

NRC Staff Responses to Public Comments on DG-1326:  
 “QUALITY ASSURANCE PROGRAM CRITERIA (DESIGN AND CONSTRUCTION)”  
 Federal Register 82 FR 15242 (March 27, 2017)

I. INTRODUCTION

This document presents the NRC’s responses to written public comments received on Draft Guide (DG)-1326, “Quality Assurance Program Criteria (Design and Construction)” (ADAMS Accession No. ML16180A264), in response to a separate *Federal Register* entry (82 FR 15242, March 27, 2017).

II. OVERVIEW OF COMMENTERS AND COMMENTS

The staff received 3 comment submissions and a total of 15 individual comments. Table 1 presents information on the commenters who submitted comments on DG-1326.

Table 1.

Name	Affiliation	ADAMS Accession No.		Identifier
		Incoming	Annotated	
Jarno Makkonen	-	ML17096A264		UNK1
Mark A. Richter	Nuclear Energy Institute (NEI)	ML17145A285		NEI
Byron Frank	-	ML17163A091		UNK2

Comments were binned into the following categories for convenience:

- a. Comments on the Scope of Acceptance of the Various Revisions to NQA-1
- b. Comments on Audit Participation
- c. Comments on Electronic Records
- d. Comments on External Audits
- e. Editorial Comments

a. Comments on the Scope of Acceptance of the Various Revisions to NQA-1

**Comment:** Recently issued public drafts of updates to the American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel Code (B&PVC) Section III, Subsection NCA indicate that the ASME committees are not changing the edition of NQA-1 which needs to be satisfied. As a result, component manufacturers who construct components to ASME B&PVC Section III requirements will have to conform to multiple editions of the NQA-1 Standard. [UNK1-1]

**NRC Response:** The NRC disagrees that component manufactures who contract components to ASME B&PVC will have to conform to multiple editions of NQA-1 as a result of this RG. The RG endorses multiple versions of NQA-1 of which one should be specified by the licensee in the purchasing document. Manufacturers are required to follow the NQA-1 and code requirements specified in the purchasing documents. Additionally, NRC endorsement of the latest NQA-1 revisions does not void endorsement of the previous revisions. No change was made to the RG as a result of this comment.

**Comment:** Referencing different editions of standards as all being acceptable introduces risk. It is possible that unless language is included which specifies that the licensees should pick one edition and follow it fully, licensees may cherry pick the requirements from different editions in order to minimize the requirement to something less than if one of the approved editions were fully followed. [UNK1-2]

**NRC Response:** The NRC disagrees with the comment. The NRC finds that the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015 each contain the minimum requirements necessary to fulfil the regulations of Appendix B to 10 CFR Part 50. The staff anticipates that a licensee would select and follow one edition and if deviations are made, that the deviations would be appropriately justified. No change was made to the RG as a result of this comment.

**Comment:** The first paragraph in the Section B, “Background” states that, “The staff determined that the NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015 provide the most current guidance for QA.” As stated, this sentence appears to equally assign preference to NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015 above all previously endorsed revisions of NQA-1. To clarify, “provide the most current guidance for QA” should be changed to “provide adequate guidance for QA” [NEI-3]

**NRC Response:** The staff disagrees with the comment. The NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015 do provide the most current guidance for QA, however NRC endorsement of the latest NQA-1 revisions does not void endorsement of the previous revisions. No change was made to the RG as a result of this comment.

*b. Comments on Audit Participation*

**Comment:** The alternative demonstration of ability discussed in Section C, 1.a(1) should include a statement concerning acceptance of this demonstration. [NEI-1]

**NRC Response:** The NRC agrees with the comment. Section C, 1.a(1) was revised to indicate that the alternative approach for satisfying the lead auditor qualification requirement of participating in a minimum of five QA audits within a 3-year period is subject to review and acceptance by the responsible QA organization.

**Comment:** In Section C, 1.a(1), the phrase “comparable industry experience” may be very loosely translated. Translation could offer latitude that may allow qualification of individuals who lack the in-field practice necessary to perform as a lead auditor. [NEI-4]

**NRC Response:** The NRC disagrees with the comment. This section of the RG provides an exception to the audit participation requirements for the prospective lead auditors in regard to participating in a minimum of five QA audits within a 3-year period. All other lead auditor qualification requirements, as described in NQA-1, Requirement 2 are still applicable. No change was made to the RG as a result of this comment.

