

**NRC Responses to Comments**  
**Comments on Draft RG 1.28 Rev. 4 (DG-1215)**  
**[page number references based on ADAMS document ML090150402 – 7/6/09]**

Comments were received from four sources:

| Comment numbers | Organization    | Date    | Address                             | Representative |
|-----------------|-----------------|---------|-------------------------------------|----------------|
| 1-2             | Progress Energy | 8/18/09 | Wendy.woltz@pgnmail.com             | W. Woltz       |
| 3-8             | Dominion        | 9/8/09  | 5000 Dominion, Blvd, Glen Allen, VA | C. Funderburke |
| 9-15            | NEI             | 9/9/09  | 1776 I St ,NW Wash, DC              | D.J. Walters   |
| 16-34           | ASME            | 9/2/09  | 3 Park Avenue, NY, NY 10016         | B.A. Erler     |

Comment and response are tabulated below

| Comment # | Section/Page               | Text  | Comment   | NRC Response   |
|-----------|----------------------------|---|---|--|
| 1         | General Comment on DG-1215 | <p>Discussion – identification of standard.</p> <p>“The Part I and Part II requirements included in the NQA-1a-2008 Addenda to NQA-1-2008, “Quality Assurance Requirements for Nuclear Facility Applications” (Ref.5), for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants are acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to the additions and modifications of NQA-1a-2008 Addenda to NQA-1-2008 identified below.</p> | <p>Reference throughout is to NQA-1a-2008 Addenda. We believe the correct reference should be to the NQA-1a-2009 Addenda.</p> | <p>Accepted - The reference to the standard will be “NQA-1-2008 and the NQA-1a-2009 Addenda.</p> <p>The NQA-1-2008 Addenda was initially referenced, as this was the version of the standard publicly available during the DG-1215 comment period. The staff had intended to change the reference once the comment period was complete and if only minor changes had been made to the addenda.</p> |

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| 2                | Section C<br>Regulatory Position<br>2.b.(4)(d)<br>Page 5 | Discussion – audit evaluation.<br><br>(d) results of audits from other sources (e.g., ASME or NRC audits).   | Paragraph C.2.b.(4)(d) states that the annual supplier evaluation should consider “(d) results of audits from other sources (e.g., ASME or NRC audits).” The results of an ASME audit other than “pass and received an appropriate stamp or certificate,” is not available for review (i.e., the ASME audit report details are not available to us for review, only the list of suppliers on the ASME WEB who have a stamp or certificate is available). (We want to ensure it is clear that the results of ASME audits would only entail verifying a supplier has a valid and appropriate stamp or certificate). | Accepted – Paragraph C.2.b.(4)(d) will be revised to state the following: “results of audits from other sources (e.g., NUPIC audit reports or NRC inspection reports).”   |
| 3                | Section C<br>Regulatory Position<br>Pages 2-5            | Discussion – identification of standard.   | <u>Reference to NQA-1</u><br>In Section C, Regulatory Position, the reference in the first sentence and throughout the document to “NQA-1a-2008” appears to be incorrect. We believe the correct reference should be “NQA-1a-2009 Addenda to NQA-1-2008.”   | Accepted - See response to Comment #1.  |
| 4                | Section C<br>Regulatory Position<br>Page 2               | Discussion – identification of standard.   | <u>Reference to NQA-1</u><br>In the first paragraph of Section C, the wording of the first sentence can be read to limit the reference. “The Part I and Part II requirements included in the NQA-1a-2008 Addenda to NQA-1-2008,” can be read to be endorsing only the NQA-1a-2008 Addenda and not NQA-1-2008. The reference should be clarified. The intent is to endorse NQA-1-2008 with the additions and modifications of NQA-1a-2009 Addenda to NQA-1-2008.   | Accepted - See response to Comment #1.  |
| 5                | Section C<br>Regulatory Position<br>Page 2               | Discussion – extent of standard endorsement.<br><br>“The Part I and Part II requirements included in the NQA-1a-2008 Addenda to NQA-1-2008, “Quality Assurance Requirements for Nuclear Facility Applications” | <u>Clarifications of Referenced RG 1.39 and Subpart 2.18 Applicability</u><br>The first sentence of Section C, Regulatory Position, states, “The Part I and Part II requirements included in the NQA-1a-2008 Addenda to NQA-1-2008, “Quality Assurance Requirements for Nuclear Facility Applications” (Ref. 5), for the implementation of a QA Program during the design and construction phases of nuclear power plants and fuel reprocessing plants are acceptable to the NRC staff and  | No Change - As stated in the introduction, this regulatory guide describes methods that the NRC staff considers acceptable for complying with the provisions of Appendix B to 10 CFR Part 50 for establishing and |

