section 606
CD-3 Approval of Start of Construction		
18	Complete and review the Final Design or determine that the design is sufficiently mature to start procurement or construction. Does the Final Design include items or services requiring CGD? Have they been identified? Have CGD activities been planned, scheduled, and resources allocated[8]?	DOE O 413.3B, Appendix A, Table 2.3
19	Update the Quality Assurance Program for construction, field design changes, and procurement activities. Does the Quality Assurance Program for Construction adequately implement specified DOE requirements for CGD[9, 10]?.	DOE O 413.3B, Appendix A, Table 2.3
20	Has the contractor developed and implemented a QAP with a graded approach that implements ASME NQA-1-2008 with the ASME NQA-1a-2009 addenda, as suggested as an applicable nuclear QA standard in DOE O 414.1D?.	DOE O 414.1D, Attachment 1, Section 1 EM-QA-001, Rev. 1, Section 3
21	If long lead procurements from a commercial supplier are initiated, were CGD activities adequately performed before use of the long lead material?	ASME NQA-1a-2009, Requirement 7, Section 700

[8] The Office of Environmental Management, *Guidance for Commercial Grade* Dedication suggests that prior to initiating the CGD process an estimate of the cost to perform the CGD process be completed.

[9] Section 603 (h) of ASME NQA-1a-2009, Subpart 2.14 states "Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys." The Office of Environmental Safety and Quality Guidance for Commercial Grade Dedication suggests that review packages ensure the persons who perform vendor surveys are knowledgeable in: a) the use of performance-based surveys; and b) screening third-party surveys. ASME NQA-1 does not prescribe specific criteria for personnel performing CGD surveys and "Knowledgeable in the use of" is not explicitly defined by the Office of Environmental Management.

[10] The Office of Environmental Management, *Guidance for Commercial Grade Dedication* suggests that dedication plans be developed by engineering with input from QA. Input from QA is not an ASME NQA-1 requirement.

	Lines of Inquiry (LOI)	Reference
22	If engineering services or developers of computer software were employed prior to the start of construction that did not have a compliant ASME NQA-1 QA program, was CGD utilized to verify the acceptability of these services and computer programs, prior to their use?"	ASME NQA-1a-2009, Requirement 7, Section 700
23	Did the technical evaluation adequately identify critical characteristics?	ASME NQA-1a-2009, Subpart 2.14, Sections 401 and 500
24	Did dedication activities adequately verify implementation of critical characteristics?	ASME NQA-1a-2009, Subpart 2.14, Section 600
25	Were the technical evaluation and verification of the critical characteristics properly documented, approved, and maintained as QA records? Did documentation for CGD activities meet ASME NQA-1 requirements?	ASME NQA-1-2008, Requirement 17, Section 100
26	Have the item or service deficiencies identified during CGD dedication activities been adequately addressed?	ASME NQA-1a-2009, Subpart 2.14, Section 606
CD-4 Approval of Start of Operations and Project Completion		
27	Verify that Key Performance Parameters and Project Completion Criteria have been met and that mission requirements have been achieved. Project completion criteria include safe operation. Do the CGD activities provide reasonable assurance that dedicated items and services will perform their intended safety function(s)?	DOE O 413.3B, Appendix A, Table 2.4 ASME NQA-1a-2009, Subpart 2.14
28	Have the project procedures for CGD activities been followed?	ASME NQA-1-2008, Requirement 5, Section 100
29	Were records of CGD activities, including the technical evaluation and verification of critical characteristics correctly documented and handled as QA records	ASME NQA-1-2008, Requirement 17, Section 100
30	Were CGD activities planned?	ASME NQA-1a-2009, Subpart 2.14, Section 300
31	If design changes were necessary, was the CGD process completed adequately for items or services impacted by design changes?	ASME NQA-1-2008, Requirement 3, Section 600
32	Were CGD activities completed before commercial grade services or items were used?	ASME NQA-1a-2009, Requirement 7, Section 700

	Lines of Inquiry (LOI)	Reference
33	If engineering services or developers of computer software were employed that did not have a compliant ASME NQA-1 QA program, was CGD utilized to verify the acceptability of these services and computer programs, prior to their use?"	ASME NQA-1a-2009, Requirement 7, Section 700
34	Did the technical evaluation adequately identify critical characteristics?	ASME NQA-1a-2009, Subpart 2.14, Section 400
35	Did dedication activities adequately verify implementation of critical characteristics?	ASME NQA-1a-2009, Subpart 2.14, Section 600
36	Were commercially dedicated items controlled in accordance with ASME NQA-1?	ASME NQA-1-2008 Requirement 8, Section 100
37	Have the item or service deficiencies identified during CGD dedication activities been adequately addressed?	ASME NQA-1a-2009, Subpart 2.14, Section 606
Operations and Post Operations		
38	Do operating procedures address the specified CGD requirements for the use commercial grade replacement items, facility design changes, and maintenance of the safety basis?	DOE O 414.1D, Attachment 2, Section 4.a
39	Have the requirements for replacement activities[11] in Subpart 2.14 of the ASME NQA-1a-2009 addenda, been effectively implemented?	ASME NQA-1-2008, Requirement 5, Section 100
40	Were the technical evaluation and verification of the critical characteristics properly documented?	ASME NQA-1a-2009, Subpart 2.14, Sections 400, and 600 ASME NQA-1-2008, Requirement 17, Section 100
41	Have CGD procedures been followed?	ASME NQA-1-2008, Requirement 5, Section 100
42	Did documentation for CGD activities meet ASME NQA-1 records requirements?	ASME NQA-1-2008, Requirement 17, Section 100

[11] See sections 401, 402 and 403 of ASME NQA-1a-2009, Subpart 2.14.