PUBLIC COMMENTS – NUREG – 0800, Standard Review Plan (SRP), Section 17.5,
"Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants,"
Draft Revision 1

No.	SRP 17.5 Page Section	Comment Author ML No.	COMMENT	NRC RESPONSE
1.	17.5-2 I.C., I.Q., II.C., and II.Q.	NEI ML14329A026	The titles for the areas of review should be consistent with the criterion from Appendix B to 10 CFR Part 50 that they reference. a. "C. Design Control and Verification" should be changed to be consistent with Criterion III "Design Control" b. "Q. Records" should be changed to be consistent with Criterion XVII. "Quality Assurance Records"	Agree. For these two items the titles should match the Appendix B to 10 CFR Part 50, criterion title. I.C. and II.C. "Design Control and Verification," will be changed to "Design Control." I.Q and II.Q "Records," will be changed to "Quality Assurance Records."
2.	17.5-6, II.A.7.d.	NEI ML14329A026	This new criteria is overly restrictive and may preclude the individual from having any other oversight responsibility, even if another responsibility has no impact on the ability to fulfill their QA responsibilities. We agree that it is important that the individual not be precluded from performing their QA responsibilities, and we recommend the criteria should be phrased as follows, consistent with NQA-1 2008/2009: "Has sufficient authority and organizational freedom to implement the QA program, and is sufficiently independent from cost and schedule."	Agree. The current draft wording in II.A.7.d states: "Has no other duties or responsibilities unrelated to QA that would prevent his full attention to QA matters." The staff will revise II.A.7.d. to state: "Has sufficient authority and organizational freedom to implement the QA program, and is sufficiently independent from cost and schedule."
3.	17.5-6 II.A.8	NEI ML14329A026	The concept that all quality verification is performed by the QA organization or by organizations independent of the organization performing the task is not consistently applied in the Standard Review Plan Section 17.5 (SRP). There are several exceptions, for example design verification, identified in NQA-1 and in the NRC approved NEI 11-04A "Nuclear Generation Quality Assurance Program Description," where the qualifier can be in the same organization. This criterion should reflect that exceptions are permitted in some specific instances.	Agree. The current draft wording in II.A.8 states: "Verification of conformance to established requirements is accomplished by individuals or groups within the QA organization who do not have direct responsibility for performing the work being verified or by individuals or groups trained and qualified in QA concepts and practices and independent of the organization responsible for performing the task." The staff will add the following at the end of the wording above for II.A.8. "(This does not apply to design reviews/verifications when meeting provision for design reviews/verifications in Section II.C.19.)" Additional independent verification are addressed in the respective section of the SRP or other staff guidance documents

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4.	17.5-7 II.A.11	NEI ML14329A026	The last sentence appears to be incomplete. Adding the words "compliant with the requirements of" between "QA program" and "10 CFR 50.34(f)(3)(iii)(F)" may convey the intended meaning	Agree in part. The current draft wording in II.A.11 states: "Management ensures that the size of the QA organization is commensurate with its duties and responsibilities. This does not apply to QA programs (10 CFR 50.34(f)(3)(iii)(F))." The staff will revise II.A.11. to state: "Management ensures that the size of the QA organization is commensurate with its duties and responsibilities. (This applies to DC applicants, ESP, and construction QA programs.) (10 CFR 50.34(f)(3)(iii)(F)). Note: the new wording is the same as Revision 0, Item II.A.7.
5.	17.5-7 II.B.1	NEI ML14329A026	The sentence is long and confusing. It should be revised and split into two sentences to be clearer.	Agree. The current draft wording in II.B.1.states: "The QA program ensures that there is regular management review of the QA program to assess its effectiveness and the adequacy of its scope and implementation, which describe the provisions for reviews by management above or outside the QA organization to ensure achieving an objective program assessment." The staff will revise II.B.1, to state : Provisions are included for regular management review of the QA program to assess the effectiveness and the adequacy of the scope and implementation. The persons performing the review are management above or outside the QA organization to ensure an objective assessment..
6.	17.5-11 II.B.13.b.(6).i.	NEI ML14329A026	The last sentence is more appropriately worded as follows: "The Independent Review Committee also verifies that changes do not adversely affect safety, and <u>determines</u> if a technical specification change or NRC review is required." The underline indicates changes to the draft criteria.*	Agree in part. The current draft wording in II.B.13.b.(6).i states: (6) The Independent Review committee is responsible for performing the following: i. Reviews the proposed changes to the facility as described in the SAR. The Independent Review Committee also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required." The staff will revise II.B.13.b.(6)i. to state: (6) The IRC is responsible for performing the following:

