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**Subject:** American Society of Mechanical Engineers Comments on Draft Regulatory Guide DG-1215, Quality Assurance Program Requirements (Design and Construction)

**Reference:** Draft Regulatory Guide DG-1215, (Proposed Revision 4 of Regulatory Guide 1.28 dated July 2009), Quality Assurance Program Requirements (Design and Construction) (Adams Accession No. ML 090150402)

Dear Sir or Madam:

The ASME Board of Nuclear Codes and Standards (BNCS) and the ASME Nuclear Quality Assurance Committee (NQA) supports the NRC's position to revise Regulatory Guide 1.28, Rev. 3 to endorse ASME NQA-1-2008 and ASME-1a-2009 and provide the "latest guidance for QA program requirements developed in one consensus standard." The RG revision is needed to provide consistency with current regulatory activity related to new generation and facility design and construction

ASME is pleased to have the opportunity to provide the following comments and suggestions on the Draft Regulatory Guide DG-1215:

General

1. The regulatory guide (RG) should minimize NRC administrative processes, historical references and descriptions of the evolutionary development of the NQA-1 Standard. Much of the information presented is included in the Forward of the NQA-1 Standard. The focus of the RG should be to clearly identify the regulatory position differences on new design and construction from the content of NQA-1-2008 and NQA-1a-2009 Addenda.
2. The correct reference to the description of the NQA Standard being considered for endorsement is "NQA-1-2008 and the NQA-1a-2009 Addenda." This appears in several locations.
3. NQA -1 text that is quoted verbatim in the RG should be identified with quotation marks.

A. Introduction

1. The citing of 10 CFR Part 50.34(b)(6)(ii) in the first paragraph is directed towards "controls to assure safe operation" but this regulatory guide is clearly directed towards the "design and construction phases." Consider deleting this reference since it is out of the current scope of the guide. The listing of RG-1.33 in the third paragraph is appropriate, since it is noted as a reference.

B. Background

1. The second, third and fourth sentences of the first paragraph should be deleted. The sentences provide no useful information that is not available in RG 1.28, Rev.3.

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2. The list of work activities in the second sentence of the second paragraph should be revised to change "installment" to "installation."
3. The third sentence of the second paragraph for Appendix A that includes the overview of the history should be deleted.

### C. Regulatory Position

1. Regulatory positions 1.a.(1) and 1.a.(2) are consistent with NQA-1 since it states in Requirement 17, paragraph 400, that "Records shall be classified as lifetime or nonpermanent and maintained by the Owner, or authorized agent...." Paragraphs 401 and 402 are subsets of paragraph 400 and do contradict paragraph 400. The NRC position provides only minor clarification that the "owner or authorized agent" is responsible for retention of permanent and nonpermanent records for the identified retention period by repetition of the statement in paragraph 400. The user of the RG will have to carefully read the NQA Standard to identify the regulatory position point of clarification. This regulatory position should be deleted or consolidated into a single defining statement without repeating the NQA text due to its minor point of clarification
2. For regulatory position 1.a.(3) the first and second sentences are a reference to RG 1.28, Revision 3 with a justification for the change. Since this does not constitute a regulatory position, we suggest the first and second sentences be deleted. For the existing third sentence, add "NQA-1, Part III" to clarify the location within NQA-1 so the sentence will read, "NQA-1, Part III, Nonmandatory Appendix 17A-1, ..."
3. The paragraph after regulatory position 2, Audits is the exact text from NQA-1 and is not needed as an introduction for the audit section positions. There is no corresponding introduction for regulatory position 1, Quality Assurance Records. Consider deleting the paragraph.
4. The first sentence of regulatory position 2.b.(2) is duplicated in regulatory position 2.b.(1). Consider deleting the first sentence of regulatory position 2.b.(2) and adding the second sentence to the paragraph for regulatory position 2.b.(1).
5. Regulatory position 2.b.(5) should be relocated to follow regulatory position 2.b.(3), since it was located in this position in SRP 17.5 and is more closely related to this position.
6. The implication in regulatory position 2.b.(4)(d) that an "ASME audit" can be directly used in the annual evaluation of a supplier should be clarified. The ASME certification survey report or notes are not available for public review. Organizations that do not successfully meet their ASME survey requirements do not retain their N-stamp certification, which is the only public available "result" of an ASME survey. ASME has always maintained that for retention of a certificate an organization is in compliance with the Code. The current certification status of an organization is easily checked on the ASME website and maintenance of a supplier's certification is usually part of an N-stamp supplier's annual supplier evaluation. Consider revising regulatory position 2.b.(4)(d) to read as follows: "(d) results of surveys or audits from other sources (e.g. ASME certificate renewal or NRC audits).
7. The paragraph that summarizes IN 86-21 is not a numbered regulatory position and users may inappropriately associate it with regulatory position 2.b.(4)(d) for ASME that it immediately follows. ASME does not disagree with the IN 86-21 content summary, which is related more to supplier qualification and audits instead of annual supplier evaluations. Consider deleting the paragraph in the current location and relocating it as a "Note:" following regulatory position 2.b.(3) since this is a more appropriate location.
8. In regulatory position 2.b.(6) the correct term for ILAC is International Laboratory Accreditation Cooperation. For consistency, the acronym (A2LA) for the Association of Laboratory Accreditation should also be listed.

9. Criterion 2, Quality Assurance Program, in SRP 17.5 contained a grace period for the performance of audits that is not included in NQA-1, Part I or Part II. We request that the grace period be included in a new regulatory position 2.c, Grace Period and read as follows:

A general grace period of 90 days may be applied to provisions of Position 2.a and 2.b that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations, internal audits and audits that must be performed on a triennial basis are examples where the 90 day general grace 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.

#### References

1. For reference 9, the current document has an issue date of March 2007.

#### Appendix A

1. While Appendix A does provide background information, it does not focus the reader on the quality requirements or regulatory positions for new design and construction of nuclear facilities. The tables and cross references are not necessary for licensees that are utilizing SRP 17.5, which does not even reference all the Regulatory Guides that are in Table A-3. By deleting Appendix A, we believe the industry would benefit by not spending needless hours of review attempting to determine if Appendix A contains any relevant information for new design and construction.

ASME and its NQA Committee are committed to continue to work closely with the NRC to bring together where appropriate the requirements in NQA-1 and expectations of the NRC.

If you have any questions, please contact me or direct them to Mr. Kevin Ennis, ASME Director, Nuclear Codes and Standards by telephone at (212) 591-7075 or by e-mail ([ennisk@asme.org](mailto:ennisk@asme.org)).

Very Truly Yours,



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