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|           |              | (Ref. 5), for the implementation of a QA program during the design and construction phases of nuclear power plants and fuel reprocessing plants are acceptable to the NRC staff and provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to the additions and modifications of NQA-1a-2008 Addenda to NQA-1-2008 identified below.” | <p>provide an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50, subject to the additions and modifications of NQA-1a-2008 to NQA-1-2008 identified below.”</p> <p>Based on the explicit wording, the Regulatory Guide appears to be endorsing both Parts I and II of NQA-1-2008; therefore, Subpart 2.3, “Quality Assurance Requirements for Housekeeping for Nuclear Power Plants,” would also be endorsed and considered a requirement. NUREG-0800, Standard Review Plan 17.5, “Quality Assurance Program Description – Design Certification, Early Site Permit and new License Applicants,” Section U., “QA Program Commitments, does not require a commitment to either RG 1.39, “Housekeeping Requirements for Water-Cooled Nuclear Power Plants,” or NQA-1-2008, Subpart 2.3. The NRC should clarify if Subpart 2.3 is intended as a required commitment. Otherwise, utilities will need to justify an alternative to that information or include it as part of the Quality Assurance Program Description. If Subpart 2.3 is determined to be a required commitment, then the NRC should update Standard Review Plan 17.5 and withdraw RG 1.39, since ANSI N45.2,3, “Housekeeping During the Construction Phase of Nuclear Power Plants,” is replaced with NQA-1, Subpart 2.3.</p> | implementing a QA program. The staff reviews and evaluates submitted QA program descriptions in accordance with the applicable sections of SRP 17.5. What the staff has determined is that either method is acceptable for meeting QA requirements related to housekeeping for nuclear power plants. The relaxation to RG 1.39 was given based on a mature industry. A new applicant may not have the requisite experience necessary to support use of the alternative given in SRP 17.5 and approved in the staff’s safety evaluation (Accession No. ML052710274). No justification for the alternative would need to be provided by existing utilities as the staff guidance has already documented the change. |
| 6         |              | Discussion – commitment to Subpart 2.18, “Quality Assurance Requirements for Maintenance of Nuclear Facilities.”  | <p><u>Clarifications of Referenced RG 1.39 and Subpart 2.18 Applicability</u></p> <p>NUREG-0800, Standard Review Plan 17.5, “Quality Assurance program Description – Design Certification, Early Site Permit and New License Applicants, Section U., “QA Program Commitments, does not require a commitment to NQA-1-2008, Subpart 2.18, “Quality Assurance Requirements</p>   | No Change - As stated in the introduction, this regulatory guide describes methods that the NRC staff considers acceptable for complying with the provisions of Appendix B to   |