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				i. Reviews the proposed changes to the facility as described in the SAR. The IRC also verifies that changes do not adversely affect safety, if a technical specification change is required, and if an NRC review is required. (The acronym "IRC" will be used for independent review committee).
7.	17.5-15 II.C.16.	NEI ML14329A026	The new criterion related to the review procedures by the QA organization is inconsistent with the role of the QA organization. The QA organization provides oversight of the design process but does not approve individual drawings. The criteria as proposed would require the QA organization to be involved in every design drawing, specification and subsequent change. Consistent with NQA-1, we recommend the criteria be revised as follows: "Procedures are established and described requiring that design drawings and specifications be reviewed by individuals knowledgeable of QA requirements to ensure that the documents are prepared reviewed, and approved in accordance with the company procedures and that the documents contain the necessary QA requirements such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results." Underline indicates changes to the draft criteria	Do not agree. The QA organization is responsible to ensure that relevant QA aspects of the procedure review is accomplished. The current draft wording in II.C.16 states (note text in italics): "Procedures are established and described requiring that design drawings and specifications be *reviewed by the QA organization to ensure that the documents are prepared, reviewed, and approved with company procedures and that the documents contain the necessary QA requirements* such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results."
8.	17.5-18 II.F.8	NEI ML14329A026	The draft SRP Revision 1 changes the criterion from "all" of the conditions needing to be met to "one" of the conditions needing to be met; however, the revised criterion is not clear. It may be clearer if the language is revised to match Section 6.1 of the NRC approved NEI 11-04A	Agree. The current draft wording in II.F.8. states: 8. Procedures used during the operational phase are reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every 2 years to determine if changes are necessary or desirable (ANSI/ANS 3.2). Procedures do not have to be reviewed every 2 years provided that *one of the following is met*: (Approved via January 13, 2000 SE, ADAMS Accession No. ML003675798) a. Applicable procedures are reviewed following any modification to a system. b. Applicable procedures are reviewed following an unusual incident, unexpected transient, significant operator error, or equipment failure. c. Procedures are updated during use when discrepancies are found.

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				d. Procedures are reviewed by knowledgeable individuals prior to use if not used in the previous 2 years. e. A QA program audit of procedures is conducted every 2 years. The staff will revise the italic text above to "..all of the following are met."
9.	17.5-27	NEI ML14329A026	Criteria defining "Lifetime" and "Nonpermanent" records were removed (from Revision 0, these are items Q.11 through 1.13 on pages 17.5-28 and 17.5-29). It is not clear whether the NRC's intention is that these terms would be defined by each licensee. We believe that providing a common definition of these terms in Section 17.5 would provide clarity, and we recommend that the definitions from Revision 0 be inserted to Q.12 and Q.13 Section 17.5	Definitions for "Lifetime" and "Nonpermanent" are in NQA-1. The staff has documented its positions in regard to NQA-1 2008 Edition and 2009 Addenda in RG 1.28, Revision 4. Therefore, there is no need to repeat this information in the SRP. (Items II.Q,11., II.Q.12., II.Q.13. in SRP 17.5, Revision 0).

A. 3. The QA program requires independence between the organization performing checking functions from the organization responsible for performing the functions. (This provision does not apply to ESP applicant QA programs. This provision is not applicable to design reviews/verifications. The provision for design review/verification is addressed in Section II (10 CFR 50.34(f)(3)(iii)(A)).

Propose
(Change Section II to Section II.C.19.)