*c. Comments on Electronic Records*

**Comment:** In Section C, 3.b(1)(e), “Random inspections” is non-specific and may lead to different interpretations of what is required. NIRMA TG 15-2011, Section 8.4.5 provides

suggested specific actions and intervals and should be recommended as the basis of any review of possible record degradation. [NEI-2]

**NRC Response:** The NRC agrees with this comment. Section C, 3.b(1)(e) was revised to indicate that inspection of media records is required to ensure no degradation of records.

**Comment:** The approval for the use of the four NIRMA Technical Guides (TGs) listed in Section C, 3(b) is a noteworthy addition to the RG and should be made more visible by noting this addition in the summary paragraph introducing Section C. [UNK2-4]

**NRC Response:** The NRC disagrees with the comment. The approval of the NIRMA TGs is highlighted in Section B of the RG. No change was made to the RG as a result of this comment.

d. Comments on External Audits

**Comment:** In Section C, 4.b(2), it would be better to specify that the triennial audit period starts on the day of the closing meeting of the performed audit. [UNK1-4]

**NRC Response:** The NRC disagrees with the comment. The guidance for audits contained within the endorsed versions of ANSI/ASME NQA-1 was determined to be adequate in RG 1.28, Revision 3 and Revision 4. No change was made to the RG as a result of this comment.

**Comment:** Section C, 4.b(2) states, in part, that, “The licensee or applicant may perform an audit when the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program that has the required scope for purchases placed during the triennial period.” This seems to imply that that the licensee can issue a purchase order for some work to a supplier that has not been audited (and a pre-award survey has not been done) and then when some of the work is completed, then perform the audit. This approach would be highly risky for on-site worker as well as engineering or computer application development, therefore the recommendation is to remove the aforementioned statement. [UNK1-5]

**NRC Response:** The NRC agrees, in part, with the comment. The NRC agrees that it is a risk for the licensee to issue a purchase order without auditing the supplier. However, Criterion VII, “Control of Purchased Material, Equipment and Services,” of Appendix B to 10 CFR Part 50, requires that measures be established, as appropriate, for source evaluation, objective evidence of quality furnished by the contractor or subcontractor, and examination of products upon delivery, but does not explicitly require that the purchaser perform an audit prior to issuing a purchase order. No change was made to the RG as a result of this comment.

**Comment:** In Section C, 4.b(4)(c), Authorized Inspection Agency audits or other accreditation body audits could be considered.[UNK1-7]

**NRC Response:** The NRC agrees that other accreditation body audits should be taken into consideration; however, the NRC believes that this is already encompassed in Section C, 4.b(4)(c). No change was made to the RG as a result of this comment.

e. Editorial Comments

**Comment:** Section C, 3.b(1) should read. “For the management of electronic records, appropriate controls on quality assurance include the following:” [UNK1-3]

**NRC Response:** The NRC agrees with the comment and has revised the RG accordingly.

**Comment:** Section C, 4.b(4)(c) should read, “operating experience of products furnished by the supplier and results of audits from other sources...” [UNK1-6]

**NRC Response:** The NRC disagrees with the comment. Operating experience should only be considered relative to the scope of the procurement (i.e. the same or a similar product). No change was made to the RG as a result of this comment.

**Comment:** In Section B, “Background,” the phrase, “computer software use” should be changed to “computer software development,” consistent with the scope of Subpart 2.7. [UNK2-1]

**NRC Response:** The NRC agrees with the comment and has revised the RG accordingly.

**Comment:** In Section B, “Background,” change “Subsection 2.22” to “Subpart 2.22.” [UNK2-2]

**NRC Response:** The NRC agrees with this comment and has revised the RG accordingly.

**Comment:** In Section C, it would be helpful for items 1, 2, 3 and 4 to identify with part of NQA-1 the exception of clarification refers to. [UNK2-3]

**NRC Response:** The NRC agrees with this comment and the RG has been revised accordingly.