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|           |  |   | for Maintenance of Nuclear Facilities.” Likewise, the NRC should clarify if Subpart 2.18 is intended as a required commitment or not. Otherwise, utilities will need to justify an alternative to that information or include it as part of the Quality Assurance program Description. If Subpart 2.18 is determined to be a required commitment, then the NRC should update Standard Review Plan 17.5.   | 10 CFR Part 50 for establishing and implementing a QA program. The staff reviews and evaluates submitted QA program descriptions in accordance with the applicable sections of SRP 17.5. As SRP 17.5 has no mention of Subpart 2.18 and has accepted the NEI QA program template, which does not reference Subpart 2.18, the staff determined that no clarification was necessary.   |
| 7&8       | Section C<br>Regulatory<br>Position<br>1.a.(3)<br>Page 3 | Discussion – retention period of programmatic and product nonpermanent records. | <p><u>Clarification of Reference Appendix 17A-1 Applicability</u></p> <p>Regulatory Position 1.a.(3) states: “Revision 3 of this regulatory guide provided guidance on the retention period for programmatic and product nonpermanent records. However, because there are additional regulatory requirements for specific records and established industry practice, this guidance was deemed obsolete and no longer necessary. Non-mandatory Appendix 17A-1, “Guidance on Quality Assurance Records,” in Paragraph 200, “List of Typical Lifetime Records,” list typical lifetime records containing information that meets Requirement 17 of Part I.”</p> <p>This paragraph appears to implicitly be invoking Part III, Subpart 3.1, Nonmandatory Appendix 17A-1, “Guidance on Quality Assurance Records.” This position should be clarified to explicitly state if Part III, Nonmandatory Appendix 17A-1, “Guidance on Quality Assurance Records,” is considered a requirement or not.</p> | Accepted - In Part I of NQA-1 and SRP 17.5, guidance was provided on record retention. Neither, Part 1 or SRP 17.5 contains a specific list of required documents. Through QA program change submittals, licenses have been determining what documents need to be retained and for how long. As noted, in DG-1215, there are several stipulations; nomenclature of records may vary, the type of record that most nearly describes the record in question should be followed with respect to its retention |

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|           |              |      | <p><u>Recordkeeping</u></p> <p>In the event NQA-1-2008, Part III, Subpart 3.1, Nonmandatory Appendix 17A-1, "Guidance on Quality Assurance Records," Paragraph 200, "List of Typical Lifetime Records," is considered to be a requirement, there are concerns with some of the records listed in Paragraph 200. The list includes a number of records that have not previously been considered lifetime records. Although the proposed draft specifically identifies no backfit imposition, many of these examples are not consistent with previous NRC guidance and precedence, and some appear to be inappropriate for lifetime retention. Examples from Paragraph 200 include:</p> <p>From Section 206 "Operational Records," item (aa), Quality Assurance and Quality Control manuals are identified as lifetime records; however, NRC RG 1.28, Rev. 3, Table 1, "Retention Times for Lifetime and Nonpermanent Records," indicates Quality Assurance and Quality Control manuals are nonpermanent records with a 3-year retention requirement.</p> <p>From Section 206, "Operational Records," item (w), Fire Protection, "records are identified as lifetime records; however, NRC GR 1.28, Rev. 3, Table 1, "Retention Times for Lifetime and nonpermanent Records," indicate Fire Protection "reports" are lifetime records. Fire Protection "records" is a more general terminology and more inclusive than Fire Protection "reports." Many general Fire Protection "records" may not rise to the standard of a quality related "report," and therefore, do not merit lifetime recordkeeping.</p> <p>From Section 206, "Operational Records," item (x), Nonconformance/Corrective Action Reports are identified as lifetime records; however, NRC RG 1.28, Rev. 3, Table 1, "Retention Time for Lifetime and Nonpermanent Records," indicates that only Nonconformance Reports are lifetime</p> | <p>classification, and the applicant or license should be cognizant that the list is not considered all- inclusive. Most importantly, the licensee itself is responsible for ensuring, in accordance with Criterion XVII of Appendix B to 10 CFR Part 50, that it maintains sufficient records to furnish evidence of activities affecting quality. In the previous revision of RG 1.28, the list of documents did not state it was an all-inclusive list. The responsibility to maintain adequate records still resides with the licensee or applicant.</p> <p>The list retains its past and present status as a guide, providing examples relevant to the definition of lifetime and nonpermanent records. A new sentence will be added after the third sentence in paragraph C.1.(3), stating "The list of typical lifetime records in Nonmandatory Appendix 17A-1 should be considered for guidance purposes only."</p> |

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| 9                | Section A<br>Introduction<br>Page 1   | Discussion – identification of standard.     | DG-1215, 1 <sup>st</sup> paragraph, seems to imply that the only document being endorsed is the 2009 Addenda and not the 2008 edition of NQA-1 with the 2009 Addenda. If it is the NRC's intent to endorse NQA-1-2008 with the additions and modifications of NQA-1a-2009, then this should be clarified. The correct reference for the Addenda is NQA-1a-2009 and not NQA-1a-2008.                  | Accepted – with correction. See response to #1 for explanation.  |
| 10               | Section C<br>Regulatory Position<br>Pages 2-5                                       | Discussion – extent of standard endorsement. | Based on the intent of the guidance document to endorse Parts I and II of NQA-1-2008 with NQA-1a-2009, we are concerned that SRP 17.5 and the NEI template do not require us to use Subpart 2.3; however, this will now be a part of the standard endorsed by the RG, and COL applicants will need to justify an alternative to that information, or we will need to include it as part of the QAPD. | No Change - See response to Comment #5.  |
| 11               | Section C<br>Regulatory Position<br>1.a.(3)<br>Page 3                               | Discussion – extent of standard endorsement. | Regulatory Position 1.a.(3), (starts with "Revision 3 of this regulatory guide provided guidance on the retention"), is not clear as to whether or not the Regulatory Guide is invoking Part III, Nonmandatory Appendix 17A-1 as part of the requirements. We do not believe the NRC should invoke non-mandatory appendices. The NRC should clarify the intent of this position.                     | Accepted. Added clarifying statement to C.1.(3).   |
| 12               | Section B<br>Discussion<br>Background<br>Page 2, and<br>Appendix A<br>Pages A-1-A-4 | Discussion – QA historical content.          | The value in providing all the historical information contained within the document is not clear.  | No Change - The purpose as stated is to provide an overview and continuation of the history and consolidation of NRC and industry. In order to understand how this consolidation was reached, the staff believed it was relevant to continue the discussion from Revision 3, of RG 1.28, issued in 1985. |

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| 13               | Section C<br>Regulatory<br>Position<br>Pages 2-5         | Discussion – extent of standard endorsement.  | We are concerned that SRP 17.5 and the NEI template do not require industry to use Subpart 2.18; however, this will now be a part of the standard endorsed by the RG, and COL applicant will need to justify an alternative to that information. Part II, Subpart 2.18, addresses requirements for maintenance. This does not appear to be appropriate for application to the Design and Construction of a nuclear power facility.   | No change - See response to Comment #6.  |
| 14               | Section C<br>Regulatory<br>Position<br>1.a.<br>Pages 2-3 | Discussion – lifetime and nonpermanent records.   | In Section C.1., delete paragraph a., "Lifetime and Nonpermanent Records," in its entirety. This section, along with its subsections, simply restates NQA-1-2008 Requirement 17 Paragraph 401 and 402. Rewrite Paragraph b. to provide supplemental guidance for electronic records and make it Regulatory Position C.1.   | No Change - The goal of a standard is to meet the needs of several stakeholders. Requirements for electronic records were considered unique. Because electronic records were not currently discussed in the NQA-1 standard, a specific regulatory position countering the standard's position was needed. Adequate guidance to NRC stakeholders is provided in a generic communication and SRP 17.5. |
| 15               | Section B<br>Discussion<br>Background<br>Page 2          | Discussion – suggested endorsement of NEI 06-14A, "Quality Assurance Program Description," in the regulatory guide. | The draft regulatory guide describes methods the U.S. Nuclear Regulatory Commission (NRC) staff considers acceptable for complying with the provisions of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Facilities." However, the NRC has also endorsed NEI 06-14A, "Quality Assurance Program Description," which provides a generic template for use in developing an applicant-specific quality assurance program description required as part of an early site permit (ESP) and combined license (COL) application. The template is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, which at the time was the latest NRC-approved | No Change - The quality program requirements identified in 10 CFR 52 do not reach the level of detail at which the acceptability of NEI 06-14A would be questioned as a quality program template.<br><br>The draft RG identifies a method acceptable to the staff of meeting the regulations. In general,  |

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|           |   |   | <p>standard for a Quality Assurance Program as referenced in the Standard Review Plan (NUREG-0800). The draft regulatory guide endorses a later version of later version of NQA-1.</p> <p>10 CFR Part 52 requires COL applicants to conform to the latest approved NRC Regulatory Guides. If a COL applicant cannot conform, justification is required. In this regard, we recommend that Draft Regulatory Guide 1215 include a statement that NEI 06-14A is an acceptable product for use in future COL and ESP applications, and that no additional justification is necessary in the application. Absent such a clarification, applicants will have to justify why they are not conforming to the newer NQA -1 standard endorsed in the regulatory guide.</p> | RGs endorse a standard, not an applicant's proposed methodology for meeting the regulations. There is no known change from the position given in the RG to what was in the NEI template. Therefore, the staff does not anticipate an applicant having to provide justification for not conforming to the draft RG. |
| 16        | Section B<br>Discussion<br>Background<br>Page 2, and<br>Appendix A<br>Pages A-1-A-4 | Discussion – administrative and historical content. | <p><u>General</u></p> <p>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.</p>  | No Change - See response to Comment # 12.  |
| 17        | General comment on DG-1215  | Discussion – identification of standard.            | <p><u>General</u></p> <p>The correct reference to the description of the NQA Standard being considered for endorsement is "NQA-1 -2008 and the NQA-1 a-2009 Addenda." This appears in several locations.</p>   | Accepted - See response to Comment #1.   |
| 18        | General comment on DG-1215  | Editorial – punctuation.                            | <p><u>General</u></p> <p>NQA -1 text that is quoted verbatim in the RG should be identified with quotation marks.</p>  | Accepted - Identified NQA text will have quotation marks.  |



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| 19               | Section A<br>Introduction<br>Page 1             | Discussion – relevance of 10 CFR Part 50.34(b)(6)(ii).  | <u>Introduction</u><br>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. | Accepted - The correct citation is "10 CFR Part 50.34(a)(7) which requires a description of the quality assurance program to be applied to the design fabricating, construction and testing of the structures, systems, and components of the facility. |
| 20               | Section B<br>Discussion<br>Background<br>Page 2 | Discussion – QA historical content.<br><br>"The methods described in this revision are generally equivalent to the methods described in Revision 3 of this regulatory guide, which endorsed NQA-1-1983 through the 1983 addenda referred to as the NQA-1a-1983 Addenda. A number of standards were consolidated in NQA-1-1983 and NQA-1a-1983 Addenda. RG 1.28, Revision 3, consolidated the regulatory guides that endorsed the consolidated standards." | <u>Background</u><br>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  | No Change - See response to Comment #12.  |
| 21               | Section B<br>Discussion<br>Background<br>Page 2 | Editorial – word change.<br>"The work activities include, but are not limited to, management, planning, site investigation, design, computer software use, commercial-grade dedication, procurement, fabrication, installment, inspection, and testing."  | <u>Background</u><br>The list of work activities in the second sentence of the second paragraph should be revised to change "installment" to "installation."   | Accepted- The word "installment" will be replaced with "installation."  |

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| 22               | Appendix A<br>Page A-1  | Discussion of QA historical content.<br><br>“Appendix A to this regulatory guide gives an overview and continuation of the history and consolidation of NRC-endorsed standards.” | <u>Background</u><br>The third sentence of the second paragraph for Appendix A that includes the overview of the history should be deleted.  | No Change - See response to comment #12.   |
| 23               | Section C<br>Regulatory Position<br>1.a.(1) and<br>1.a.(2)<br>Pages 2-3 | Discussion – permanent and nonpermanent records.   | <u>Regulatory Position</u><br>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. | Accepted - The Regulatory Positions will re-worded to state;<br>“1.a.(1), Paragraph 400, “Classification,” of Requirement 17, “Quality Assistance Records,” provides guidance on retention of lifetime and nonpermanent records. Paragraph 401, “Lifetime Records,” discusses the scope and responsibilities of these records. The owner or authorized agent is responsible for maintaining lifetime records for the life of a particular item while it is installed in the plant or stored for future use.”<br><br>“1.a.(2), Paragraph 402 “Nonpermanent records” discusses the scope and responsibilities of these records.” |

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| 24               | Section C<br>Regulatory Position<br>1.a.(3)<br>Page 3 | Discussion – permanent and nonpermanent records.<br><br>“Revision 3 of this regulatory guide provided guidance on the retention period for programmatic and product nonpermanent records. However, because there are additional regulatory requirements for specific records and established industry practice, this guidance was deemed obsolete and no longer necessary.”                | <u>Regulatory Position</u><br>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,..." | Accepted – Text changed as proposed.      |
| 25               | Section C<br>Regulatory Position<br>2.<br>Page 4      | Discussion – removal of text.<br><br>“Paragraph 200, “Scheduling,” of Requirement 18, “Audits,” states that audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Additional audits of specific subjects shall supplement scheduled audits when necessary to provide adequate coverage.” | <u>Regulatory Position</u><br>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.   | Accepted – The paragraph will be deleted. |

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| 26               | Section C<br>Regulatory Position<br>2.b.(1) and<br>2.b.(2) | Discussion – removal of text.<br><br>“Procurement audits of suppliers are not necessary for procuring items that are relatively simple and standard in design, manufacturing, and testing and that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery.” | <u>Regulatory Position</u><br>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).  | Accepted - The first sentence of regulatory positions 2.b.(2) will be deleted, as proposed. However, the staff did not join the two paragraphs, as each describes independent regulatory positions. |
| 27               | Section C<br>Regulatory Position<br>2.b.(3) and<br>2.b.(5) | Editorial – move text.   | <u>Regulatory Position</u><br>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.   | Accepted - Regulatory position 2.b.(5) will be moved to follow 2.b.(3).   |
| 28               | Section C<br>Regulatory Position<br>2.b.(4)(d)<br>Page 5   | Discussion – audit evaluation.<br><br>“(d) results of audits from other sources (e.g., ASME or NRC audits).”   | <u>Regulatory Position</u><br>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). | No Change – See response to Comment #2.   |

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| 29               | Section C<br>Regulatory Position<br>2.b.(4)(d)<br>Page 5 | Discussion – IN 86-21.                       | <u>Regulatory Position</u><br>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. | Partially Accepted - See response to Comment #2. As clarified in the paragraph following C.2.b(4)(d), IN 86-21 informed applicants and licenses that NRC recognizes the ASME Accreditation Program and associated certificates of authorization as evidence that the holder of the certificates of authorization has a documented QA program that meets the requirements of Appendix B to 10CFR 50. However, recognition of the ASME Accreditation Program applies only to the programmatic aspects of the QA programs. |
| 30               | Section C<br>Regulatory Position<br>22.b.(6)<br>Page 5   | Editorial – missing word.                    | <u>Regulatory Position</u><br>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.   | Accepted - The omitted word "Laboratory," will be inserted into the title.  |
| 31               | Section C<br>Regulatory Position<br>2.<br>Pages 4-5      | Discussion – addition of audit grace period. | <u>Regulatory Position</u><br>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:<br><br>A general grace period of 90 days may be applied to-   | Accepted - The 90-day grace period for the performance of audits will be added as new Regulatory Position 2.6.  |

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|           |                             |                                      | 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.  |   |
| 32        | References 9.               | Editorial – reference document date. | <u>References</u><br>For reference 9, the current document has an issue date of March 2007.  | Accepted - The issue date for reference 9 (SRP 17.5) will be changed to "initial issuance, March 2007."   |
| 33        | Appendix A<br>Pages A-1-A-4 | Discussion – QA historical content.  | <u>Appendix A</u><br>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. | No Change - See response to Comment #12.  |
| 34        | N/A                         | Question – plans to revise SRP 17.5  | Question: Does the NRC plan to revise SRP 17.5 to address NQA-1a-2008 Addenda to NQA-1-2008. (I believe that it currently addresses NQA-1-1994)? SRP 17.5 is used by NRC to review licensee submitted QA programs, so if SRP 17.5 is revised, then future submitted QA programs could be impacted.   | A question on point of clarification related to revising SRP 17.5 to reflect endorsement of NQA-1-2008 and the NQA-1a-2009 Addenda. SRP 17.5 will be revised in the future. |

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| 35               | Regulatory Position (5) and Ref 10 | Reference to International Laboratory Accreditation (ILAC) Program and Standard ISO/IEC 17025-2005 | The oversight of laboratories which participate in the ILAC is currently under review. It was strongly desired to include this process within the regulatory position to account for audits of commercial grade calibration services. However due to ongoing negotiations over the relationships governing the oversight process, it should be removed at this time, and included in the next revision of the regulatory guide. (assuming negotiations are complete). | The reference to the ILAC and ISO/IEC 17025-2005 was removed, and will be reconsidered when appropriate. |
|                  |                                    |  |   |  |